

The National Action Plan for Novel Influenza, etc.

July 2, 2024

Overview

Introduction

[Purpose of the Revision to the National Action Plan for Novel Influenza, etc.]

Since the first case of novel coronavirus infectious disease (COVID-19)¹ was confirmed in Japan in January 2020, the spread of COVID-19 has been threatening the lives and health of the people, and the national life and socioeconomic activities have been greatly impacted. In this unprecedented infectious disease crisis, the entire nation, including the people, politicians, administrators, medical personnel, and business operators, have been working together to deal with the ever-changing situation.

The recent revision to the National Action Plan for Novel Influenza, etc. (hereinafter referred to as the “National Action Plan”) aims to create a society that can respond to a wide range of crises caused by infectious diseases, including, but not limited to, novel influenza and novel coronavirus, etc.², based on the issues identified in the measures against COVID-19 (hereinafter referred to as the “COVID-19 measures”) and related legislative amendments to date.

Based on the National Action Plan, all possible measures to prepare for infectious disease crisis in normal times will be taken, and in crisis, a rapid and steady implementation of necessary measures based on the characteristics of infectious diseases and scientific knowledge will be made.

[Overview of the Revised National Action Plan]

The National Action Plan aims to organize measures for the case of crisis in advance and improve preparedness in normal times in order to take rapid action in the event of an infectious disease crisis. In crisis, the basic action policy (based on the basic action policy prescribed in Article 18, paragraph (1) of the Act on Special Measures against Novel Influenza, etc. (Act No. 31 of 2012, hereinafter referred to as the “Act on Special Measures”)), will be established and measures will be implemented with reference to the various options of countermeasures in the National Action Plan.

The previous National Action Plan, formulated in 2013, is now being fundamentally

¹ Those whose pathogen is a coronavirus belonging to the genus Beta coronavirus (limited to those newly reported by the People's Republic of China to the World Health Organization (WHO) in January 2020 as the ones with the ability to transmit to humans).

² Points towards the novel coronavirus infectious disease prescribed in Article 6, paragraph (7), item (iii) of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 1998, hereinafter referred to as the “Infectious Diseases Control Law”) and re-emerging coronavirus infection prescribed in Item 4 of the same law. The same shall apply hereinafter.

revised for the first time. Specifically, various countermeasures have been drastically enhanced and delivered concretely based on matters such as the following:

- The experience from COVID-19 measures and the development of related regulations;
- The development of systems for responding to the infectious disease crisis through the establishment of the Cabinet Agency for Infectious Disease Crisis Management (hereinafter referred to as “CAICM”) and the Japan Institute for Health Security³ (hereinafter referred to as “JIHS”); and
- The strengthening of governance through the establishment and expansion of the national and prefectural governments’ authority for comprehensive coordination and direction.

In addition, the target diseases include not only novel influenza, novel coronavirus infectious disease, etc., but also a wide range of other respiratory infections, and the description of the target diseases is divided into three phases (preparation phase, initial phase, and response phase), with a particular emphasis on efforts for the preparation phase.

Moreover, the number of countermeasure items will be expanded from six items under the previous National Action Plan to 13 items, and the items that have become an issue in the COVID-19 measures will be made independent, and the description will be enhanced. In light of the possibility of prolonged infection, the response to multiple waves of infection spread and the flexible switching of measures in response to matters such as the spread of vaccines and therapeutic agents will also be clarified.

Furthermore, to ensure effectiveness, follow-up on the implementation status and periodic revisions will be made, and practical training will be conducted with the participation of various entities, including the national and prefectural governments.

Structure and Main Contents of the National Action Plan

[Structure of the National Action Plan as a Whole]

The basic structure of the National Action Plan is as follows:

- Part 1 will be the Significance of the “Act on Special Measures against Novel Influenza, etc. and Objectives of the National Action Plan,” which describe matters such as the background of the infectious disease crisis and recognition of the situation, the concept of the Act on Special Measures, and the positioning of the

³ Until the establishment of JIHS, references to “JIHS” in this National Action Plan shall be read as “National Institute of Infectious Diseases,” “National Center for Global Health and Medicine” or “National Institute of Infectious Diseases and National Center for Global Health and Medicine” which perform equivalent work before the establishment of JIHS. The roles and other functions played by the JIHS are described in Part 2, Chapter 3, Section 1.

National Action Plan.

- Part 2 will be the “Basic Policy on the Implementation of Countermeasures against Novel Influenza, etc.,” which presents general ideas and points to keep in mind regarding countermeasures against novel influenza, etc.
- Part 3 will be the “Concepts and Actions for Each Countermeasure Item of Novel Influenza, etc.,” which describes the concept and specific measures for each countermeasure item of novel influenza, etc.

[Part 1: Objectives of the National Action Plan in Light of Infectious Disease Crisis in the Past]

Part 1 provides an overview from the perspective of improving the institutional framework for countermeasures against novel influenza, etc., that have been taken so far while summarizing Japan’s experience with handling an infectious disease crisis and the current situation surrounding the risks of infectious disease crisis. Based on this, through the revision of the National Action Plan, the aim is to realize the goals of “building systems capable of responding to an infectious disease crisis in normal times,” “reducing the impact on national life and socioeconomic activities,” and “respecting fundamental human rights” to achieve a society that can respond to infectious disease crisis in a strong and flexible manner.

[Part 2: Objectives and Basic Concepts of the Countermeasures Against Novel Influenza, etc.]

Part 2 organizes the objectives and basic concepts of countermeasures against novel influenza, etc.

In Chapter 1 of this Part, Sections 1 and 2 organize the objectives and basic concepts of countermeasures against novel influenza, etc., in general terms and set forth two main objectives as basic strategies: (1) prevention of the spread of infection and (2) minimization of the impact on the national life and economy.

Section 3 of the same chapter describes the phases of the outbreak of novel influenza, etc., and in anticipation of a medium- to long-term responses, it sets three time periods: the preparation phase, the initial phase, and the response phase. Further, the section indicates that the concept and policy of countermeasures will change for each phase.

Specifically, during the preparation phase, emphasis will be placed on building and strengthening the following systems: training and human resource development necessary for rapid and accurate implementation of countermeasures in crisis; building a system for

information collection and analysis, and risk assessment using Digital Transformation (DX); developing a medical care delivery system and testing system through the conclusion of agreements; and research and development, production, and supply of vaccines and therapeutic agents.

In the initial phase, after detecting the information of the outbreak of infectious disease in Japan and abroad, collecting information through border measures,⁴ surveillance, etc., and conducting the risk assessment based on the analysis, as well as providing and sharing information on the findings, interactive risk communication⁵, and initiation of research and development of vaccines and therapeutic agents, will be taken in an extremely rapid manner.

In the response phase after the establishment of the Government Countermeasures Headquarters for the Novel Influenza, etc. (hereinafter referred to as the “Government Countermeasures Headquarters”) and the formulation of the basic action policy, the first response will have containment in mind, while also taking into consideration trends of infection in foreign countries, as there will be limited knowledge on the characteristics of the pathogen at the initial stage of the outbreak of the novel influenza, etc. Therefore, based on the agreements concluded in the preparation phase, the medical care delivery system and the testing system will be enhanced, and the spread of infection will be controlled to the extent that it can be handled by the secured medical care delivery system by means of responding to patients and close contacts with patients through necessary testing and measures to prevent the spread of infection. Afterward, a risk assessment will be conducted, taking into consideration the characteristics of the novel influenza, etc., the characteristics of the pathogen, and the medical care delivery system, and the countermeasures to be taken will be flexibly adjusted accordingly. In particular, during the period when the ability to cope with the situation is enhanced by the use of vaccines and therapeutic agents, measures that have a significant impact on national life and socioeconomic activities, such as border measures and measures to prevent the spread of infection, will be considered whether they should be downsized, etc., according to risk assessment, and likewise, the implementation system of related organizations will also be considered as needed.

⁴ Border measures are only intended to be effective in delaying the entry of pathogens into Japan as much as possible, and are not intended to completely prevent the entry of pathogens into Japan.

⁵ Risk communication is an activity that aims to share risk information and perspectives through the exchange of information and opinions among individuals, institutions, and groups, and is a concept that emphasizes the interaction of various involved parties for appropriate risk response (decision making based on necessary information, behavior change, trust building, etc.).

In Sections 4 and 5 of the same chapter, the policy of switching countermeasures based on a balance between prevention of the spread of infection and socioeconomic activities is presented as a point to keep in mind for taking countermeasures against novel influenza, etc., as well as for enhancing preparedness in normal times. Moreover, it clarifies the roles of parties such as the national government, local governments, medical institutions, designated (local) public institutions, business operators, and the people, etc., in order to realize each of the countermeasures listed in Part 3.

(Five Cross-cutting Perspectives)

Chapter 2 of Part 2 divides the items of countermeasures against novel influenza, etc., into 13 items, and in addition to the basic principles and goals of each item, it organizes what actions are required from the following cross-cutting perspectives from I to V, which common to several countermeasure items.

I. Human Resource Development

The objective is to develop human resources for infectious disease crisis management in normal times from a medium- to long-term perspective, and as an effort to develop highly specialized human resources and broaden the base of human resources for infectious disease crisis management, the following efforts will be delivered: training and drills for a wider range of targets (crisis management, public relations divisions, etc.) and the securing and development of human resources in the region, such as those who will take the lead in local countermeasures and staff of public health centers who will serve as the core of infectious disease countermeasures.

II. Cooperation between the National Government and Local Governments

In responding to the infectious disease crisis, it is important to have an appropriate division of roles, with the national government formulating basic policies and local governments performing operations based on relevant laws and regulations. For this reason, a system of cooperation between the national government and local governments should be established in normal times to facilitate the smooth collection, sharing and analysis, etc. of data and information on infectious diseases. In addition, by disseminating information using various methods from the national government to local governments, the local governments shall appropriately provide information to residents, business operators, etc., as well as exchange opinions and conduct training in normal times to periodically strengthen the coordination system.

In addition, because people move and the infection spreads across the boundaries of local governments along with other aspects, it is also important to cooperate among

prefectural governments, between prefectural governments and municipalities, and among public health centers in the event of an outbreak of novel influenza, etc., and such wide-area cooperation among local governments should be actively addressed and prepared in normal times.

III. Promotion of DX

In responding to the infectious disease crisis, it is important to enhance response capability through the promotion of DX and technological innovation. Therefore, measures will be taken to conduct the development of a foundation for the collection, sharing, and analysis of information between the national and local governments, and between the governments and medical institutions; strengthening the response capability by reducing the workload of public health centers, medical institutions, etc.; and constructing a nationwide network by digitization and standardization of vaccination procedures. Along with these measures, measures to promote medical DX will be taken, such as the standardization of electronic medical records, linking electronic medical records and outbreak reports, and utilizing clinical information for research and development in the future.

IV. Support for Research and Development

It is important to facilitate the early commercialization of vaccines, diagnostic drugs, therapeutic agents, and other medications by promoting research and development and clinical research from the early stage of responding to infectious disease crisis. For this purpose, in order to facilitate research and development in crisis, in normal times, a network of medical institutions, research institutions, pharmaceutical companies, etc., should be promoted to support research and development in companies. In addition, from the initial stage, epidemiological and clinical information will be collected under the initiative of the national government and utilized for clinical research and development at related organizations.

V. International Cooperation

As infectious disease crisis spread globally across national borders, international cooperation is essential in combating diseases. As a member of the international community, Japan shall play an active role in dealing with the spread of infectious diseases that transcend national borders. Specifically, in cooperation with international organizations, foreign governments, research institutes, etc., information will be collected in normal times (to ascertain trends of outbreak of emerging infectious diseases and other

disease, and detect new cases) and in crisis (to take flexible border measures and utilize the information for research and development).

(Role of the JIHS in Ensuring the Effectiveness of the National Action Plan)

Section 3 of Part 2 describes efforts to ensure the effectiveness of the National Action Plan. Section 1 describes the roles played by the JIHS as the following:

- The JIHS and public health institutes, etc., universities and other research institutes, medical institutions, etc., should collaborate and cooperate with each other in normal times to further strengthen the network of information on infectious diseases, collect necessary information, and conduct risk assessments based on such information.
- Provide scientific knowledge and advice to the government and provide and share easy-to-understand information to the people.
- Promote research and development in Japan by acting as a hub for networks related to clinical research.
- Promote human resource development and international cooperation with international organizations, foreign public health organizations, etc.

(Promotion of Policies Based on the Concept of Evidence-based Policy Making (EBPM))

Part II, Chapter 3, Section 2 states that in order to ensure the effectiveness of the National Action Plan, it is necessary to promote policies based on the concept of EBPM both in normal times and in crisis. As a precondition for this, it is important to have a system that can collect and analyze appropriate data.

In addition, necessary studies should be conducted on the implementation of practical training with the participation of diverse actors, the implementation of regular follow-ups every fiscal year, and the revision of this National Action Plan approximately once every six years, and based on the results, necessary measures should be taken.

[Part 3: Concepts and Actions for the 13 Items against Novel Influenza, etc.]

Part 3 describes the specific measures required to achieve the basic principles and goals of the 13 items outlined in Chapter 2 of Part 2, which are divided into the preparation phase, the initial phase, and the response phase.

(Chapter 1: Implementation System)

From the preparation phase, a system for taking effective countermeasures will be secured through mutual cooperation among various entities, such as the national government, local governments, JIHS, research institutes, and medical institutions, as well as international coordination. In addition, in normal times, human resources will be trained and secured, and response capabilities will be strengthened through practical training. During crisis, precise policy decisions will be made based on the basic action policy centered on the Government Countermeasures Headquarters. In addition, financial resources will be secured through necessary fiscal measures by the national government and the issuance of prefectural or municipal.

JIHS will establish a system in normal times for responding to health crises during crisis, such as responding to requests for scientific knowledge from the CAICM and the Ministry of Health, Labour and Welfare (MHLW), and conducting research and studies, as well as a system that will enable rapid responses in the event of an infectious disease crisis.

(Chapter 2: Information Collection and Analysis)

An infectious disease intelligence⁶ structure under the initiative of JIHS will be established to form, maintain, and improve networks with related domestic and international organizations and experts, as well as promote DX for rapid information collection and analysis. In addition, in the case of making decisions on infectious disease countermeasures, a comprehensive risk assessment of infectious diseases and medical care conditions should be conducted, and the situation of national life and the economy should be understood.

(Chapter 3: Surveillance)

In addition to promoting DX, including the establishment of an infectious disease

⁶ Infectious disease intelligence is the systematic and comprehensive collection, analysis, and interpretation of data on infectious diseases from all sources in order to detect and assess public health risks from infectious diseases, determine prevention and control methods, and provide information (intelligence) that can be used for policy and practical decisions.

surveillance system that strengthens cooperation with related organizations and collaboration between electronic medical records and outbreak reports, infectious disease surveillance will be conducted continuously from the preparation phase. During crisis, infectious disease surveillance should be conducted according to the situation, such as promptly initiating suspected case surveillance⁷ for the concerned infectious disease.

(Chapter 4: Providing and Sharing of Information and Risk Communication)

Under infectious disease crisis, there is a risk of conflicting information, prejudice, discrimination, so-called “fake news,” and false information of unknown authenticity (hereinafter referred to as “disinformation and misinformation”). Therefore, in order to effectively take measures against infectious diseases, it is important to promote the sharing of risk information and perspectives through interactive communication as much as possible so that the people can make appropriate judgments and actions. For this reason, public awareness activities on infectious diseases will be carried out, a risk communication system will be established, and methods for providing and sharing information will be reviewed in normal times.

(Chapter 5: Border Measures)

In order to slow down the speed of the entry and spread of novel influenza, etc. and other pathogens into Japan as much as possible, and to allow time for preparations, such as securing the medical care delivery system, border measures, including testing, isolation, detention, request to stay in accommodation, etc., and health monitoring should be taken. In doing so, the effectiveness of the measures and their impact on national life and socioeconomic activities should be comprehensively considered and implemented, taking into account the characteristics of the infectious disease and the status of the spread of infection in Japan and abroad. Based on new information, measures that have become less necessary should be reviewed, such as reducing or suspending them as the situation evolves.

(Chapter 6: Prevention of Spread)

⁷ This is a suspected case surveillance based on Article 14, paragraphs (7) and (8) of the Infectious Diseases Control Law, and requires prefectures, etc., which have received notification from the MHLW, to notify the MHLW of the following cases specified by an Ordinance of the MHLW among suspected cases of Category II, Category III, Category IV, or Category V infectious diseases, where the severity of the disease is serious when a person has such an infectious disease. This system requires physicians of hospitals or clinics located within the area of jurisdiction to report when a patient with said infectious disease is diagnosed or when the corpse of a person who died due to said infectious disease is autopsied.

In order to keep the number of patients requiring treatment within the range of the medical care delivery system while expanding the system, it is important to control the speed and peak of the spread of infection through measures for the prevention of spread. Therefore, in the event of a medical crisis, comprehensive judgment will be made based on risk assessment, and if necessary, priority measures to prevent the spread of novel influenza, etc., based on the Act on Special Measures (hereinafter referred to as “intensive measures for prevention of the spread of infection”) and state of emergency measures to prevent the spread of novel influenza, etc. (hereinafter referred to as “emergency measures”) will be taken. The impact on national life and socioeconomic activities will be reduced by organizing reference indicators for the implementation of these measures and changing measures flexibly and rapidly in the situation.

(Chapter 7: Vaccines)

During the preparation phase, based on the “Strategy for Strengthening Vaccine Development and Production System” (determined by the Cabinet on June 1, 2021), research and development of vaccines against priority infectious diseases⁸ has been promoted, and the foundation for research and development will be strengthened. In crisis, systems for securing vaccines developed in Japan and overseas, as well as for immediate vaccination, will be established. Digitization of vaccination procedures and risk communication will be promoted.

(Chapter 8: Medical Care)

From the preparation phase, based on prevention plans under the Infectious Disease Control Law and medical care plans under the Medical Care Act (Law No. 205 of 1948), the medical care delivery system will be established through the conclusion of medical care agreements so that such a system can be rapidly secured after the initial phase. In medical crises during crisis, the national and prefectural governments will coordinate the dispatch of personnel and transportation of patients to ensure surge capacity while keeping compatibility with conventional medical care in mind.

(Chapter 9: Therapeutics)

Research and development of therapeutic agents for priority infectious diseases will be

⁸ Priority infectious diseases are those designated by the MHLW as infectious diseases for which it is necessary to ensure the availability of highly important medical countermeasures (MCM) to the crisis, such as life-saving, epidemic control, and maintenance of social activities. In order to provide a basis for countermeasures in the event of future outbreaks of novel influenza, etc., measures for medical countermeasures targeting priority infectious diseases will be implemented in normal times.

promoted in normal times to strengthen the foundation of research and development. In order to secure therapeutic agents and establish therapeutic methods during crisis, consistent measures and support for research and development, clinical trials, marketing approval, manufacturing, distribution, administration, collection of prognostic information and response will be promoted.

(Chapter 10: Testing)

Timely testing will be conducted on the people who require it in order to detect patients at an early stage and appropriately understand the epidemic situation. Further, appropriate medical care delivery and an accurate implementation and flexible changing of countermeasures will be conducted. In normal times, the testing system will be conducted by securing equipment and materials and managing the accuracy of the testing, and the testing system should be set up immediately after the outbreak. In the response phase, flexible changes in testing policies will be made in light of the characteristics of the pathogens and testing.

(Chapter 11: Health)

In order to implement countermeasures according to the situation of infection and the medical care delivery system in the region, public health centers and public health institutes, etc., which are the core entities in the event of infectious disease crisis, shall carry out testing, surveillance, active epidemiological investigation, hospitalization recommendations and measures, hospitalization coordination, coordination of home and accommodation-based recovery, transfers, health observation, provision of foods and daily necessities, and providing and sharing of information and risk communication. In addition, in implementing these tasks, centralization in prefectural governments, outsourcing, and measures in cooperation with municipalities should be taken as necessary. Moreover, to prepare for the rapid increase in workload in the event of the spread of the disease, systems should be established in normal times, operations to be prioritized during a crisis should be reviewed, and work efficiency and labor-saving should be achieved through the use of ICT, etc.

(Chapter 12 Supplies)

In order to ensure that medical institutions and other related organizations have

sufficient infectious disease control supplies, etc.,⁹ the supply-demand situation should be checked, and stockpiling should be promoted in the preparation phase. In the initial phase and response phase, measures should be taken to prevent supply disruptions, such as smooth production requests and instructions for the infectious disease control supplies, etc., based on the system established in the preparation phase.

(Chapter 13: National Life and Economy)

In view of the possible impact on national life and socioeconomic activities in crisis, the government will encourage business operators and the people to make necessary preparations for business continuity, etc., in the preparation phase. In addition, during crisis, the government will take measures by taking into account the effect on the mind and body caused by measures to prevent the spread, including intensive measures for prevention of the spread of infection and emergency measures, and will also support those who are in need of foods and daily necessities.

[Toward the Improvement of Response Capability to Infectious Disease Crisis Based on the National Action Plan]

Based on this National Action Plan, the action plans of prefectural governments and municipalities and the operational plans of designated (local) public institutions will be revised. It is extremely important that these related plans should function as a whole in order to take rapid and effective measures against novel influenza, etc. The national government will provide the support necessary for the formulation of these related plans and will enhance the effectiveness of the National Action Plan through training and follow-up with local governments and other related organizations so that the national government, local governments, and other organizations can work together to improve Japan's overall ability to respond to infectious disease crisis.

⁹ The pharmaceutical products prescribed in Article 53-16, paragraph (1) of the Infectious Diseases Control Law (Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960, hereinafter referred to as the “Pharmaceutical Affairs Act”)) medical devices (medical devices as defined in Article 2, paragraph (4) of the Pharmaceutical Affairs Act), personal protective equipment (personal tools to prevent exposure to pathogens, etc., by being worn), other supplies, and supplies and materials deemed essential for the production of these supplies.

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Part 1: Significance of the Act on Special Measures against Novel Influenza, etc. and
Objectives of the National Action Plan

Chapter 1: Significance of the Act on Special Measures against Novel Influenza, etc.

Section 1: The Situation Surrounding Infectious Disease Crisis

In recent years, the progress of development on a global scale has led to urbanization and dense populations in developing countries, as well as increased risk of coming into contact with animals that are hosts for unknown viruses, etc., which have increased the likelihood of encountering unknown infectious diseases. Furthermore, globalization has significantly expanded international travel, increasing the risk of such unknown infectious diseases spreading worldwide immediately if they occur. As outbreaks of infectious diseases have occurred in the past, such as Severe Acute Respiratory Syndrome (SARS) and the Zika virus infections, and as the COVID-19 has triggered a global pandemic since 2020, emerging infectious diseases and other types of diseases have become an international threat. It is necessary to reiterate recognizing, once again, that the world faces the risk of emerging infectious diseases and is in a situation where infectious disease crisis can easily spread.

However, it is difficult to accurately predict the timing of such emerging infectious diseases, and it is impossible to prevent their occurrence entirely. Therefore, it is important to establish a more robust system to prepare for infectious disease crisis in normal times.

Additionally, some pathogens that cause pandemics are assumed to be zoonotic. In order to prevent pandemics, it is essential to not only focus on human diseases but also to implement cross-sectoral efforts across human, animal, and environmental fields through a “One Health” approach¹⁰. Addressing zoonotic diseases by promoting the One Health approach is also an important perspective. In addition, even for known infectious diseases, there are some diseases that increase the risk of future infection due to the acquisition of antimicrobial resistance (AMR), which makes certain types of antimicrobial drugs less effective or ineffective. It is also important to reduce the risk of future spread of infection by promoting such AMR measures and other steady efforts on a daily basis.

¹⁰ To address efforts for solving cross-sectoral issues related to human and animal health, as well as the environment through collaboration among all parties concerned.

Section 2: Enactment of the Act on Special Measures against Novel Influenza, etc.

Novel influenza occurs in cycles of approximately 10 to 40 years, in which a novel virus emerges that is significantly different in antigenicity from the influenza viruses that cause annual outbreaks. Since most people have not acquired immunity to such novel viruses, there is concern that these could lead to pandemics, causing significant health hazards and accompanying social impacts.

Additionally, even with known pathogens like coronaviruses, there is a concern that a pandemic could occur if a novel virus emerges, against which most people have not acquired immunity due to mutation, etc.

Furthermore, regarding new infectious diseases, which are unknown in details, there is a possibility that those with high infectivity and transmissibility could emerge, causing significant social impact.

If these infectious diseases occur, it is necessary to respond as part of national crisis management.

The Act on Special Measures is designed to protect the lives and health of the people and to minimize the impact on the national life and economy in the event of an outbreak of high pathogenicity¹¹ infectious diseases, such as novel influenza infection, etc., and similarly designated infectious diseases or new infectious diseases that pose risk. It outlines the responsibilities of the national government, local governments, designated (local) public institutions, business operators, and others, as well as the measures to be taken during an outbreak of novel influenza, etc., and special measures, such as intensive measures for prevention of the spread of infection, etc., and emergency measures. Together with the Infectious Diseases Control Law, etc., the Act on Special Measures aims to establish a comprehensive system nationwide to strengthen countermeasures against novel influenza, etc.

The novel influenza¹², etc., covered under the Act on Special Measures is defined as posing a risk of spreading nationwide and rapidly, along with a risk that the extent of the disease may become severe because most of the people have not yet acquired immunity along with other factors. It also poses a significant threat to the national life and economy. Specifically, it refers to the following:

- (i) Novel influenza infection, etc.¹³

¹¹ The term "pathogenicity" refers academically to the "property of a pathogen to cause disease." However, in this National Action Plan, for the sake of clarity, it is used to mean the "property of a pathogen to cause disease and the severity of the disease caused by the pathogen." Academically, when it is necessary to distinguish between the "property of causing disease" and the "severity of the disease," the term "virulence" is used to refer to "the severity of the disease."

¹² Article 2, item (i) of the Act on Special Measures

¹³ Article 6, paragraph (7) of the Infectious Diseases Control Law

- (ii) Designated infectious diseases¹⁴ (those for which the extent of the resulting disease is serious in the case of suffering from the concerned disease, and those with a risk of nationwide spread and rapid spread)
- (iii) New infectious diseases¹⁵ (those with a risk of nationwide spread and rapid spread).

¹⁴ Article 6, paragraph (8) of the Infectious Diseases Control Law

¹⁵ Article 6, paragraph (9) of the Infectious Diseases Control Law

Section 3: Government's Infectious Disease Crisis Management System

In order to strengthen the government's command function for responses to future infectious disease crisis, the Cabinet Act (Act No. 5 of 1947) was revised, and in September 2023, the CAICM was established within the Cabinet Secretariat. The CAICM is responsible for consistently overseeing the comprehensive coordination of infectious disease response among relevant ministries and agencies, both in normal times and during crisis.

At the same time, to strengthen infectious disease response capabilities, the Department of Infectious Disease Prevention and Control was established within the MHLW in the same month.

Furthermore, based on the Act for the Japan Institute for Health Security (Act No. 46 of 2023), a new expert organization will be established to provide high-quality scientific knowledge to the CAICM and the MHLW. This organization will integrate the National Institute of Infectious Diseases and the National Center for Global Health and Medicine, and the JIHS is scheduled to be established in April 2025 as an organization that comprehensively handles information analysis, research, crisis response for infectious diseases, human resource development, international cooperation, and the delivery of medical care.

As part of the government's infectious disease crisis management system, the CAICM will serve as the command organization to ensure integrated response with relevant ministries and agencies, including the MHLW, and will establish systems to receive scientific knowledge related to infectious disease crisis management from the JIHS.

Additionally, when creating or revising the National Action Plan or basic action policy, the national government must first seek¹⁶ the opinions of the Council for the Promotion of Countermeasures against Novel Influenza, etc.¹⁷ (hereinafter referred to as the "Promotion Council").

¹⁶ Article 6, paragraph (5); Article 18, paragraph (4); and Article 70-3, item (ii) of the Act on Special Measures

¹⁷ Refers to the Promotion Council stipulated in Article 70-2, paragraph (2) of the Act on Special Measures.

Chapter 2: Formulation of the National Action Plan and Responding to the Infectious Disease Crisis

Section 1: Formulation of the National Action Plan

Japan started working on measures related to novel influenza before the enactment of the Act on Special Measures. In 2005, Japan created the “Action Plan for Novel Influenza” in line with the “WHO Global Influenza Preparedness Plan¹⁸,” and since then, several partial revisions have been made.

Following the experience of dealing with novel influenza (A/H1N1) in 2009, the Action Plan for Novel Influenza was revised in 2011 to prepare for a case in which a novel influenza with high pathogenicity emerges and spreads. Additionally, considering the lessons, etc.,¹⁹ learned from the novel influenza (A/H1N1) response, discussions were conducted to enhance the effectiveness of countermeasures through legal reforms, leading to the enactment of the Act on Special Measures in April 2012.

In 2013, based on the provisions of Article 6 of the Act on Special Measures, and considering the “Interim Summary of the Novel Influenza and New Infectious Diseases Countermeasures Expert Committee” (February 7, 2013), the National Action Plan was created.

The National Action Plan outlines the basic policies for implementing countermeasures against novel influenza, etc., as well as the measures to be undertaken by the national government. It also establishes criteria for prefectural governments to create their prefectural action plans and for designated public institutions to develop their operational plans. Rather than being based solely on specific infectious diseases or past examples, the plan anticipates the possibility of new respiratory infections, etc. beyond novel influenza and novel coronavirus infectious disease, etc. It provides options for countermeasures with consideration of the characteristics of any novel influenza, etc., that may arise to ensure that responses can be adapted to various situations.

Additionally, based on the latest scientific knowledge regarding novel influenza, etc., improvements from experience and training related to novel influenza, etc., and countermeasures, the national government will conduct regular reviews and make appropriate changes to the National Action Plan as needed.

¹⁸ "WHO Global Influenza Preparedness Plan," 2005 WHO Guidance Document.

¹⁹ In June 2010, the MHLW compiled the results of the review of H1N1 influenza (A/H1N1) countermeasures in a report titled H1N1 Influenza (A/H1N1) Countermeasures Overview Conference Report.

Section 2: Experience from the COVID-19 Measures

At the end of December 2019, a cluster of pneumonia cases with unknown causes emerged in Wuhan City, Hubei Province, People's Republic of China. In January 2020, cases of persons infected with COVID-19 were confirmed in Japan as well.

Subsequently, in the same month, the establishment of the Government Countermeasures Headquarters (COVID-19 Countermeasures Headquarters) was determined by the cabinet. In February of that year, the COVID-19 Response Expert Committee was launched, and the "Basic Policy for COVID-19 Measures" was decided. In March of the same year, the Act on Special Measures was revised to include COVID-19 in the target disease of the Act. A system that the government undertakes as a whole based on the Act on Special Measures has been established, including the establishment of the Government Countermeasures Headquarters and the formulation of the basic action policy based on the Act on Special Measures.

Subsequently, based on the Act on Special Measures, a declaration of a state of emergency (referred to as the "declaration of a state of emergency of novel influenza, etc." under Article 32, paragraph (1) of the Act on Special Measures) was issued. The Act also included strengthening the medical care delivery system, emergency measures by supplementary budgets, measures using reserve funds, revising the Act on Special Measures, such as establishing intensive measures for prevention of the spread of infection, addressing mutant strains, conducting vaccination, and relaxing behavioral restrictions. These responses were adapted according to the characteristics of the virus and changes in the situation as part of the national crisis management against COVID-19.

Then, on May 8, 2023, after more than three years since the confirmation of persons infected in Japan, the COVID-19 was reclassified as a Category V infectious disease under the Infectious Diseases Control Law. On the same day, the Government Countermeasures Headquarters and the basic action policy were abolished.

During the over three years of responding to COVID-19 based on the Act on Special Measures, it has become strongly recognized through this experience that infectious disease crisis affect every aspect of society and pose not only a significant threat to the lives and health of the people but also bring about a major threat to the stability of the economy and social life.

As for the scope of the impact of the infectious disease crisis, against the COVID-19, every person was faced with the infectious disease crisis as affected parties concerned from various positions and situations. The experience during this period has once again highlighted the need for society as a whole to respond to pandemics caused

by infectious diseases as part of national crisis management.

Furthermore, the infectious disease crisis did not end with the response to COVID-19. The next infectious disease crisis is inevitable and will certainly occur in the future.

Section 3: Objectives of Revising the National Action Plan

The revision of the National Action Plan is designed to enhance measures with the aim of ensuring a more thorough response in the next infectious disease crisis based on the issues identified in response to the actual infectious disease crisis.

Starting in September 2023, the Promotion Council reviewed²⁰ the COVID-19 measures to organize issues, and the following were raised as main issues:

- Insufficient preparedness in normal times
- Need for flexible and rapid responses to changing situations
- Information dissemination

Based on the experience and challenges from the COVID-19 measures, when responding to the next infectious disease crisis, it is necessary to aim for a society that can respond strongly and flexibly to infectious disease crisis, balancing the prevention of infection with socioeconomic activities.

In order to achieve such a society, it is necessary to accomplish the following three goals:

- Build a system that can respond to infectious disease crisis in normal times
- Mitigate the impact on national life and socioeconomic activities
- Respect fundamental human rights

The National Action Plan will be comprehensively revised to achieve these goals.

²⁰ In December 2023, the Promotion Council compiled "Opinions on the Revision of the National Action Plan for Novel Influenza, etc."

Part 2: Basic Policies on the Implementation of Measures for Novel Influenza, etc.

Chapter 1: Objectives of Measures for Novel Influenza, etc. and Basic Approach to Implementation, etc.

Section 1: Objectives and Basic Strategies of Measures for Novel Influenza, etc.

It is difficult to accurately predict the timing of outbreaks for novel influenza, etc., and it is impossible to prevent the outbreaks themselves. Moreover, if a novel influenza, etc., emerges anywhere in the world, it is likely that its entry into our country cannot be avoided. If novel influenza, etc., with high pathogenicity and with potential for an outbreak occurs, it could significantly impact the lives and health of the people, as well as the national life and economy. Indeed, in the long term, many people may be at risk of contracting novel influenza, etc., if patients are concentrated in a certain period of time, keeping in mind that the capacity of the medical care delivery system may be exceeded. Therefore, it is necessary²¹ to take measures with the two points listed below as the main objectives by positioning countermeasures against novel influenza, etc., as an important issue related to national crisis management.

- (1) Suppress and contain the spread of infection as much as possible and protect the lives and health of the people.
 - Delay the peak of the epidemic by suppressing the spread of infection and secure time for the establishment of the medical care delivery system and vaccine manufacturing.
 - Reduce the number of patients at the peak of epidemic as much as possible to lessen the burden on the medical care delivery system and to strengthen the medical care delivery system so that the number of patients does not exceed its capacity, ensuring that patients in need of treatment can receive appropriate medical care.
 - Reduce the number of severe cases and deaths through the provision of appropriate medical care.
- (2) Minimize the impact on the national life and economy
 - Smoothly conduct the transition of measures based on a balance between infection prevention and socioeconomic activities in order to mitigate the impact on national life and socioeconomic activities.
 - Ensure the stability of the national life and economy.

²¹ Article 1 of the Act on Special Measures

- Reduce the number of absentees through regional infectious disease measures, etc.
- Strive to maintain operations related to medical care delivery or operations contributing to the stability of the national life and economy through the formulation and implementation, etc. of business continuity plans.

Section 2: Basic Approach to Measures against Novel Influenza, etc.

It must be kept in mind that measures against novel influenza, etc., need to be flexible and adaptable to the stages of occurrence and changing circumstances. Based on the experiences of past pandemics, such as novel influenza and COVID-19, focusing too heavily on preparing for specific cases could pose significant risks. The National Action Plan does not solely consider specific infectious diseases or past cases but also presents various response options, which consider the characteristics of the novel influenza, etc., that outbreaked, to ensure readiness for diverse situations, with anticipating the possibility of new respiratory infections, etc. other than novel influenza or novel coronavirus infectious disease, etc.

In Japan, based on scientific knowledge and measures taken by other countries, and while considering Japan's geographical conditions, population concentration in major cities, declining birthrate and aging population, social conditions, such as the level of transportation infrastructure development, the characteristics of the medical care delivery system, and the nationality, such as healthcare-seeking behavior, the aim is to achieve a balanced strategy by combining various measures comprehensively and effectively. On this basis, a strategy with a series of steps based on the following points will be established according to the situation from before the outbreak of novel influenza, etc., to the end of the epidemic. (The specific measures will be described in Part 3, "Concepts and Efforts for Each Measure against Novel Influenza, etc.")

In the actual event of an outbreak of novel influenza, etc., measures to be implemented will be selected and decided from those described in this National Action Plan and other plans, taking into consideration the characteristics of the infection, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility²², and other factors), the state of the epidemic, the local situation, and other relevant factors. This will be done with comprehensive consideration of human rights, the effectiveness and feasibility of the measures, and the impact of those measures on the national life and economy.

- In the phase of pre-outbreak (the preparation phase), it is important to thoroughly prepare for the outbreak of novel influenza, etc., for example, by establishing an implementation system for border measures, developing a regional medical care delivery system, stockpiling antiviral drugs for influenza, etc., research and development and securing supply systems of vaccines and therapeutic

²² Drug susceptibility refers to the pathogen's sensitivity (effectiveness or resistance) to antimicrobial agents that are effective in treating infections.

agents, etc., raising awareness among the people, formulating business continuity plans, etc., by the governments and business operators, promoting DX and human resource development, and regularly inspecting and improving the response system through practical training.

- In the initial phase, when there is an outbreak of an infectious disease that may be classified as novel influenza, etc., including in the case of outbreak in Japan, it is essential to immediately switch to an initial response system.

If an infectious disease with the potential to be classified as novel influenza, etc., outbreaks overseas, it is necessary to formulate countermeasures on the premise that completely preventing the entry of pathogens into the country is difficult. At the stage when there is an outbreak of a disease abroad, to establish a robust system domestically, it is important to leverage the characteristics of Japan as an island nation and to delay the speed of pathogen entry and infection spread as much as possible by strengthening quarantine measures.

- At the phase to respond with containment in mind at the beginning of the outbreak in Japan (the response phase), various measures, which include implements hospitalization, treatment with antiviral drugs for influenza, etc., consideration of voluntary restraint for those at risk and preventive administration of antiviral drugs for influenza, etc., and requests for reduction of non-essential outings or restrictions on facility use according to pathogenicity, are to be taken, aiming at suppress the speed of infection spread.
- When information on pathogenicity, infectivity, transmissibility, etc., is limited at the onset of outbreaks domestically or internationally, it is necessary to assume the risk of cases where pathogenicity, infectivity, transmissibility, and other factors are intensive, based on the lessons learned in the past, and implement strong suppression measures. However, at all times, it is important to gather and analyze new information, assess the necessity of measures, and switch to appropriate actions right after obtaining more information, for example, through measures to suppress the spread of infection and to reduce the number of cases as much as possible. Additionally, measures that become less necessary should be revised, including their reduction or cessation, in response to the evolving situation.
- When infections spread domestically, and responses are based on the characteristics of pathogens (the response phase), it is necessary for the national

and local governments, business operators, etc., to collaborate with each other and make maximum efforts to ensure medical care delivery systems and maintain the national life and economy. However, it is anticipated that various situations may arise, including heightened societal tension and the possibility that measures may not always fit changing circumstances. Therefore, it is expected that things may not go as initially planned, and it is required to understand the social situation and respond flexibly according to the circumstances.

- Depending on the regional conditions, prefectural governments and relevant ministries and agencies will consult with the Government Countermeasures Headquarters to implement flexible measures and make considerations and adjustments to ensure that on-site medical institutions can operate more effectively.
- Subsequently, during the period when response capabilities improve with vaccines and therapeutic agents, etc. (the response phase), measures will be switched flexibly and promptly at appropriate times in response to changes in scientific knowledge, testing systems, medical care delivery systems, and the distribution of vaccines and therapeutic agents.
- Eventually, the epidemic situation will come to an end²³, and the time will come to shift to basic infectious disease measures that are not based on the Act on Special Measures.

Novel influenza, etc., poses a significant risk of causing serious harm to the lives and health of the people, and so measures need to be delivered comprehensively by combining infectious disease measures other than pharmaceutical intervention, such as requests for voluntary restraint of non-essential outings, requests for restrictions on facility use, and reductions in business activities to limit contact opportunities, with medical care responses that include vaccines and therapeutic agents, etc.

Particularly, infectious disease measures other than pharmaceutical intervention are expected to be effective when undertaken by society as a whole. It is crucial that all business operators not only actively engage in infection prevention at their workplaces but also proactively consider implementing measures, such as narrowing down essential operations to prevent the spread of infection.

It is also necessary to inform the people about the potential for a significant reduction in the level of service provided by business operators, due to illness among the business operators' employees, and to seek understanding from the people.

²³ The situation is one where there is an outbreak of patients domestically, but the outbreak does not require measures based on the Act on Special Measures.

Moreover, to avoid the limitations of the medical care delivery system and social disruption caused by the epidemic of novel influenza, etc., since there is a limitation to the measures conducted solely by the national government, prefectural governments, municipalities (including special wards, same hereinafter), and designated (local) public institutions, it is necessary for business operators and the people to take appropriate actions to prevent infection and the spread of infection, as well as to make preparations, such as stockpiling, etc. Measures against novel influenza, etc., should be based on everyday practices, such as handwashing and wearing masks, which are fundamental for respiratory infections, including seasonal influenza, etc. Particularly, in the case of emerging infectious diseases, etc., where vaccines or therapeutic agents are unlikely to be available, public health measures become even more critical.

Section 3: Scenarios for Broadly Addressing Various Infectious Diseases

(1) Considerations for Scenarios in Crisis

Considering the possibility of multiple waves of infections occurring in the medium to long term while bearing in mind past respiratory infections other than novel influenza infection, coronavirus infectious disease, and others, scenarios should be designed to cover a broad range of responses. Therefore, scenarios in crisis will be anticipated based on considerations (i) through (iv) listed below.

- (i) Rather than assuming only specific infections or past cases, consider the possibility of new respiratory infections, etc., other than novel influenza infection, coronavirus infectious disease, etc. Also, consider measures corresponding to the characteristics of pathogens.
- (ii) In the early stages of an outbreak, where only limited knowledge about the pathogens is available, thoroughly prevent the spread of infection and aim for an early convergence of the epidemic.
- (iii) In principle, switch measures flexibly and promptly at appropriate times in accordance with changes in circumstances, such as the understanding of the pathogen's properties through the accumulation of scientific knowledge, the development of testing and medical care delivery systems, and the widespread adoption of vaccines and therapeutic agents, as well as socioeconomic and other conditions.
- (iv) Assume scenarios that include changes in pathogenicity, infectivity, transmissibility, etc., due to mutations of pathogens, as well as the case of repeated infection spread and prolonged countermeasures associated with these.

Additionally, when considering scenarios in crisis, a broad classification for risk assessment is established concerning the characteristics of pathogens (such as pathogenicity, infectivity, transmissibility, and drug susceptibility, etc.) and typical approaches²⁴ to response in each case are indicated. On this basis, to make flexible responses possible, specific measures of switching will be detailed in Part 3 under "Considerations and Initiatives for Each Measure in Novel Influenza, etc."

In planning scenarios for emergencies, establish broad classifications for risk assessment based on the characteristics of pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) and provide typical response strategies for each case. Additionally, to enable flexible responses, detail specific measures for

²⁴ For a broad classification of risk assessment and responses for each case, see Part 3, Chapter 6, Section 3 as an example for the prevention of spread.

switching strategies in Part 3 of “Approaches and Measures against Novel Influenza, etc.”

Measures for novel influenza, etc., are broadly divided into two main sections: advance preparation, such as prevention and preparatory measures (the preparation phase), and responses after an outbreak occurs (the initial phase and the response phase).

(2) Scenarios for Infectious Disease Crisis in Crisis (Overall Flow of Response by Period)

Specifically, based on the concept of scenarios in crisis described in (1) above, to respond broadly in accordance with the characteristics of infectious diseases, the prolonged nature of infectious disease crisis, and changes in the situation, the initial and response phases are categorized as follows to contribute to switching to flexible and rapid measures, and scenarios in crisis are assumed. The response to infectious disease crisis will be carried out based on the characteristics of responses by period.

○ Initial phase (A)

Since the rapid outbreak of infectious diseases and the situation with its potential have been detected, the Government Countermeasures Headquarters has been established, and the basic action policy has been formulated. Until this was put into practice, in order to ensure time for preparation against the spread of infection by slowing down the spread of infection as much as possible while clarifying the characteristics of the infectious disease and the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), efforts will be made rapidly and flexibly based on the characteristics of novel influenza, etc., and the progression of the situation.

The response phase is divided into periods (B) through (D):

- The period for responding with containment in mind (B)
- The period for responding, such as according to the characteristics of the pathogens (C-1)
- The period when response capabilities improve due to vaccines, therapeutic agents, etc. (C-2)
- The period for transitioning to basic infectious disease measures not based on the Act on Special Measures (D)

○ Response phase: The period for responding with containment in mind (B)

After the establishment of the Government Countermeasures Headquarters, in the

early stages of a domestic outbreak of novel influenza, etc., with limited knowledge about the characteristics of the pathogens, and while considering infection trends in other countries, the initial response will focus on containment (if it is confirmed to be novel influenza at this stage, note that there is a possibility of starting responses with anti-influenza virus drugs or pre-pandemic vaccines, and preventing the spread of infection through testing and medical care).

For the subsequent period during which the infection spreads, the measures will be categorized as follows from the viewpoint of switching measures:

- Response phase: The period for responding, such as according to the characteristics of the pathogens (C-1)

If containment of the infection becomes difficult, based on risk assessments according to the characteristics of the pathogens as revealed through accumulated knowledge and considering the speed of the spread of infection and the incubation period, it should be considered whether to take measures to prevent the spread of infection so that the infection wave (in terms of speed and peak, etc.) can be suppressed to a level that can be handled by the secured medical care delivery system.

- Response phase: The period when response capabilities improve due to vaccines, therapeutic agents, etc. (C-2)

Based on the increased response capability to novel influenza, etc., due to the dissemination of vaccines and therapeutic agents, measures should be flexibly and promptly adjusted based on scientific knowledge (however, it should also be considered that there may be a need to strengthen measures due to mutations of pathogens).

- Response phase: The period for transitioning to basic infectious disease measures not based on the Act on Special Measures (D)

Ultimately, the transition to basic infectious disease measures not based on the Act on Special Measures (exit) will be achieved by means of advancing immunity acquisition through vaccines, etc., a decrease in pathogenicity, infectivity, transmissibility, etc., due to pathogen mutations, and the response capability for novel influenza, etc., exceeding a certain level.

Based on the overall flow of infection crisis response from the initial phase to the response phase, the section “Considerations and Measures for Each Countermeasure

Item for Novel Influenza, etc.” in Part 3 will define the options for measures needed at each period.

During the “Period for responding according to the characteristics of the pathogens” (C-1) of the response phase, a broad classification of risk assessment from the perspectives of pathogenicity, infectivity, transmissibility, etc., will be conducted, and specific details for each measure item will be defined according to each classification. Additionally, when establishing measures based on the broad classification of risk assessment from the perspectives of pathogenicity, infectivity, transmissibility, etc., considerations will include possibilities of responses to waves of multiple infections, prolonged measures, and changes in pathogenicity, infectivity, transmissibility, etc.

Additionally, for the “Period when response capabilities improve due to vaccines, therapeutic agents and other factors” (C-2) of the response phase, it is also possible that this period may not arrive depending on the availability of vaccines and therapeutic agents or the status of their development, and the “Period for transitioning to basic infectious disease measures not based on the Act on Special Measures” (D) of the response phase may be reached instead.

Furthermore, with regards to measures necessary for the case where groups susceptible to infection or severe outcomes are particularly children²⁵, young people, and elderly people, the impact on society and the medical care delivery system will vary. Therefore, measures are defined, keeping in mind that the nature of preparations and interventions will also change.

²⁵ In this National Action Plan, in accordance with the "Basic Policy on the New Promotion System for Child-Related Measures - Establishment of the Children and Families Agency Aiming for a Children-Centered Society" (determined by the Cabinet on December 21, 2021), the term "children" will be used, except for legal terms, etc.

Section 4: Considerations for Implementing Measures for Novel Influenza, etc.

The national government, prefectural governments, municipalities, or designated (local) public institutions, in the event of an outbreak of novel influenza, etc., or during its preparation phase, shall collaborate and cooperate with each other in accordance with the Act on Special Measures, other laws and regulations, this National Action Plan, and their respective action or operational plans to ensure the accurate and swift implementation of novel influenza, etc., countermeasures. In doing so, attention shall be paid to the points below.

(1) Organization and Expansion of Preparations in Normal Times

It is important to establish a system to respond to infectious disease crisis in normal times. Therefore, by implementing initiatives (A) through (E), listed below, efforts will be made to enhance preparedness in normal times, enable the establishment of a rapid initial response system through training, as well as promote DX, which is the foundation for information gathering, sharing, and analysis.

(A) Sharing of measures to be taken during the outbreak of novel influenza, etc., and organizing the preparations

While sharing among relevant parties the measures to be taken in the outbreak of novel influenza, etc., which is inevitable in the future, preparations necessary for the implementation will be made.

(B) Improving the ability to detect initial infection cases and establishing systems for a rapid initial response

When it comes to the initial response, various scenarios are assumed, including cases where an unknown infectious disease occurs or novel influenza, etc., emerges domestically. In addition to enhancing the ability to detect initial cases, systems should be established to enable the government to promptly initiate an initial response after detecting the first case of infection.

(C) Continuous review and improvement through public awareness activities and training programs for relevant parties and the people

Infectious disease crisis is inevitable in the future, and it is essential that public awareness is shared broadly among related organizations involved in infectious disease measures and the people. Along with this, to make preparedness for future infectious disease crisis more thorough, continuous review and improvement of

preparedness in normal times will be conducted through the implementation of training based on various scenarios and by different responsible entities.

- (D) Preparedness for medical care delivery systems, testing systems, research and development systems for vaccines, diagnostics, therapeutic agents, and risk communication

Beginning with the enhancement of the medical care delivery systems in normal times based on system reforms, such as in the Infectious Diseases Control Law and Medical Care Act, in order to enable rapid responses in crisis, efforts in normal times on the establishment of testing systems, research and development systems for vaccines, diagnostics, therapeutic agents, and risk communication are to proceed.

- (E) Promotion of DX and human resource development for burden reduction, effective use of information, and collaboration between the national government and local governments

In addition to promoting DX to reduce the burden on public health centers, etc., effectively utilize information related to medical care, and facilitate smooth cooperation, etc., between the national government and local governments, efforts will be made with a cross-cutting perspective in mind that is common to multiple measure items, including human resource development, cooperation between the national government and local governments, support for research and development, and international cooperation.

- (2) Switching Measures Considering the Balance Between the Prevention of Infection Spread and Socioeconomic Activities

In taking measures, it is important to alleviate the impact on the national life and socioeconomic activities through measures based on balance and appropriate information provision and sharing, as well as to ensure physical, mental and social health. For this purpose, measures should be taken to protect the lives and health of the people and minimize the impact on national life and socioeconomic activities by smoothly switching measures based on the balance between preventing the spread of infection and socioeconomic activities through measures (A) through (E) listed below.

- (A) Switching measures based on scientific evidence as much as possible

In switching measures, a risk assessment that includes the characteristics of the

infectious disease, etc., the characteristics of the pathogens, and the outbreak status of the infectious disease should be considered. In order to respond based on scientific evidence as much as possible, a system for collecting such data and a system for timely and appropriate risk assessment should be established in normal times.

- (B) Infectious disease measures considering the medical care delivery system and the impact on national life and economy

In crisis, it is important to control the speed and peak of the spread of infection to a level that can be handled by the medical care delivery system while rapidly expanding the medical care delivery system based on the prevention plan and medical care plan. Based on the risk assessment, if there is a possibility of exceeding this level, etc., measures to prevent the spread of infection, etc., should be taken in a timely and appropriate manner. At such times, careful attention should be paid to the impact on matters such as national life and socioeconomic activities, including the people and business operators to be affected.

- (C) Flexibly and promptly switch measures based on changes in the situation

Measures will be taken on the basis of switching flexibly and promptly at appropriate times in accordance with changes in circumstances, such as the understanding of the characteristics of the pathogens through the accumulation of scientific knowledge, the development of testing and medical care delivery systems, and the dissemination of vaccines and therapeutic agents, as well as socioeconomics, etc. In addition, the indicators and factors to decide on the switching of measures should be defined in advance to the extent possible.

- (D) Timing categories by each measure item

In order to allow for a flexible response, the timing to switch measures should be described for each individual countermeasure item according to risk assessment, etc., and guidelines for the timing to switch individual measures, etc., should be provided as necessary.

- (E) Providing and sharing information to gain understanding and cooperation from the people

In implementing measures, gaining the understanding and cooperation of the people is of the utmost importance. Therefore, in normal times, it is necessary to

disseminate basic knowledge about infectious diseases and infectious disease measures through various channels, including school education, and to provide and share information in an easy-to-understand manner for deepening the understanding among the people of all ages, including children. Through these efforts, information based on scientific evidence will be provided and shared as much as possible to promote appropriate decisions and actions. Especially when implementing measures involving strong behavioral restrictions, such as intensive measures for prevention of the spread of infection and emergency measures, it is important to clearly communicate and explain the content of the measures and their scientific basis, considering the impact on the people and business operators affected by these measures.

(3) Respect for Fundamental Human Rights

The national government, prefectural governments, and municipalities shall respect fundamental human rights when implementing measures against novel influenza, etc. When requesting or implementing restrictions on actions under the Act on Special Measures and giving restrictions on the freedoms and rights of the public, the limitations shall be the minimum that is necessary to carry out the measures effectively²⁶.

When implementing measures against novel influenza, etc., it is fundamental to provide sufficient explanations to the people, and to gain their understanding from the perspective of risk communication on the assumption that there is a legal basis.

Furthermore, prejudice and discrimination concerning novel influenza, etc., such as accusations against infected individuals, their families, and medical personnel, are violations of human rights to those people and must not occur. Such prejudice and discrimination can hinder patients from seeking medical care and cause delays in the suppression of infection spread. Additionally, from the perspective of maintaining the morale of health care workers working, etc., on novel influenza, etc., it is crucial to prevent these issues.

Moreover, in implementing measures for novel influenza, etc., attention should be paid to the socially vulnerable groups who are more likely to be affected. In the event of an infectious disease crisis, efforts should be made to ensure the confidence of the people and to prevent social division caused by novel influenza, etc.

²⁰ Article 5 of the Act on Special Measures.

(4) The Nature of the Act on Special Measures as Crisis Management

The Act on Special Measures is a system designed for crisis management in an infectious disease crisis and is designed to enable various measures to be taken in preparation for emergency situations. However, even if novel influenza infection, etc., designated infectious diseases, or new infectious diseases occur, it is possible that there may be no need to implement intensive measures for prevention of the spread of infection or emergency measures since the degree of pathogenicity is manageable and vaccines, therapeutic agents, etc. are effective. Thus, it should be noted that these measures are not necessarily applied in every situation.

(5) Ensuring Coordination and Cooperation Among Related Organizations

The Government Countermeasures Headquarters, Prefectural Countermeasures Headquarters²⁷, and Municipal Countermeasures Headquarters²⁸ will work closely together to comprehensively promote measures against novel influenza, etc.

If a request is made from prefectural governments to the national government or from municipalities to prefectural governments for comprehensive coordination regarding novel influenza, etc., measures, the national government or prefectural governments shall respect the purpose of the request and, if necessary, rapidly carry out the required comprehensive coordination²⁹.

(6) Response in Social Welfare Facilities, such as Facilities for Elderly People and People with Disabilities

For medical care delivery systems, etc., necessary in social welfare facilities, such as facilities for elderly people or people with disabilities during an infectious disease crisis, they should be examined in normal times, and preparations should be made in advance for crisis.

(7) Disaster Response under Infectious Disease Crisis

The national government should also consider disaster response under infectious disease crisis, enhance disaster stockpiles and medical care delivery systems in normal times, and advance the securing of evacuation centers, etc., mainly through municipalities. The national government should also promote the establishment of cooperation systems for information sharing regarding the evacuation for home care

²⁷ Article 22 of the Act on Special Measures.

²⁸ Article 34 of the Act on Special Measures.

²⁹ Article 24, paragraph (4) and Article 36, paragraph (2) of the Act on Special Measures.

patients and others in prefectures and municipalities. In the event of a disaster, such as an earthquake occurring during an infectious disease crisis, the national government should work with prefectural governments and municipalities to appropriately grasp the situation in the affected areas. Prefectural governments and municipalities should rapidly, if necessary, strengthen infectious disease measures at evacuation centers, share information with home care patients, etc., and support evacuation efforts.

(8) Creation and Preservation of Records

The national government, prefectural governments, and municipalities should, at the stage when novel influenza, etc., occur, create, store, and publish records related to the implementation of countermeasures at the Government Countermeasures Headquarters, Prefectural Countermeasures Headquarters, and Municipal Countermeasures Headquarters.

Section 5: Division of Roles for Promoting Measures

(1) Roles of the National Government

In the event of an outbreak of novel influenza, etc., the national government, on its own, takes appropriate and rapid measures against the novel influenza, etc., and supports local governments and designated (local) public institutions in taking appropriate and rapid measures against the novel influenza, etc., thereby ensuring a responsibility to maintain a thorough system as a country nationwide³⁰. Additionally, the national government secures international cooperation with organizations, such as WHO and other countries, and works on countermeasures.

Moreover, the national government shall strive³¹ to advance research and studies on novel influenza, etc., and vaccines related to this and other pharmaceuticals, as well as to promote³² international cooperation in research and studies related to novel influenza, etc. Through these efforts, the national government will push forward measures for the early development and procurement of vaccines, diagnostics, and therapeutic agents, etc., in the event of a novel influenza, etc. outbreak.

The government, prior to the outbreak of novel influenza, etc., shall steadily implement the novel influenza, etc., measures designated in the preparation phase based on the National Action Plan, and shall strive to review and improve these measures through regular training and other efforts.

The government shall comprehensively advance its unified efforts through the framework of the Ministerial Meeting on Measures Against Novel Influenza, etc.³³ (hereinafter referred to as the "Ministerial Conference") and the Meeting of Relevant Ministries and Agencies on Countermeasures regarding Novel Influenza, etc.³⁴ (hereinafter referred to as the "Interministerial Coordination Conference"), which assists the Ministerial Conference.

Designated administrative agencies, based on the National Action Plan and other guidelines, shall coordinate with each other and determine, in advance, specific responses according to the stage of an outbreak in their respective administrative fields in the event of the outbreak of novel influenza, etc.

The national government, in the event of the outbreak of novel influenza, etc., will

³⁰ Article 3, paragraph (1) of the Act on Special Measures.

³¹ Article 3, paragraph (2) of the Act on Special Measures.

³² Article 3, paragraph (3) of the Act on Special Measures.

³³ Held in accordance with the "Holding of the Ministerial Meeting on Measures Against Novel Influenza, etc. " (verbal understanding by the Cabinet Meeting on September 20, 2011).

³⁴ Held in accordance with the "Establishment of the Meeting of Relevant Ministries and Agencies on Countermeasures regarding Novel Influenza, etc. " (March 2, 2004, agreement of relevant ministries and agencies).

decide on the basic action policy at the Government Countermeasures Headquarters and strongly promote the measures.

In doing so, the national government will advance the measures while listening to the opinions of the Promotion Council and other relevant meetings. Additionally, to obtain the understanding and cooperation of the people and business operators, etc., the national government will provide and share basic information about the infectious disease and infectious disease measures.

(2) Roles of Local Governments

Local governments, in the event of the outbreak of novel influenza, etc., are responsible for accurately and rapidly implementing measures within their jurisdiction based on the basic action policy and for comprehensively promoting novel influenza, etc., countermeasures implemented by related organizations within their area³⁵.

[Prefectural Governments]

Prefectural governments play a central role as the main entities responsible for implementing measures under the Act on Special Measures and the Infectious Diseases Control Law. Based on the basic action policy, they are required to make accurate judgments and responses regarding the prevention of spread in addition to the establishment of medical care delivery systems in their regions.

For this purpose, measures should be taken in normal times to prepare the medical care delivery system by concluding medical care agreements with medical institutions on medical measures for securing hospital beds, providing care for clinics for outpatients with fever, home care patients, etc., logistical support, or dispatching medical personnel, as well as make systematic preparations for the medical care delivery system, public health centers, testing system, and response capabilities for accommodation-based recovery, etc., by concluding an agreement on testing and other measures with private testing companies or medical institutions at normal times along with establishing the testing system, etc. In this way, in the event of an infectious disease crisis, the system will be rapidly transitioned and infectious disease measures will be implemented.

During such efforts, it is important for prefectural governments to discuss prevention plans, medical care plans, etc., through the Prefectural Coordination Councils³⁶, etc., which consists of cities and special wards with public health centers (hereinafter

³⁵ Article 3, paragraph (4) of the Act on Special Measures.

³⁶ Article 10-2 of the Infectious Diseases Control Law.

referred to as “cities with public health centers, etc.”), designated medical institutions for infectious diseases³⁷, etc. In addition, the status of efforts based on the prevention plan shall be reported to the national government every fiscal year to confirm progress. Through these efforts, all parties concerned will work together in normal times to improve the medical care delivery system and prevent outbreaks of novel influenza, etc., and make improvements based on the PDCA cycle.

[Municipalities]

Municipalities are the administrative units closest to residents and are required to implement measures accurately based on the basic action policy regarding the vaccination of residents, provision of food and daily necessities, and support for those in need in the event of an outbreak of novel influenza, etc. In implementing these measures, municipalities must work in close coordination with prefectural governments and neighboring municipalities.

Additionally, for cities with public health centers, etc., the Infectious Diseases Control Law requires them to play roles pertaining to those of prefectures in terms of preventing the spread of infection. Therefore, they must plan and prepare for the capabilities of public health centers and testing systems, report the effort status according to their prevention plan to the national government every fiscal year, and confirm progress. In an infectious disease crisis, they must quickly transition their systems and implement infectious disease measures.

Prefectures and cities with public health centers, etc. (hereinafter referred to as “prefectural governments”) will conduct discussions on matters, such as the prevention of spread, and establish cooperation before the outbreak of novel influenza, etc.³⁸

³⁷ Among the designated medical institutions for infectious diseases stipulated in Article 6, paragraph (12) of the Infectious Diseases Control Law, only “designated medical institutions for specified infectious diseases,” “designated medical institutions for Class I infectious diseases,” and “designated medical institutions for Class II infectious diseases” shall be considered under this National Action Plan.

³⁸ In normal times, the following measures are necessary:

- When preparing prefectural action plans and stipulating matters related to other local governments, be sure to implement the coordination measures stipulated in the Act on Special Measures, such as hearing the opinions of other local governments (Article 7, paragraph (4) of the Act on Special Measures). Additionally, when preparing drafts of the prefectural action plan, establish a forum to consult with academic experts (Article 7, paragraph (3) of the Act on Special Measures). This forum should also include representatives from municipalities to ensure that coordination measures beyond those specified by the Act on Special Measures are considered, facilitating collaboration between the prefecture and cities with public health centers within the prefecture.
- Strive to implement joint training with other local governments, including cities with public health centers within the prefecture (Article 12, paragraph (1) of the Act on Special Measures).

(3) Roles of Medical Institutions

From the perspective of minimizing health hazards from novel influenza, etc., conclude medical care agreements with prefectural governments before the outbreak of novel influenza, etc., in order to secure the regional medical care delivery system, and promote training and drills on nosocomial infection control and securing necessary infectious disease control supplies etc., including personal protective equipment. It is also important to formulate a business continuity plan, including a medical treatment system for patients with novel influenza, etc., and to promote cooperation with related organizations in each region by utilizing the Prefectural Coordination Councils, etc.

During the outbreak of novel influenza, etc., medical institutions are, upon request from the prefectural governments based on the medical care agreements, required to secure hospital beds, provide medical care at clinics for outpatient patients with a fever, home care patients, etc., and provide logistical support or dispatch medical personnel in order to ensure the medical care delivery system for infectious diseases in addition to conventional medical care.

(4) Roles of Designated (Local) Public Institutions

Designated (local) public institutions, in the event of the outbreak of novel influenza, etc., have the responsibility to implement measures against novel influenza, etc., based³⁹ on the Act on Special Measures.

(5) Registered Business Operators

For business operators engaged in delivering medical care that fall under the specified vaccination targets outlined in Article 28 of the Act on Special Measures or business operators that contribute to the stability of the national life and economy, it is important to actively prepare for implementing infectious disease measures in the workplace and ensuring business continuity of essential operations before an outbreak of novel influenza, etc., so that they can fulfill their social mission from the perspective of maintaining a minimum standard of living for the people.

Efforts should be made to continue the implementation of such operations during the outbreak of novel influenza, etc.⁴⁰

³⁹ Article 3, paragraph (5) of the Act on Special Measures.

⁴⁰ Article 4, paragraph (3) of the Act on Special Measures.

(6) General Business Operators

Business operators are required to implement infectious disease measures in preparation for the outbreak of novel influenza, etc.

In the event of an outbreak of novel influenza, etc., which may cause extremely serious damage to the lives and health of the people, it may be necessary to scale back some operations from the standpoint of preventing infection. In particular, those who conduct business where many people gather are required to take thorough measures to prevent infection⁴¹. Therefore, it is necessary to take measures, such as making efforts to stockpile sanitary supplies, etc. in normal times, including masks and disinfectants.

(7) The People

From before the outbreak of novel influenza, etc., individuals should strive to obtain knowledge on measures, such as information on novel influenza, etc., and actions to take during the outbreak. In addition to regular health management, individuals should strive to practice basic infectious disease measures (such as ventilation, cough etiquette practices (such as wearing masks), handwashing, avoiding crowds, etc.). Furthermore, efforts should be made at the individual level to stockpile hygiene items, such as masks and disinfectants, as well as food and daily necessities, in preparation for outbreaks of novel influenza, etc.

During the outbreak of novel influenza, etc., individuals should strive to obtain information about the outbreak situation and the measures being taken, such as vaccinations, and to take measures to suppress the spread of infection⁴² at the individual level.

⁴¹ Article 4, paragraphs (1) and (2) of the Act on Special Measures.

⁴² Article 4, Paragraph 1 of the Act on Special Measures.

Chapter 2: Measures for Novel Influenza, etc., and Cross-cutting Perspectives

Section 1: Measures in the National Action Plan

(1) Main Measures in the National Action Plan

This National Action Plan sets forth specific measures to achieve the two main objectives of novel influenza, etc., measures: (1) suppress and contain the spread of infection as much as possible and protect the lives and health of the people, and (2) minimize the impact on the national life and economy.

To indicate the timing for switching between each measure and to make it clear and manageable for local governments and related organizations, the 13 items that follow below are established as the main measures in the National Action Plan.

- (i) Implementation system
- (ii) Information collection and analysis
- (iii) Surveillance
- (iv) Providing and sharing of information and risk communication
- (v) Border measures
- (vi) Prevention of spread
- (vii) Vaccines
- (viii) Medical care
- (ix) Therapeutics
- (x) Testing
- (xi) Health
- (xii) Supplies
- (xiii) National life and Economy

(2) Basic Principles and Goals for Each Measure Item

The 13 main items of this National Action Plan need to be implemented as a series of measures because each item is related to each other in order to realize the main objective of the measures against novel influenza, etc. Therefore, it is important to understand the basic principles and goals of each measure from (i) to (xiii) listed below and to implement measures with an awareness of the overall picture and interconnections among them.

(i) Implementation system

Infectious disease crisis can cause widespread and severe damage to the lives and health of the people, as well as to the national life and economy. Therefore, it is necessary to address these issues as a matter of national crisis management. It is

important for various entities, including the national government, local governments, JIHS, research institutes, and medical institutions, to collaborate with one another, as well as for the national government to coordinate with foreign governments, and international organizations for implementing effective measures.

Therefore, before the outbreak of novel influenza, etc., it is necessary to maintain close coordination among related organizations while enhancing response capabilities through securing and training personnel and conducting practical training. During the outbreak of novel influenza, etc., based on preparations made in normal times, rapid information gathering and analysis and risk assessment should be conducted to facilitate accurate policy decisions and their implementation. Therefore, the spread of infection can be controlled as much as possible, the lives and health of the people should be protected, and the impact on the national life and economy should be minimized.

(ii) Information collection and analysis

While aiming to prevent the spread of infection, it is important to systematically and comprehensively conduct information collection and analysis, as well as risk assessment, so as to contribute to policy decisions that balance the protection of the national life and economy according to circumstance.

Therefore, prior to the outbreak of novel influenza, etc., systems for efficient collection, analysis, and provision of information should be established, and a means of organizing and grasping information should be secured for periodic information collection and analysis and for crisis. During an outbreak of novel influenza, etc., it is crucial to conduct information collection and analysis and risk assessment regarding infectious diseases and medical care while also gathering information on the national life and economy. This will help ensure that decisions are made with consideration of both infection control and socioeconomic activities, aiming for a balanced approach.

(iii) Surveillance

To contribute to decision-making in infectious disease crisis management, it is important to rapidly and appropriately conduct early detection of novel influenza, etc., monitor outbreak trends, and assess risks.

To this end, surveillance structure should be established, and systems should be developed before the outbreaks of novel influenza, etc., and surveillance should be conducted in normal times, such as by monitoring trends in outbreaks of infectious diseases. During the outbreak of novel influenza, etc., infectious disease

surveillance and risk assessment in crisis should be conducted so that decisions can be made to strengthen or mitigate infectious disease control measures.

(iv) Providing and sharing of information and risk communication

Under the infectious disease crisis, there is a risk of conflicting information, which is likely to bring about anxiety, prejudice, and discrimination, and the dissemination of disinformation and misinformation. Under these circumstances, it is necessary to effectively implement various infectious disease measures while giving due consideration to freedom of expression. It is also important to rapidly provide accurate information with the people based on scientific evidence available at the time, communicate interactively as much as possible, and share risk information and perspectives with the people, local governments, medical institutions, and business operators, etc., so that people can make appropriate judgements and actions.

Therefore, it is necessary for the national government to understand the awareness of the people on infectious diseases and improve understanding of the infectious disease crisis in normal times. Along with these efforts, in preparation for anticipated situations, it is necessary to review the risk communication methods and improve the risk communication systems and activities.

(v) Border measures

In the event of the outbreak of novel influenza, etc., abroad, on the premise that it is difficult to completely prevent the entry of pathogens into Japan, based on the characteristics of novel influenza, etc., and the situation of the spread of infection overseas, the entry of pathogens of novel influenza, etc., into Japan will be delayed as long as possible by rapidly strengthening quarantine measures and implementing border measures, such as entry restrictions, etc. This will provide time to prepare for responses to infectious disease crisis, such as securing the domestic medical care delivery system, etc., and other necessary infectious disease crisis measures. Additionally, the smooth repatriation of Japanese nationals who wish to return from abroad will be realized.

When deciding on strengthened quarantine measures and entry restrictions as border measures, the characteristics of infectious diseases and the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) and other circumstances should be taken into consideration. On this premise, the human rights of patients, etc., the effectiveness and feasibility of the measures,

and their impact on the national life and socioeconomic activities should be comprehensively taken into account, and the contents of the measures shall be reviewed and implemented.

When information about pathogenicity, infectivity, transmissibility, etc., is limited during the initial outbreak of novel influenza, etc., it is necessary to anticipate risks associated with high pathogenicity, infectivity, transmissibility, etc., based on past knowledge, etc., and to implement robust border measures. However, it is crucial to continuously gather new information, evaluate the necessity of these measures, and switch to appropriate measures as further information becomes available. Additionally, as the situation evolves, it is important to review border measures that are deemed less necessary in terms of changing, reducing, discontinuing, or taking other such actions for their implementation methods.

(vi) Prevention of spread

The aim is to suppress the spread of novel influenza, etc., as much as possible, minimize health hazards, and minimize impacts on national life and socioeconomic activities. By delivering appropriate medical care, etc., in conjunction with implementing prevention of spread measures as necessary, it is essential to help control the speed and peak of infections and keep the number of patients requiring treatment within the capacity of the medical care delivery system. Especially when there are no effective therapeutic agents, or until vaccination is implemented, measures to prevent spread are vital from a public health perspective. Therefore, in the case where timely and appropriate risk assessments based on the characteristics of the pathogens, etc., are conducted, and even with a strengthened medical care delivery system, there is a risk of a large-scale infection spread to a level where medical care is in short supply, rapid implementation of intensive measures for prevention of the spread of infection and emergency measures under the Act on Special Measures should be delivered in necessary regions and periods, etc.

On the other hand, Article 5 of the Act on Special Measures states that when restrictions are placed on the freedoms and rights of the people, such restrictions should be the minimum necessary for implementing measures against novel influenza, etc., and it should be considered that measures to prevent spread significantly impact socioeconomic activities. On this basis, it is important to flexibly review the reduction or discontinuation of measures in place to prevent spread in response to changes in circumstances, such as information about

pathogenicity, infectivity, transmissibility, etc., of novel influenza, etc., and the development and distribution, etc., of vaccines and therapeutic agents.

(vii) Vaccines

In addition to protecting the health of the people by preventing individuals from being infected, appearance symptoms, and aggravation through vaccination, vaccinations can also help reduce the number of patients seeking treatment and keep the number of hospitalized and patients in critical condition within the capacity of the medical care delivery system, contributing to minimizing health hazards and impacts on socioeconomic activities caused by such as novel influenza. Therefore, it is important to take the necessary measures to enable rapid development and supply of safe and effective vaccines in a crisis, even in normal times, based on the “Strategy for Strengthening Vaccine Development and Production System.” Additionally, the national government, prefectural governments, and municipalities need to prepare for developing specific systems and implementation methods for vaccination in collaboration with medical institutions, business operators, related organizations, etc., in normal times.

During outbreaks of such as novel influenza, it is essential to ensure the rapid supply of safe and effective vaccines through all available means, by not only domestic development and production but also such as imports from abroad and domestic production of products developed abroad. Also, for vaccinations, flexible operations should be carried out based on new findings regarding such as novel influenza, considering prior plans.

(viii) Medical care

In the event of the outbreak of novel influenza, etc., it can spread nationwide and rapidly, and pose a significant threat to the lives and health of the people. Therefore, the delivery of medical care is an essential factor in achieving the goal of minimizing health hazards and ensuring that the people can live with peace of mind. Moreover, minimizing health hazards also contributes to minimizing the impact on socioeconomic activities.

In order to prevent shortages in infectious disease medical care and conventional medical care in an infectious disease crisis and to continue providing medical care without delay, systems for providing infectious disease medical care in crisis, with collaboration among related organizations, should be established in normal times. The system should be based on prevention plans and medical care plans, and

strengthened through drills and training, etc. While keeping in mind the compatibility with conventional medical care, the system for providing infectious disease medical care should be secured and flexibly adjusted according to changing situations related to pathogenicity, infectivity, transmissibility, etc., thereby protecting the lives and health of the people.

(ix) Therapeutics

In the event of the outbreak of novel influenza, etc., it can spread nationally and rapidly, posing a serious threat to the lives and health of the people. Therefore, providing medical care is an essential factor in minimizing health hazards and impacts on socioeconomic activities, with therapeutics playing a crucial role.

During the outbreak of novel influenza, etc., it is important to bring therapeutics into practical use at an early period and make them available to patients. Therefore, in normal times, measures should be taken to enhance the research and development capabilities of research institutions such as universities, and pharmaceutical companies, etc., while also focusing on human resource development and securing, as well as the maintenance and improvement of technology. Additionally, information collection and analysis should be conducted for infections that require the development of therapeutic agents (priority infectious diseases) to promote research and development that also considers unknown infectious diseases. When novel influenza, etc., occurs, the research and development system established in normal times should be utilized to promptly implement efforts toward the practical application of therapeutics.

Additionally, to ensure a stable supply of therapeutic agents during the outbreak of novel influenza, etc., and to rapidly administer them to the necessary patients, manufacturing capacity should be enhanced in normal times, as well as necessary preparations and training should be conducted by organizing systems for smooth distribution to medical institutions and pharmacies so that the system can be rapidly established during the outbreak of novel influenza, etc.

(x) Testing

The purpose of testing during the outbreak of novel influenza, etc., is to prevent spread through the early detection of patients and the diagnosis of patients to lead them with early treatment and understand the actual situation of the spread of novel influenza, etc. Furthermore, the proper implementation of testing is crucial for the appropriate consideration and implementation of prevention of spread measures,

as well as for the flexible and prompt change of those measures. Additionally, ensuring that those who required testing can quickly receive it, when necessary, contributes to minimizing the impact of novel influenza, etc., on individuals and society and helps balance the prevention of spread with socioeconomic activities.

Therefore, during the outbreak of novel influenza etc., it is essential that necessary testing is conducted smoothly, which requires steady preparation in normal times, including maintaining testing equipment, securing testing supplies, and ensuring personnel. Additionally, it is crucial to rapidly establish systems for research and development and testing expansion from the onset of the outbreak of novel influenza, etc. Furthermore, in response to changes in the situation, it is important to change the testing policy flexibly and rapidly based on risk assessments, based on the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) and the properties of testing.

(xi) Health

The outbreak situation of novel influenza, etc., varies by region, and prefectural governments, etc., must implement measures tailored to the regional infection status and medical care delivery system to protect the lives and health of residents. In doing so, it is crucial to appropriately provide and share information with residents and conduct risk communication to gain understanding and cooperation from the community.

Moreover, prefectural governments must proactively implement measures using the Prefectural Coordination Councils, etc., in normal times, anticipating the exercise of authority for comprehensive coordination and instruction in preventing the outbreak of novel influenza, etc., across municipal boundaries.

To implement effective measures against novel influenza, etc., public health centers and public health institutes, etc., play a crucial role by conducting testing, analyzing the results, and carrying out active epidemiological investigations to trace contacts and estimate infection sources, thereby providing and sharing important information about outbreak trends of the patients with prefectural governments, etc.

Public health centers and public health institutes, etc., are expected to face a sudden increase in workloads, such as active epidemiological investigations, health observation, and analysis of the testing results when novel influenza, etc., infections spread, and numerous patients arise. Therefore, in normal times, prefectural governments etc., must build information collection and personnel

systems, organize tasks with priority to address during outbreaks, and enhance efficiency while advancing labor-saving through ICT utilization, etc. The national government should provide the necessary support to facilitate these efforts to promote coordinated measures against novel influenza, etc., at the regional level across the country.

(xii) Supplies

In the event of the outbreak of novel influenza, etc., there is a risk of nationwide and rapid spread, which may lead to a significant increase in the use of infectious disease control supplies, etc. It is crucial to prevent shortages of these supplies, which could hinder quarantine, medical care, and testing, thereby impacting the lives and health of the people. Therefore, in normal times, it is important to promote stockpiling and implement measures for smooth supply to ensure that sufficient infectious disease control supplies, etc., are secured in related organizations, including medical institutions, etc.

In normal times, in addition to promoting the stockpiling of infectious disease control supplies, etc., in institutions such as medical institutions, systems that can monitor the supply and demand situation and address production requests, etc., during the outbreak of novel influenza, etc., should be established.

During the outbreak of novel influenza, etc., the supply and demand situation of infectious disease control supplies, etc., for example, should be monitored. If a shortage is anticipated, production requests, etc., should be made to increase the infectious disease control supplies, etc., as necessary in order to ensure that such necessary supplies are secured in medical institutions.

Moreover, even if, after implementing these measures, there is still a shortage of personal protective equipment, the national government will take further action, such as distributing necessary personal protective equipment to medical institutions.

(xiii) National life and economy

In the event of an outbreak of novel influenza, etc., there is a risk of harm to the lives and health of the people, as well as significant impacts on the national life and socioeconomic activities. Therefore, the national and local governments encourage business operators and the people, etc., to make necessary preparations for an outbreak of novel influenza, etc. Additionally, designated (local) public institutions should undertake necessary preparations, such as formulating

operational plans.

In the event of a novel influenza, etc., outbreak, the national and local governments will implement necessary measures and support to ensure the stability of national life and socioeconomic activities. Meanwhile, business operators and the people, etc., should strive for business continuity and infection prevention on their own based on their preparations in normal times.

(3) Cross-cutting Perspectives Common to Multiple Countermeasure Items

To enhance the effectiveness of measures against novel influenza, etc., perspectives I through V, listed below, should be considered across multiple action items. The specific considerations are as follows below.

- I. Human resource development
- II. Cooperation between the national government and local governments
- III. Promotion of DX
- IV. Support for research and development
- V. International cooperation

I. Human resource development

To improve the response capability for infectious disease crisis management, it is essential to continuously conduct human resource development related to infectious disease crisis management from a medium to long term perspective, even in normal times.

In this process, it is important to advance the development of highly specialized personnel and, while also recognizing that many people may be involved in infectious disease crisis management, to expand the base of personnel engaged in infectious disease crisis response by conducting human resource development through broader training and workshops, etc.

Additionally, it is also important to secure personnel who can take leadership in local measures during future infectious disease crisis.

In particular, it is extremely important to cultivate and secure personnel who possess specialized knowledge in infectious disease measures, can engage in information gathering and measures formulation, and can also play an active role in studying infectious disease in the field of infectious disease measures.

For the development of such personnel, the “Field Epidemiology Training Program (FETP-J),” implemented by JIHS under the commission of the MHLW, plays an important role. It is expected that, based on experiences from COVID-19 measures

and efforts in infectious disease intelligence, etc., in normal times, broader participation from local governments will be encouraged while enhancing the course content.

Additionally, it is also important to continuously develop experts in infectious disease crisis management who possess comprehensive knowledge and skills regarding infectious diseases, including clinical and epidemiological knowledge, public health response abilities, and international coordination abilities, through programs such as the MHLW's "Infectious Disease Emergency Specialist (IDES) Training Program."⁴³

From the perspective of cultivating and securing such personnel, it is necessary to consider support for career development as well, including placement approaches for specialized personnel with knowledge of infectious disease crisis management in normal times.

It is also important for prefectural governments, etc., to promote the training of experts in public health and epidemiology, starting with infectious disease control, in regions and to support their career development while utilizing initiatives, such as the FETP-J and graduates of such courses, as well as to secure and train human resources at public health centers, etc., which will serve as the core of infectious disease control in local governments.

In addition, it is necessary to implement drills and training related to infectious disease response, including risk communication, and to strengthen the involvement of public health institutes, etc., in infectious disease measures in normal times. Also, drills and training, etc., for establishing a coordinated response system across all agencies during outbreaks of novel influenza, etc., are required, along with fostering collaboration and cooperation between infectious disease response and crisis management departments on a regular basis.

In addition, in light of the fact that the Medical Care Act has established a position for disaster and infectious disease healthcare workers (DMAT, DPAT advance teams, and disaster support nurses) who are dispatched in the event of a disaster or the outbreak of infectious disease, it is necessary to continue working to secure personnel, etc., as a part of efforts to strengthen the medical care delivery system in the event of an outbreak of novel influenza, etc.

⁴³ "IDES" stands for Infectious Disease Emergency Specialist, and is a program designed to train personnel capable of responding to infectious disease crisis management both domestically and internationally. The program aims to acquire knowledge of infectious diseases, administrative capabilities (management), and international response abilities.

Moreover, considering the establishment of “IHEAT⁴⁴,” a system in which public health nurses and other local health professionals support operations in public health centers, etc., during outbreaks of novel influenza, etc., under the Community Health Act (Act No. 101 of 1947), it is necessary to continuously work on securing and developing IHEAT personnel⁴⁵ for support.

It is also important to create opportunities for sharing the knowledge of those with experience of COVID-19 measures with other staff members, ensuring a broad-based system capable of responding to novel influenza, etc. Efforts should also be made to promote the necessary training and human resource development while utilizing know-how and insights from adjacent areas, such as the all-agency system in disaster response, etc.

In regional medical institutions, etc., it is expected that human resource development, which is for improving response capabilities to novel influenza, etc., and establishing a broad-based response system through doctors and nurses specializing in infectious diseases, researchers engaged in matters such as pathogen analysis, therapeutic agents and vaccine development, personnel capable of promoting clinical research, including clinical trials, etc., should be promoted in normal times through training and workshops, etc., conducted by local governments and related organizations, etc.

II. Cooperation between the national government and local governments

In responding to novel influenza, etc., the role of local governments is incredibly important. Under an appropriate division of roles between the national and local governments, the national government establishes basic policies, and based on these, prefectural governments play a central role as the implementing bodies under the Infectious Diseases Control Law and the Act on Special Measures, etc. Prefectural governments carry out a wide range of measures, including preventing the spread of infection and ensuring medical care delivery systems tailored to regional circumstances. Additionally, municipalities, as the administrative units closest to residents, are expected to take on roles, such as providing vaccinations and ensuring the provision of food and daily necessities.

⁴⁴ "IHEAT" stands for Infectious Disease Health Emergency Assistance Team. It is a system established under the Infectious Diseases Control Law aimed at effectively utilizing external professionals when there is a public announcement of the outbreak, etc. of novel influenza, etc., or in the event of other health crises. It involves local health professionals supporting operations at public health centers during such health emergencies.

⁴⁵ Refers to the operational support personnel specified in Article 21 of the Community Health Act. The same applies below.

In order to ensure robust preparedness for novel influenza, etc., it is essential to establish a cooperative framework between the national and local governments in normal times. Furthermore, since responses to novel influenza, etc., may involve the movement of people and the spread of infection across local government boundaries, etc., cooperation between prefectural governments, between prefectural governments and municipalities, and among public health centers becomes crucial during outbreaks. It is also important to actively engage in and prepare for such wide-area cooperation among local governments in normal times.

In particular, with regard to human resource development and other preparations in normal times, which are difficult for small municipalities to handle on their own, it will be necessary for local governments to cooperate with each other on a wide scale, and for prefectural governments and the national government to provide support in normal times.

In order to enable rapid response from the early stages of an outbreak of novel influenza, etc., smooth collection, sharing, analysis, etc., of data and information related to the novel influenza, etc., are required to be possible during an infectious disease crisis. Therefore, efforts should be made to build cooperative frameworks and networks between the national government and prefectural governments, etc., in normal times.

Additionally, to ensure that local governments provide appropriate information and share it with residents, business operators, and related organizations, etc. during outbreaks of novel influenza, the national government should offer information to local governments in the clearest possible way. In preparation for the next infectious disease crisis, the national government will consider methods for reducing workload and improving clarity regarding information provision and sharing, etc., from the national government to local governments.

In taking measures against novel influenza, etc., it is important that the national government and local governments exchange opinions in normal times, and in planning and implementing measures against novel influenza, etc., at the time of an outbreak of novel influenza, etc., it is important to hold dialogues with local governments that are responsible for the site of the measures and to reflect the opinions of local governments appropriately. It is also important for the national and local governments to conduct joint training, etc., and to periodically check and improve the coordination system.

III. Promotion of DX

(i) Promotion of DX

Recent advancements in DX have led to the rapid understanding of outbreak situations, etc., of novel influenza, etc., and to real-time information sharing among related parties, which are expected to reduce workloads and strengthen cooperation among related parties. Additionally, promoting the utilization of data for research and development, etc., holds great potential for enhancing response capabilities to novel influenza, etc.

For example, during the COVID-19 response, the rapid spread of infection led to an increase in the number of outbreak reports based on the Infectious Diseases Control Law, which significantly increased the burden on the staff of public health centers in terms of inputting data and other tasks. For this reason, the “Health Center Real-time Information-sharing System on COVID-19 (HER-SYS)” was developed to enable the online submission of outbreak reports from medical institutions in 2020. In addition, patients themselves were able to report their own health status online, reducing the burden on the staff of public health centers and others in health observation work, etc. Moreover, the “Gathering Medical Information System (G-MIS)” was used to centrally monitor the use of hospital beds and the availability of infectious disease control supplies, etc., at medical institutions nationwide, and the system was used at quarantine sites to obtain information on people entering Japan and to implement health monitoring, etc., after entry into Japan, thereby striving to improve operational efficiency and ensure the speed of information gathering.

Based on the COVID-19 responses, it is essential to aim for enhanced response capabilities in infectious disease crisis management, including medical DX, and to promote DX in preparation for responding to the infectious disease crisis, such as novel influenza, etc.

As a part of promoting DX, it is important to establish a national network through the digitalization and standardization of vaccination procedures, such as identifying vaccination targets and managing vaccination records, as well as standardizing electronic medical record information, etc. It is also important to develop a foundation for information collection, sharing, and analysis between the national and local governments, among local governments, and between administrative agencies and medical institutions, etc. The national government and JIHS should consider the protection of personal information and privacy when collecting clinical information for building a foundation for the research and

development of vaccines, therapeutic agents, etc. At the same time, they should also work to build systems toward contributing to the establishment of the research and development of therapeutics by, for example, building systems for extracting information from electronic medical records. In addition, to alleviate the burden of inputting outbreak reports in medical institutions, etc., consideration should be carried out regarding the linking of electronic medical records with outbreak reports.

Furthermore, consideration will be given to the development of human resources and data management, which are necessary for the promotion of DX, and issues will be organized and examined with the aim of promoting the utilization of collected information.

In advancing these efforts, it is crucial to provide timely and appropriate information to the people, taking into account the needs of those with visual or hearing impairments, etc.

(ii) Other new technologies.

Against the COVID-19, new technologies not previously utilized in infectious disease control were attempted, including technological innovations in vaccines, simulations of transmission routes, etc., using the supercomputer “Fugaku,” analysis of human flow data using mobile phone data, etc., and the development of applications that notify users of contact with people who have tested positive via mobile phones (Bluetooth). Additionally, the use of sewage surveillance, previously used for poliovirus, was also attempted for COVID-19 measures. In recent years, there have been technological innovations in drug development and generative AI, etc., using new technologies. In addressing measures against novel influenza, etc., it is crucial to consider the societal implementation of new technologies as well, including the initiatives in response to COVID-19.

IV. Support for Research and Development

A representative example of technological innovation and the societal implementation of new technologies in the COVID-19 response is the technological innovation in vaccines. The vaccines used against the COVID-19 included not only traditional inactivated vaccines but also rapidly developed vaccines utilizing diverse new modalities, such as mRNA (messenger RNA) vaccines, viral vector vaccines, and recombinant protein vaccines. Furthermore, the vaccine was put into practical use in an extremely short period of time around the world through modifications to

the implementation methods and approval processes of clinical trials. As a result, countries that succeeded in vaccine development and countries and regions that quickly introduced vaccines were able to provide large-scale vaccinations, which played a significant role in countermeasures owing to its effectiveness in preventing severe cases of the disease, etc.

Thus, it is extremely important to promote research and development and clinical research toward the early development of vaccines, diagnostics and therapeutic agents, etc., whose efficacy and safety are ensured at an early stage of an outbreak of novel influenza, etc. from the viewpoint of enhancing the ability to cope with.

By advancing technological development in normal times, enhancing testing capabilities of diagnostics that can test accurately and quickly, testing equipment, testing reagents, and rapid testing kits, etc., that can deal with increased demand for testing after the spread of infection, and disseminating therapeutics at an early stage, it will become possible for medical institutions in many regions to respond. Research and development aimed at the early practical application of therapeutic agents and diagnostics play a crucial role in preventing from spread of infection and strengthening medical care delivery systems.

Moreover, the effectiveness of preventing severe cases, etc., through the dissemination of vaccines is also important for addressing against such as novel influenza. Therefore, research and development of vaccines play a crucial role for an early practical application.

Furthermore, the dissemination of vaccines, diagnostics, therapeutic agents, etc., will enhance testing and medical care delivery systems, leading to improved immunity, etc., and further protection of the lives and health of the people. As a result, the measures can be switched at the appropriate time in accordance with these changes in the situation, based on the balance between the prevention from the spread of infection and socioeconomic activities.

As above, advancing research and development is crucial and significantly impacts overall strategies in response to novel influenza, etc. On the other hand, efforts in normal times are essential for rapid research and development in the outbreaks. In normal times, there may be no demand for such drugs for infectious disease crisis⁴⁶, resulting in a lack of market predictability and numerous challenges for pharmaceutical companies in terms of investing in development and achieving

⁴⁶ In infectious disease crisis management, this refers to essential pharmaceuticals and medical devices that serve as critical medical countermeasures for saving lives, controlling outbreaks, and maintaining social activities.

practical applications. In order to promote the research and development of vaccines, diagnostics, therapeutic agents, etc., in normal times and to enable rapid response to outbreaks, such as novel influenza, etc., support measures should be organized. Another such support measure is the establishment of a long-term and continuous research support system as well as the development of human resources with expertise in research and development and clinical trials, and together, these will help to increase market predictability and make it easier for pharmaceutical-related companies to embark on development. In addition, the national government will educate the people about the significance of research and development and clinical trials (e.g., clinical trials).

Not only the vaccines treated with priority under the “Strategy for Strengthening Vaccine Development and Production System,” but diagnostics and therapeutic agents also play a crucial role in addressing against such as novel influenza, which implies that it is necessary to further promote research and development.

It is also important that epidemiological and clinical information, etc., collected at an early stage is utilized in such research and development. In order to achieve this, it is crucial to promote collaboration among various stakeholders concerned, including medical institutions conducting clinical research, relevant academic societies, universities, and pharmaceutical companies, with JIHS as the focal point. Additionally, it is important to keep in mind the importance of international collaboration with research institutions in other countries.

V. International Cooperation

- (i) The importance of international cooperation in responding to novel influenza, etc.

It is necessary to keep in mind that international cooperation is becoming increasingly important in collecting information on and response to novel influenza, etc.

It is also necessary to pay attention to trends in the international frameworks for responding to infectious disease crisis established by international organizations, such as the WHO.

Especially in the area of infectious disease control, each country’s active contribution and role as a member of the international society will not only benefit the international society in confronting the spread of infectious diseases across borders but will also give its own country an advantage in dealing with infectious diseases. It is important for Japan to cooperate with developed countries and take

measures in order to contribute to international society through ways such as international cooperation with developing countries.

International collaboration is also essential from the perspective of research and development. In the international society, efforts for international cooperation are underway to rapidly develop vaccines, diagnostics, therapeutic agents, etc., following the outbreak of novel influenza, etc. It is also necessary to examine whether there is room for simplification or acceleration, etc., of procedures based on Pharmaceutical Affairs Act and other related laws and regulations to enable rapid research and development with international collaboration and to facilitate such efforts through international cooperation.

(ii) Efforts for international cooperation

Novel influenza, etc., spread globally across borders, making international cooperation essential for response.

In order to prepare for the outbreak of novel influenza, etc., it is crucial to cooperate with international organizations, such as the WHO and research institutions in other countries, to understand the trends of occurrence of emerging infectious diseases, etc., as well as enhance the ability to detect initial cases.

During the outbreak of novel influenza, etc., international collaboration for information gathering, especially in the early stages, plays a crucial role. It is necessary for our country to appropriately engage in international information dissemination. In order to implement rapid border measures and adjust responses according to the situation, it is important to assess factors such as risks associated with the emerging novel influenza, etc., and monitor trends in other countries.

International collaboration with research institutions in other countries is also important for the research and development of vaccines, diagnostics, therapeutic agents, and similar products.

In responding to novel influenza, etc., contributing to international cooperation, such as supporting developing countries, is an important aspect that our country should achieve, and it is also necessary to participate in international initiatives led by international organizations, etc.

In order to strengthen such international cooperation, efforts will also be made in the medium to long term to train and secure international healthcare personnel, including those for infectious disease control.

Chapter 3: Efforts to Ensure the Effectiveness of National Action Plans

Section 1: The Role of JIHS

In preparing more thoroughly for the next infectious disease crisis, the JIHS plays a crucial role. As JIHS is legally required⁴⁷ to report scientific findings to the CAICM and the MHLW, its expected roles in responding to novel influenza, etc., include items (1) through (5) below.

(1) Risk assessment based on information gathering using networks with public health institutes, etc.

The foundation for addressing measures against novel influenza, etc., lies in understanding the characteristics of the specific novel influenza, etc., including the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) and conducting risk assessments based on this information.

There are many aspects that are unknown in regard to emerging infectious diseases, etc., and it is not always possible to obtain sufficient scientific knowledge from the outset, which then leads to a certain level of uncertainty. It should be noted that there is a certain “science in progress” element that makes it unavoidable to take measures while also verifying tentative hypotheses in an overall process where, for example, the characteristics of the pathogen gradually become clearer.

On this basis, it is important to accurately conduct risk assessments as the foundation for responding to novel influenza, etc. In order to achieve this, it is essential to establish and operate systems for information collection, analysis, and risk assessment in normal times.

In order to build such systems, it is expected that JIHS, which plays a role as a hub for infectious disease intelligence, will strengthen surveillance and information collection and analysis structures and will also cooperate and collaborate with research institutions, etc., and medical institutions abroad, and universities, etc., along with local governments, such as public health institutes, etc., thereby further strengthening the network for infectious disease information as part of an endeavor to enhance the capacity to detect initial cases and improve risk assessment capabilities.

(2) Rapid provision of scientific knowledge, clear information provision and sharing of advice on countermeasures

JIHS is expected to play a crucial role in situations that require a rapid provision of

⁴⁷ Article 23, paragraph (1), item (v) and paragraph (2) of the Act for the Japan Institute for Health Security

scientific knowledge and advice on measures based on scientific evidence.

In particular, during the early stages of an outbreak of novel influenza, etc., an essential role of JIHS is analyzing the characteristics of the pathogen and transmission routes, etc., through the accumulation of cases, and based on risk assessments, considering the content of measures against novel influenza, etc., and facilitating case definitions and effective testing methods, etc. JIHS also serves an important role in continuously conducting risk assessments, taking into consideration changes in the situation, and providing the necessary advice to the national government to facilitate adjustments in efforts toward advancing measures against novel influenza, etc.

As part of such roles, clinical and epidemiological surveys are to be conducted to rapidly collect knowledge that cannot be obtained through surveillance conducted in normal times, like the “First Few Hundred Studies (FF100),” from a few hundred cases that meet the case definition at the beginning of an outbreak of novel influenza, etc. The findings necessary for the obtained measures are expected to be returned to related organizations, such as the national government and prefectural governments, as well as the people. It is also important to develop systems for conducting such surveys and analyses. Along with this, it is necessary to monitor the acquisition status of immunity through infection and vaccination as well.

Additionally, it is also an important role to create guidelines, such as for medical treatment and testing methods for novel influenza, etc., based on the experience of taking the initiative in treating patients with novel influenza, etc., and the findings gained from treatment experience and survey and research at other designated medical institutions, etc., for infectious diseases, etc., and to support the establishment of medical care delivery systems in each region by providing these findings.

Furthermore, it is expected to provide and share information on measures against novel influenza, etc., including collected data, risk assessments of pathogens, therapeutics, etc., in a clear manner to contribute to promoting an understanding among the people, and alleviating their concerns.

In addition, there is an expectation to advance research on the utilization of new technological innovations, such as simulations of transmission routes and analysis of human flow data, etc., as well as existing technologies for measures against novel influenza, etc.

(3) Role as a hub for networks in research and development and clinical research, etc.

JIHS is expected to conduct clinical research from the initial phase in conjunction with rapid research and development of vaccines, diagnostics, and therapeutic agents

on its own by utilizing networks with foreign research institutions, etc., domestic research institutions and pharmaceutical companies, etc., as well as to support research and development in Japan. It is necessary for JIHS to promote the expansion, etc., of initiatives like the “Repository of Data and Biospecimen of Infectious Disease (REBIND)” and to serve as a hub for networks related to research and development, clinical studies, etc.

Therefore, it is important to consider how to secure the necessary system and budget so that the JIHS can function as a hub for networks in research and development, clinical research, etc., including the establishment of a mechanism that allows the JIHS to make proposals, etc., to the national government regarding the direction of research needed in areas related to measures against novel influenza, etc.

(4) Human Resource Development

In order to enhance response capabilities to novel influenza, etc., specialized human resource development is crucial, and there are high expectations for JIHS’s initiatives in human resource development. To this end, JIHS will promote the development of specialized human resources, such as public health personnel to deal with infectious diseases, medical personnel, and personnel capable of analyzing pathogens and promoting research and development in cooperation with universities and other related organizations. Moreover, there is a particular need to further enhance and strengthen the functions of the JIHS, which develops human resources playing a central role in epidemiological surveys, risk assessments, and public health responses at local governments and other organizations, starting with the FETP-J, which the JIHS conducts by being commissioned by the MHLW. In addition, for example, JIHS is strongly expected to contribute to the improvement of response capabilities to novel influenza, etc., by utilizing its expertise in, for example, testing accuracy management and risk communication related to infectious diseases, along with this to further contribute to the development of human resources who will take the initiative in the event of an outbreak of novel influenza, etc.

Additionally, the training of specialized personnel who can promote medical care and clinical research related to novel influenza, etc., is another crucial role for JIHS, and further enhancement is required.

(5) International Cooperation

JIHS will strengthen its system for the centralized aggregation, management, analysis, and risk assessment of necessary information from international organizations,

such as WHO, and public health agencies, such as the Centers for Disease Control and Prevention. It is required to improve early detection and risk assessment capabilities for emerging infectious diseases, as well as enhance research and development systems through collaboration with foreign universities and research institutions, along with the establishment of international infectious disease information networks.

Section 2: Ensuring the Effectiveness of the National Action Plan

(1) Promotion of policies based on the concept of Evidence-Based Policy Making (EBPM)

In order to ensure the effectiveness of the National Action Plan, etc., and to make responses to novel influenza, etc., more robust, it is important that each initiative related to measures against novel influenza, etc., is as specific and systematic as possible.

In addition to the timing of the response to switching measures that balance infection control and socioeconomic activities, both in normal times and during crisis, policies will be implemented based on the concept of EBPM to utilize information, statistics, and other data that are significantly relevant for measuring policy effectiveness. As a prerequisite for this, it is important to have a system that enables the collection and analysis of appropriate data.

(2) Maintaining momentum for preparedness against novel influenza, etc.

The National Action Plan is a means to ensure thorough preparedness for novel influenza, etc., in normal times, and it is essential to maintain and enhance the preparedness system even after the National Action Plan is revised.

Novel influenza, etc., is unpredictable and can occur at any time. Therefore, it is crucial to continuously implement efforts to enhance preparedness and awareness on a daily basis, as well as to prepare for natural disasters.

Based on the experience of COVID-19 response, in which local governments, the people were widely involved in the response, momentum will be maintained to enhance preparedness for novel influenza, etc., in normal times through training, drills, awareness-raising activities, etc., so that the preparedness for novel influenza, etc., will be enhanced.

(3) Implementation of practical training with the participation of diverse entities

The idea that “You cannot do during an emergency what you cannot do during training” applies not only to disasters but also to responses to novel influenza, etc. It is immensely important to conduct training to facilitate ongoing inspection and improvement in preparedness in normal times. The national and local governments should encourage continuous efforts for related organizations to implement training and to carry out inspections and improvements based on it.

(4) Regular follow-ups and necessary revisions

It is important to make necessary revisions to relevant documents, such as this

National Action Plan and guidelines, in accordance with changes in the situation, such as points of improvement gained from training, enhancement of policies through regular reviews of the prevention plan under the Infectious Diseases Control Law and the medical care plan under the Medical Care Act, as well as new insights gained regarding emerging infectious diseases, etc.

From this perspective, the CAICM will conduct periodic follow-ups and visualizations of the status of efforts every fiscal year while hearing the opinions of the Promotion Council, etc., regarding efforts based on relevant documents, such as this National Action Plan and guidelines, and efforts to develop and secure human resources related to measures against novel influenza, etc.

In addition to improving efforts through regular follow-ups, etc., necessary examinations for revising the National Action Plan will be conducted approximately every six years, considering factors such as the status of emerging infectious diseases, etc., both domestically and internationally and responses to those diseases, and the review status of various systems related to measures against novel influenza, etc., including prevention plans and medical care plans, and required measures will be implemented based on the results of these examinations.

In cases where novel influenza, etc., occur and actual responses to the infectious disease crisis management are implemented, this National Action Plan and related documents will be revised based on those response experiences, regardless of the above period.

(5) Prefectural action plans and municipal action plans, etc.

Based on the revision of this National Action Plan, prefectural governments and municipalities will also revise their action plans to ensure more thorough preparedness against novel influenza, etc.

The national government will provide information, etc., to contribute to the enhancement of action plans, mainly by the CAICM, from the perspective of deepening collaboration with local governments for the review of the action plans by prefectures and municipalities.

Furthermore, regarding measures against novel influenza, etc., in normal times, from the CAICM to prefectural governments and municipalities, the CAICM will enhance the support of measures taken by prefectures and municipalities, for example, by providing information worth enhancing measures in normal times, horizontally deploying good practices and offering information on necessary training.

(6) Designated (Local) Public Institutions Entity Business Plans

Designated (local) public institutions will also look back on their responses to COVID-19 and consider necessary measures to ensure the continuity of operations from the perspective of making preparedness for novel influenza, etc., more robust. They will review their operational plans based on the outcomes of these assessments and the promotion of DX and dissemination status of telework, etc.

Part 3: Approach and Efforts for Each Countermeasure Item against Novel Influenza, etc.

Chapter 1: Implementation System

Section 1: Preparation phase

(1) Purpose

In the event of an outbreak or suspected outbreak of novel influenza, etc., domestically or internationally, it is important for the national government to accurately identify the situation and promote unified government initiatives. To this end, the national government will clarify the roles of related organizations, establish a command and order system, etc., that will function in crisis, organize and confirm an expandable organizational structure, adjust personnel to fulfill their respective roles, organize operations that can be reduced, etc. In addition, the national government will strive to identify issues, make improvements, enhance proficiency through training and drills, etc., as well as strengthen cooperation among related organizations through measures, such as holding regular meetings.

(2) Required Response

1-1. Review of the National Action Plan

The national government will obtain the opinions of the Promotion Council in advance and, under the provisions of the Act on Special Measures⁴⁸, review the National Action Plan for dealing with outbreaks of novel influenza, etc., as necessary. (CAICM; all other ministries and agencies)

1-2. Implementation of practical training

The national government, JIHS, prefectural and municipal governments, designated (local) public institutions, and medical institutions will implement practical training in preparation for outbreaks of novel influenza, etc., taking into account the content of the National Action Plan. (CAICM; MHLW; all other ministries and agencies)

1-3. Establishment and strengthening of the systems of the national government, etc.

- (i) The national government will promote the revision of business continuity plans of central government ministries and agencies and take other measures to develop and enhance initiative systems in the national and other sectors by securing the necessary personnel system and other resources to implement

⁴⁸ Article 6, paragraphs (5) and (8) of the Act on Special Measures.

operations that should be enhanced and expanded in the event of an outbreak of novel influenza, etc., and by continuing operations that should be maintained even in crisis. (CAICM; all other ministries and agencies)

- (ii) The national government and JIHS will promote the training and development, etc., of expert personnel and administrative officials, and others involved in countermeasures against novel influenza, etc., while providing support for career development, etc. (CAICM; all other ministries and agencies)
- (iii) The national government will report on the progress of initiatives, etc., during the preparation phase to the Promotion Council and promote initiatives through the PDCA cycle, such as by obtaining opinions on points for improvement. (CAICM; relevant ministries and agencies)
- (iv) The national government and JIHS will enhance their cooperation with experts in fields related to infectious disease crisis management, such as medical care, public health, and socioeconomics, so that they can rapidly provide and share information and obtain advice in crisis. (CAICM; MHLW)
- (v) The national government will establish the necessary systems, including the appointment of a public relations officer in charge of press conferences, in order to provide and share information in an integrated and consistent “one-voice” manner⁴⁹ as a nation, as well as organize the methods of providing and sharing information, etc., by the relevant ministries and agencies in a one-voice manner. (CAICM; MHLW; relevant ministries and agencies)
- (vi) JIHS will work with the national government to provide and share basic information on infectious diseases, information on the outbreak status of infectious diseases, information on novel influenza, etc., and countermeasures against them, etc., to the people in an easily understandable manner. (MHLW; CAICM)
- (vii) The national government and JIHS will closely cooperate, such as by regularly sharing information, etc., in normal times, and will make the necessary preparations so that they can respond rapidly in the event of an outbreak of novel influenza, etc. (CAICM; MHLW)
- (viii) JIHS will establish an ordinal system that can respond to requests for scientific knowledge from the CAICM and the MHLW, as well as a system designed to respond to health crises in crisis, such as research and surveys. In addition, it will establish a system that can respond rapidly in the event of an

⁴⁹ The One-voice Principle is not about limiting the number of spokespeople to one, but about providing and sharing information consistently, even when it comes from multiple sources responsible for crisis management.

infectious disease crisis. (CAICM; MHLW)

- (ix) The national government will cooperate with relevant parties within and outside Japan in the information collection and analysis of infectious disease crisis management, systematically and comprehensively collect, analyze, and interpret information from all available sources, and establish a system to obtain information that can be used for policy decision-making and practical judgment. (CAICM; MHLW; all other ministries and agencies)

1-4. Formulation of action plans, etc., by local governments, etc., and development and enhancement of systems

- (i) Prefectural and municipal governments and designated (local) public institutions will respectively formulate and revise prefectural action plans, municipal action plans, and operational plans for designated (local) public institutions, and the national government will support the formulation and revision of these plans. Prefectural and municipal governments will obtain the opinions of people with expertise in infectious diseases and other academic experts⁵⁰ in advance when they formulate or revise their respective action plans. (CAICM; MHLW; ministries and agencies that have jurisdiction over the operation)
- (ii) Prefectural and municipal governments will formulate and revise business continuity plans to secure the necessary personnel, etc., to implement operations that should be enhanced and expanded in the event of an outbreak of novel influenza, etc., and to ensure the continuity of operations that should be maintained even in crisis. The national government will also support the formulation and revision of such business continuity plans. Prefectural governments' business continuity plans will be formulated, taking into consideration their consistency with the business continuity plans of public health centers, etc. under the jurisdiction of the prefectural governments, as well as the business continuity plans of municipalities. (CAICM; MHLW)
- (iii) In addition to the provisions of the Act on Special Measures, prefectural governments will, by ordinance, provide the necessary matters concerning the Prefectural Countermeasures Headquarters⁵¹. (CAICM)
- (iv) In order to establish a response system for all agencies in the event of an outbreak of novel influenza, etc., prefectural governments will implement drills

⁵⁰ Article 7, paragraphs (3) and (9), and Article 8, paragraphs (7) and (8) of the Act on Special Measures.

⁵¹ Article 26 of the Act on Special Measures.

and training, etc., and will also enhance cooperation between the infectious disease response department and the crisis management department and coordinate the division of roles. (CAICM)

- (v) Prefectural and municipal governments, designated (local) public institutions, medical institutions, etc., will implement the training, etc., of healthcare workers, expert personnel, administrative officials, and others involved in measures against novel influenza, etc. In particular, prefectural governments, etc., will make efforts to secure and develop personnel at public health centers and public health institutes, etc., which are at the core of local infectious disease countermeasures, while actively utilizing training, etc., provided by the national government, JIHS, and prefectural governments. The national government and JIHS will support these initiatives to secure and develop such personnel. (CAICM; MHLW; relevant ministries and agencies)
- (vi) The national government will support the initiatives of prefectural governments, etc., in the development of facilities and equipment, etc., necessary for countermeasures against novel influenza, etc. (MHLW; relevant ministries and agencies)

1-5. Enhancing cooperation among the national and local governments, etc.

- (i) The national government, prefectural and municipal governments, and designated (local) public institutions will cooperate to share information in normal times, confirm their systems for cooperation, and conduct training in preparation for an outbreak of novel influenza, etc. (CAICM; all other ministries and agencies)
- (ii) The national government, prefectural and municipal governments, and designated (local) public institutions will establish a system of cooperation, including the exchange of information and other activities with related organizations, such as domestic industry groups and related academic associations, in preparation for an outbreak of novel influenza, etc. (CAICM; MHLW; ministries and agencies that have jurisdiction over the operation)
- (iii) The national government will provide the necessary support to help prefectural governments promote cooperation with police, firefighting, the Japan Coast Guard (JCG), the Self-Defense Forces, etc. (National Police Agency (NPA); Fire and Disaster Management Agency (FDMA); MHLW; JCG; Ministry of Defense (MOD))
- (iv) In accordance with the Infectious Disease Control Law, prefectural

governments will organize their own Prefectural Coordination Council⁵² composed of cities with public health centers, etc., in their jurisdiction, and will use such as the council to discuss such matters as methods of coordinating hospital admissions, securing medical personnel, public health center systems and policies on testing systems and the conduct of testing, methods of information sharing, etc. The prefectural governments will formulate and revise their prevention plans, taking into account the results of these discussions and the basic guidelines⁵³, etc. stipulated by the national government. In addition, when they formulate or revise the prevention plan, efforts will be made to ensure consistency with the action plan formulated by prefectural governments, etc., based on the Act on Special Measures, the medical care plan under the Medical Care Act, and the health crisis response plan based on the basic guidelines for promotion of community health measures⁵⁴. (MHLW)

- (v) Prefectural governments will coordinate with municipalities in advance and steadily prepare the specific operational methods for acting on behalf of and supporting the specified measures for novel influenza, etc., as described in Section 3 (Response Phase), 3-1-5 (specified measures for novel influenza, etc., as stipulated in Article 2, Item 2-2 of the Act on Special Measures, the same hereinafter.) (CAICM; MHLW)
- (vi) In the event that it is necessary from the perspective of preparing a system for infectious disease responses in advance and securing human resources, etc., prefectural governments will exercise the authority for comprehensive coordination over municipalities, medical institutions, private institutions, such as infectious disease testing and research institutions⁵⁵, etc.⁵⁶, and steadily promote preparations. (MHLW)

1-6. Development and strengthening of international cooperation systems

- (i) The national government and JIHS will establish a system that allows for the rapid sharing of information with international organizations and foreign governments, etc., in the event of an outbreak of novel influenza, etc. (MHLW; Ministry of Agriculture, Forestry and Fisheries (MAFF); Ministry of Education,

⁵² Article 10-2, paragraph (1) of the Infectious Diseases Control Law.

⁵³ Article 9 and Article 10, paragraph (1) of the Infectious Diseases Control Law.

⁵⁴ Article 10, paragraphs (8) and (17) of the Infectious Diseases Control Law.

⁵⁵ This refers to an institution that conducts research on methods of treating infectious diseases or other research or testing related to infectious diseases, such as pathogen testing, as stipulated in Article 15, paragraph (16) of the Infectious Diseases Control Law. The same shall apply hereinafter.

⁵⁶ Article 63-3, paragraph (1) of the Infectious Diseases Control Law.

Culture, Sports, Science and Technology (MEXT); Ministry of the Environment (MOE); Ministry of Foreign Affairs (MOFA))

- (ii) The national government and JIHS will participate in the cooperative and collaborative systems for international cooperative initiatives related to the development of vaccines, diagnostic agents, and therapeutics, etc. (National Healthcare Policy Secretariat; MOFA; MHLW; MEXT; MAFF; Ministry of Economy, Trade and Industry (METI))
- (iii) The national government and JIHS will host trainees from, send experts to, and provide onsite training, etc., with foreign governments and international organizations, etc., for human resource development, such as health care workers, expert personnel, administrative officials, and others. (MOFA; MHLW; MAFF; MEXT)
- (iv) The national government and JIHS will conduct joint training with foreign governments and international organizations, etc., on the assumption of an outbreak of novel influenza, etc. (CAICM; MOFA; MHLW; MAFF)
- (v) The national government and JIHS will organize an expert personnel team to be dispatched overseas, consisting of epidemiological, laboratory, clinical, livestock health, and other personnel so that they can dispatch the personnel in response to requests from international organizations or the country of the outbreak in the event of an outbreak of novel influenza, etc. (MOFA; MHLW; MAFF; MOE)
- (vi) JIHS, in cooperation with universities and other related organizations, will conduct research and studies, including toward strengthening international partnerships, and the national government will support such research and studies. (MHLW; MAFF; MEXT; MOE)
- (vii) JIHS will establish a cooperation system with related organizations, including overseas research institutes, etc., in order to rapidly collect information and receive the provision of samples and other support in the event of the outbreak of novel influenza, etc. (MHLW)
- (viii) In order to prevent an outbreak of novel influenza, etc., derived from wild animals and domestic poultry, etc., the national government will promote initiatives, etc., related to international zoonosis prevention and quarantine based on the one-health approach concept. (MOFA; MHLW; MAFF; MOE)

Section 2: Initial phase

(1) Purpose

In the event of the outbreak or a suspected outbreak of novel influenza, etc., domestically and internationally, the national government must accurately grasp the situation as part of its national crisis management, taking urgent and comprehensive countermeasures to protect the lives and health of the people. To this end, based on deliberations, etc., in the preparation phase, the national government will hold the Ministerial Conference and the Interministerial Coordination Conference as necessary, enhance the implementation system of countermeasures in the national government and related organizations, and rapidly implement countermeasures against novel influenza, etc., in the initial phase.

(2) Required Response

2-1. Measures to be taken in the event of suspected outbreak of novel influenza, etc.

- (i) In the event of a suspected outbreak of novel influenza, etc., domestically or internationally, the national government will share information among relevant ministries and agencies, etc., and, if necessary, report the matter to the WHO in accordance with the International Health Regulations (IHR). (CAICM; MOFA; MHLW; all other ministries and agencies)
- (ii) The national government and JIHS will strengthen the information collection and analysis on trends of the outbreak, etc., domestically and internationally, conduct them effectively and rapidly, and rapidly implement risk assessment and share the results of such assessments. (CAICM; MHLW; relevant ministries and agencies)
- (iii) The Secretary General for Infectious Disease Crisis Management, Cabinet Secretariat, will, depending on the situation, hold emergency consultations with relevant ministries and agencies, as well as report information on the situation to the Prime Minister and receive the necessary instructions. The Deputy Chief Cabinet Secretary for Crisis Management will work with the CAICM upon receiving an ad hoc order, when a situation arises that requires crisis management countermeasures related to infectious diseases⁵⁷. (CAICM, etc.; Cabinet Secretariat; MHLW)
- (iv) The national government will rapidly hold the Interministerial Coordination Conference or, if necessary, the Ministerial Conference to gather, share and

⁵⁷ Article 15, paragraph (3) of the Cabinet Law.

analyze information to discuss and determine the government's initial action policy. (CAICM; all other ministries and agencies)

- (v) The national government, as necessary, will have JIHS attend Interministerial Coordination Conference and Ministerial Conference to express its opinions on scientific knowledge, etc., of which it is aware. (CAICM; MHLW)

2-2. Measures to be taken when an outbreak of novel influenza, etc., is confirmed

- (i) When an outbreak of novel influenza, etc., is confirmed, such as when the WHO has disclosed an outbreak of a new infectious disease that may spread rapidly (PHEIC declaration, etc.), the national government will immediately share information among the relevant departments, ministries and agencies, etc. In addition, in order to accurately implement measures under the Infectious Diseases Control Law, the Quarantine Act (Act No. 201 of 1951) and the Act on Special Measures, which are necessary in accordance with trends in outbreaks of infectious diseases and changes in the situation, the national government will examine which of these laws apply to which types of cases, and make any necessary amendments to the Cabinet Order. If the MHLW recognizes that there is an outbreak of novel influenza, etc., the Minister will immediately make a public announcement⁵⁸ and report to the Prime Minister⁵⁹. (CAICM; MOFA; MHLW)
- (ii) Upon receiving a report, as described in (i) above, the Prime Minister will establish the Government Countermeasures Headquarters followed by a Cabinet meeting, report the name, location, and period of the headquarters to the Diet, and announce the headquarters publicly, except in cases where it is recognized that the severity of symptoms of contracted cases is generally the same as or less than that of seasonal influenza⁶⁰.

Prefectural governments will immediately establish their own Prefectural Countermeasures Headquarters⁶¹. At the same time, if necessary, municipalities will consider establishing a countermeasures headquarters to prepare for measures related to the countermeasures against novel influenza, etc. (CAICM; MHLW)

- (iii) The national government will strengthen the system of the CAICM by

⁵⁸ Article 44-2, paragraph (1), Article 44-7, paragraph (1) and Article 44-10, paragraph (1) of the Infectious Diseases Control Law.

⁵⁹ Article 14 of the Act on Special Measures.

⁶⁰ Article 15 of the Act on Special Measures.

⁶¹ Article 22, paragraph (1) of the Act on Special Measures.

assigning, as necessary, senior officials of ministries and agencies designated in advance during the preparation phase to serve concurrently in the CAICM and by having other officials participate in the CAICM, and will also work to ensure the unity of the national government in countermeasures against novel influenza, etc. (CAICM; relevant ministries and agencies)

- (iv) In conjunction with the establishment of the Government Countermeasures Headquarters, the national government will convene supporting officials from within and outside the MHLW to enhance the system of the Ministry, which plays a central role in practical measures for infectious disease countermeasures, and rapidly establish an implementation system for countermeasures against novel influenza, etc. (MHLW; all other ministries and agencies)
- (v) The national government, as necessary, will have JIHS attend the Government Countermeasures Headquarters to express its opinions on the scientific knowledge, etc., of which it is aware⁶². (CAICM; MHLW)
- (vi) The national government will determine the basic action policy on the basis of the National Action Plan and immediately announce it to raise public awareness⁶³, taking into consideration the knowledge provided by JIHS, etc., after obtaining the opinions of the Promotion Council (except in urgent cases where there is no time to obtain the opinions of the Promotion Council; the same shall apply hereinafter when the national government obtains the opinions of the Promotion Council at the time of formulating or revising the basic action policy). (CAICM; MHLW; all other ministries and agencies)
- (vii) The national government and prefectural and municipal governments will, as necessary, promote a response through agencies as a whole so that the necessary personnel system can be strengthened, taking into account Section 1 (the preparation phase) 1-3 and 1-4. (CAICM; MHLW; all other ministries and agencies)
- (viii) In cases where it is recognized that the severity of symptoms of contracted cases is generally the same as or less than that of seasonal influenza, the national government will implement basic countermeasures against infectious diseases under the Infectious Diseases Control Law and other relevant laws. (MHLW; relevant ministries and agencies)

⁶² Article 16, paragraph (8) of the Act on Special Measures.

⁶³ Article 18, paragraphs (3), (4) and (5) of the Act on Special Measures.

2-3. Strengthening of international cooperation system

- (i) In response to requests from international organizations or the country of the outbreak, the national government will consider overseas dispatch specialist teams, which is to be organized based on the study during the preparation phase. (MOFA; MHLW; MAFF)
- (ii) The national government will cooperate in the support provided by the WHO to the country of the outbreak. (MHLW; relevant ministries and agencies)
- (iii) The national government will cooperate with the WHO, the World Organization for Animal Health (WOAH), etc., in the identification and analysis of pathogens and case definition, and will share information, etc. (MHLW; MOFA; MEXT; MAFF)
- (iv) JIHS will promote cooperation with overseas research institutes, etc., with which it has cooperation relationships so that information can be rapidly collected and samples can be provided, in addition to required cooperation. (MHLW)

2-4. Securing the budget necessary to implement rapid countermeasures

When the national government becomes aware of an outbreak or potential outbreak of novel influenza, etc., it will rapidly secure the necessary budget and rapidly implement countermeasures. In order to enable prefectural and municipal governments to implement agile and effective countermeasures, the national government will rapidly consider providing financial support to the prefectural and municipal governments⁶⁴ and take the necessary measures. Further, prefectural and municipal governments will, as required, consider issuing prefectural or municipal bonds⁶⁵ for countermeasure expenses and make the necessary preparations. (CAICM; Ministry of Internal Affairs and Communications (MIC); MHLW; relevant ministries and agencies.)

⁶⁴ Article 69, Article 69-2, paragraph (1) and Article 70, paragraphs (1) and (2) of the Act on Special Measures.

⁶⁵ Article 70-2, paragraph (1) of the Act on Special Measures. In addition, beyond prefectural governments, etc., the municipal governments designated by the Minister of Internal Affairs and Communications as those experiencing or are likely to experience significant difficulties in their financial operations due to the outbreak of novel influenza, etc., may issue prefectural or municipal bonds.

Section 3: Response phase

(1) Purpose

Following the initial phase, depending on the characteristics of the pathogens, etc., it is important to ensure the sustainability of the implementation system of countermeasures at the national government and related organizations, as a long-term response is assumed from the epidemic of novel influenza, etc., within Japan, through the transition to basic countermeasures against infectious diseases not covered by the Act on Special Measures, to the end of the epidemic, including pathogen mutation during this period.

The national government and related organizations will flexibly develop and review the implementation system of countermeasures according to the situation surrounding infectious disease crisis, the national life and economy, and the implementation status of each countermeasure, as well as flexibly and agilely switch the countermeasures to respond to infectious disease crisis as rapidly as possible and with the least potential impact in the event of major changes in the situation, such as medical crisis, pathogen mutations, and the development and introduction of vaccines and therapeutics.

(2) Required Response

3-1. Basic implementation system

After the establishment of the Government Countermeasures Headquarters, the implementation system described below will be rapidly formulated.

3-1-1. System for implementing measures

- (i) The national government and JIHS will continuously share information on the characteristics of the infectious diseases, the infection status, and the shortage of medical care delivery system, as well as information on the national life and socioeconomic activities of the people. In addition, the national government will implement appropriate countermeasures against novel influenza, etc., according to the basic action policy, after obtaining the opinions of the Promotion Council to amend the basic action policy, as necessary, and announce them publicly. (CAICM; MHLW; relevant ministries and agencies)
- (ii) Prefectural governments should establish a system, such as a department that centrally grasps information on the regional infection status in cooperation with the public health centers and public health institutes, etc., and implement appropriate countermeasures against novel influenza, etc., according to the actual regional situation, taking into account the information collected and risk

assessment by the department, etc. (CAICM; MHLW)

- (iii) JIHS will shift to an organizational structure that enables rapid decision-making and information analysis in order to rapidly provide scientific knowledge, including information on the characteristics of infectious diseases, as required by CAICM and the MHLW. (CAICM; MHLW)
- (iv) The national and prefectural governments will take the necessary measures in consideration of the effects on the mind and body on the officials involved in the countermeasures against novel influenza, etc. (All ministries and agencies)

3-1-2. Comprehensive coordination and direction by the national government

- (i) When the national government recognizes the need to implement countermeasures against novel influenza, etc., accurately and rapidly, the national government will provide comprehensive coordination to prefectural governments and designated public institutions regarding countermeasures against novel influenza, etc., according to the basic action policy⁶⁶. If the national government recognizes that it is particularly necessary to implement countermeasures against novel influenza, etc., accurately and rapidly, for example, when outbreaks of novel influenza, etc., are likely to have an enormous impact on the national life and economy, but the necessary measures according to the said comprehensive coordination are not implemented, and urgent and integrated countermeasures must be taken by prefectural governments and designated public institutions, the national government will issue the necessary orders to the extent necessary to implement the said countermeasures⁶⁷.

The comprehensive coordination and orders will be issued for the purpose of preventing spread of novel influenza, etc., to other municipalities and the nation as a whole through the accurate and rapid implementation of countermeasures against novel influenza, etc., in local governments, etc. This may be done, for example, when local governments have different policies for implementing measures, such as restricting the use of facilities and shortening operating hours, and when it is necessary for the local governments to take integrated countermeasures to effectively prevent the spread of infection throughout the country. (CAICM)

- (ii) In cases, such as where it is necessary to secure or transfer human resources

⁶⁶ Article 20, Paragraph 1 of the Act on Special Measures.

⁶⁷ Article 20, paragraph 3 of the Act on Special Measures. Note that the orders to designated public institutions other than JIHS can be issued only upon the declaration of a state of emergency. (Article 33, paragraph (1) of the Act on Special Measures)

beyond the area of prefectures, etc., under the Infectious Diseases Control Law, the national government will provide comprehensive coordination to prefectural governments, etc., medical institutions and other related organizations regarding the necessary measures to prevent the spread of infectious diseases⁶⁸. In addition, in cases where prefectural governments, etc., do not properly manage the affairs stipulated in the Infectious Disease Control Law, etc., the national government will issue the necessary orders when the national government finds it particularly necessary to prevent a nationwide and rapid spread of the infectious disease⁶⁹.

Furthermore, when the national government intends to issue the necessary orders concerning the affairs related to new infectious diseases conducted by prefectural governments, etc., the national government will seek the opinion of the Health Science Council in advance⁷⁰. However, in the case of an emergency, the national government will rapidly report to the Health Science Council on the ordered measures⁷¹. (MHLW)

3-1-3. Comprehensive coordination by prefectural governments

- (i) When prefectural governments find it necessary for the accurate and rapid implementation of countermeasures against novel influenza, etc., pertaining to the area of the said prefectures, the prefectural governments will provide comprehensive coordination regarding the countermeasures against novel influenza, etc., pertaining to the area of the prefecture implemented by the said prefecture, relevant municipalities and relevant designated (local) public institutions⁷². (CAICM; MHLW)
- (ii) In addition, when prefectural governments find it necessary to prevent the outbreak or spread of novel influenza, etc., under the Infectious Diseases Control Law, the prefectural governments will provide municipal governments, medical institutions, infectious disease testing and research, etc., institutes, and other related organizations with the necessary comprehensive coordination regarding hospitalization recommendations or hospitalization measures and other measures taken by them, as stipulated in the Infectious Diseases Control Law⁷³. Furthermore, when prefectural governments recognize an urgent need to prevent an outbreak or the spread of novel influenza, etc., the prefectural governments

⁶⁸ Article 44-5, paragraph (1), Article 44-8 or Article 51-4, paragraph (1) of the Infectious Diseases Control Law.

⁶⁹ Article 51-5, paragraph (1) or Article 63-2, paragraph (2) of the Infectious Diseases Control Law.

⁷⁰ Article 51-5, paragraph (2) of the Infectious Diseases Control Law.

⁷¹ Article 51-5, Paragraph 3 of the Infectious Diseases Control Law.

⁷² Article 24, Paragraph 1 of the Act on Special Measures.

⁷³ Article 63-3, Paragraph 1 of the Infectious Diseases Control Law.

will issue the necessary orders to the cities with public health centers, etc., regarding the hospitalization recommendation or hospitalization measures stipulated in the Infectious Diseases Control Law⁷⁴. (MHLW)

3-1-4. Establishment of national onsite headquarters for countermeasures

Depending on the outbreak status, when the national government finds it necessary to provide expert investigative support to the prefectures in the early stages of the outbreak, the government will establish a national onsite headquarters for countermeasures⁷⁵. (CAICM; MHLW; relevant ministries and agencies)

3-1-5. Response to dispatch and support of staff

- (i) When the national government receives a request from a local government to dispatch personnel, or from a designated (local) public institution to provide support, the national government will consider the response under the Act on Special Measures and take the necessary measures⁷⁶. (CAICM; MHLW; relevant ministries and agencies)
- (ii) When prefectural governments find it necessary to implement specified measures for novel influenza, etc., pertaining to its area, the prefectural governments will request support from other prefectures⁷⁷. (CAICM; MHLW)
- (iii) In cases such as when there is a shortage of doctors, nurses, etc., who have a certain level of knowledge in dealing with infectious diseases and who make decisions on hospitalization, etc., of infected people or coordinate hospitalization, etc., the prefectural governments will request other prefectural governments to provide support in securing the said medical personnel, as necessary⁷⁸. (MHLW)
- (iv) If a municipal government recognizes that it is unable to conduct all or most of its affairs due to an outbreak of novel influenza, etc., it will request the prefectural government, to which the said municipality belongs, to conduct the affairs of specified measures for the novel influenza, etc., on its behalf⁷⁹, and the said prefectural government will respond to such request⁸⁰. (CAICM; MHLW)
- (v) When a municipal government finds it necessary to implement specified

⁷⁴ Article 63-4 of the Infectious Diseases Control Law.

⁷⁵ Article 16, paragraph (9) of the Act on Special Measures.

⁷⁶ Article 26-6, Article 26-7 and Article 27 of the Act on Special Measures.

⁷⁷ Article 26-3, paragraph (1) of the Act on Special Measures.

⁷⁸ Article 44-4-2 of the Infectious Diseases Control Law.

⁷⁹ Article 26-2, paragraph (1) of the Act on Special Measures.

⁸⁰ Article 26-2, paragraph (2) of the Act on Special Measures.

measures for novel influenza, etc., pertaining to its area, the municipal government will request support from other municipal governments or the prefectural government to which the said municipal government belongs⁸¹. The said prefectural government will respond to the request for support unless there is a legitimate reason to the contrary⁸². (CAICM; MHLW)

3-1-6. Enhancement of the international cooperation system

- (i) The national government will report information on domestic outbreaks to the WHO without delay, including case definitions and measures taken, which are required to be reported by the International Health Regulations (IHR). (MHLW)
- (ii) The national government will cooperate with international organizations and foreign governments, etc., in the development of vaccines, diagnostics, therapeutic agents, etc. (MHLW; relevant ministries and agencies)

3-1-7. Necessary financial measures

- (i) The national government will take the necessary financial measures to cover the cost required for the implementation of countermeasures against novel influenza, etc.⁸³ (CAICM; MIC; MHLW; relevant ministries and agencies)
- (ii) Prefectural and municipal governments will effectively utilize financial support from the national government and, if necessary, secure financial resources⁸⁴ by issuing prefectural or municipal bonds to implement the necessary countermeasures. (CAICM; MIC)

3-2. Consideration, etc., of intensive measures for prevention of the spread of infection and emergency measures

Procedures for the implementation of intensive measures for prevention of the spread of infection and emergency measures are described below. For the approach, etc., concerning the implementation of these measures, refer to the description in Chapter 6 (“Prevention of Spread”).

⁸¹ Article 26-3, paragraph (2) and Article 26-4 of the Act on Special Measures.

⁸² Article 26-4 of the Act on Special Measures.

⁸³ Article 69, Article 69-2, paragraph (1) and Article 70, paragraphs (1) and (2) of the Act on Special Measures.

⁸⁴ Article 70-2, paragraph (1) of the Act on Special Measures. In addition, beyond prefectural governments, etc., the municipal governments designated by the Minister of Internal Affairs and Communications as those that are experiencing or are likely to experience significant difficulties in their financial operations due to the outbreak of novel influenza, etc., may issue prefectural or municipal bonds.

3-2-1. Public announcement of intensive measures for prevention of the spread of infection

3-2-1-1. Procedures up to public announcement of intensive measures for prevention of the spread of infection

The national government will amend the basic action policy and make a public announcement, etc., of intensive measures for prevention of the spread of infection after obtaining the opinions of the Promotion Council, taking into account the status of domestic outbreaks of novel influenza, etc., or requests, etc., from prefectural governments⁸⁵. (CAICM; MHLW; all other ministries and agencies)

The public announcement of intensive measures for prevention of the spread of infection indicates that novel influenza, etc., has broken out domestically, and the infection has spread to a specific area in a prefecture, which may have a serious impact on the national life and economy, and therefore, the intensive measures for prevention of the spread of infection need to be intensively implemented to prevent the spread of the novel influenza, etc., in the area. Procedures for the implementation of intensive measures for prevention of the spread of infection are described below.

3-2-1-1-1. Reporting of relevant information

Regarding the system for collecting and analyzing information domestically or internationally that has been implemented since the preparation and initial phases, the national government and JIHS will flexibly change the methods and systems for collecting and analyzing such information according to the needs of the time, and will also obtain the opinions of experts, etc., conduct risk assessment, and report relevant information necessary for making decisions on implementation of intensive measures for prevention of the spread of infection to the head of the Government Countermeasures Headquarters. (CAICM; MHLW; all other ministries and agencies)

3-2-1-1-2. Obtaining opinions of the Promotion Council

The national government will obtain the opinions of the Promotion Council on any changes to the basic action policy in order to determine important matters concerning the implementation of intensive measures for prevention of the spread of infection⁸⁶ (CAICM; MHLW).

⁸⁵ Article 31-6, paragraph (1) of the Act on Special Measures.

⁸⁶ Article 18, paragraphs (4) and (5) of the Act on Special Measures.

3-2-1-1-3. Determination regarding intensive measures for prevention of the spread of infection

The national government will determine whether to implement intensive measures for prevention of the spread of infection. In addition, the national government will determine the proposed changes based on the opinions of the Promotion Council regarding changes to the basic action policy. (CAICM; MHLW)

3-2-1-1-4. Public announcements, etc.

The national government will publicly announce intensive measures for prevention of the spread of infection and change the basic action policy. (CAICM)

3-2-1-2. Designation of periods and areas

The national government will publicly announce the periods and areas during which intensive measures for prevention of the spread of infection will be implemented.⁸⁷ In addition, as for the area to be publicly announced, the national government will designate the prefecture in which the outbreak area is located. However, it should also be kept in mind that the area can be set up flexibly based on considerations such as the flow of people. (CAICM)

3-2-1-3. Request or order by prefectural governments

Before issuing a request or an order to change operating hours or take other necessary measures as intensive measures for prevention of the spread of infection, prefectural governments will obtain the opinions of people with expertise in infectious diseases and other academic experts⁸⁸. (CAICM)

3-2-1-4. Termination of situations that require the implementation of intensive measures for prevention of the spread of infection

When the national government recognizes that there is no longer a need to implement intensive measures for prevention of the spread of infection, the national government will obtain the opinion of the Promotion Council and rapidly make a public announcement that the situation, which required intensive measures to prevent the spread of the infection, has ended⁸⁹. (CAICM; MHLW; all other ministries and agencies)

⁸⁷ Article 31-6, paragraph (1) of the Act on Special Measures.

⁸⁸ Article 31-8, paragraph (4) of the Act on Special Measures.

⁸⁹ Article 31-6, paragraph (4) of the Act on Special Measures.

3-2-2. Procedures for a declaration of a state of emergency

A declaration of a state of emergency indicates a situation in which the limits of the medical care delivery system may be exceeded, the capacity to protect the lives and health of the people compromised, and social confusion may occur unless a state of emergency is declared. The procedures for a declaration of a state of emergency, public announcement of the periods and areas, lifting of the declaration, etc., are the same as the procedures for intensive measures for prevention of the spread of infection, as described in 3-2-1 above, with the differences listed below.

- (i) The national government will report to the Diet that the national government has made a declaration of a state of emergency⁹⁰. In addition, when the national government recognizes that there is no longer a need to declare a state of emergency, the government will declare the lifting of the state of emergency of novel influenza, etc., and report it to the Diet⁹¹. (CAICM)
- (ii) If the declaration of a state of emergency is made, the municipal governments will immediately establish a municipal countermeasures headquarters⁹². When a municipal government finds it necessary for the accurate and rapid implementation of emergency measures pertaining to the area of the said municipality, the municipal government will provide comprehensive coordination regarding the emergency measures⁹³. (CAICM)

3-3. Phase to shift to basic infectious disease measures not based on the Act on Special Measures

3-3-1. Abolition of the Government Countermeasures Headquarters

When it has become clear that the severity of symptoms of contracted cases of novel influenza, etc., is generally similar or less than that of seasonal influenza, or when it has been announced that the disease is no longer recognized as a novel influenza, etc., or a designated infectious disease under the Infectious Diseases Control Law because, for example, the majority of the people have acquired immunity or for other reasons, or when, under the Infectious Diseases Control Law, the national government has abolished the Cabinet Order stipulating the application

⁹⁰ Article 32, Paragraphs 1 and 3 of the Act on Special Measures.

⁹¹ Article 32, Paragraph 5 of the Act on Special Measures.

⁹² Article 34, Paragraph 1 of the Act on Special Measures Furthermore, under the provision of Article 25 of the Act on Special Measures, which shall be applied mutatis mutandis by replacing the terms and phrases in Article 37 of the Act on Special Measures, the municipal government will abolish the municipal countermeasures headquarters without delay when the declaration of the lifting of the state of emergency of novel influenza, etc., has been made.

⁹³ Article 36, Paragraph 1 of the Act on Special Measures.

of measures under the provisions of the Infectious Diseases Control Law against the new infectious disease, the national government will, if necessary, obtain the opinion of the Promotion Council and abolish the Government Countermeasures Headquarters, report it to the Diet, and make a public announcement⁹⁴. (CAICM; MHLW; all other ministries and agencies)

3-3-2. Abolition of Prefectural Countermeasures Headquarters

Prefectural governments will abolish their Prefectural Countermeasures Headquarters without delay when the Government Countermeasures Headquarters has been abolished⁹⁵. (CAICM)

⁹⁴ Article 21, paragraphs (1) and (2) of the Act on Special Measures.

⁹⁵ Article 25 of the Act on Special Measures.

Chapter 2: Information Collection and Analysis

Section 1: Preparation phase

(1) Purpose

In infectious disease crisis management, information collection and analysis are an important basis for determining the countermeasures against novel influenza, etc., including identification and assessment of public health risks due to novel influenza, etc., prevention of infectious diseases and preparation in normal time, early detection of outbreaks of novel influenza, etc., and response after outbreaks.

In information collection and analysis, the national government will systematically and comprehensively collect and analyze information on infectious diseases from all available sources, conduct risk assessment, and provide information that will contribute to policy decision-making and practical judgments as an initiative of the infectious disease intelligence, to contribute to the determination of countermeasures against novel influenza, etc.

The information to be collected and analyzed includes the status of outbreaks of infectious diseases and the domestic and international responses to them, domestic epidemiological information obtained through infectious disease surveillance, etc., information on the characteristics of the infectious diseases, the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), and clinical features, as well as information on the medical care delivery system, the flow of people, the national life and economy, and information on the risk of an infectious disease epidemic, including the social impact, etc.

In normal times, the national government, in addition to the periodical information collection and analysis, will prepare for crisis, such as organizing information content and securing the means for identifying such information.

In addition, the next chapter, “Surveillance,” will be specifically described about infectious disease surveillance, etc.

(2) Required Response

1-1. Implementation System

- (i) The national government will cooperate with JIHS and others while sharing the purpose of information collection and analysis on infectious diseases in normal times and establish a system for domestic and international information collection and analysis that contributes to infectious disease intelligence and conducting risk assessment (hereinafter referred to as the “Infectious Disease Intelligence System”). In addition, the national government will make efforts to

form, maintain, and improve human and organizational networks by deepening exchanges and contacts with related organizations and experts, etc., within and outside of Japan.

In particular, to ensure that the results of information collection and analysis contributing to infectious disease intelligence are centralized rapidly and efficiently in the event of crisis, the national government will establish human and organizational relationships with related organizations domestically and internationally in normal times and will work to enhance the cooperation system.

For example, the national government will establish a system for enabling the collection and analysis of information through the cooperation by collaborative frameworks for bilateral and multilateral sharing, etc., of infectious disease information (such as those of WHO, the Global Health Security Initiative (GHSI), the Japan-China-Korea Tripartite Health Ministers Meeting) as well as the cooperation with various related organizations, such as diplomatic establishments abroad and the Japan International Cooperation Agency (JICA), etc. (MHLW; MOFA; MEXT)

- (ii) The diplomatic establishments abroad and quarantine stations will rapidly report to the relevant departments of ministries and agencies that have jurisdiction over these organizations when they receive information on infectious diseases. (MHLW; MOFA)
- (iii) The national government will make efforts to rapidly share the necessary results of information collection and analysis with JIHS, prefectural governments, etc., public health institutes, etc., and other related organizations. (MHLW)
- (iv) The national government, JIHS, and prefectural governments, etc., will prepare for crisis and develop a system for collecting information that will contribute to active epidemiological investigation and clinical research in normal times. (MHLW)
- (v) The national government and JIHS will prepare for the collection and analysis of information on the national life and economy, as well as the social impact in normal times, etc., such as by organizing the information to be collected and researching methods for collecting and analyzing such information. (CAICM; relevant ministries and agencies)

1-2. Information collection and analysis in normal times

The national government will efficiently collect and analyze information from

within and outside Japan and conduct risk assessments through the infectious disease intelligence system developed mainly by JIHS. It will use this information for policy decision-making and practical judgment. In collecting and analyzing information, the national government, in cooperation with JIHS, will utilize human and organizational networks with foreign governments, international organizations, overseas universities and research institutes, expert personnel of infectious disease overseas, diplomatic establishments abroad, and domestic and international related organizations, etc., in normal times. (MHLW; MOFA; MEXT)

1-3. Training

The national government, in cooperation with prefectural governments, etc., JIHS and others, will confirm the operational status of the implementation system of the information collection and analysis, etc., through training, etc., in preparation for a novel influenza, etc. outbreak. (MHLW; MOFA)

1-4. Securing personnel

For the smooth implementation of information collection and analysis, the national government, in cooperation with JIHS and other organizations, will train infectious disease expert personnel with expertise in various fields (public health, epidemiology, data science⁹⁶, etc.) in normal times, secure and utilize personnel, provide training for crisis, etc., confirm the size and expertise of personnel required for crisis, and adjust staffing, etc. (MHLW; MOFA; MEXT)

1-5. Promotion of DX

In order to collect and analyze information rapidly in normal times, the national government and JIHS will promote DX, including automation and labor saving of information input, centralization of information, and database linkage.

For example, in the collection of clinical information for the establishment of a foundation for the research and development of vaccines, therapeutic agents etc., the national government and JIHS will establish a system to extract information from electronic medical records, etc., which will contribute to the research and development of vaccines, therapeutic agents, etc., and the establishment of therapeutic methods.

In addition, the national government and JIHS will promote consideration of the

⁹⁶ For example, this could include areas related to formulating simulations of infection trends.

linkage between electronic medical records and outbreak reports to strive to reduce the burden of input operations related to outbreak reports, etc., under the Infectious Disease Control Law at medical institutions. (MHLW)

1-6. Measures against sensitive data leaks, etc.

The national government will organize the enhancement of information security and response procedures in the event of an incident to counter the leakage of sensitive information, such as domestic epidemiological information, the characteristics of infectious diseases and the characteristics of the of pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) obtained from infectious disease surveillance, etc., prior to publication. When the national government organizes such enhancement and response procedures, care should be taken to coordinate response procedures with related organizations, etc., with which information coordination, etc., is being conducted. (MHLW; MOFA; MEXT)

Section 2: Initial phase

(1) Purpose

In the initial phase, the national government will need to collect and analyze information on the characteristics of the new infectious diseases and the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) and rapidly conduct risk assessment.

The national government will enhance the infectious disease intelligence system, rapidly confirm information on new infectious diseases detected at an early stage, conduct risk assessment at an initial stage, and collect and analyze information that contributes to decision-making in infectious disease crisis management, etc.

(2) Required Response

2-1. Implementation System

In cooperation with JIHS, the national government will rapidly enhance the infectious disease intelligence system in the event of the outbreak of novel influenza, etc., and develop a system for information collection and analysis and assessing risks related to the said infectious disease. (MHLW; MOFA; MEXT)

2-2. Risk assessment

2-2-1. Risk assessment based on information collection and analysis

- (i) The national government and JIHS will analyze the information on the characteristics of the novel influenza, etc., the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), the status of outbreaks in Japan and clinical features, and the impact on public health and medical care, etc., and then conduct a comprehensive risk assessment. In assessing the risk, the national government will implement such risk assessment based on information collected and analyzed from prefectural governments, etc., international organizations, research institutes, diplomatic establishments abroad, quarantine stations, etc., information from academic papers, etc., information from onsite dispatch surveys, information on infectious disease risks, such as the medical care delivery system, the flow of people, the results of various simulations on infection trends, and so on. (MHLW)
- (ii) On the basis of the risk assessment, etc., the national government and prefectural governments, etc., will decide to rapidly switch to a crisis system for each system of medical care delivery, testing, and public health centers, etc., and make the necessary preparations. (MHLW)

- (iii) The national government and JIHS will also collect information on the national life and economy, as well as the social impact, etc., and aim to rapidly analyze the impact of the infectious disease crisis on the life and economy, etc. (CAICM; relevant ministries and agencies)

2-2-2. Enhancement of risk assessment system

- (i) The national government and JIHS, in cooperation with prefectural governments, etc., will enhance the infectious disease intelligence system to collect and analyze the necessary information efficiently and effectively, and implement risk assessment continuously. (MHLW)
- (ii) Moreover, in order to efficiently consolidate information that contributes to infectious disease intelligence in the event of crisis, the national government will make maximum use of the human and organizational networks established during the preparation phase to collect and analyze information rapidly and continuously. (MHLW)
- (iii) In addition to the initiatives implemented from the preparation phase, the national government will actively collect and analyze information in the early stages of the outbreak and conduct risk assessments in the early stages by dispatching survey teams to endemic countries and regions and participating in conferences and surveys, etc., held by international organizations and foreign governments, etc., in crisis.

Furthermore, the national government will provide and share information on methods of information collection and analysis in an easily understandable manner to the people. (MHLW; MOFA)

2-2-3. Decision-making and implementation of infectious disease countermeasures based on risk assessment

The national government, in cooperation with prefectural governments, etc., and JIHS, will rapidly make decisions and implement countermeasures against infectious diseases based on risk assessments. (MHLW)

2-3. Sharing of information and countermeasures obtained through information collection and analysis

In the event of a new outbreak of infectious diseases, the national government will share information and countermeasures obtained through domestic and international information collection and analysis with prefectural governments, etc., and will

rapidly provide and share such information and countermeasures with the people.
(MHLW; CAICM; MOFA; MEXT)

Section 3: Response phase

(1) Purpose

With the aim of preventing the spread of infection through an enhanced infectious disease intelligence system, information collection and analysis and risk assessment related to novel influenza, etc., will be conducted to collect and analyze information that will contribute to making decisions and other actions regarding countermeasures against novel influenza, etc.

In addition, risk assessment will be continuously conducted to contribute to decision-making, with a view to compatibility with flexible and agile change of measures, etc., to balance between preventing the spread of infection and the national life and economy, according to the situation surrounding the outbreak of novel influenza, etc.

Particularly in the response phase, decisions may be required on the implementation of intensive measures for prevention of the spread of infection, emergency measures, etc. Therefore, the national government will strengthen the collection and analysis of information on the risks of infectious diseases, such as the medical care delivery system and the flow of people, as well as information on the national life and economy, etc., and the social impact, etc.

(2) Required Response

3-1. Implementation System

The national government, in cooperation with JIHS, will enhance the infectious disease intelligence system to rapidly collect and analyze information and conduct risk assessments on novel influenza, etc.

In addition, the national government will flexibly review information collection and analysis methods and implementation systems in response to the course of the infectious disease crisis, changes in the situation, and the need for policy decision-making and practical judgment based on these changes. (MHLW; MOFA; MEXT)

3-2. Risk assessment

3-2-1. Risk assessment based on information collection and analysis

- (i) The national government, JIHS, prefectural governments, etc., will analyze information on the characteristics of the novel influenza, etc., the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), the status of outbreaks in Japan, and clinical features, and conduct a comprehensive risk assessment. In assessing the risk, the national government will implement such risk assessments based on the information collection and

analysis by international organizations, research institutes, etc., reports from quarantine stations, JIHS and prefectural governments, etc., and results, etc., obtained through active epidemiological investigation, etc.

In doing so, the national government will implement a comprehensive risk assessment in response to the course of the infectious disease crisis, changes in the situation, and the need for policy decision-making and practical judgments based on these changes. (MHLW)

- (ii) In making decisions on infectious disease countermeasures based on risk assessment, the national government and JIHS will collect and consider the necessary information on the national life and economy, etc., and the social impact, etc., as well. (CAICM; relevant ministries and agencies)

3-2-2. Consideration and implementation of information collection and analysis methods based on risk assessment

- (i) The national government and JIHS, in cooperation with prefectural governments, etc., will enhance the infectious disease intelligence system based on risk assessment and continue to utilize the system. (MHLW)
- (ii) Moreover, in order to efficiently consolidate information that contributes to infectious disease intelligence in the event of crisis, the national government will make maximum use of the human and organizational networks established during the preparation phase and the initial phase to collect and analyze information rapidly and continuously. (MHLW)
- (iii) The national government will actively collect and analyze information and conduct risk assessments such as by participating in conferences and surveys, etc., held by international organizations and foreign governments, etc., in crisis. (MHLW; MOFA)
- (iv) The national government will enhance the analysis of the national life and economy to identify the impact of infectious disease crisis on the national life and economy, etc., in preparation for the implementation of intensive measures for prevention of the spread of infection and emergency measures, especially in the case of the spread of infection domestically. (CAICM; relevant ministries and agencies)
- (v) Prefectural governments, etc., will review the scope of coverage and survey items of active epidemiological investigation, etc., according to the actual regional situation while taking into account the policies indicated by the national government. (MHLW)

- (vi) The national government will provide prefectural governments, etc., with the results of analysis on the implementation of intensive measures for prevention of the spread of infection and emergency measures, etc., and will provide and share information to the people in an easily understandable manner. (MHLW; CAICM)

3-2-3. Decision-making and implementation of infectious disease countermeasures based on risk assessment

The national government, in cooperation with prefectural governments, etc., and JIHS, will rapidly make decisions and implement countermeasures against infectious diseases based on risk assessments. In addition, the national government will review and change the countermeasures against infectious diseases in a flexible and agile manner based on the epidemic status and risk assessment. (MHLW)

3-3. Sharing of information and countermeasures obtained through information collection and analysis

The national government will share information and countermeasures obtained through the domestic and international information collection and with prefectural governments, etc., and will rapidly provide and share such information and countermeasures with the people. (MHLW; CAICM; MOFA; MEXT)

Chapter 3: Surveillance

Section 1: Preparation phase

(1) Purpose

“Surveillance,” as used in the National Action Plan, refers to initiatives such as collecting and analyzing trends in patient outbreaks, the influx of pathogens from overseas, etc., in a sustained and multilayered manner using a systematic and unified method at the time of outbreaks of novel influenza and other infectious diseases, in order to rapidly return the results to infectious disease prevention and countermeasures.

In the event of an infectious disease crisis, it is important to detect outbreaks at an early stage, collect and analyze information, and assess risks rapidly. To this end, it is necessary to establish an implementation system for the surveillance of infectious diseases in normal times and to develop such systems, etc.

For this purpose, in normal times, abnormal outbreaks of infectious diseases should be detected at an early stage by utilizing the infectious disease surveillance system⁹⁷ and all sources of information, as well as information on the situation surrounding the outbreak of novel influenza, etc., in each region, changes in patient outbreak trends, the characteristics of infectious diseases and the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), clinical features, etc., should be collected. On the basis of this information, risk assessment and decision-making in infectious disease risk management will be carried out.

(2) Required Response

1-1. Implementation System

- (i) The national government will establish a structure to receive reports of patients from designated notification facilities⁹⁸ and reports of pathogen detection status and genomic information, etc., from JIHS and public health institutes, etc., so that prefectural governments, etc., can identify trends related to outbreaks of infectious diseases in normal times.

In addition, the national government, in cooperation with JIHS, will consolidate and analyze information on outbreak trends of infectious diseases overseas, etc., in order to detect domestic outbreaks of novel influenza, etc., at

⁹⁷ The system is used to aggregate and return information, etc., reported under the provisions of Articles 12 and 14 of the Infectious Diseases Control Law, and also has a health observation function that was used in response to COVID-19.

⁹⁸ Hospitals or clinics designated by prefectural governors under the provisions of Article 14, paragraph (1) of the Infectious Diseases Control Law, which are the facilities in charge of notifying the outbreaks of Category V Infectious Diseases specified by an Ordinance of the HLMW, or Category II, III, IV Infectious Diseases or suspected cases of Category V Infectious Diseases specified by an Ordinance of the MHLW.

an early stage. (MHLW)

- (ii) The national government will make the necessary preparations in normal times so that it can rapidly shift to the implementation system for infectious disease surveillance in crisis based on reports from prefectural governments, etc., and risk assessments by JIHS. (MHLW)
- (iii) The national government and JIHS will implement technical instruction and support for infectious disease surveillance and human resource development for prefectural governments, etc., in normal times and assess and verify the implementation system in crisis for infectious disease surveillance of prefectural governments, etc., through training, and other measures. (MHLW)
- (iv) In cooperation with JIHS, the national government will, taking into account the knowledge obtained through infectious disease intelligence, share information and exchange opinions with related organizations, including domestic private testing companies, foreign governments, and international organizations (WHO, WOA, Food and Agriculture Organization of the United Nations (FAO), etc.) in normal times so that a rapid and efficient infectious disease surveillance implementation system can be established in crisis. (MHLW)

1-2. Infectious disease surveillance in normal times

- (i) The national government and prefectural governments, etc., will identify the nationwide epidemic status of acute respiratory infections, such as seasonal influenza and coronavirus infectious disease, etc., from multiple sources of information, including trends in patient outbreaks at designated notification facilities and hospitalized patient outbreaks, etc., in normal times.

In addition, as part of the research to enhance the infectious disease surveillance system, the national government, in cooperation with JIHS and other organizations, will implement surveillance that does not involve direct collection of specimens from patients in normal times, such as sewage surveillance, etc., and will periodically make a public announcement of the analysis results, etc., of such surveillance. (MHLW; Ministry of Land, Infrastructure, Transport and Tourism (MLIT))

- (ii) The national government and prefectural governments, etc., in cooperation with JIHS, etc., will obtain specimens of influenza patients from designated notification facilities and identify influenza virus types and subtypes, the characteristics of infectious diseases, and the characteristics of the pathogen

(pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), in normal times, as well as utilize the infectious disease surveillance system and share information on the outbreak status. (MHLW)

- (iii) Based on the concept of the One Health approach, the national government and prefectural governments, etc., in cooperation with JIHS, the Livestock Hygiene Service Center, the National Agriculture and Food Research Organization, the National Institute for Environmental Studies, etc., will monitor the presence or absence of influenza viruses, etc., in domestic poultry, swine and wild animals, as well as for outbreaks of new strains of influenza, etc.

In addition, when information is provided by a medical institution to the public health centers regarding a person who may have been infected with avian influenza or another zoonotic influenza, a system will be established to rapidly share information among relevant parties. (MHLW; MAFF; MOE)

- (iv) The national government, in cooperation with prefectural governments, etc., and JIHS, etc., will acquire proficiency in the operation of early detection of novel influenza, etc., through suspected case surveillance using the infectious disease surveillance system⁹⁹, through training and other measures, under the assumption of an outbreak of novel influenza, etc.

The national government will also manage and improve the infectious disease surveillance system. (MHLW)

1-3. Implementation of human resource development and training

The national government, in cooperation with JIHS and prefectural governments, etc., will consider in advance the size of personnel needed in crisis and implement training for those in charge in order to develop and secure human resources related to infectious disease surveillance. (MHLW)

1-4. Promotion of DX

The national government and JIHS will promote DX to enable an efficient and rapid collection of information on infectious disease outbreaks in normal times, as well as rapid decision-making on infectious disease crisis management in crisis and collection of information, such as the severity of illness that contributes to infectious

⁹⁹ This is suspected case surveillance under the provisions of Article 14, paragraphs (1) and (2) of the Infectious Diseases Control Law, and is a system in which a manager of a designated notification facility designated by a prefectural government diagnoses a patient with Category V Infectious Disease (including an asymptomatic pathogen carrier), or a patient with Category II Infectious Disease, Category III Infectious Disease, Category IV Infectious Disease, or a suspected case surveillance for Category V Infectious Disease, etc., or examines the body of a person who has died from Category V Infectious Disease, and reports the results.

disease countermeasures. For example, the national government and JIHS will promote consideration of the linkage between electronic medical records and outbreak reports as part of an endeavor to reduce the burden of input operations related to outbreak reports under the Infectious Disease Control Law at medical institutions, etc.

In addition, the national government will periodically improve the infectious disease surveillance system and other systems to contribute to the implementation of effective infectious disease countermeasures in prefectural governments, etc. (MHLW)

1-5. Sharing of analysis results

The national government, in cooperation with JIHS, will rapidly share the analysis results of surveillance, including information on the characteristics of the infectious diseases, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), genomic information, and clinical features, with prefectural governments, etc., and provide and share accurate information based on the analysis results to the people in an easily understandable manner. (MHLW)

Section 2: Initial phase

(1) Purpose

In the event of an outbreak of an infectious disease crisis (including suspected cases) within and outside of Japan, it is necessary for the national government to rapidly and accurately identify the changes in outbreak status and outbreak trends of infectious diseases in each region from the early stages of the outbreak, and rapidly collect information on the characteristics of the infectious diseases, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), clinical features, and other relevant information.

In the initial phase, the national government will enhance the infectious disease surveillance system, confirm information on new infectious diseases detected at an early stage, and apply the information toward risk assessments and decision-making in infectious disease crisis management, etc.

(2) Required Response

2-1. Implementation System

The national government, in cooperation with JIHS, will make decisions on the transition to an implementation system for infectious disease surveillance in crisis based on risk assessment in the early stages of an outbreak of novel influenza, etc., and promote the development of the implementation system.

In addition, the national government will cooperate with the WHO, the WOA, etc., in the identification and analysis of pathogens and case definition, and will share information, etc., with them. (MHLW; MOFA; MEXT; MAFF)

2-2. Risk assessment

2-2-1. Initiation of infectious disease surveillance in crisis¹⁰⁰

The national government, in cooperation with prefectural governments, etc., JIHS, and related organizations, will continue the surveillance of infectious diseases as has been implemented since the preparation phase, and when an outbreak of a new infectious disease is detected, will rapidly make a case definition of a suspected case and initiate suspected case surveillance¹⁰¹ for the infectious disease. In addition, the

¹⁰⁰ With regards to infectious disease surveillance in crisis, based on case definitions, multiple types of surveillance for new infectious diseases will be implemented, including trends in patient outbreaks (patient outbreak surveillance), collection of the number of hospitalized and critically ill patients (hospitalization surveillance), collection of viral genomic information (pathogen genome surveillance), sewage surveillance, and other types of surveillance.

¹⁰¹ This is a suspected case surveillance under the provision of Article 14, Paragraphs 7 and 8 of the Infectious Diseases

national government, in cooperation with prefectural governments, etc., JIHS, and related organizations, will strengthen a rapid and accurate identification of trends in patient outbreaks, etc., by enhancing patient outbreak surveillance, etc., including the notifiable disease surveillance of patients with novel influenza, etc.

Also, the national government will initiate infectious disease surveillance in crisis, including the information collection on the number of hospitalized and critically ill patients (hospitalization surveillance), pathogen genome surveillance, etc., in order to obtain the necessary knowledge on the characteristics of the infectious diseases, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), clinical features and therapeutic effects, and the status of antibody retention among the people.

Specimens collected from people who may have been infected with the novel influenza, etc., will be identified as subtypes, etc., at local public health institutes, etc., and JIHS will confirm this identification. (MHLW; MAFF; MOE)

2-2-2. Enhancement of implementation system for infectious disease surveillance based on risk assessment

The national government and JIHS will analyze the characteristics of the infectious diseases, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), clinical features, etc., based on information collected through infectious disease surveillance and knowledge obtained from infectious disease intelligence, etc. The national government and JIHS will assess the necessity of enhancing the infectious disease surveillance implementation system, etc., based on the risk assessment at the initial stage of the project, taking these findings into consideration. (MHLW)

2-2-3. Decision-making and implementation of infectious disease countermeasures based on risk assessment

The national government, in cooperation with prefectural governments, etc., and JIHS, will rapidly make decisions and implement countermeasures against infectious diseases based on risk assessment at the initial stage, taking into account information collected through infectious disease surveillance, etc. (MHLW)

Control Law, and requires prefectures, etc., and is a system in which a prefectural government, etc., upon receiving notification from the MHLW, requires a physician of a hospital or clinic located within its area of jurisdiction to report when a patient is diagnosed as having a Category II, III, IV infectious disease or a suspected case surveillance for a Category V infectious disease, which is specified by Ordinance of the MHLW, and the patient's condition is critical in the case of contracting said infectious disease, etc., or when the physician examines the body of a person who has died from said infectious disease.

2-3. Sharing of information obtained through infectious disease surveillance

The national government, in cooperation with prefectural governments, etc., and JIHS, will rapidly identify the domestic outbreak status of infectious diseases, etc., and share it with prefectural governments, etc., including information on the characteristics of the infectious diseases, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), genomic information, clinical features, etc., as well as rapidly provide information on the outbreak status, etc., of infectious diseases and countermeasures to the people. (MHLW)

Section 3: Response phase

(1) Purpose

Through a strengthened infectious disease surveillance implementation system to be applied in crisis, the national government will collect information on changes in the outbreak status and outbreak trends of novel influenza, etc., in each region, the characteristics of the infectious diseases and the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), clinical features and treatment effects, antibody retention status among the people, and will link the information to risk assessment and decision-making in infectious disease risk management.

In addition, the national government will consider the appropriate infectious disease surveillance implementation system and review the system according to the situation surrounding the outbreak of novel influenza, etc.

(2) Required Response

3-1. Implementation System

The national government, in cooperation with JIHS, will establish the infectious disease surveillance implementation system to be applied in crisis based on risk assessment to enable the rapid implementation of information collection on novel influenza, etc.

In addition, the national government will conduct necessary reviews of the implementation methods of infectious disease surveillance according to the situation surrounding the outbreak of novel influenza, etc., and consider and review the appropriate infectious disease surveillance implementation system. (MHLW)

3-2. Risk assessment

3-2-1. Implementation of infectious disease surveillance in crisis

The national government, in cooperation with prefectural governments, etc., and JIHS, will require the submission of discharge reports¹⁰², etc., to identify the characteristics of novel influenza, etc., and clinical features of patients, etc. In

¹⁰² This is a reporting system for the discharge, etc., of a patient with novel influenza, etc., under the provisions of Article 44-3-6 of the Infectious Disease Control Law, a patient with a designated infectious disease (as applied *mutatis mutandis* in accordance with Article 44-9, paragraph (1) of the Infectious Disease Control Law), and a person with findings of a new infectious disease under the provisions of Article 50-7, in which, when the patient with novel influenza, etc., the patient with a designated infectious disease, and the person with findings of a new infectious disease are discharged from hospital or pass away, the cases shall be reported by a physician of a designated medical institutions for infectious diseases specified by an Ordinance of the MHLW to the prefectural governments, etc., with jurisdiction over the location of the said designated medical institutions for infectious diseases and to the MHLW.

addition, the national government, in cooperation with prefectural governments, etc., JIHS, and related organizations, will implement surveillance regarding the domestic status of the outbreak and outbreak trends of novel influenza, etc., the characteristics of the infectious diseases, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), and clinical features, etc., according to the epidemic status.

As the number of domestic patients increases, and as information and scientific knowledge on the characteristics of the novel influenza, etc., and clinical features of patients, etc., are accumulated, the significance of notifiable disease surveillance of patients will decline, and the burden on prefectural governments, etc., and clinical environments will also become excessive.

Therefore, when it becomes possible to identify infection trends by even sentinel surveillance based on patient reports from medical institutions, the national government will reassess the necessity of notifiable disease surveillance, considering the workload of medical institutions and public health centers, etc., due to the increase in the number of patients, will consider an appropriate implementation system for infectious disease surveillance, including sentinel surveillance, and will conduct the transition at an appropriate time.

In addition to the infectious disease surveillance implemented by the national government, prefectural governments, etc., will implement infectious disease surveillance based on their own decision according to regional infection trends, etc., as necessary. (MHLW; MAFF; MOE)

3-2-2. Consideration and implementation of surveillance methods based on risk assessment

The national government, in cooperation with JIHS, will assess the necessity of enhancing nationwide infectious disease surveillance and the necessity of concentrating and streamlining the targets of infectious disease surveillance and those subject to notification, etc., based on a risk assessment that takes into account the characteristics of the infectious diseases and the epidemic status of the diseases. Even after the initial phase, as necessary, the national government will assess the characteristics of the infectious diseases, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), clinical features, etc., through epidemiological surveys and Health, Labour Sciences Research, etc., and implement the necessary responses and reviews. (MHLW)

3-2-3. Decision-making and implementation of infectious disease countermeasures based on risk assessments

The national government, in cooperation with prefectural governments, etc., and JIHS, will rapidly make decisions and implement countermeasures against infectious diseases based on risk assessments, taking into account information collected through infectious disease surveillance, etc. In addition, the national government will change the countermeasures against infectious diseases in a flexible and agile manner based on the epidemic status and risk assessment. (MHLW)

3-3. Sharing of information obtained through infectious disease surveillance

The national government, in cooperation with prefectural governments, etc., and JIHS, will rapidly identify the outbreak status, etc., of novel influenza, etc., within Japan through infectious disease surveillance, and share it with prefectural governments, etc., including information on the characteristics of the infectious diseases, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), genomic information, clinical features, etc., as well as will rapidly provide and share information such as the outbreak status of novel influenza, etc., to the people.

In particular, in the case of strengthening or moderating countermeasures, etc., against novel influenza, etc., the national government will share information based on risk assessment and provide and share information to the people, in an easily understandable manner based on scientific evidence as much as possible in order to obtain understanding and cooperation for various countermeasures. (MHLW)

Chapter 4: Providing and Sharing of Information and Risk Communication

Section 1: Preparation phase

(1) Purpose

To effectively implement infectious disease measures under the crisis, it is important for the national government to share risk information and perspectives with the people, local governments, medical institutions, business operators, etc., so that the people, can make appropriate judgements and actions. Therefore, it is necessary for the national government to understand the awareness of the people on of infectious diseases and improve understanding of the infectious disease crisis in normal times. Along with these efforts, it is necessary to review the risk communication methods and improve the risk communication systems and activities.

Specifically, to enable the people to make appropriate judgements and actions on the best available scientific evidence, in normal times in a timely manner, the national government will provide and share the necessary information on infectious disease measures and related matters including public awareness activities, increasing literacy¹⁰³ on infectious diseases. Along with these efforts, the national government strive to further increase awareness and reliability in the provision and sharing of information by the national government.

In addition, the national government will identify the elements and means of providing and sharing information with the people, according to the outbreak status and the reactions of the people subject to communication and the information they need, and will review and stipulate in advance the methods for utilizing them in providing and sharing more information so that the national government can conduct risk communication based on interactive communication to the greatest extent possible according to the outbreak status of novel influenza, etc.

(2) Required Response

1-1. Providing and sharing information with the people, before the outbreak of novel influenza, etc.

1-1-1. Providing and sharing information on infectious diseases

The national government, in cooperation with JIHS, etc., will provide and share easy-to-understand information continuously and timely, in as many languages as possible, in order to deepen the understanding of the people, using various media, about basic information on the infectious diseases, basic infectious disease measures

¹⁰³ Part of the ability to obtain, understand, and use medical and scientific knowledge and information about health (health literacy).

(ventilation, coughing manners, including wearing masks, etc., hand washing, avoiding crowded places, etc.), information on the outbreak status of infectious diseases, etc., information on novel influenza, etc., and its actions to be taken in case of outbreaks, etc.¹⁰⁴. Through these initiatives, the national government will endeavor to further increase the awareness of the people, and reliability in the provision and sharing of information by the national government as a useful source of information.

In this context, the national government will raise awareness of the fact that infectious disease measures at the individual level can also make a significant contribution to preventing the spread of infection in society.

In addition, childcare facilities, schools or workplaces, are likely to be the starting points for the spread of infection in the region, such as mass infection outbreaks, and facilities for the elderly, are likely to have mass infections of those considered to be at high risk of severe illness. Therefore, the national government, in cooperation with prefectural and municipal health and sanitary departments or boards of education, will carefully provide and share information on infectious diseases and public health measures. In addition, the national government will provide and share easy-to-understand information with children, including onsite in-school education. (CAICM; MEXT; MHLW; relevant ministries and agencies)

1-1-2. Awareness raising against prejudice and discrimination

The national government will raise awareness of the fact that anyone can be infected with infectious diseases and that prejudice and discrimination against infected people, their families, institutions to which they belong, healthcare workers, etc., are not permissible. The national government should also raise awareness of the possibility of legal liability in such cases, and that such prejudice and discrimination, may hinder infectious diseases measures such as by refraining patients from seeking medical consultation¹⁰⁵. Through these initiatives, the national government will endeavor to further increase the people's awareness and reliability in providing and sharing information by the national government as a useful source of information. (CAICM; Ministry of Justice (MOJ); MEXT; MHLW; relevant ministries and agencies)

1-1-3. Awareness of disinformation and misinformation

Under the infectious disease crisis, the national government will raise awareness

¹⁰⁴ Article 13, Paragraph 1 of the Act on Special Measures.

¹⁰⁵ Article 13, paragraph (2) of the Act on Special Measures.

of disinformation and misinformation through various media to improve the literacy of the people on the media and information, taking into account the progress and spread of AI (Artificial Intelligence) technology, because the dissemination of disinformation and misinformation and the problem of infodemics¹⁰⁶ amplified by SNS, etc., may occur. (MIC; MEXT; MHLW; relevant ministries and agencies)

In addition, the national government will monitor the spread of disinformation and misinformation, such as information with uncertain scientific evidence concerning vaccination or therapeutics, taking into account the situation, and the national government will deal with it appropriately, such as by repeatedly providing and sharing information based on scientific knowledge and other relevant information so that the people can smoothly obtain accurate information. (CAICM; MHLW; relevant ministries and agencies)

Through these initiatives, the national government will endeavor to further increase the people's awareness and reliability in the provision and sharing of information by the national government as a useful source of information. (CAICM; MIC; MEXT; MHLW; relevant ministries and agencies)

1-2. Development of systems for providing and sharing information at the time of outbreak of novel influenza, etc.

The national government will take the initiatives described below to develop systems for providing and sharing information.

1-2-1. Development of systems for rapid and integrated information providing and sharing

- (i) The national government will review the contents of information to be provided and shared with the people, according to the outbreak status of novel influenza, etc. In addition, in order to enable the people, to obtain the necessary information, the national government will review the media and methods to provide and share information while giving appropriate consideration to the elderly, children, foreign nationals with insufficient Japanese language skills, and persons with visual or hearing impairments. (CAICM; MHLW; relevant ministries and agencies)
- (ii) In order to provide and share information with one voice integrally and consistently manner as the national government, the national government will

¹⁰⁶ A situation in which a mixture of highly reliable and unreliable information spreads rapidly along with anxiety and fear, causing confusion in society.

develop the necessary systems, including the appointment of public relations officers in charge of press conferences, and review the methods of providing and sharing information that relevant ministries and agencies will conduct with one voice. (CAICM; MHLW; relevant ministries and agencies)

- (iii) The national government will review, in advance, methods of providing and sharing information in both directions so that information can be smoothly provided and shared through local governments and industry associations at the time of outbreak of novel influenza, etc. (CAICM; MHLW; relevant ministries and agencies)
- (iv) In order to provide and share the information necessary for infectious disease measures while paying attention to the protection of personal information and privacy, the national government will clarify and disseminate the interpretation and operation of relevant laws and regulations, and revising as necessary publication standards, on an outbreak status of infectious diseases, etc., in accordance with the characteristics of infectious diseases so that they can easily serve as guidelines for specific measures to be taken by local governments. (MHLW)
- (v) In normal times, the national government will appropriately provide and share information internationally while endeavor to establish cooperative system with embassies in Tokyo, etc. (MOFA; CAICM; MHLW; relevant ministries and agencies)

1-2-2. Development of interactive communication system and promotion of initiatives

- (i) In order to appropriately conduct risk communication based on interactive communication to the greatest extent possible, the national government will identify the reactions of the people subject to communication and the information they need, including monitoring the spread of disinformation and misinformation, review methods and develop systems for providing and sharing more information. (CAICM; MHLW; relevant ministries and agencies)
- (ii) The national government will prepare for the establishment of a national call center, etc., to respond to the requests of the people for consultation at the time of an outbreak of novel influenza, etc. The national government will also request prefectural and municipal governments to prepare for setting up call centers, etc. (MHLW; relevant ministries and agencies)
- (iii) In order to provide and share information in an easy-to-understand manner to the people, the national government will promote risk communication research

and initiatives, including questionnaire surveys, as well as implement training for staff and endeavor to enhance and improve the methods. (CAICM; MHLW; relevant ministries and agencies)

Section 2: Initial phase

(1) Purpose

Based on any outbreaks or suspected outbreaks of novel influenza, etc., the national government needs to provide and share accurate information on the characteristics of the novel influenza, etc., or measures according to the situation, with the people in order to encourage them to prepare for the spread of infectious disease.

Specifically, to enable the people to make appropriate judgements and actions on the best available scientific evidence, the national government will take into account the concerns of the people, and provide and share accurate information rapidly and easily based on scientific evidence identified at the time, so that the overview of the relevant infectious disease can be understood.

In this context, the national government will endeavor to conduct risk communication based on interactive communication to the greatest extent possible. In addition, the national government will provide and share information such as that prejudice and discrimination against infected people are not permissible and can hinder infectious disease measures. The national government will also endeavor to relieve the anxieties of the people such as by repeatedly providing and sharing information based on scientific knowledge obtained at the time, in consideration of the spread of disinformation and misinformation.

(2) Required Response

Based on the scientific knowledge provided by JIHS, etc., and available at the time, the national government will provide and share the information listed below to the people regarding the characteristics of the novel influenza, etc., the domestic or international outbreak status, and effective infection prevention measures, etc., so that the people can have an overview of the infectious disease.

2-1. Rapid and integrated information providing and sharing

- (i) Since the media, through which the people receive information, and the ways that the people understand such information are various, the national government will provide and share the above information rapidly and integrally by developing and utilizing all available information media, taking into account the methods predetermined in the preparation phase.

In this context, the national government will further raise awareness that contribute to behavior change, including the fact that infectious disease measures at the individual level can make a significant contribution to preventing the

spread of infection in society, and will endeavor to issue messages that encourage a calm response.

In addition, in order to enable the people to obtain the necessary information, the national government will provide and share information through easy-to-understand content in an easily understandable method while giving appropriate consideration to the elderly, children, foreign nationals with insufficient Japanese language skills, and persons with visual or hearing impairments. (CAICM; MHLW; relevant ministries and agencies)

- (ii) The national government will launch a website where information on relevant ministries and agencies, local governments, and designated (local) public institutions can be collected and viewed comprehensively as necessary to improve the convenience of information collection for the people. (CAICM)
- (iii) JIHS, in cooperation with the national government, will provide and share information in an easy-to-understand manner to the people on the characteristics of the infectious disease or scientific knowledge on the outbreak status. (MHLW)
- (iv) The national government will provide and share information through local governments, industry associations, taking into account the method of information provision and sharing, which was reviewed in the preparation phase. (CAICM; MHLW; relevant ministries and agencies)
- (v) In order to provide and share information necessary for infectious disease measures while paying attention to the protection of personal information and privacy, the national government will clarify and disseminate the interpretation and operation of relevant laws and regulations, and revising as necessary publication standards on an outbreak status of novel influenza, etc., in accordance with the characteristics of the infectious diseases so that they can easily serve as guidelines for specific measures to be taken by local governments. (MHLW)
- (vi) The national government will appropriately provide and share information internationally. (MOFA; CAICM; MHLW; relevant ministries and agencies)

2-2. Implementation of interactive communication

- (i) It is important to obtain the understanding and cooperation of related parties in order to smoothly proceed with infectious disease measures. Therefore, the national government will not only provide information in one direction but will also endeavor to conduct risk communication based on interactive communication to the greatest extent possible, by identifying the reactions and

interests of the people subject to communication through trends in social media, opinions received through call centers and through questionnaire surveys, etc. (CAICM; MHLW)

- (ii) The national government will formulate Q&As, etc., for posting on its website and for prefectural and municipal governments, as well as set up call centers, etc. From the questions received through the call centers, etc., the national government will review the concerns and other matters of the people, and reflect them in the Q&As, etc., as well as share them with the relevant ministries and agencies and reflect them in the contents of the information to be provided and shared. (MHLW; relevant ministries and agencies)
- (iii) The national government will distribute Q&As to prefectural and municipal governments online or by other means and request them to set up call centers, etc. (MHLW; relevant ministries and agencies)

2-3. Measures against prejudice, discrimination, and disinformation and misinformation.

The national government will appropriately provide and share information, taking into account the situation, about the fact that anyone can be infected with infectious diseases, that prejudice and discrimination, against infected people, their families, institutions to which they belong, health care workers, etc., are not permissible and may lead to legal liability, and may also hinder infectious diseases measures, such as by refraining patients from seeking medical consultation. In addition, the national government will review information on various consultation services provided by the national government, local governments, NPOs, etc., about prejudice and discrimination, and announce this information to the people. (CAICM; MOJ; MEXT; MHLW; relevant ministries and agencies)

In addition, the national government will monitor the spread of disinformation and misinformation, such as information with uncertain scientific evidence concerning vaccination and therapeutics, taking into account the situation, and the national government will deal with the situation appropriately, by repeatedly providing and sharing information based on scientific knowledge obtained at the time and other relevant information so that the people can smoothly obtain accurate information. (CAICM; MHLW; relevant ministries and agencies)

The national government will make the necessary requests and cooperate with the initiatives of social media and other platform operators as their measures against prejudice, discrimination and disinformation and misinformation. (CAICM; MIC;

MOJ; MHLW; relevant ministries and agencies)

Section 3: Response phase

(1) Purpose

To effectively implement infectious disease measures under the crisis, it is important for the national government to share risk information and its perspectives so that the people can make appropriate judgements and actions. To this end, the national government should encourage the people to deepen their understanding of the measures and lead to appropriate actions as risk reduction partners while taking into consideration their concerns.

Specifically, to enable the people to make appropriate judgements and actions on the best available scientific evidence, the national government will take into account the concerns of the people, and provide and share accurate information rapidly and easily based on scientific evidence identified at the time.

In this context, the national government will endeavor to conduct risk communication based on interactive communication to the greatest extent possible. In addition, the national government will provide and share information that infectious disease measures at the individual level can make a significant contribution to preventing the spread of infection in society. Moreover, the national government will also provide and share information that prejudice and discrimination against infected people are not permissible and can hinder infectious disease measures, and will also endeavor to relieve the anxieties of the people by repeatedly providing and sharing information based on scientific knowledge, obtained at the time, in consideration the spread of disinformation and misinformation.

(2) Required Response

Based on the scientific knowledge provided by JIHS, etc., and available at the time, the national government will provide and share the information listed below to the people including domestic related organizations. Simultaneously, the national government will clarify the decision-making process, reasons (how decisions were made in consideration of what scientific knowledge.) and the implementing entity of the measures, regarding the domestic and international outbreak status of novel influenza, etc., and measures to prevent the spread of infection.

3-1. Basic policies

3-1-1. Rapid and integrated information provision and sharing

- (i) Since the media through which the people receive information and the ways that the people understand such information are various the national government

will provide and share the above information rapidly and integrally by developing and utilizing all available information media, based on the methods predetermined in the preparation phase.

In this context, the national government will further raise awareness that contribute to behavior change, including in relation to the fact that infectious disease measures at the individual level can make a significant contribution to preventing the spread of infection in society, and will endeavor to issue messages that encourage a calm response.

In addition, in order to enable the people to obtain the necessary information, the national government will provide and share information through easy-to-understand content in an easily understandable method while giving appropriate consideration to the elderly, children, foreign nationals with insufficient Japanese language skills, and persons with visual or hearing impairments. (CAICM; MHLW; relevant ministries and agencies)

- (ii) The national government will operate a website where information, on relevant ministries and agencies, local governments, and designated (local) public institutions can be collected and viewed comprehensively as necessary to improve the convenience of information collection for the people. (CAICM)
- (iii) JIHS, in cooperation with the national government, will provide and share information in an easy-to-understand manner to the people on the characteristics of infectious diseases or scientific knowledge on outbreak status. (MHLW)
- (iv) The national government will provide and share information through local governments and industry associations taking into account the method information should be provided and shared, which was reviewed in the preparation phase. (CAICM; MHLW; relevant ministries and agencies)
- (v) In order to provide and share information necessary for infectious disease measures while paying attention to the protection of personal information and privacy, the national government will clarify and disseminate the interpretation and operation of relevant laws and regulations, while revising as necessary publication standards on an outbreak status of novel influenza, etc., in accordance with the characteristics of the infectious diseases so that they can easily serve as guidelines for specific measures to be taken by local governments. (MHLW)
- (vi) The national government will appropriately provide and share information internationally. (MOFA; CAICM; MHLW; relevant ministries and agencies)

3-1-2. Implementation of interactive communication

- (i) Since it is important to obtain the understanding and cooperation of related parties in order to smoothly proceed with infectious disease measures. Therefore, the national government will not only provide information in one direction but will also endeavor to conduct risk communication based on interactive communication to the greatest extent possible by identifying the reactions and interests of the people subject to communication through trends in social media, opinions received through call centers and through questionnaire surveys, etc. (CAICM; MHLW)
- (ii) The national government will revise the Q&As, etc., for posting on its website and for prefectural and municipal governments, as well as enhance its call center and other systems. From the questions received through the call center, etc., the national government will review the concerns of the people and business operators, etc., and reflect them in the Q&As, etc., as well as share them with the relevant ministries and agencies, and reflect them in the contents of the information to be provided and shared. (MHLW; relevant ministries and agencies)
- (iii) The national government will distribute the revised version of the Q&As to prefectural and municipal governments online or by other means, and request them to continue the call centers, etc. (MHLW; relevant ministries and agencies)

3-1-3. Measures against prejudice, discrimination, and disinformation and misinformation.

The national government will appropriately provide and share information, taking into account the situation, about the fact that anyone can be infected with an infectious disease, that prejudice and discrimination against infected people, their families, institutions to which they belong, health care workers, etc., are not permissible and may lead to legal liability, and may also hinder infectious diseases measures, such as by refraining patients from seeking medical consultation. In addition, the national government will review information on various consultation services provided by the national government, local governments, NPOs, etc., about prejudice and discrimination, and announce this information to the people. (CAICM; MOJ; MEXT; MHLW; relevant ministries and agencies)

In addition, the national government will monitor the spread of disinformation and misinformation, such as information with uncertain scientific evidence concerning vaccination and therapeutics, taking into account the situation, and the national

government will deal with the situation appropriately such as by repeatedly providing and sharing information based on scientific knowledge obtained at the time and other relevant information so that the people can smoothly obtain accurate information. (CAICM; MHLW; relevant ministries and agencies)

The national government will make the necessary requests and cooperate with the initiatives of social media and other platform operators as a measure against prejudice, discrimination, and disinformation and misinformation. (CAICM; MIC; MOJ; MHLW; relevant ministries and agencies)

3-2. Policy decision and revision based on risk assessment

Based on the situation in which the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) and other factors become clear, the national government will take actions as described below.

3-2-1. Phase to take measures with containment at the forefront

In the early stages of the domestic outbreak of novel influenza, etc., the national government will keep containment in mind and make sure to prevent the spread of infection. In this context, in order to gain the understanding and cooperation on measures to prevent the spread of infection, if only limited knowledge on the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) is available, the national government will carefully explain the fact and the rationale for making policy decisions. In addition, since the fact that increasing the anxieties of the people can cause prejudice and discrimination against infected people, the national government will explain once again in an easy-to-understand manner, based on scientific evidence to the greatest extent possible, that prejudice, discrimination are not permissible, that they may hinder infectious disease measures, and that infectious disease measures at the individual level will make a significant contribution to preventing the spread of infection in society. The national government will also explain matters such as that when it requests the people to voluntarily avoid unnecessary outings and travel between prefectures, etc., such behavioral restrictions are necessary to prevent the spread of infection at an early stage, and that rapid initiatives to prevent the spread of infection by business operators are also necessary to prevent the spread of infection at an early stage. (MHLW; CAICM; relevant ministries and agencies)

3-2-2. Phase to take measures according to the characteristics of the pathogen

3-2-2-1. Explanation of measures according to risk assessment based on the characteristics of pathogens, etc.

Measures to prevent the spread of infection may be revised according to the broad classification of risk assessment based on the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) and other factors. In this context, the national government will simply explain the measures taken to prevent the spread of infection based on the scientific knowledge identified at the time, including any changes from the previous measures and the reasons for such changes, so that the people can appropriately respond to such new measures. (MHLW; CAICM; relevant ministries and agencies)

3-2-2-2. Explanation of measures to be taken when symptoms of children, young people, and the elderly, etc., are likely to become severe

The national government will simply explain the reasons for implementing the measures, based on scientific evidence to the greatest extent possible, since the intensity of measures under the Act on Special Measures and the method of requesting cooperation to the people may differ, according to the risk assessment based on the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug sensitivity, etc.) and the age groups who are largely affected. In this context, the national government will focus on the age groups that are most affected for gaining their understanding and cooperation on the measures to be taken such as by sharing risk information and perspectives while conducting interactive risk communication as much as possible. (MHLW; CAICM; relevant ministries and agencies)

3-2-3. Phase to shift toward basic infectious disease measures not based on the Act on Special Measures

In the phase of shift to basic infectious disease measures that are not based on the Act on Special Measures due to the acquisition of immunity through vaccines, etc., the decrease in pathogenicity, infectivity, transmissibility by pathogen mutation, and the ability to respond to novel influenza, etc. exceeding a certain level, the national government will carefully provide and share information on the points of attention (review of the medical care delivery system and infectious disease measures, etc.) with the shift to normal times. In addition, since there may be some people who feel uneasy about shifting to infectious disease measures that are left to individual judgements, the national government will conduct interactive risk communication as

much as possible, and gain their understanding and cooperation on the measures to be taken by sharing risk information and their perspectives. Also, the national government will gradually downsize its public relations system. (MHLW; CAICM; relevant ministries and agencies)

Chapter 5: Border Measures

Section 1: Preparation phase

(1) Purpose

The national government will establish a system related to border measures and provide drills and training in normal times, as well as secure supplies and facilities necessary for the implementation of border measures and develop a system to take smooth and rapid border measures in the event of the outbreak of novel influenza, etc., outside Japan.

In addition, by establishing a system for collecting and providing information on infectious diseases overseas, the national government, in the event of the outbreak of novel influenza, etc. overseas, will provide and share timely and appropriate information to Japanese people located abroad and those planning to leave Japan.

(2) Required Response

1-1. Establishment of a system for implementing border measures

- (i) The national government will provide training for relevant parties involved in border measures to acquire basic knowledge on novel influenza, etc., and training to develop human resources to respond to the enhancement of quarantine measures, as well as provide training, including joint implementation with related organizations, to enhance the effectiveness of border measures. (CAICM; Immigration Services Agency (ISA); MOFA; Ministry of Finance (MOF); MHLW; MLIT)
- (ii) The national government will specify target values for the stockpiling of personal protective equipment, etc., securing facilities, and testing capabilities, and will periodically check (monitor) the status of these items. (MHLW; ISA; MOF)
- (iii) The national government will conclude agreements, etc., with medical institutions, accommodation facilities, and transportation facilities used for isolation¹⁰⁷, detention¹⁰⁸, and facility-standby under the Quarantine Act, as well as to establish a cooperation system with prefectural governments, etc., in order to enable smooth hospitalization, etc.
Furthermore, the said agreements, etc., will be appropriately checked for content annually and renewed as necessary. (MHLW)
- (iv) The national government will establish an implementation system for PCR

¹⁰⁷ Article 14, paragraph (1), item (i) and Article 15, paragraph (1) of the Quarantine Act.

¹⁰⁸ Article 14, paragraph (1), item (ii) and Article 16, paragraph (2) of the Quarantine Act.

testing and other tests at quarantine stations for novel influenza, etc., and will build a cooperative system, such as concluding an agreement as necessary so that PCR testing and other tests can be requested to the nearest public health institutes, etc., and private testing companies, as necessary. (MHLW)

- (v) The national government will develop and update as needed the systems necessary to facilitate the input of questionnaires by returnees, etc., the health monitoring¹⁰⁹ of returnees, etc., and the sharing of information, etc., to prefectural governments, etc. (MHLW; Digital Agency)
- (vi) In preparation for the outbreak of novel influenza, etc., the national government will promote the development of systems related to the implementation of border measures, such as the enhancement of quarantine measures for returnees, etc., the concentration of quarantine airports and ports, requests for restrictions on the operation of ships and aircraft, entry restrictions, and visa restrictions, etc. (MHLW; ISA; MOFA; MLIT)

1-2. Development of a system for providing and sharing information to Japanese people located abroad and those planning to leave Japan

- (i) The national government will establish a system to collect information related to the infection status of novel influenza, etc., in other countries or regions (in particular, countries or regions that have exchanges through regular flights with various regions of Japan) and information related to border measures. (MHLW; MOFA)
- (ii) The national government will establish a system to provide and share the collected information in an easy-to-understand manner to Japanese people located abroad and those planning to leave Japan, as well as to call for their attention. (MHLW; MOFA)

1-3. Cooperation with local governments, etc.

In concluding agreements under the provisions of the Quarantine Act¹¹⁰, the national government will cooperate with medical institutions and prefectural governments and enhance cooperation with medical institutions and prefectural governments in normal times through the implementation of training in preparation for crisis. (MHLW)

¹⁰⁹ Article 18, paragraph (4) of the Quarantine Act.

¹¹⁰ Article 23-4 of the Quarantine Act.

Section 2: Initial phase

(1) Purpose

On the premise that it is difficult to completely prevent the entry of pathogens into Japan, based on the characteristics of novel influenza, etc., and the situation of the spread of infection overseas, etc., the national government will rapidly consider and implement border measures based on the characteristics of the novel influenza, etc., and the status of the spread of infection overseas. In such a way, the national government will reduce the speed of entry and spread of infection of novel influenza, etc., as much as possible and ensure time to prepare for responding to measures against infectious disease crisis, such as securing, etc., the domestic medical care delivery system, etc.

Furthermore, if information is limited on the characteristics of the infectious diseases and the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) at the beginning of an outbreak and in other cases, the national government will need to estimate the risk of high pathogenicity, infectivity, transmissibility, etc., based on past knowledge, etc., and implement enhanced border measures, but will constantly collect new information¹¹¹ and assess the necessity of such measures, and will change to appropriate countermeasures as soon as further information becomes available. In addition, border measures will be reviewed as the situation evolves.

(2) Required Response

2-1. Response to novel influenza, etc., in the early stages of an outbreak

- (i) When an outbreak of novel influenza, etc., is suspected, the national government, with the cooperation of shipping and airline companies, etc., will collect information on ships and aircraft coming to Japan from the country or region of the outbreak or via a third country (a country or region other than the country or region of the outbreak, the same hereinafter), including the place of departure, number of passengers, number of returnees, etc., by nationality, etc. (ISA; MLIT)
- (ii) The national government collects information on the situation surrounding the outbreak and border measures in major countries, countries or regions of the outbreak. (MHLW; MOFA)

¹¹¹ Information on the time of onset of infectious diseases and the progression of symptoms, etc., of people who have tested positive, obtained through medical examinations and health monitoring, etc., of such people who have tested positive conducted in quarantine, is also important for obtaining knowledge of the said infectious diseases.

- (iii) When an outbreak of novel influenza, etc., is suspected, even before WHO announces the outbreak of a new infectious disease that may spread rapidly (PHEIC declaration, etc.), etc., the national government will strive to detect patients, etc., upon their return to or entry into the country by confirming whether they stayed in the country or region of the outbreak and their health status, etc., by distributing questionnaires¹¹² to returnees, etc. In addition, for those returning from or entering via a third country from the country or region of the outbreak, the national government, with the cooperation of shipping and airline companies, etc., will distribute questionnaires, check the departure stamp on their passports to identify whether or not they stayed in the country or region of the outbreak, etc., thereby increasing the effectiveness of quarantine. (MHLW; ISA; MLIT)
- (iv) If a person who may have been infected with novel influenza, etc., is found at immigration and customs control, the national government will immediately notify the quarantine station, ask for instructions, and refer the person back to quarantine procedures¹¹³. (ISA; MOF)
- (v) The national government will request the shipping and airline companies, etc., to deny boarding, if necessary, when a symptomatic person (a person who shows any signs of an abnormal health condition, such as fever or cough, the same hereinafter) attempts to perform the boarding procedures. (MHLW; MLIT)
- (vi) The national government will request shipping and airline companies, etc., to respond to the case where a symptomatic person is found on board, to take the necessary countermeasures against infectious diseases on board. (MHLW; MLIT)
- (vii) The national government, with the cooperation of shipping and airline companies, will strive to detect patients after their return to or entry into Japan such as by distributing health cards that describe points of attention if the onset of the disease occurs after return to or entry into Japan to all returnees, etc. (MHLW)
- (viii) The national government will provide and share the collected information in an easy-to-understand manner to Japanese people located abroad and those planning to leave Japan and call for their alert. (MHLW; MOFA)
- (ix) When an outbreak of novel influenza, etc., is suspected, the national government will issue an infectious disease risk information regardless of

¹¹² Article 12 of the Quarantine Act.

¹¹³ Article 23-6 of the Quarantine Act.

whether or not WHO has announced an outbreak of a new infectious disease that is likely to spread rapidly (PHEIC declaration, etc.), etc., and alert Japanese people located abroad and those planning to leave Japan to stop non-urgent and non-essential overseas travel, etc. The national government will comprehensively take the status of the country or region of the outbreak and other factors into consideration, as well as the travel suspension advisory or the evacuation advisory. (MOFA)

- (x) The national government will request business operators, if necessary, to avoid business trips to the country or region of the outbreak. In addition, the national government, while collecting information from relevant ministries and agencies and local governments, will request business operators that have expatriates or business travelers abroad to call them back to Japan rapidly, as necessary. (Ministries and agencies with business jurisdiction)
- (xi) The national government will take the necessary infectious disease measures for those involved in border measures, such as wearing personal protective equipment, specified vaccination, and prophylactic administration of antiviral drugs in case of exposure to the virus from patients, as necessary. (MHLW; ISA; MOF)

2-2. Decision on type of novel influenza, etc., under the Quarantine Act, etc.¹¹⁴

The national government will consider which type the said infectious diseases belong to under the Quarantine Act and, if necessary, designate them as an infectious disease by Cabinet Order. (MHLW)

2-3. Enhancement of quarantine measures

- (i) The national government will coordinate with the port or airport management company, etc., to secure, etc., space and flow lines for waiting, inspection, etc., in the port or airport where the quarantine is to be implemented, and will develop the environment for the quarantine measures. (MHLW; MLIT)
- (ii) The national government, in cooperation with JIHS, will conduct technical verification for the implementation of PCR testing and other tests and establish a system in which the quarantine station can utilize its own testing equipment (including public health institutes, etc., and private testing companies that established a cooperation system in Section 1 (Preparation phase) 1-1(iv).

¹¹⁴ Article 2, Article 34, and Article 34-2 of the Quarantine Act.

(MHLW)

- (iii) The national government will secure facilities and means of transportation to accommodate those who are subject to isolation, detention, or requests to stay in accommodation, based on agreements, etc., as described in Section 1 (Preparation phase), 1-1, (iii). (MHLW)
- (iv) When the implementation of detention is recognized to be difficult due to a lack of facilities for detention, the national government will, in principle, use the said facilities near specified quarantine port and specified quarantine airports (hereinafter referred to as “specified quarantine ports, etc.”)¹¹⁵ subject to the consent of the managers thereof. When managers refuse to give their consent without any legitimate reason, the national government will consider using¹¹⁶ the said facilities under the Act on Special Measures. (MHLW)
- (v) The national government will conduct medical examinations, testing¹¹⁷, isolation, detention, request to stay in Residences, etc.¹¹⁸, or accommodations, and health monitoring, etc. The national government will determine and implement the scope of coverage, taking into account the characteristics of the infectious disease, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), the infection status of the said country or region of the outbreak, testing capability, and the securing status of medical institutions and accommodation facilities, among other factors. (CAICM; MHLW)
- (vi) For those with positive test results, the national government will isolate them in a medical institution and request to stay in accommodation¹¹⁹ for them. (MHLW)
- (vii) For those who are negative or not subject to testing, the national government will implement detention at medical institutions or accommodation facilities, request to stay in Residence, etc., or accommodations, and health monitoring, in accordance with the scope of coverage determined according to (v) above. The national government will change the scope of people subject to suspension, requests for stay, and health monitoring according to the status of the testing of people who have tested positive at that time, and the infection status in the country or region of the outbreak. (MHLW)

¹¹⁵ Article 29 of the Act on Special Measures.

¹¹⁶ Article 29, paragraph (5) of the Act on Special Measures.

¹¹⁷ Article 13, paragraph (1) of the Quarantine Act.

¹¹⁸ Article 14, paragraph (1), item (iii) and Article 16-2, paragraph (2) of the Quarantine Act.

¹¹⁹ Article 14, paragraph (1), item (iii) and Article 16-2, paragraph (1) of the Quarantine Act.

- (viii) For people staying in Residence, etc., the national government will do a request of refraining from using public transportation¹²⁰ to them when they move to their Residence, etc., taking into account the characteristics of the infectious disease and the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.). (MHLW)
- (ix) In the event that infection from asymptomatic pathogen carriers is observed for the said infectious disease, the national government will strive to enhance the quarantine measures described in (v) to (vii) above, taking into account the characteristics of the said infectious disease and the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.). (MHLW)
- (x) The national government will consider implementing measures based on the Quarantine Act, such as instructions to prevent the outbreak or spread of quarantinable infectious diseases, measures to thoroughly implement border measures¹²¹, such as instructions to stay in Residence, etc., and to collect reports of not going out, as well as measures against those who do not cooperate with border measures. In addition, the national government will widely disseminate information on the details of border measures, including these measures, domestically and internationally. (MHLW)
- (xi) In order to properly implement quarantine measures, the national government will determine specified quarantine ports, etc.,¹²² to consolidate such measures, taking into account the infection status of the country or region of the outbreak, the operation status of ships and aircraft, and the securing status of the quarantine system. (MHLW; MLIT)
- (xii) In line with the strengthening of quarantine measures, the national government will, as necessary, conduct vigilance activities, etc., at and around quarantine airports and ports, and will instruct or coordinate prefectural police departments, etc., to conduct vigilance activities, etc. (NPA, JCG)

2-4. Entry restrictions, etc.

- (i) The national government will determine the designation of countries or regions subject to denial of landing and the suspension of entry of foreign nationals from those countries or regions in principle, etc., at the Government

¹²⁰ Article 14, paragraph (1), item (iii) and Article 16-2, paragraph (2) of the Quarantine Act.

¹²¹ Article 13-3, Article 16-2 and Article 16-3 of the Quarantine Act.

¹²² Article 29 of the Act on Special Measures.

Countermeasures Headquarters by taking into consideration factors such as the characteristics of the infectious disease, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) and the infection status in the countries or regions of the outbreak while also considering WHO and other foreign countries' trends. (CAICM; ISA; MOFA; MHLW)

- (ii) Based on the determination of the Government Countermeasures Headquarters on the suspension of entry of foreign nationals in principle, etc., the national government will apply Article 5, paragraph (1), item (xiv)¹²³ of the Immigration Control and Refugee Recognition Act (Cabinet Order No. 319 of 1951, hereinafter referred to as "Immigration Control Act") to foreign nationals who have a history of stay in the designated countries or regions subject to the denial of landing. (ISA; MOFA; MHLW)
- (iii) The national government will set the upper limit of the total number of those who enter Japan and control the total number of those who enter Japan while taking into consideration the number of Japanese people located abroad who wish to return to Japan, according to the infection status in the countries or regions of the outbreak and quarantine system and other factors. Specifically, this will be implemented through restrictions on ship and aircraft operations, etc., as described in (v) below. (CAICM; ISA; MOFA; MHLW; MLIT)
- (iv) The national government will implement the necessary visa restrictions¹²⁴ (suspension of effect of issued visas, tougher visa screening, temporary suspension of visa exemption measures, etc.) based on the determination of the Government Countermeasures Headquarters, such as suspension of entry of foreign nationals in principle. (MOFA)
- (v) The national government will request shipping and airline companies to restrict the operation of ships and aircraft departing from or arriving in countries or regions of the outbreak, if necessary¹²⁵, to prevent the entry of novel influenza, etc., into Japan, taking into account the quarantine system and other factors. (CAICM; ISA; MOFA; MHLW; MLIT)

2-5. Countermeasures against illegal entrants

- (i) When illegal entrants from countries or regions of an outbreak are foreseen,

¹²³ In applying Article 5, paragraph (1), item (xiv) of the Immigration Control Act to a foreign national who may have been infected with a target infectious disease, it is assumed that the said infectious disease in question is an infectious disease under the provisions of Article 5, paragraph (1), item (i) of the Immigration Control Act.

¹²⁴ Article 4, paragraph (1), item (xiii) of the Ministry of Foreign Affairs Establishment Act (Act No. 94 of 1999).

¹²⁵ Article 30, Paragraph 2 of the Act on Special Measures.

the national government will strengthen mutual cooperation among enforcement organizations. When the national government receives or recognizes information that infected or possibly infected people are found among illegal entrants, the national government will take the necessary infectious disease measures and the necessary procedures while ensuring cooperation with public health centers and other organizations. (ISA; JCG; NPA)

- (ii) The national government will strengthen surveillance and enforcement measures, such as onsite inspections of ships and aircraft arriving from countries or regions of the outbreak, and measures to prevent slip-through, and enforcement of patrols at immigration checkpoints and transit areas, as well as instructing or coordinating with prefectural police departments, etc., to conduct vigilance activities, etc. (ISA; JCG; NPA)
- (iii) In order to prevent the illegal entry of infected people, the national government will strengthen vigilance activities, such as patrols in coastal areas and at sea, and will also provide instruction to or coordinate with prefectural police departments, etc., to conduct vigilance activities, etc. (NPA, JCG)

2-6. System operation

The national government will begin to operate functions for filling out questionnaires, etc., through the system developed in Section 1 (Preparation Phase) 1-1-(v) for quarantine procedures, such as distribution of questionnaires, etc., and will also launch the operation of the system to facilitate health monitoring, etc., in the implementation of isolation measures, etc. (MHLW; Digital Agency)

2-7. Provision and sharing of information to countries and regions concerned

The national government will provide and share information on border measures related to 2-3 through 2-6 above to the countries and regions concerned. (MOFA)

2-8. Cooperation with local governments, etc.

- (i) The national government will enhance cooperation between quarantine stations and related organizations, such as prefectural governments, etc., and medical institutions, and provide technical support for the implementation of testing, such as PCR testing and other tests for novel influenza, etc., in accordance with the strengthening of quarantine measures, and rapidly establish a testing system. (MHLW)
- (ii) The national government will provide the information obtained from the

questionnaires, etc., to prefectural governments, etc., as predetermined in the preparation phase. (MHLW)

- (iii) Prefectural governments, etc., in cooperation with the national government, will conduct health monitoring for people staying in Residence, etc.¹²⁶ (MHLW)

2-9. Support for Japanese people located abroad

- (i) The national government, either directly or through companies, schools, etc., will alert Japanese people located (including those on business or studying abroad) in the countries and regions of the outbreak, taking precautions toward the infection, and will disseminate information about measures to be taken when they are suspected of having been infected in the countries and regions of the outbreak, etc. (MOFA; MEXT; Ministries and agencies with business jurisdiction)
- (ii) The national government, in cooperation with relevant countries, will provide the necessary support, such as providing information on the operation of scheduled flights and requesting airlines when additional flights are needed, so that Japanese people located abroad who wish to return to Japan can do so during the operation of scheduled flights, etc., to the greatest extent possible. In addition, in setting the maximum number of people allowed to enter Japan and managing the total number of people entering Japan, special consideration will be given to Japanese people located abroad who wish to return to Japan due to local emergencies or other situations. (MOFA; MLIT)
- (iii) After the suspension of regular flights, etc., the national government will immediately consider alternative means of return for Japanese people located abroad, based on the status of the country or region of the outbreak while considering the need to strengthen quarantine, and will decide the handling policy, and then communicate it to Japanese people located in the country or region of the outbreak through the website of the MOFA, diplomatic establishments abroad, shipping and airline companies, travel agencies, etc. (MOFA; MHLW; MLIT; JCG; MOD)
- (iv) In accordance with the decided handling policy, the national government will take the necessary measures to handle the returnees, such as securing the means of return, taking preventive measures against infectious diseases for those concerned, and adjusting the quarantine system, including securing medical

¹²⁶ Article 15-3, Paragraph 1 of the Infectious Diseases Control Law.

institutions or accommodation facilities when implementing isolation and detention measures, etc. (MOFA; MHLW; MLIT; JCG; MOD)

- (v) The national government will consider anti-influenza drug prescriptions, etc., through onsite medical institutions, etc., to infected or potentially infected Japanese people located abroad, and will also consider the use of drugs deployed at diplomatic establishments abroad and other measures, as necessary. (MOFA)
- (vi) The national government, either directly or through companies, schools, etc., will alert, etc., Japanese people located abroad who have been or may have been infected in order to prevent the spread of infection. (MOFA; MEXT; Competent Ministries and Agencies)

Section 3: Response phase

(1) Purpose

The national government will consider and implement the reinforcing or mitigating of border measures in a timely, appropriate, and flexible manner, considering the impact, etc., on the national life and socioeconomic activities, taking into account the characteristics of the novel influenza, etc., and the spread of infection within and outside Japan, in order to delay, as much as possible, the speed of entry and spread of infection by new pathogens (including mutant strains) and to secure time to prepare against the spread of infection.

(2) Required Response

3-1. Period to respond with containment in mind

The national government will continue its responses from Section 2 (Initial Phase), 2-1, and 2-3 to 2-9, while taking into account changes in the situation.

In doing so, if prefectural governments request it under the provisions of the Infectious Diseases Control Law, and if the national government recognizes that it is necessary to prevent the spread of novel influenza, etc., taking into account the systems, etc., of the prefectural governments, etc., the national government will implement the health monitoring in Section 2 (Initial Phase), 2-8 (iii) on behalf of the said prefectural governments, etc.¹²⁷ (MHLW)

3-2. Period of response according to the characteristics of the pathogen, etc.

The national government will continue its responses from Sections 2 (Initial Phase), 2-1, and 2-3 to 2-9, and will consider and implement border measures based on the results of risk assessments, taking into account the domestic or international infection status, the status of the domestic medical care delivery system, the effects of countermeasures, and the impact, etc., on the national life and socioeconomic activities.

In addition, if new mutant strains of the said infectious disease break out overseas, the national government will strengthen border measures until the characteristics of the said pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) can be confirmed, and will switch the strength of the measures based on the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) and the domestic or international infection status, etc. (CAICM;

¹²⁷ Article 15-3, Paragraph 5 of the Infectious Diseases Control Law.

ISA; MOFA; MHLW; MLIT)

3-3. Period when response capability increases due to vaccines and therapeutic agents, etc.

The national government will take initiatives (i) to (iii), listed below, while continuing the responses from Section 2 (Initial Phase), 2-1 and 2-3 to 2-9.

- (i) Since the risk associated with the spread of infection is expected to decrease with the development and distribution of vaccines and therapeutic agents, the national government will consider and implement changes, moderations, or discontinuation of border measures in accordance with the status of development and dissemination of such vaccines and therapeutics. (CAICM; ISA; MOFA; MHLW; MLIT)
- (ii) The national government will reduce or discontinue border measures when they are no longer recognized as reasonable, due to changes in the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) or the domestic or international status of infection, etc., while taking into account the status of the domestic medical care delivery system, the effects of the measures, their impact on the national life and socioeconomic activities, etc. (CAICM; ISA; MOFA; MHLW; MLIT)
- (iii) In the case where new mutant strains of the said infectious disease break out overseas, the national government will strengthen border measures until the characteristics of the said pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) can be confirmed and will switch the strength of the measures based on the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), the domestic or international infection status, etc. (CAICM; ISA; MOFA; MHLW; MLIT)

3-4. Publication of policy on changes to border measures

When the national government is strengthening, moderating, or discontinuing border measures, the national government will announce the policy domestically and internationally, and request related organizations, etc., to take the necessary responses. (CAICM; ISA; MOFA; MHLW; MLIT)

Chapter 6: Prevention of Spread

Section 1: Preparation phase

(1) Purpose

In the event of an outbreak of novel influenza, etc., the national government will protect the lives and health of the people by controlling the speed and peak of the spread of infection to a level that the secured medical care delivery system can handle. To this end, the national government will organize the indicators and data, etc., that are necessary for reference when the national government implements countermeasures, etc., in normal times.

In addition, the national government will initiate the promotion of understanding among the people and business operators to obtain their cooperation in the measures to prevent the spread of infection during crisis and to mitigate the social impact of the measures to prevent the spread of infection.

(2) Required Response

1-1. Consideration of reference indicators, etc., regarding implementing countermeasures

The national government will organize the contents, acquisition methods, and acquisition timing, etc., of indicators and data, etc., that should be referred to when the national government implements countermeasures, etc., in order to agilely implement measures to prevent the spread of infection during crisis, or to flexibly switch the measures. In doing so, the national government will use, as much as possible, existing indicators and data, etc., that are periodically collected in normal times to ensure smooth identification in the event of crisis. (CAICM)

1-2. Promotion of understanding and preparation for strengthening measures, etc., in the event of an outbreak of novel influenza, etc.

- (i) The national and prefectural governments, based on their respective action plans, will disseminate and publicize the contents and significance of the measures assumed as those against novel influenza, etc. In doing so, the national government will promote an understanding of the importance of each person's cooperation in infectious disease measures to prevent the spread of novel influenza, etc., and to protect the lives and health of the people, and the need to conduct practical training, etc. (CAICM; MHLW)
- (ii) The national, prefectural, and municipal governments and schools, etc., will endeavor to disseminate basic infectious disease measures, such as ventilation,

cough etiquette by wearing masks, etc., washing hands, and avoiding crowds.

In addition, they will endeavor to promote an understanding of the measures in crisis, etc., such as contacting consultation centers for instructions if an infection of one's self is suspected, refraining from non-urgent and non-essential outings, and practicing cough etiquette by wearing a mask, etc., to prevent the spread of infection even in normal times. (CAICM; MEXT; MHLW; ministries and agencies that have jurisdiction over the operation)

- (iii) The national and prefectural governments will endeavor to promote an understanding of the measures to prevent the spread of novel influenza, etc., by individuals and business operators that can be implemented in the event of an outbreak of novel influenza, etc., including requests for business closure due to intensive measures for prevention of the spread of infection, requests for voluntary restraint from non-essential and non-urgent outings, and requests to restrict the use of facilities due to emergency measures in a state of emergency of novel influenza, etc.¹²⁸ (CAICM; MHLW; relevant ministries and agencies)
- (iv) Since public transport operators are designated as (local) public institutions in order to secure passenger transportation, from the viewpoint of ensuring appropriate transportation, it is assumed that they will request people with symptoms of the said infectious disease to refrain from boarding, call for a thorough cough etiquette by wearing masks, etc., staggered commuting, and the use of bicycles, etc. The national government will disseminate the results of the research and studies on points to note, etc., when they operate such services for the designated (local) public institutions. (MLIT; CAICM; MHLW)

¹²⁸ Meaning an emergency situation, such as novel influenza, etc., under the provisions of Article 32, paragraph (1) of the Act on Special Measures. The same shall apply hereinafter.

Section 2: Initial phase

(1) Purpose

In the event of an outbreak of novel influenza, etc., the national government will curb the speed and peak of the spread of infection through the appropriate and prompt implementation of measures to prevent the spread of infection, to secure time and endeavor to develop the medical care delivery system, etc., and to reduce the number of hospital visits, hospitalized patients, etc., during the peak period so that the secured medical care delivery system can respond to the outbreak. To this end, the national government will make preparations, etc., to prevent the spread of the infection domestically and to take rapid responses in the event of the outbreak.

(2) Required Response

2-1. Preparation of measures to prevent the spread of infection within Japan

- (i) The national and prefectural governments, etc., will cooperate with each other to prepare for patients with novel influenza, etc., within Japan, and promote confirmation of responses to the patients (such as hospitalization recommendations and measures) and to close contacts with patients, including those living with patients, etc., (such as request to avoid unnecessary outings, requests to undergo health observation, guidance on how to address symptoms) based on the Infectious Diseases Control Law.

In addition, the national and prefectural governments, etc., will cooperate with each other and make effective use of information received from quarantine stations concerning returnees, etc., suspected of having been infected with novel influenza, etc. (MHLW)

- (ii) JIHS, in cooperation with domestic or international experts, will rapidly provide the national and prefectural governments, etc., with information that contributes to effective measures to prevent the spread of infection, based on analysis of information, etc., on the characteristics of the infectious diseases, the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), clinical features, etc., and risk assessments. (MHLW)
- (iii) The national government, in preparation for the spread of the disease within Japan, will request local governments or designated (local) public institutions, etc., to prepare for a response based on the business continuity plans or the operational plans. (CAICM; designated public institution competent ministries and agencies)

Section 3: Response phase

(1) Purpose

The national government will take measures to prevent the spread of infection in order to curb the speed and peak of the spread of novel influenza, etc., avoid medical crisis, and protect the lives and health of the people. In doing so, the national government will give adequate consideration to the impact on the national life and socioeconomic activities as well.

In addition, the national government will strive to reduce the impact on the national life and socioeconomic activities by using the indicators and data, etc., considered in the preparation phase, comprehensively considering the effects and impacts of measures, including emergency measures, and switching measures in a flexible and agile manner.

(2) Required Response

3-1. Contents of measures to prevent the spread of infection

The following describes some options for implementing measures to prevent the spread of the disease. Based on the analysis of information and risk assessment by the national government and JIHS, the national government will take appropriate measures to prevent the spread of infection, according to the characteristics of the infectious disease, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), the mutation status, the infection status, and the status of the acquisition of immunity by the people.¹²⁹ In taking measures to prevent the spread of infection, the national government will also give adequate consideration to the impact on the national life and socioeconomic activities.

3-1-1. Response to patients and close contacts with patients

In cooperation with the national government, prefectural governments, etc., will take measures in accordance with local infection status, etc., based on the Infectious Diseases Control Law, such as responses to patients (hospitalization recommendations and measures, etc.)¹³⁰ and responses to close contacts with patients, such as people living with patients (requests to avoid unnecessary outings, etc.)¹³¹. In addition, based on the knowledge obtained through the collection of

¹²⁹ In this section, unless otherwise specifically mentioned or annotated in the relevant laws and regulations, it is assumed that the request is made under the provisions of Article 24, paragraph (9) of the Act on Special Measures.

¹³⁰ Article 19 of the Infectious Diseases Control Law as applied *mutatis mutandis* pursuant to Article 26, paragraph 2 of the Infectious Diseases Control Law.

¹³¹ Article 44-3, Paragraph 1 of the Infectious Diseases Control Law.

information on the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), etc., if there are measures considered effective, such as infection source estimation through active epidemiological investigation, etc., and measures to prevent the spread of infection by identifying close contacts with patients, such measures will also be taken in combination, if available. (MHLW)

3-1-2. Requests to residents other than patients and close contacts with patients, etc.

3-1-2-1. Requests, etc., concerning outings, etc.

Prefectural governments will, in accordance with the actual situation in the region, request voluntary restraint to places, etc., where the risk of infection is elevated, such as facilities where group infections have broken out or places where an unspecified number of people gather, and will also request the people to refrain from inter-prefectural movement.

In addition, as part of the intensive measures for prevention of the spread of infection, prefectural governments will request voluntary restraint¹³² to business operators operating in priority areas¹³³ where business hours have been changed, or as part of emergency measures, will request the people not to leave their residences, etc., in a state of emergency of novel influenza, etc., unless it is necessary to maintain their daily lives¹³⁴. (CAICM)

3-1-2-2. Requests for basic infectious disease measures, etc.

The national and prefectural governments will encourage the people to take basic infectious disease measures, such as ventilation, cough etiquette including mask-wearing, handwashing, and avoiding crowds, as well as staggered commuting, telework, the use of online meetings, etc., and will request thorough implementation of such measures, as necessary. (CAICM; MHLW; ministries and agencies that have jurisdiction over the operation)

3-1-2-3. Advisory on evacuation, suspension of travel, etc.

The national government will issue alerts against infection risk and alert Japanese people located abroad and those planning to leave Japan to stop non-urgent and non-essential overseas travel, etc., and if necessary, advise them to evacuate or suspend

¹³² Article 31-8, Paragraph 2 of the Act on Special Measures.

¹³³ Refers to areas where intensive measures for prevention of the spread of infection under the provisions of Article 31-6, Paragraph 1, Item 2 of the Act on Special Measures.

¹³⁴ Article 45, Paragraph 1 of the Act on Special Measures.

their travel, taking into careful consideration of the situation, etc., in the country or region of the outbreak. (CAICM; MOFA; MLIT)

3-1-3. Requests to business operators, schools, etc.

3-1-3-1. Change of business hours, request for business closure, etc.

Prefectural governments will, if necessary, request a change of business hours to those who operate businesses in business categories recognized as needing to take intensive measures for prevention of the spread of infection¹³⁵.

In addition, as part of a declaration of a state of emergency, the prefectural governments will request that those who manage facilities used by large numbers of people, such as schools¹³⁶, or those who hold events at such facilities (hereinafter referred to as “facility managers, etc.”) restrict the use of the facilities (limit the number of people or hold events with no in-person spectators) or suspend the use of the facilities (closure), etc¹³⁷. (CAICM; MEXT; ministries and agencies that have jurisdiction over the operation)

3-1-3-2. Request for measures to prevent the spread of infection

Prefectural governments will, as necessary, request that business operators and facility managers, etc., subject to requests under the intensive measures for prevention of the spread of infection or the declaration of a state of emergency, etc., described in 3-1-3-1 above, to take measures necessary to prevent the spread of novel influenza, etc., such as encouraging employees to be tested and taking other measures¹³⁸. (CAICM; ministries and agencies that have jurisdiction over the operation)

3-1-3-3. Order, etc., to take measures pertaining to the requests in 3-1-3-1 and 3-1-3-2

In cases where business operators or facility managers, etc., subject to a request under the intensive measures for prevention of the spread of infection or emergency measures, described in 3-1-3-1 or 3-1-3-2 above, do not respond to the request without justifiable reasons, prefectural governments will order the said people to take measures pertaining to the request, only when particularly necessary¹³⁹. (CAICM)

¹³⁵ Article 31-8, paragraph (1) of the Act on Special Measures.

¹³⁶ Limited to facilities under the provisions of Article 11 of the Enforcement Order of the Act on Special Measures against Novel Influenza, etc. (Cabinet Order No. 122 of 2013).

¹³⁷ Article 45, paragraph (2) of the Act on Special Measures.

¹³⁸ Article 31-8, paragraph (1) and Article 45, paragraph (2) of the Act on Special Measures.

¹³⁹ Article 31-8, paragraph (3) and Article 45, paragraph (3) of the Act on Special Measures. In case of violation of the

3-1-3-4. Publication of facility name

Prefectural governments will publicize the names of business operators and facilities that have received requests or orders under the intensive measures for prevention of the spread of infection or emergency measures, described in 3-1-3-1 through 3-1-3-3 above, if it is decided that publicizing the names of such business operators and facilities will lead to ensuring users' reasonable actions¹⁴⁰. In addition, the national government will provide and share information on the contents that contribute to the decisions of prefectural governments. (CAICM)

3-1-3-5. Requests to other business operators

- (i) The national and prefectural governments will request business operators to take thorough infectious disease measures in the workplace and will encourage their employees to take basic infectious disease measures, etc., or request their cooperation to do so thoroughly. In addition, the national and prefectural governments will request cooperation, such as encouraging employees with symptoms of the said infectious disease to take care of their health and seek medical consultation, work through telework for employees who do not need to be present onsite in order to work, and consideration, etc., for employees who are parents or guardians when their children's schools, etc., are suspended temporarily. (CAICM; MHLW; ministries and agencies that have jurisdiction over the operation)
- (ii) The national government will request prefectural governments, etc., and related organizations to strengthen infectious disease measures at facilities where people with underlying diseases gather, such as hospitals and elderly care facilities, and at facilities where large numbers of people live, etc. (MHLW)
- (iii) Prefectural governments will request that facility managers, etc., thoroughly implement basic infectious disease measures and formulate plans to ensure safety, such as by limiting the number of people at facilities, etc., where there is an elevated risk of infection, such as facilities where group infections have broken out or places where unspecified large numbers of people gather. (CAICM)
- (iv) The national government will, as necessary, issue recommendations to

said order, a fine may be imposed under the provisions of Article 79 and Article 80, item (i) of the Act on Special Measures.

¹⁴⁰ Article 31-8, paragraph (5) and Article 45, paragraph (5) of the Act on Special Measures.

postpone or cancel business trips to countries or regions where the risk of infection is increasing. (CAICM; MOFA; MLIT; ministries and agencies that have jurisdiction over the operation)

- (v) The national government will consider initiatives to promote voluntary infectious disease measures by business operators and respective industries. (CAICM; ministries and agencies that have jurisdiction over the operation)

3-1-3-6. Request for closure of classes, schools, etc.

The national and prefectural governments will, as necessary, provide and share information that contributes to the implementation of infectious disease measures in schools, childcare facilities, etc., based on the infection status, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), and other factors. In addition, the national and prefectural governments will request school administrators, etc., to appropriately implement temporary suspension¹⁴¹ (class closures, grade closures, or school closures), etc., based on the School Health and Safety Act (Act No. 56 of 1958), in consideration of the regional infection status and other factors. (CAICM; Children and Families Agency (CFA); MEXT)

3-1-4. Requests for public transport operators

3-1-4-1. Requests for basic infectious disease measures, etc.

The national government requests public transport operators, etc., to take appropriate infectious disease measures, such as encouraging users to wear masks. (CAICM; MHLW; MLIT)

3-1-4-2. Requests for reduced flights, etc.

In order to reduce the number of people staying at night and to minimize opportunities for people-to-people contact, the national government will request public transportation operators, etc., to change their operation methods, etc., as necessary¹⁴². (CAICM; MLIT)

3-2. Concept of implementation of measures for prevention of spread according to the phase

3-2-1. Phase to take measures with containment at the forefront

The national and prefectural governments will take into account the limited

¹⁴¹ Article 20 of the School Health and Safety Act.

¹⁴² Article 20, paragraph (1) of the Act on Special Measures.

medical care resources, such as designated medical institutions for infectious diseases, the current lack of established effective therapeutic methods for novel influenza, etc., and that the people have not yet acquired sufficient immunity against the said infectious diseases, etc., and will implement the necessary inspections to avoid medical crisis and to protect the lives and health of the people. In addition to the responses, etc., to patients and close contacts with patients described in 3-1-1 above, the national and prefectural governments will take measures to contain the disease by reducing opportunities for people-to-people contact and other measures.

To achieve this, the national and prefectural governments will take measures to prevent the spread of infection stronger than those described in 3-1 above, including a consideration of the implementation of intensive measures for prevention of the spread of infection and emergency measures, as necessary (the approach to implanting intensive measures for prevention of the spread of infection and emergency measures is described in 3-3). (CAICM)

3-2-2. Phase to take measures according to the characteristics of the pathogen, etc.

The national government will announce the approach listed below to respond according to the broad categories of risk assessment, taking into account the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), etc. However, in the event of crisis, the national government will decide on the response based on the results of the analysis and risk assessment conducted by the national government and JIHS based on information on the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), clinical features, and other factors. (CAICM)

3-2-2-1. Cases where both pathogenicity, infectivity and transmissibility, etc., are high

Since the risk of severe illness, etc., is extremely high when a person is infected, and the highly infectivity and transmissibility may lead to an increase in the number of infected people, resulting in a medical crisis, which may affect the lives and health of the majority of the people, the national government will take stronger measures to prevent the spread of infection, including implementation of intensive measures for prevention of the spread of infection and emergency measures, as described in 3-2-1 above. (CAICM)

3-2-2-2. Cases of high pathogenicity and low infectivity and transmissibility

In cases where the risk of severe illness, etc., is very high but the speed of the

spread of infection is relatively slow, the national government will generally aim to prevent the spread of infection such as by thoroughly responding to patients and people in close contacts with patients, as described in 3-1-1 above.

If there is still a risk of disruption in the delivery of medical care, etc., the national government will consider implementing intensive measures for prevention of the spread of infection and emergency measures. (CAICM)

3-2-2-3. Cases of low pathogenicity and high infectivity and transmissibility

In cases where the risk of infection is relatively low, but the speed of the spread of infection is fast, the national government will generally implement measures to prevent the spread of infection, which are less intense among the measures listed in 3-1 above, while ensuring a system of accommodation-based recovery, home-based recovery, etc., and will respond to the situation by appropriately reviewing the division of roles among medical institutions based on the prevention plan and the medical care plan.

In cases where there remains a threat of medical crisis in a region after implementing the above measures, etc., the national government will strengthen its support for prefectural governments. Specifically, prefectural governments will announce the outbreak of the said status and call for cooperation in preventing further spread of infection, and the national government will cooperate and coordinate with relevant ministries, agencies, industry groups, etc., deliver good practices and support the introduction of infectious disease measures, and provide advice and instructions, etc., on infectious disease measures in order to support the prefectural governments in implementing more effective and efficient infectious disease measures in the said prefectures.

If there is still a risk of disruption in the provision of medical care, etc., the national government will consider implementing intensive measures for prevention of the spread of infection and emergency measures. (CAICM)

3-2-2-4. Cases in which children, young people, elderly people, etc., are likely to become infected or severely ill

If the risk of infection or severe illness is high for particular groups, such as children, elderly people, and people with a medical history that includes certain pre-existing medical conditions or an ongoing illness, who tend to be more susceptible to infection or severe illness, etc., the national government will consider implementing focused infectious disease countermeasures for those groups.

For example, in cases where children are susceptible to infection or serious illness, the national government will implement measures while paying attention to the impact that measures taken at schools and childcare facilities, etc., may have on children, and will also take into consideration the risk of infection from parents or guardians and people living with children. In addition, in order to protect the lives and health of children, the national and prefectural governments will request the closure of classes and schools, etc., as described in 3-1-3-6 above, depending on factors such as the infection status in the region. Nevertheless, if the infection status in the region does not improve and children are at high risk of infection and severe illness, etc., the national and prefectural governments will consider preventing the spread of infection at schools, etc., by restricting the use, etc., of school facilities, etc.¹⁴³ (CAICM)

3-2-3. Phase when the response capacity increases owing to vaccines and therapeutics, etc.

When it is recognized that the risk associated with the spread of infection has decreased due to the development and dissemination of vaccines and therapeutic agents, the national and prefectural governments will consider a rapid transition to basic infectious disease countermeasures that are not under the Act on Special Measures while implementing measures to prevent the spread of infection that are less intense among the measures listed in 3-1 above.

Furthermore, if the pathogen's pathogenicity or infectivity and transmissibility increases due to mutation, etc., the national and prefectural governments will take measures based on the approach listed in 3-2-2 above, depending on the risk. However, even in such cases, the national and prefectural governments will consider this while taking into account the impact on the national life and socioeconomic activities that would result from prolonged countermeasures. (CAICM; MHLW)

3-2-4. Phase to shift to basic infectious disease measures not based on the Act on Special Measures

The national and prefectural governments will assess the measures to prevent the spread of infection that they have implemented so far and, as necessary, improve measures in preparation for the mutation of pathogens and the next infectious disease crisis, etc. (CAICM; MHLW)

¹⁴³ Article 45, paragraph (2) of the Act on Special Measures.

3-3. Consideration of the public announcement of the intensive measures for prevention of the spread of infection and the declaration of a state of emergency, etc.

In carrying out a response, etc., based on the approach in 3-2 above, the consideration of implementing intensive measures for prevention of the spread of infection and emergency measures will follow (i) through (iii) below. Furthermore, as for the procedures, etc., related to the implementation of these measures, the description in Chapter 1, Section 3 (Response Phase in “Implementation System”), 3-2 will be referenced.

- (i) Prefectural governments will conduct a risk assessment and consider whether to request the national government to implement intensive measures for prevention of the spread of infection or emergency measures based on information, such as the infection status and medical crisis status in the region. (CAICM)
- (ii) In close cooperation with JIHS and prefectural governments, etc., and taking into account factors such as scientific knowledge obtained from JIHS, etc., and the status of the medical care delivery system in each prefecture, etc., based on the situation surrounding the outbreak of novel influenza, etc., trends in patient outbreaks, hospital bed occupancy rates, outpatient care shortages, rates of severe cases, etc., and when it is recognized that disruptions in medical care may occur or are likely to occur, the national government will issue a public announcement of the intensive measures for prevention of the spread of infection or a declaration of a state of emergency.

In doing so, the national government will also confirm the situation of consumption, information on mental health and social unrest, etc., and other indicators related to national life and socioeconomic activities, including their trends, and will take these measures after comprehensively considering the effects of the measures and their impact on the national life and socioeconomic activities. The national government will then proceed to publicly announce the intensive measures for prevention of the spread of infection, or declare a state of emergency for the periods, areas, business types, etc., in which the national government recognizes it as necessary to take such measures. (CAICM)

- (iii) However, the national government will assess the necessity and content of these measures at each of the periods listed in 3-2 above, paying particular attention to the points listed below. (CAICM)
- (A) Phase to take measures with containment at the forefront

Even in situations where scientific knowledge is considered to be insufficient, if containment is recognized to be necessary in consideration of the situation surrounding the medical care delivery system, etc., the national government will consider and rapidly implement the necessary measures, including the intensive measures for prevention of the spread of infection and emergency measures while providing and sharing information with the people about the said situation.

(B) Phase to take measures according to the characteristics of the pathogen, etc.

In areas where it is deemed necessary in light of the situation surrounding the medical care delivery systems, etc., measures will be taken for the minimum periods, areas, business types, etc., as is considered the minimum required, based on scientific knowledge provided by JIHS, etc., and after comprehensively taking into account the effects of the measures and their impact on the national life and socioeconomic activities.

(C) Phase when the response capacity increases owing to vaccines and therapeutics, etc.

The national government will take the same measures as those listed in (B) above, but based on the decreased risk of severe illness, etc., it will consider the periods, areas, and types of business to which the measures will be taken while placing more importance on the impact on the national life and socioeconomic activities due to the prolonged implementation of the measures.

Chapter 7: Vaccines

Section 1: Preparation phase

(1) Purpose

To protect the lives and health of the people during the outbreak of novel influenza, etc., and to minimize the impact on national life and the economy, it is imperative to steadily advance preparations in normal times. These preparations include the swift development and manufacturing of vaccines tailored to the novel influenza, etc., ensuring the rapid supply of the necessary quantities and facilitating the smooth execution of vaccinations.

By providing support for the research and development of vaccines in normal times, a framework will be established that enables the rapid development of vaccines and the swift manufacturing of vaccines with confirmation of their efficacy and safety in the event of the outbreak of novel influenza, etc. Furthermore, in order to facilitate smooth vaccination in the event of the outbreak of novel influenza, etc., the necessary preparations will be undertaken in collaboration with the national, prefectural, and municipal governments, as well as medical institution, business operators, etc.

(2) Required response

1-1. Research and development

1-1-1. Promotion of research and development

(i) The national government, in accordance with the “Strategy for Strengthening Vaccine Development and Production System,” will implement the necessary measures¹⁴⁴ to establish a system that enables the rapid development and supply of vaccines. This measure by the national government promotes advancing the research and development of vaccines for novel influenza, etc.

(A) The national government will promote research and development that contributes to the development of domestically produced vaccines in normal times in collaboration with the Strategic Center of Biomedical Advanced

¹⁴⁴ Measures required to establish a system that enables a rapid development and supply of vaccines.

- Formation of world-class research and development bases. (MEXT; MHLW)
- Enhancement of strategic funding function for research expenses. (National Healthcare Policy Secretariat; MEXT; MHLW; METI)
- Development and expansion of clinical trial environments. (MHLW; MOFA)
- Acceleration of the marketing approval process and establishment of standards (MHLW)
- Development of vaccine manufacturing bases. (METI; MHLW)
- Fostering of drug discovery ventures. (METI; MHLW)
- Fostering and development of the vaccine development and manufacturing industry. (MHLW; MOFA)
- Promotion of international cooperation. (MHLW; MOFA)
- Expansion of monitoring systems as a prerequisite for vaccine development. (MHLW; MEXT)

Vaccine Research and Development for Preparedness and Response (SCARDA), established within the Japan Agency for Medical Research and Development (AMED). Furthermore, the national government will advance seamless and global research and development on vaccines, from basic research to practical application, through industry-academia-government collaboration. (National Healthcare Policy Secretariat; MEXT)

- (B) To advance the research and development of vaccines that lack market demand in normal times, it is of utmost importance to establish a framework that enhances the predictability of research and development activities, thereby encouraging pharmaceutical companies to engage in the development process.

Moreover, in conducting clinical trials for vaccines, the timing and scale, etc., of the outbreak of novel influenza, etc., are unpredictable, making it difficult to estimate the required funding for each fiscal year. Additionally, large-scale clinical trials involving tens of thousands of participants are necessary, leading to potentially high costs of research and development. To address these challenges and ensure the availability of vaccines, the national government will implement both push type research and development support and pull type research and development support targeted at pharmaceutical companies, etc. By securing the market viability of vaccines post-approval, the national government aims to promote ongoing research and development in normal times and establish a comprehensive ecosystem that enhances public health preparedness. (MHLW; National Healthcare Policy Secretariat)

- (ii) While taking into account international trends, the national government will comprehensively evaluate the necessity of public health-related procurement and stockpiling domestically, as well as the demand abroad, etc., in relation to pull type research and development support. Based on this evaluation, the national government will deliberate on the most appropriate approach and reach a conclusion regarding its implementation. (MHLW)
- (iii) Through the aforementioned initiatives, the national government will provide consistent support for the securement of vaccines, which are essential for public health measures, from basic research to post-market availability. (MHLW; National Healthcare Policy Secretariat; MEXT)

1-1-2. Designation of priority infectious diseases

The national government, in collaboration with JIHS, will analyze and evaluate

infectious diseases from a crisis management perspective, determining which diseases necessitate the availability of medical countermeasures (hereinafter referred to as “MCM”) within the country. Based on this analysis, such diseases will be designated as priority infectious diseases. (MHLW)

1-1-3. Establishment of research and development systems

- (i) The national government, with support from SCARDA, will establish world-class research and development hubs capable of conducting vaccine research and development in normal times, with a focus on enabling rapid response during emergencies, such as the formation of industry-academia-government collaboration consortia. Additionally, the national government will promote the development of systems designed for crisis, which will involve training on the processes and collaboration, etc., required, from the acquisition of pathogens to the development of vaccines during the initial phase. (National Healthcare Policy Secretariat; MEXT; MHLW; METI)
- (ii) The national government will establish a system to swiftly evaluate the efficacy, etc., of existing vaccines in the event of the outbreak of novel influenza, etc. Under the “Strategy for Strengthening Vaccine Development and Production System,” with support from SCARDA, industry, academia, and government will collaborate on vaccine development for priority infectious diseases. This collaboration will include revising the conceptual framework and updating the list of priority infectious diseases to be targeted, taking into account factors such as the epidemiological situation and the progress in vaccine development for these diseases. (MHLW; National Healthcare Policy Secretariat; MEXT; METI)
- (iii) The national government and JIHS, in collaboration with related organizations, will assess and implement measures to ensure the stable supply of experimental animals, including primates, which are essential for advancing research and development. Additionally, they will evaluate and execute strategies to establish and secure the necessary facilities and personnel to conduct non-clinical trials involving experimental animals, including large primates. (MHLW; relevant ministries and agencies)

1-1-4. Collaboration with research institutes, etc.

- (i) The national government and JIHS will, in collaboration with domestic and international research institutions, pharmaceutical companies, etc., work to acquire pathogen samples, genome sequence data, and other relevant

information at an early stage. This information will then be distributed and provided to related organizations engaged in research and development, thereby advancing vaccine development efforts in normal times onward. (MHLW; MEXT)

- (ii) To support vaccine development, the national government will work to address challenges associated with conducting research using pathogens, including issues related to their acquisition, transportation, and distribution. (MHLW; MEXT)

1-1-5. Establishment of a framework for large-scale clinical trials

The national government, in collaboration with JIHS, will enhance the domestic infrastructure for clinical trials to facilitate the rapid enrollment of a large number of participants in large-scale clinical trials during crisis. Additionally, the national government will develop a framework that enables the conduct of international clinical trials. (MHLW)

1-1-6. Establishment of a framework for manufacturing, etc., vaccine

- (i) The national government will promote the development of a manufacturing system for novel influenza vaccines, with the aim of manufacturing sufficient pandemic vaccines for the people nationwide within six months of determining the virus strain for vaccine manufacturing following the outbreak of novel influenza. (MHLW; METI)
- (ii) The national government will also promote the research and development of new modalities, administration methods, etc., as well as the establishment of manufacturing systems, to enable the rapid development and manufacturing of vaccines for other infectious diseases. Additionally, by supporting the domestic development of mRNA vaccines and other vaccines for infectious diseases that are already on epidemic, such as COVID-19, the national government aims to increase the number of businesses with experience in developing vaccines using these new modalities, etc. (National Healthcare Policy Secretariat; MHLW; METI)

1-1-7. Consideration of pre-pandemic vaccine vaccination methods, etc.

In order to support the development of effective vaccination methods, etc., for pre-pandemic vaccines during a novel influenza outbreak, the national government will, considering the latest epidemic trends, utilize a portion of vaccines already

formulated to assess their efficacy, safety, etc. in both animal and human studies, thereby obtaining knowledge to inform their use during an actual outbreak. (MHLW)

1-1-8. Consideration of efficacy and safety evaluation

JIHS will conduct an examination regarding the implementation of efficacy and safety evaluations following the introduction of vaccines. (MHLW)

1-1-9. Fostering and utilization of human resources in vaccine research and development

The national government and JIHS, in collaboration with universities and other research institutions, shall promote human resource development engaged in vaccine research and development by fostering talent in areas ranging from basic research on infectious diseases to clinical trials and other related fields. Additionally, the national and prefectural governments, etc. shall support these research institutions. Moreover, the national government and prefectural governments, etc., by actively utilizing the trained personnel through support for career development, etc., shall enhance the implementation system for clinical research at clinical research core hospitals, designated medical institutions for infectious diseases, and other institutions that participate in the collaborative networks with research-promoting medical and research institutions, etc. (MHLW; MEXT)

1-2. Securing vaccines

1-2-1. Pre-pandemic vaccines (in the case of novel influenza)

- (i) Because it takes time following an outbreak to develop and manufacture a pandemic vaccine, the national government, as an interim measure for novel influenza, will advance the manufacturing and stockpiling (with partial formulation) of pre-pandemic vaccine bulk to enable the vaccination of health care workers and those who are engaged in activities crucial to maintaining the stability of the national life and socioeconomic activities as part of infectious disease measures, etc. (MHLW)
- (ii) The national government shall periodically evaluate the introduction, etc., of new modalities and manufacturing methods for pre-pandemic vaccines in normal times. (National Healthcare Policy Secretariat; MHLW)
- (iii) When the national government undertakes the manufacturing and stockpiling of pre-pandemic vaccines, the national government will determine the vaccine strain to be produced based on the latest epidemiological data and risk

assessments. Additionally, to inform the implement, etc., of effective vaccination during the outbreak of novel influenza, the national government will promote clinical research on the efficacy and safety of formulated pre-pandemic vaccines, taking into account the latest epidemiological trends. (MHLW)

- (iv) The national government will stockpile pre-pandemic vaccines in a formulated state in advance, ensuring that the necessary quantities are readily available for swift administration following the outbreak of novel influenza. (MHLW)
- (v) The national government will utilize the existing manufacturing infrastructure for pandemic vaccines against novel influenza in normal times to manufacture pre-pandemic vaccines. (MHLW)

1-2-2. Pandemic vaccines

1-2-2-1. Establishment of vaccine manufacturing bases and dual-use facilities

The national government, in alignment with the “Strategy for Strengthening Vaccine Development and Production Systems,” will support the establishment, etc., of domestic manufacturing facilities that can produce biopharmaceuticals according to the needs of companies in normal times and switch to vaccine production during crises (dual-use facilities), in addition to the development of vaccine manufacturing bases. In order to ensure that the vaccine manufacturing facilities established as dual-use facilities can be smoothly switched to manufacturing in crisis, the current status of related organizations, researchers, and business operators, etc., related to the development and production of vaccines, from (A) to (C) below, should be shared among relevant ministries and agencies, and the necessary support and policies should be established and constantly renewed. (METI; National Healthcare Policy Secretariat; MEXT; MHLW)

- (A) Status of vaccine development for priority infectious diseases in SCARDA.
- (B) Information on the types, specifications, manufacturing capacities, and lead times for manufacturing that can be manufactured by businesses with dual-use facilities, as well as the status of material procurement and staffing arrangements, etc., required for these entities to transition to pandemic vaccine manufacturing.
- (C) The procedures for recognition as crisis, vaccine identification, directives to businesses, and the allocation of responsibilities among relevant ministries and agencies.

1-2-2-2. Information sharing for the rapid securing of vaccines

To ensure the swift domestic procurement of pandemic vaccines for the people nationwide in the event of the outbreak of novel influenza, etc., the national government will share the information outlined in (A) and (B) below among relevant ministries and agencies, establish the necessary support and policies, and continuously update these measures. (MHLW)

- (A) Information on domestic vaccine manufacturing bases (Types of products that can be manufactured by each business, standards, manufacturing capacity, lead times for initiating manufacturing, etc.)
- (B) Information, etc., on the total quantity of vaccines that can be produced domestically for each modality, lead times for initiating manufacturing, and lead times required to produce the quantities expected to be needed domestically.

1-2-2-3. Coordination for securing imported vaccines

The national government shall establish the fundamental principles for securing imported vaccines, taking into account the manufacturing capacity, etc., of domestic vaccine manufacturing bases, and preparing for situations where domestic manufacturing alone may be insufficient. Additionally, the national government shall outline the necessary confirmation items and coordination processes, etc., with overseas vaccine manufacturers to ensure the procurement of imported vaccines. (MHLW)

1-2-3. Identification of resources required for vaccine vaccination

The national government shall ascertain the status of domestic manufacturing businesses and importers and the volume of domestic stockpiles of the materials necessary for vaccination, such as needles and syringes, as well as the estimated quantities that can be secured in the event of an outbreak of novel influenza, etc. (MHLW)

1-3. Vaccine supply systems

1-3-1. Establishment of a vaccine distribution system

The national government shall request prefectures to establish systems (A) through (C), listed below, for the smooth distribution of vaccines in consultation with relevant parties, including municipal governments within their jurisdiction, prefectural medical association, and prefectural wholesale distributor association. (MHLW)

- (A) A system capable of swiftly assessing the inventory status of wholesale distributors and medical institutions, etc., within the jurisdiction.
- (B) Methods for reallocating inventory among wholesale distributors in the event of supply imbalances of vaccines.
- (C) Methods for coordinating with municipal governments and defining roles and responsibilities.

1-3-2. Development of a vaccine distribution system

The national government, in preparation for centralized vaccine supply management, shall establish a system capable of aggregating the requested vaccine quantities from medical institutions, etc., and determining the distribution volumes to municipal governments or prefectural governments, thereby facilitating efficient vaccine allocation. (MHLW)

1-4. Registration, etc., of business operators that meet criteria (for specified vaccination¹⁴⁵)

When the national government establishes criteria for those who are eligible for specified vaccination, it is essential that the criteria are recognized as having significant public interest and societal value under the Act on Special Measures to ensure sufficient public understanding, given that specified vaccination are generally administered before resident vaccination. The national government, considering this fundamental principle, shall define the detailed requirements for registered business operators and public officials. Furthermore, if the stockpiled pre-pandemic vaccines are effective for specified vaccination, these vaccines will be used. However, if their efficacy against the emergent pandemic influenza is low, pandemic vaccines will be used instead. (MHLW; CAICM; relevant ministries and agencies)

1-4-1. Publicizing the registration of registered business operators

The national government shall advance the registration of registered business operators into a managed database based on applications from businesses that meet

¹⁴⁵ Based on Article 28 of the Act on Special Measures, it refers to emergency vaccinations conducted when the national government deems them urgently necessary to ensure the provision of medical services and the stability of the national life and the economy. Those who may be eligible for these specific vaccination include the following:
(i) Individuals engaged in operations that contribute to the provision of medical care services or the stability of the national life and the economy, who are employed by businesses registered with the MHLW (hereinafter referred to as “registered business operators”), and who meet the criteria established by the MHLW;
(ii) National public officials involved in the implementation of countermeasures against novel influenza, etc.;
(iii) Local public officials involved in the implementation of countermeasures against novel influenza, etc.

the criteria for specified vaccination. To facilitate this process, the national government will develop a registration implementation manual that outlines the vaccination system related to specified vaccination, the requirements for business continuity, the registration procedures. etc. This manual will be disseminated to relevant businesses through the cooperation of prefectural and municipal governments, as well as relevant ministries and agencies, to ensure awareness and participation in the registration process. (MHLW; CAICM; relevant ministries and agencies)

1-4-2. Registration of registered business operators

The national government, in collaboration with relevant ministries and agencies, as well as with the cooperation of prefectural and municipal governments, shall accept registration applications from businesses and register those that meet the established criteria as registered business operators. (MHLW; relevant ministries and agencies)

1-5. Establishment of a vaccination system

1-5-1. Vaccination system

The national government shall organize the securement of vaccination sites and health care workers involved in vaccination, as well as the concept of prioritization of vaccination so that a vaccination system can be rapidly established in the event of the outbreak of novel influenza, etc. In addition, the national government, etc., shall establish a system that allows medical institutions nationwide and municipal governments or prefectural governments nationwide to enter into a collective agreement to enable vaccination in local government jurisdictions other than the local government jurisdiction in which they reside.

Furthermore, municipal governments or prefectural governments, in cooperation with medical associations and other relevant parties, shall conduct the necessary training to establish a vaccination system, including the personnel, venues, materials, etc., necessary for vaccination in normal times. (MHLW)

1-5-2. Specified vaccination

For those registered business operators and national public officials who may be subject to specified vaccination as part of the response to novel influenza, etc., the national government will serve as the implementing body. For local public officials involved in novel influenza, etc. response, the prefectural or municipal governments

to which they belong will serve as the implementing body. As a general rule, these vaccinations will be carried out collectively, which needs the establishment of a vaccination system from the preparation phase to ensure smooth operations. In particular, for registered business operators operating in sectors crucial to the stability of the national life and the economy, the establishment of a vaccination system will be a requirement for registration.

Therefore, the national government will request registered business operators, relevant ministries and agencies, and prefectural governments to establish a vaccination system that will enable the rapid execution of specified vaccination of its subject, with the principle of collective administration as the standard approach. (MHLW; relevant ministries and agencies)

1-5-3. Resident vaccination

When the national government recognizes that an urgent response is necessary to prevent severe harm to the lives and health of the people from the novel influenza, etc., as well as to ensure that the stability of the national life and the economy is not compromised, it may amend the basic action policy to specify the individuals and the period eligible for vaccination in accordance with Article 6, paragraph (3) of the Immunization Act (Act No. 68 of 1948)¹⁴⁶. The national government, taking into account the impact on the lives and health of the people, as well as the long-term effects on the national life and the economy¹⁴⁷, will establish the basic principles regarding the prioritization of resident vaccination in advance. This approach focuses on protecting the future of the country and minimizing the severity and mortality associated with novel influenza, etc., to the greatest extent possible. Furthermore, preparations will be made in normal times, as outlined in (A) through (C) below, to ensure the rapid implementation of vaccination and other related measures.

- (A) Municipal governments or prefectural governments, with the cooperation of the national government and other relevant entities, shall work to establish a system that enables the rapid vaccination to residents within their respective jurisdictions¹⁴⁸. (MHLW)
- (B) Municipal governments or prefectural governments shall utilize systems to promote consignment contracts with medical institutions nationwide, etc., and take the necessary measures to enable vaccinations to be administered by local

¹⁴⁶ Article 27-2, paragraph (1) of the Act on Special Measures.

¹⁴⁷ Article 27-2, paragraph (2) of the Act on Special Measures.

¹⁴⁸ Article 6, paragraph (3) of the Immunization Act.

governments in jurisdictions other than the ones in which residents reside for ensuring the smooth implementation of vaccinations. (MHLW)

- (C) Municipal governments or prefectural governments, in cooperation with medical personnel, etc., such as members of medical associations and school officials, shall rapidly establish a system that enables swift vaccination. This includes preparing for the deployment of health care workers involved in vaccination, determining vaccination sites, and organizing the dissemination of information regarding vaccination schedules, reservations, etc., and other practical implementation measures. Thus, in order to support this, the national government will provide technical assistance, including the presentation of concrete models for the vaccination system. (MHLW; relevant ministries and agencies)

1-6. Providing and sharing information

The national government shall raise awareness among the people to deepen the understanding of vaccination through information on the significance and structure of the vaccination system, as well as disseminate and share fundamental information about the role, effectiveness, and safety of vaccines for measures against novel influenza, etc., supply and vaccination systems, target populations, vaccination prioritization, etc. This information will be made available through official websites, social media, and other channels. (MHLW)

1-7. Promotion of DX

- (i) The national government will advance the digitalization and standardization of vaccination procedures utilizing the Individual Number Card, which includes issuing vaccination reminders via mobile phones, etc., inputting pre-examination information through mobile phones, etc., and electronically recording vaccinations and processing cost claims from medical institutions. This initiative aims to establish a foundational system that enables swift and accurate management of vaccination records and related processes when novel influenza, etc., emerge, and municipal governments or prefectural governments commence vaccination programs. (MHLW)
- (ii) The national government shall rigorously enforce the management of the private information of the people including the prevention of sensitive data leaks. In this regard, it will promote the interlinked analysis of the vaccination records database, which includes records of suspected adverse reactions, with the

National Database of Health Insurance Claims and Specific Health Checkups of Japan (NDB) and other related databases¹⁴⁹. This integration aims to establish a foundation that can be utilized for research, etc., to enhance the efficacy and safety of vaccines. (MHLW)

- (iii) The national government, in preparation for assuming comprehensive responsibility for vaccine distribution, will establish a system capable of aggregating the desired vaccine delivery volumes from medical institutions and other relevant entities, determining the allocation amounts to municipal governments or prefectural governments, and facilitating the distribution process. Additionally, the national government will develop an information infrastructure to efficiently collect vaccination records, etc., obtained from local governments, as well as adverse reaction reports submitted by medical institutions, etc., and other entities. (MHLW)

1-8. International cooperation

The national government will participate in international frameworks for vaccine research and development, such as CEPI¹⁵⁰. Additionally, the national government will endeavor to gather information on global developments related to vaccines. (MHLW; National Healthcare Policy Secretariat; MOFA)

¹⁴⁹ Based on the Act on Assurance of Medical Care for Elderly People (Act No. 80 of 1982), which has been in force since April 2008, a database has been established to store and structure receipt information, specific health checkup information, and specific health guidance information. This database is used for the creation, implementation, and evaluation of medical cost optimization plans, as well as for surveys and analyses related to these plans.

¹⁵⁰ The Coalition for Epidemic Preparedness Innovations (CEPI) is an international fund, established in January 2017 at the World Economic Forum in Davos, that provides financial support to pharmaceutical companies and research institutions engaged in vaccine development. Contributions to CEPI are made by Japan, the Kingdom of Norway, the Federal Republic of Germany, the United Kingdom, the European Commission, the Commonwealth of Australia, Canada, the Kingdom of Belgium, the Bill & Melinda Gates Foundation, and the Wellcome Trust, among others. CEPI promotes the development of vaccines against infectious diseases with limited demand in normal times, such as Ebola hemorrhagic fever, which poses a global pandemic risk, and also supports the development of vaccines against novel coronavirus.

Section 2: Initial phase

(1) Purpose

By utilizing the research and development infrastructure that has been strengthened since the preparation phase and the vaccination system that has been planned, etc., swift collection of information on emerging pandemics, such as novel influenza, etc., will be undertaken. This will facilitate rapid vaccine research, development, and manufacturing, as well as ensure the timely procurement of the necessary vaccine quantities to enable rapid vaccination efforts.

Based on initiatives undertaken during the preparation phase, industry, academia, and government will swiftly collaborate to develop vaccines. By ensuring the manufacturing of vaccines that meet standards of efficacy and safety, the necessary quantities of vaccines will be secured.

(2) Required response

2-1. Research and development

2-1-1. Early acquisition of pathogen and genomic information

The national government and JIHS will collaborate with research institutions, etc., both domestic and international, to rapidly acquire information on pathogens and genome sequence data, etc. This information will be distributed and provided to relevant research and development institutions, and the national government and JIHS request the early commencement of pandemic vaccine research and development. (MHLW)

2-1-2. Support for research and development

To support the research and development of pandemic vaccines, the national government will consider and implement support measures (A) through (D), as follows:

- (A) Promotion of research and development support through SCARDA (National Healthcare Policy Secretariat; MEXT);
- (B) Prioritized consultation services and expedited approval reviews by the Pharmaceuticals and Medical Devices Agency (PMDA) (MHLW);
- (C) Financial support for large-scale clinical trial costs (MHLW);
- (D) Establishment of consultation desks for development companies (MHLW).

2-1-3. Information sharing and collaboration in research and development

To ensure the rapid execution of research and development for pandemic vaccines in Japan, the national government will share and coordinate current statuses (A) through (E), listed below, among relevant ministries and agencies, research institutions, researchers, business operators, and others involved in vaccine development and manufacturing. (National Healthcare Policy Secretariat; MEXT; MHLW; METI)

- (A) The status of vaccine development under SCARDA concerning the emergent novel influenza, etc.
- (B) Domestic bases capable of conducting research and development for pandemic vaccines.
- (C) Medical institutions in Japan capable of conducting clinical trials for pandemic vaccines.
- (D) Vaccine manufacturing bases established domestically.
- (E) Information on the types, standards, manufacturing volumes, and lead times for products that can be manufactured by businesses with dual-use facilities, as well as the status of materials procurement and personnel arrangements, etc., needed for those businesses to switch to pandemic vaccine manufacturing.

2-1-4. Consideration of emergency approval, etc.

- (i) The national government will rapidly assess the applicability of emergency approval mechanisms and other procedures to ensure that newly developed vaccines can be swiftly utilized for vaccination. Specifically, for the approval of pandemic vaccines related to novel influenza, the national government will expedite the review and approval process as necessary by utilizing data from prototype vaccines¹⁵¹, seasonal influenza vaccines, and pre-pandemic vaccines, and apply the emergency approval system, etc., where appropriate to ensure the process is conducted accurately and within a short timeframe. (MHLW)
- (ii) The national government will establish a framework to verify the efficacy and safety of vaccines that have undergone emergency approval. Additionally, in the approval process for newly developed vaccines, the national government will promptly review matters such as whether the development company has already

¹⁵¹ Mock vaccines. Influenza vaccines that are manufactured and developed in normal times using influenza virus strains that serve as models for vaccine manufacturing. These vaccines are prepared with the assumption that the manufacturing strain may need to be altered, including changes to the subtype, as necessary during novel influenza epidemic.

received approval for vaccines utilizing the same modality and whether the newly developed vaccine uses the same excipients, etc., and other components as those of approved vaccines. In such cases, the national government will leverage existing data related to common aspects to facilitate a swift evaluation. (MHLW)

2-2. Securing of vaccines, etc.

2-2-1. Pre-pandemic vaccines (for novel influenza)

Following the outbreak of novel influenza, the national government will assess the efficacy of pre-pandemic vaccines from its stockpile against the occurred virus. Also, for vaccines showing promising efficacy, the national government will advance preparations for their deployment, including the pre-formulation of these vaccines. Additionally, the national government will request vaccine manufacturers, including designated public institutions, to rapidly formulate the vaccine concentrate. In the event of a novel influenza outbreak, the national government will consider the extent of the spread of infection, etc., and, if necessary, may waive the testing requirements for pre-pandemic vaccines if there is insufficient time for such testing. (MHLW)

2-2-2. Pandemic vaccines

2-2-2-1. Consideration of vaccine development and manufacturing systems

The national government will rapidly collect information regarding the outbreak of novel influenza, etc., and based on the status of institutions, researchers, business operators, etc., involved in vaccine development and manufacturing, will review and establish the necessary vaccine development and manufacturing systems across relevant ministries. (MHLW; National Healthcare Policy Secretariat; METI)

2-2-2-2. Securing vaccine manufacturing facilities

- (i) The national government, taking into account the information collected from vaccine manufacturing business operators, etc., during the preparation phase, will request these businesses to engage in the manufacturing of pandemic vaccines and to secure the necessary raw materials and other resources required for manufacturing the necessary quantities of vaccines. (MHLW; METI)
- (ii) The national government will instruct businesses with dual-use facilities to either utilize these facilities for the development and manufacturing of pandemic vaccines themselves or collaborate with other businesses involved in pandemic vaccine development to leverage these dual-use facilities for such purposes. In

doing so, the national government will promote collaboration among businesses by providing information, etc., related to dual-use facilities to those engaged in pandemic vaccine development and manufacturing, thereby supporting the securement of the necessary manufacturing capacity. (MHLW; METI)

2-2-2-3. Requests for vaccine manufacturing

Upon securing, etc., the necessary vaccine strains, the national government will request vaccine manufacturers, including designated public institutions, to commence the manufacturing of pandemic vaccines¹⁵². In such a case, the national government will also coordinate efforts to ensure that manufacturing capacities are maximized to the fullest extent possible, including the temporary suspension of the manufacturing of seasonal influenza vaccines and other vaccines in favor of pandemic vaccine manufacturing. (MHLW)

2-2-2-4. Securing of vaccines

The national government shall ensure the procurement of the necessary quantities of pandemic vaccines that were developed by businesses that received marketing approval and were produced domestically for the purpose of vaccination. (MHLW)

2-2-2-5. Information gathering and response for securing imported vaccines

While the national government is in principle the domestic procurement of vaccines, it will gather information from foreign vaccine manufacturers regarding the possibility and timing of supply, etc., to Japan in situations where initial domestic supplies may be limited. Additionally, depending on the circumstances, the national government will engage in the necessary actions, such as negotiations and contract agreements, to secure the required quantity of imported vaccines. Furthermore, in coordination with manufacturers, distributors, and other relevant entities, the national government will take the necessary measures to ensure appropriate storage and transportation methods, including the use of freezers, based on the characteristics of the vaccines. (MHLW)

2-2-3. Materials required for vaccine vaccination

2-2-3-1. Survey on the Quantity of the Materials Necessary for Vaccine Administration

The national government will conduct a survey of domestic manufacturing

¹⁵² Article 53-16 of the Infectious Diseases Control Law.

businesses and importers regarding the inventory levels and future availability of materials essential for vaccine administration, such as needles and syringes. (MHLW)

2-2-3-2. Request for increased manufacturing of materials required for vaccine vaccination

In the event where shortages of materials essential for vaccine administration, such as needles and syringes, are anticipated, the national government will request business operators to increase their manufacturing and import volumes¹⁵³. (MHLW)

2-2-3-3. Securing of materials required for vaccine vaccination

The national government will ensure that sufficient quantities of the materials necessary for vaccine vaccination, such as needles and syringes, are secured to meet the needs for vaccination. (MHLW)

2-3. Vaccination system

2-3-1. Preparation of the vaccination system

The national government will take into account the pathogenicity and other characteristics of the novel influenza, etc., that has emerged, the state of the medical care delivery system at the time, and the state of national life and socioeconomic activities, and will clarify its approach to vaccination priorities with a view to implementing specified vaccination or resident vaccination, and will also make the necessary preparations for the vaccination system, etc. (MHLW; CAICM)

2-3-2. Early provision and sharing of information to local governments

The national government shall endeavor to rapidly provide and share information with municipalities and prefectures regarding vaccine supply quantities, the necessary materials, etc., methods for implementing vaccinations, and the required budgetary measures. (MHLW)

2-3-3. Establishment of a vaccination system

Municipal governments or prefectural governments shall establish a vaccination system, including securing vaccination venues and health care workers, etc., involved in the process. Additionally, the national government will assess the necessity of establishing large-scale vaccination centers and implementing workplace

¹⁵³ Article 53-16 of the Infectious Diseases Control Law.

vaccinations, etc., and will take the necessary steps to prepare for these measures, if required. (MHLW; relevant ministries and agencies)

2-3-4. Considerations for securing health care workers involved in vaccination

When deemed necessary for the administration of vaccinations, the national and prefectural governments shall request or instruct medical personnel to provide the required cooperation¹⁵⁴. Additionally, in the event of a shortage of health care workers, etc., involved in vaccination, the national and prefectural governments will consider requesting dentists, radiological technologists, and other qualified professionals to administer vaccinations¹⁵⁵. (MHLW)

¹⁵⁴ Article 31, paragraphs (3) and (4) of the Act on Special Measures.

¹⁵⁵ Article 31-2 and Article 31-3 of the Act on Special Measures.

Section 3: Response phase

(1) Purpose

The smooth distribution of secured vaccines and rapid vaccination based on the established vaccination system will be ensured. Furthermore, appropriate information will be collected regarding any symptoms, etc., resulting from the vaccination, and efforts will be made to rapidly provide relief for any health hazards.

Vaccination will be carried out in accordance with the supply and vaccination systems pre-planned during the preparation phase. Additionally, the system will be reviewed and adjusted as necessary among parties concerned, considering actual supply levels and the availability of health care workers, etc., to maintain a flexible and responsive operational framework.

(2) Required response

3-1. Research and development

- (i) The national government and JIHS will endeavor to gather information on mutations, etc., of virus strain of the novel influenza, etc. (or pathogen in the case of a new infectious disease). (MHLW)
- (ii) In the case where mutations in the epidemic strain are detected, the national government and JIHS, in collaboration with industry, academia, and government sectors, will undertake the research, development, securement, etc., of vaccines targeting the mutated virus strain (or pathogen in the case of a new infectious disease), as outlined in Section 2 (initial phase). (MHLW)
- (iii) The national government and JIHS will conduct surveys on immunity acquisition status, including antibodies, to collect information that will contribute to vaccination planning. (MHLW)
- (iv) The national government and JIHS, in collaboration with related organizations, will assess the efficacy and safety of vaccines against the epidemic strain. (MHLW)

3-2. Supply of vaccines and materials necessary for vaccination

3-2-1. Management of planned supply

The national government shall formulate a plan regarding the supply volume of vaccines and materials necessary for vaccination. Additionally, in cases where the national government assumes responsibility for the centralized supply of vaccines, injection needles, syringes, and other related materials, it will implement distribution management to ensure the smooth supply of these vaccines and materials. (MHLW)

3-2-2. Establishment of a distribution system for vaccines and related materials

The national government shall request prefectural governments to establish a system that ensures the smooth distribution of vaccines and related materials¹⁵⁶. (MHLW)

3-2-3. Early provision and sharing of information on supplied quantities, etc., of vaccine

- (i) The national government shall request vaccine manufacturing business operators and other relevant parties to provide and share information, rapidly and thoroughly, with medical institutions and other stakeholders regarding the future supplied quantities and supply schedules, etc., of vaccines and related materials. (MHLW)
- (ii) In the event of anticipated vaccine, etc., shortages, the national government shall request an acceleration of manufacturing¹⁵⁷. (MHLW)

3-3. Vaccination system

- (i) Municipal governments or prefectural governments shall conduct vaccinations based on the system established during the initial phase. (MHLW)
- (ii) The national government shall rapidly evaluate, etc., the antigenicity of circulating strains in the event of mutations in epidemic strain of the novel influenza, etc., and assess the need for additional vaccinations. If additional vaccinations are deemed necessary, the national government shall also collaborate with municipal governments and prefectural governments, as well as medical institutions, to continuously enhance the vaccination system, ensuring that vaccinations proceed smoothly and without confusion. (MHLW)
- (iii) The national government shall publish vaccination statistics, such as the number of doses administered, on its website, etc., based on records collected through the vaccination system. Additionally, the national government shall expedite the provision and sharing of this information with local governments. (MHLW)

3-3-1. Specified vaccination

3-3-1-1. Implementation of specified vaccination

¹⁵⁶ Article 6 of the Immunization Act.

¹⁵⁷ Article 53-16 of the Infectious Diseases Control Law.

In consideration of information regarding the emerging novel influenza, etc., and the prevailing social circumstances, etc., the national government determine the implementation of specified vaccination if it is deemed urgently necessary to ensure the stability of medical care services, the national life and the economy¹⁵⁸. (CAICM; relevant ministries and agencies)

3-3-1-2. Decision-making on the implementation of specified vaccination

Taking into account information regarding the emerging novel influenza, etc., and other related matters, the efficacy of pre-pandemic vaccines, the speed of vaccine manufacturing and formulation, the volume of vaccine supply, the service levels expected by the people, and the urgency, etc., of resident vaccination, the national government will determine the actual operational guidelines for specified vaccination after consulting with the Promotion Council¹⁵⁹. This includes the selection of registered business operators eligible for specified vaccination, the total number of vaccinations, and the prioritization order. (CAICM; MHLW; relevant ministries and agencies)

3-3-1-3. Administration of specified vaccination to registered business operators and national public officials

The national government, as a basic principle, shall implement specified inoculation on the basis of providing collective vaccinations to individuals eligible for vaccination within registered business operators and to national public officials involved in implementing countermeasures against novel influenza, etc., ensuring that consent is obtained from the individuals. (MHLW; relevant ministries and agencies)

3-3-1-4. Administration of specified vaccination to local public officials

Prefectural and municipal governments, in coordination with the national government, shall implement specified vaccination on the basis of providing collective vaccinations to local public officials involved in implementing countermeasures against novel influenza, etc., ensuring that consent is obtained from the individuals. (MHLW)

¹⁵⁸ Article 28 of the Act on Special Measures.

¹⁵⁹ If the stockpiled pre-pandemic vaccine is effective, it will be utilized. If the effectiveness against the newly emerged novel influenza is low, the pandemic vaccine will be used instead. Additionally, even if the pathogenicity is low and there is no urgent need for emergency specified vaccination, priority vaccination will be conducted for medical personnel.

3-3-2. Resident vaccination

3-3-2-1. Determination of resident vaccination prioritization

The national government shall determine the order of vaccination for residents, taking into account the fundamental principles of prioritization as well as information on the pathogenicity, etc., of the novel influenza, etc., particularly for specific groups at higher risk of severe illness, etc. (MHLW; CAICM)

3-3-2-2. Preparations for vaccination

The national government shall initiate preparations for vaccination¹⁶⁰, taking into account the characteristics of the emerging novel influenza, etc. Additionally, municipal governments or prefectural governments, in collaboration with the national government, shall prepare the necessary vaccination system. (MHLW)

3-3-2-3. Establishment of a vaccination system

The national government shall request municipal governments or prefectural governments to advance the establishment of a concrete vaccination system based on the framework organized and constructed by municipal governments or prefectural governments during the preparation phase and initial phase, ensuring that the people nationwide can receive vaccinations rapidly. (MHLW)

3-3-2-4. Provision and sharing of information on vaccination

Municipal governments or prefectural governments shall establish a system for appointment reservations and initiate vaccination procedures. The national government will urge prefectural and municipal governments to provide and share information related to the vaccination. (MHLW)

3-3-2-5. Expansion of the vaccination system

Municipal governments or prefectural governments, considering the state of the infection, shall examine the possibility of expanding, etc., vaccination sites beyond medical institutions, such as utilizing health centers. Additionally, to ensure that individuals who have difficulty in receiving vaccinations at designated sites, such as residents, etc. of care facilities for elderly people, can be vaccinated, municipal governments or prefectural governments should collaborate with related organizations, including long-term care insurance departments, etc. and medical

¹⁶⁰ Article 6, paragraph (3) of the Immunization Act.

associations, etc., for elderly people in prefectures and municipalities for securing and expanding the vaccination system. (MHLW)

3-3-2-6. Management of vaccination records

The national, prefectural, and municipal governments shall utilize the systems established during the preparation phase to ensure proper management of vaccination records, confirm vaccination history among prefectural governments, prevent vaccination errors, and enable individuals who have received vaccinations to access their records. (MHLW)

3-4. Reports of suspected adverse reactions, etc.

3-4-1. Collection and provision of information related to vaccine safety

The national government shall endeavor to collect information on vaccine safety, including reports of suspected adverse reactions following immunization from medical institutions and other sources. In conjunction with the latest scientific findings, international trends, etc., the national government shall implement appropriate safety measures and ensure the timely provision and sharing of relevant information with the people and other stakeholders. (MHLW)

3-4-2. Conducting research using a vaccination database

The national government shall utilize a digitized information-sharing infrastructure to collect vaccination records, etc., from local governments and reports of suspected adverse reactions from medical institutions, etc. This data will be anonymized and stored in the immunization database. Furthermore, by enabling linkage and analysis with the National Database of Health Insurance Claims and Specific Health Checkups of Japan (NDB) and other databases, the national government shall conduct research on the effectiveness and safety of vaccinations. (MHLW)

3-4-3. Provision of information from the vaccination database

The national government shall provide the information stored in the vaccination database to those who conduct services deemed to be of considerable public interest, in addition to surveys and research conducted by the National Government. (MHLW)

3-4-4. Rapid relief for health hazards

The national government shall ensure that individuals recognized as having

suffered health hazards due to vaccination can receive rapid relief by thoroughly promoting awareness of the relevant systems. In cases where there is a surge in applicants, the national government will strengthen its capacity to expedite the relief process. (MHLW)

3-5. Information provision and sharing

- (i) The national government shall engage in public education to deepen understanding of immunizations and the vaccination system, explaining the significance of vaccination, its procedures, etc., and the framework of the system. Additionally, the national government shall actively conduct risk communication on various aspects related to vaccination, including vaccination schedules, types of vaccines used, their efficacy and safety, potential adverse reactions during vaccination, their frequency, measures to address these reactions, individuals eligible for vaccination ¹⁶¹, vaccination frequency, suspected adverse reaction reports, and health hazards relief system. The national government will respond to information that may be scientifically inaccurate or misleading, ensuring that the people can make correct decisions regarding vaccination. (MHLW)
- (ii) Municipal governments or prefectural governments, in addition to disseminating information related to the vaccinations they administer (such as vaccination schedules, venues, methods for reporting suspected adverse reactions, and procedures for applying for health hazards relief), shall also ensure that the information provided and shared by the national government concerning vaccinations is communicated to and shared with the residents. (MHLW)

¹⁶¹ Consideration must be given to individuals who remain unvaccinated, etc., due to medical reasons or other factors.

Chapter 8: Medical care

Section 1: Preparation phase

(1) Purpose

In the event of the outbreak of novel influenza, etc., a significant increase in the number of patients is anticipated. Given the limitations of regional medical care resources (including medical personnel and hospital beds), it is essential to secure medical care and conventional medical care delivery systems capable of responding to the novel influenza, etc., as well as maintaining regular healthcare services during crisis. This will be achieved by concluding medical care agreements and other necessary arrangements between prefectural governments, etc., and medical institutions, etc., in normal times based on the prevention plan and medical care plan.

Furthermore, prefectural governments are encouraged to prepare and build consensus on the regional medical care delivery system for crisis by conducting training and drills involving relevant parties, particularly medical institutions, etc., and by utilizing the Prefectural Coordination Council, etc. Additionally, they should provide support to ensure that medical institutions, etc., can respond appropriately in crisis.

(2) Required response

1-1. Basic medical care delivery system

- (i) Prefectural governments shall act as command centers for medical care delivery related to the novel influenza, etc. They shall coordinate with public health centers within their jurisdictions to clarify roles during crisis in advance. By fostering functional collaboration among the numerous facilities and stakeholders, including consultation centers, designated medical institutions for infectious diseases, medical institutions which have concluded agreements that secure hospital beds, medical institutions which have concluded agreements that provide clinics for outpatients with fever, medical institutions which have concluded agreements that provide medical care for home care patients, medical institutions which have concluded agreements that offer backup support, and medical institutions which have concluded agreements that dispatch medical personnel as listed in sections 1-1-1 through 1-1-7 below, prefectural governments will ensure the provision of the necessary medical services to residents and others. (MHLW)
- (ii) In order to provide appropriate medical care for infectious diseases according to the condition of patients in crisis, the national government should indicate criteria for assigning patients to medical institutions for hospitalization,

accommodation-based recovery, home-based recovery, etc., according to their symptoms and risk of serious symptoms.

Prefectural governments shall implement measures flexibly according to regional conditions. (MHLW)

- (iii) By preparing the above-mentioned medical care delivery system for crisis in normal times, the national government will ensure the appropriate provision of both infectious disease medical care and conventional medical care during an infectious disease crisis. (MHLW)
- (iv) In times of crisis, prefectural governments shall monitor information, such as the number of secured beds and their operational status, bed occupancy rates, the occupancy rate of beds for severe cases, outpatient congestion levels, and the number of difficult emergency transport cases at medical institutions with which an agreement has been concluded. In order to enable the necessary adjustments for hospitalization, transportation, etc., prefectural governments should clearly designate and prepare a department responsible for command functions in crisis within the region from normal times. (MHLW)

1-1-1. Consultation center

Prefectural governments, etc., shall establish consultation centers rapidly upon recognizing the outbreak of novel influenza, etc., domestically or internationally. The consultation centers will receive inquiries from returnees, etc. from affected countries or regions, as well as from individuals with symptoms, and provide guidance on appropriate healthcare facilities, such as designated medical institutions for infectious diseases. (MHLW)

1-1-2. Designated medical institutions for infectious diseases

In the event of the emergence of a new infectious disease, prior to the public announcement of the outbreak, etc. of novel influenza, etc.¹⁶², designated medical institutions for infectious diseases will take the lead in managing the situation. Subsequently, the designated medical institutions for infectious diseases will continue to play a central role as the core of the regional medical care delivery system for infectious diseases. (MHLW)

¹⁶² This refers to the public announcement of the outbreak, etc. of novel influenza, etc. as stipulated in Article 16, paragraph (2) of the Infectious Diseases Control Law. The same shall apply hereinafter.

1-1-3. Medical institutions which have concluded agreements that secure hospital beds¹⁶³ (designated medical institutions with Class I Agreements¹⁶⁴)

Medical institutions which have concluded agreements that secure hospital beds will secure hospital beds and provide inpatient medical care in response to requests from prefectures based on the agreements concluded with prefectures in normal times. During the initial stage of the epidemic of novel influenza, etc. (assuming approximately three months following the public announcement of the outbreak, etc. of novel influenza, etc.; the same shall apply hereinafter in this chapter), medical institutions which have concluded agreements for measures to ensure medical levels at the initial period of an epidemic¹⁶⁵ will initially handle the situation. Subsequently, other medical institutions which have concluded agreements will gradually become involved in the response. (MHLW)

1-1-4. Medical institutions which have concluded agreements that operate clinics for outpatients with fever¹⁶⁶ (designated medical institutions with Class II Agreements¹⁶⁷)

Medical institutions which have concluded agreements that operate clinics for outpatients with fever, in accordance with agreements concluded with prefectural governments in normal times, shall establish dedicated consultation rooms for patients with fever, etc., (ensuring separation in terms of both time and spatial distance, including using prefabricated buildings, temporary tents, and parking lots) and provide medical care to such patients, in response to requests from the prefectural government, as testing systems are established nationwide. During the initial stage of the epidemic of novel influenza, etc., the medical institutions which have concluded agreements on measures to ensure medical levels at the initial period of

¹⁶³ This refers to medical institutions that have entered into agreements containing measures specified in Article 36-2, paragraph (1), item (i) of the Infectious Diseases Control Law.

¹⁶⁴ This refers to the Designated Medical Institution with Class I Agreement as defined in Article 6, paragraph (16) of the Infectious Diseases Control Law. The same shall apply hereinafter.

¹⁶⁵ This refers to the measures outlined in Article 36-9, paragraph (1) of the Infectious Diseases Control Law, which ensure that, during the initial stage of the epidemic of an infectious disease, medical institutions which have concluded agreements for securing hospital beds or clinics for outpatients with fever are compensated to maintain income levels equivalent to those prior to the outbreak until subsidies or medical service fees are enhanced. (For medical institutions which have concluded agreements that secure hospital beds, the compensation covers income from both inpatient and outpatient services, while for medical institutions which have concluded agreements that operate only clinics for outpatients with fever, it covers income from outpatient services.)

¹⁶⁶ Medical institutions that have entered into agreements containing measures specified in Article 36-2, paragraph (1), item (ii) of the Infectious Diseases Control Law.

¹⁶⁷ This refers to the Designated Medical Institution with Class II Agreement as defined in Article 6, paragraph (17) of the Infectious Diseases Control Law. The same shall apply hereinafter.

an epidemic shall take the lead, followed sequentially by other medical institutions with which an agreement has been concluded. (MHLW)

1-1-5. Medical institutions which have concluded agreements that provide medical care for home care patients, etc.¹⁶⁸ (designated medical institutions with Class II Agreements)

Medical institutions which have concluded agreements that provide medical care for home care patients, etc., based on agreements concluded with prefectural governments in normal times, upon request from the prefectural government, shall provide home visits, telephone or online consultations, dispensing and delivery of medications, etc., medication guidance, and home nursing services to home care patients, etc., those in accommodation-based recovery, and residents in care facilities for elderly people, through hospitals, clinics, pharmacies, and home nursing stations. (MHLW)

1-1-6. Medical institutions which have concluded agreements that offer backup support¹⁶⁹

Medical institutions which have concluded agreements that offer backup support, based on the agreements concluded in normal times with prefectural governments, upon request from the prefectural governments, shall accommodate patients who are not affected by novel influenza, etc., or those who have recovered from novel influenza, etc. (MHLW)

1-1-7. Medical institutions which have concluded agreements that dispatch medical personnel¹⁷⁰

Medical institutions which have concluded agreements that dispatch medical personnel, based on agreements concluded in normal times with prefectural governments, upon request from the prefectural governments, shall deploy medical personnel to other medical institutions, etc., to respond to novel influenza, etc. (MHLW)

1-2. Establishment of a medical care delivery system based on prevention plan and

¹⁶⁸ Medical institutions that have entered into agreements containing measures specified in Article 36-2, paragraph (1), item (iii) of the Infectious Diseases Control Law.

¹⁶⁹ Medical institutions that have entered into agreements containing measures specified in Article 36-2, paragraph (1), item (iv) of the Infectious Diseases Control Law.

¹⁷⁰ Medical institutions that have entered into agreements containing measures specified in Article 36-2, paragraph (1), item (x) of the Infectious Diseases Control Law.

medical care plan

- (i) Prefectural governments shall establish target values for the medical care delivery system based on the prevention plan and medical care plan¹⁷¹ while also clarifying the roles and responsibilities of regional medical institutions, etc. In preparation for the outbreak of novel influenza, etc., prefectural governments shall organize a medical care delivery system. Furthermore, based on the prevention plan and medical care plan, prefectural governments shall enter into agreements with medical institutions regarding the securement of hospital beds, the establishment of clinics for outpatients with fever, the provision of medical care to home care patients, etc., the provision of backup support, or the deployment of medical personnel¹⁷². (MHLW)
- (ii) The national government shall provide the necessary support and guidance, etc., to prefectural governments to ensure the establishment of the medical care delivery system as outlined in the prevention plan and medical care plan. Additionally, through systems, such as the Gathering Medical Information System (G-MIS), the national government shall periodically monitor and publicly disclose the status of the medical care delivery system within prefectural governments. (MHLW)
- (iii) While advancing the conclusion of agreements with private accommodation business operators and securing facilities for accommodation-based recovery¹⁷³ during the response phase, prefectural governments will conduct prior dissemination of operational methods for receiving mild cases, etc., among other necessary procedures. (MHLW)

1-3. Development of human resources through training, drills, etc.

- (i) The national government shall train and register disaster and infectious disease medical care workers¹⁷⁴ (including DMAT, DPAT, and Disaster Support Nurses) and will periodically monitor their status. (MHLW)
- (ii) The national government, in collaboration with prefectural governments and medical institutions, shall promote the training and development of medical

¹⁷¹ Article 10, paragraph (2), item (vi) and paragraph (8) of the Infectious Diseases Control Law.

¹⁷² Article 36-3 of the Infectious Diseases Control Law.

¹⁷³ Article 36-6, paragraph (1), item (i), (b) of the Infectious Diseases Control Law.

¹⁷⁴ medical care human resources dispatched to medical institutions in response to requests from prefectural governments during disasters, outbreak and epidemic of infectious disease and pandemic, based on Article 30-12-2, paragraph (1) of the Medical Care Act.

personnel specialized in the operation of ventilators, ECMO¹⁷⁵, etc., through training programs and exercises, etc., and shall periodically assess the progress of such training initiatives. (MHLW)

- (iii) The national government shall formulate guidelines pertaining to the diagnosis of novel influenza, etc., treatment based on the severity of the symptoms, measures for preventing nosocomial infections, the transfers of patients, etc., and shall ensure that these guidelines are communicated to medical institutions. (MHLW)
- (iv) Prefectural governments shall conclude agreements with medical institutions that dispatch medical personnel, including disaster and infectious disease healthcare workers, etc. Additionally, they shall conduct training and exercises for medical institutions, human resources for medical care (including disaster and infectious disease healthcare workers), fire departments, and cleaning staff at medical institutions, and report the outcomes of such training and exercises to the national government. (MHLW; relevant ministries and agencies)
- (v) JIHS, in collaboration with the national government, shall support human resource development, research and development, etc., including the exchange of personnel, with a particular focus on enhancing the functions, etc., of medical institutions, research institutes, and testing organizations. (MHLW)

1-4. Promotion of DX for outbreaks of novel influenza, etc.

The national government shall promote DX to enhance response capabilities and alleviate the operational burden in the event of the outbreak of novel influenza, etc. This includes the improvement of the Gathering Medical Information System (G-MIS), the utilization of infectious disease surveillance systems, the standardization of electronic medical record information, etc. Additionally, the national government will conduct regular assessments of the operation of systems, such as the Gathering Medical Information System (G-MIS), through training and exercises, etc., with prefectural governments and medical institutions. (MHLW; Digital Agency)

1-5. Enhancement and strengthening of facilities of medical institutions

- (i) The national government and prefectural governments shall provide support for facility and equipment enhancements to designated medical institutions for infectious diseases and medical institutions which have concluded agreements

¹⁷⁵ The abbreviation of “extracorporeal membrane oxygenation.” Treatment is carried out using an extracorporeal circulatory circuit with an artificial lung and pump.

responsible for responding to novel influenza, etc. Additionally, they shall conduct regular assessments of the preparedness status. (MHLW)

- (ii) Medical institutions shall regularly assess their zoning arrangements, as well as the preparedness of individual rooms and negative pressure rooms, even in normal times, to strengthen their response capabilities. (MHLW)

1-6. Organizing the handling of temporary medical facilities, etc.

- (i) The national government shall organize the methods for establishing and operating temporary medical facilities, securing medical personnel, etc., as well as provide guidance to prefectural governments. (MHLW; relevant ministries and agencies)
- (ii) Prefectural governments, taking into consideration the arrangement by the national government, shall organize the methods for establishing, operating, securing medical personnel, etc., for temporary medical facilities in normal times. (MHLW; relevant ministries and agencies)

1-7. Utilization of the Prefectural Coordination Council, etc.

Prefectural governments shall utilize the Prefectural Coordination Council, etc., to respond in the event of the outbreak of novel influenza, etc., and by collaborating with medical institutions, public health centers, fire departments, care facilities for elderly people, and other related entities, in order to ensure that the medical care delivery system outlined in the prevention plan and medical care plan can be effectively maintained during crisis, prefectural governments shall organize and, as needed, update procedures regarding the process from consultation and physician visits to hospitalization and discharge, methods for adjusting hospital admissions, securing medical personnel, transportation means for patients and those who have recovered, and dispatching medical personnel to care facilities for elderly people which also includes ensuring the provision of medical care in the event of responding to seriously ill patients and mass infections at the care facilities for elderly people.

Furthermore, based on these arrangements, prefectural governments shall confirm in advance with related organizations, etc., that they will ensure the medical care delivery system while utilizing the authority for comprehensive coordination¹⁷⁶ under the Infectious Disease Control Law, if necessary. (MHLW; relevant ministries and agencies)

¹⁷⁶ Article 63-3, paragraph (1) of the Infectious Diseases Control Law.

1-8. Ensuring medical care delivery system for patients requiring special considerations

- (i) Prefectural governments shall establish medical institutions that accept patients¹⁷⁷ requiring special consideration, secure hospital beds for such patients in accordance with their specific needs, and ensure coordination, etc., with related organizations, etc. (MHLW)
- (ii) Given that certain regions may face medical crisis for children, pregnant women, and others, prefectural governments shall, in normal times, engage in discussions with public health centers, fire departments, and transport operators, etc., for patients regarding the means of transferring infectious disease patients, etc., and transporting individuals with other medical conditions, etc., across broader areas, should such situations arise. (MHLW; FDMA)

¹⁷⁷ Patients with psychiatric conditions, pregnant women, children, dialysis patients, individuals with disabilities, individuals with dementia, cancer patients, foreign nationals, etc.

Section 2: Initial phase

(1) Purpose

In the event of an outbreak of an infectious disease that may be classified as a novel influenza, etc., measures will be taken to ensure an appropriate medical care delivery system to protect the lives and health of the people from the infectious disease crisis.

To this end, the national government, in collaboration with JIHS, will conduct information collection and analysis related to infectious diseases, even before the public announcement of the outbreak, etc. of novel influenza, etc. The gathered information will be rapidly provided and shared with prefectural governments and medical institutions, etc., and requests will be made to ensure that an appropriate medical care delivery system is established for prefectural governments. Based on the information provided and shared, as well as the requests made, prefectural governments shall coordinate with public health centers, medical institutions, etc., to rapidly establish procedures covering the entire process, from consultation and physician visits to hospitalization and discharge. Furthermore, prefectural governments shall continuously monitor the status of the regional medical care delivery system and provide information and guidelines to medical institutions and residents, etc., within their jurisdiction to ensure that those suspected of infection receive appropriate medical care, such as connecting them to designated medical institutions for infectious diseases through consultation centers.

(2) Required response

2-1. Sharing, etc., of knowledge regarding infectious diseases that may be classified as novel influenza, etc.

- (i) The national government, in collaboration with JIHS, shall conduct information collection and analysis related to infectious diseases that may be classified as novel influenza, etc. This includes clinical information obtained through responses at designated medical institutions for infectious diseases, data acquired from testing conducted by public health institutes, etc., information gathered by prefectural governments during practical operations, and findings obtained by research institutions and academic societies, etc. The national government will continuously update and revise details on information on diagnosis and treatment, such as the outbreak status of novel influenza, etc., the characteristics of the infectious diseases, and the characteristics of the pathogens (e.g., pathogenicity, infectivity, transmissibility, drug susceptibility, etc.). This information will be rapidly provided and shared with prefectural prefectures,

medical institutions, and the people. (CAICM; MHLW)

- (ii) Prefectural governments shall disseminate the information provided by the national government and JIHS to medical institutions, public health centers, fire departments, care facilities for elderly people, and other relevant entities. (MHLW; CAICM)

2-2. Ensuring the medical care delivery system

- (i) Prior to the public announcement of the outbreak, etc. of novel influenza, etc., the national government shall request prefectural governments to ensure that designated medical institutions for infectious diseases are prepared to rapidly provide appropriate medical care to patients. (MHLW)
- (ii) Prefectural government shall ensure a system for accepting patients with infectious diseases at designated medical institutions for infectious diseases, as well as promote the establishment of a system for hospitalization coordination in cooperation with public health centers, medical institutions, fire departments, etc., and promptly establish the flow from counseling and consultation to admission and discharge, which was organized by the Prefectural Coordination Council, etc., during the preparation phase. In addition, requests shall be made to medical institutions to ensure that the status, such as the number of secured beds, occupancy status, the utilization rate of beds, utilization rate of beds for severely ill patients, and outpatient shortage status, are entered into the Gathering Medical Information System (G-MIS). (MHLW)
- (iii) Designated medical institutions for infectious diseases shall ensure the readiness of their patient admission systems and provide appropriate medical care to patients. Furthermore, these institutions shall, upon request from prefectural governments, input the necessary information into the Gathering Medical Information System (G-MIS) ¹⁷⁸. (MHLW)
- (iv) Prefectural governments shall request medical institutions to rapidly notify public health centers, based on the case definition, if they determine that a patient may be infected with a disease that could be classified as novel influenza, etc. (MHLW)
- (v) Prefectural governments, in cooperation with municipalities, shall inform residents, etc. and others of the regional medical care delivery system and the appropriate procedures for seeking medical care, etc., at prefectural medical

¹⁷⁸ Article 36-5 of the Infectious Diseases Control Law.

institutions. (MHLW)

- (vi) The national government shall request that prefectural governments, etc., relevant entities rapidly establish a testing system at organizations that have concluded the agreement on testing and other measures under the prevention plan, ensuring the timely activation of clinics for outpatients with fever, which is a precondition for the prompt operation of fever outpatient clinics during the response phase. (MHLW)
- (vii) In order to ensure that the medical care delivery systems by contracted medical institutions can be secured without delay in the initial stage of the epidemic during the response phase, the national government requests prefectural governments to make appropriate preparations at the medical institutions which have concluded agreements on measures to ensure medical levels at the initial period of an epidemic. (MHLW)

2-3. Establishment of consultation centers

- (i) The national government shall rapidly request that prefectural governments, etc., establish consultation centers to receive inquiries from returnees, etc. from affected countries or regions, as well as from symptomatic individuals, etc., and to facilitate their access to designated medical institutions for infectious diseases, as necessary. (MHLW)
- (ii) The national government shall inform the people including symptomatic individuals who meet the case definition, of the need to consult with a consultation center. Additionally, the national government shall request that prefectural governments, etc., similarly inform their residents, etc. (MHLW)
- (iii) Prefectural governments, etc., shall establish consultation centers to address inquiries from symptomatic individuals, etc., inform the residents, etc. accordingly, and, when necessary, facilitate the referral of individuals suspected of infection to designated medical institutions for infectious diseases. (MHLW)
- (iv) Prefectural governments shall request that medical institutions, other than designated medical institutions for infectious diseases, ensure that symptomatic individuals, etc., who meet the case definition visit designated medical institutions for infectious diseases through consultation centers when such inquiries, etc., are received. (MHLW)

Section 3: Response phase

(1) Purpose

In the event of the outbreak of novel influenza, etc., there is a risk of rapid and widespread pandemic across the nation, which could significantly impact the lives and health of the people. It is imperative to provide the necessary medical care to patients affected by the novel influenza, etc., as well as to other patients by securing appropriate medical care delivery systems in order to minimize health hazards and for the people to live with peace of mind.

To this end, the national government, in collaboration with JIHS, will continue after the initial phase to conduct information collection and analysis related to novel influenza, etc., including information obtained from designated medical institutions for infectious diseases, public health institutes, etc., prefectural governments, research institutions, academic organizations, and other organizations. This information will be rapidly provided and shared with prefectural governments, medical institutions, and other relevant entities. Furthermore, based on the provided information, prefectural governments will coordinate with medical institutions, public health centers, and other related organizations to ensure that appropriate medical care is provided to patients with novel influenza, etc., as well as to other patients while adapting to the changing regional circumstances influenced by pathogenicity, infectivity, transmissibility, and other factors.

Additionally, the national and prefectural governments will also respond swiftly and flexibly in situations where there is a possibility of the spread of infection exceeding the system to be established during the preparation period, such as when some medical institutions or medical care in some areas are in short supply.

(2) Required response

3-1. Fundamental response to novel influenza, etc.

- (i) The national government, in collaboration with JIHS, will continue after the initial phase to conduct information collection and analysis regarding novel influenza, etc., including information obtained by designated medical institutions for infectious diseases, public health institutes, etc., prefectural governments, research institutes, academic organizations and other organizations. The national government will provide and share information on the outbreak of mutations of novel influenza, etc., according to the pathogenicity, infectivity, transmissibility, etc., the characteristics of the infectious diseases, the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug

susceptibility, etc.), and information on diagnosis and treatment, etc., to prefectural governments, medical institutions, the people while updating and reviewing the information, as necessary. (CAICM; MHLW)

- (ii) The national government, considering clinical information and bed occupancy rates, etc., provided by JIHS, designated medical institutions for infectious diseases, and prefectural governments, etc., will conduct periodic reviews of case definitions, admission and discharge criteria, and criteria for close contact with patients, etc. In doing so, the criteria for close contact with patients regarding health care workers will be reviewed more flexibly, taking into account the need to maintain the medical care delivery system while also ensuring the necessary measures to prevent the spread of infection. (MHLW)
- (iii) Prefectural governments will disseminate the information provided such as by the national government and JIHS to medical institutions, public health centers, fire departments, and care facilities for elderly people. At the same time, with reference to the criteria established by the national government, based on factors such as the regional infection circumstance and medical care delivery situation, they will gradually enhance the medical care delivery system and ensure the appropriate allocation of patients for hospitalization at medical institutions, for accommodation-based recovery or for home-based recovery, etc. In order to facilitate smooth coordination of hospital admissions among cities with public health centers, etc., prefectural governments will exercise the authority for comprehensive coordination and directing authority¹⁷⁹, as necessary. (MHLW; CAICM)
- (iv) Prefectural governments will request that designated medical institutions for infectious diseases provide the necessary medical care to ensure that the medical care delivery system, etc., as organized during the preparation phase through Prefectural Coordination Council, etc., is properly maintained. Additionally, prefectural governments will request that contracted medical institutions continue to provide the required medical care in accordance with agreements concluded during the preparation phase¹⁸⁰. (MHLW)
- (v) Designated medical institutions for infectious diseases will continue to play a central role as the core of the regional medical care delivery system for infectious diseases following the initial phase. Medical institutions which have concluded

¹⁷⁹ Article 63-4 of the Infectious Diseases Control Law.

¹⁸⁰ Article 36-3 of the Infectious Diseases Control Law.

agreements shall, in accordance with the agreements¹⁸¹ with prefectural governments during the preparation phase, respond to requests from prefectural governments by securing hospital beds, operating clinics for outpatients with fever, providing medical care to home care patients, etc., offering back-up support, or dispatching medical personnel. (MHLW)

- (vi) The national and prefectural governments shall implement measures to compensate¹⁸² medical institutions which have concluded agreements responsible for securing hospital beds and establishing clinics for outpatients with fever in the initial stage of the epidemic, ensuring they receive income at the same level as before the epidemic until special reimbursement measures or financial support, such as subsidies, are established. Furthermore, the national and prefectural governments shall support medical institutions, etc., providing medical care to patients, taking into consideration matters such as the infection status and the characteristics of the infectious disease. (MHLW)
- (vii) Prefectural governments, continuing from the initial phase, shall request medical institutions to accurately input data into the Gathering Medical Information System (G-MIS) regarding the number of secured beds, operational status, bed occupancy rates, utilization rates of beds for critically ill patients, the status of outpatient capacity, etc. While monitoring this information, etc., prefectural governments will coordinate hospital admissions accordingly. (MHLW)
- (viii) Medical institutions shall, in response to requests from prefectural governments, input data into the Gathering Medical Information System (G-MIS)¹⁸³. (MHLW)
- (ix) Medical institutions shall input data regarding the stockpile and allocation status of infectious disease control supplies, etc. (such as personal protective equipment) into the Gathering Medical Information System (G-MIS). In cases where a shortage of such infectious disease control supplies, etc. is anticipated, the medical institutions shall report this to the prefectural government through the Gathering Medical Information System (G-MIS). Prefectural governments, in cooperation with the national government, etc., shall establish a system to supply infectious disease control supplies, etc. in response to requests from

¹⁸¹ Article 36-3 of the Infectious Diseases Control Law.

¹⁸² For contracted medical institutions that secure hospital beds, the compensation covers income from both inpatient and outpatient services, while for medical institutions which have concluded agreements operating only clinics for outpatients with fever, it covers income from outpatient services.

¹⁸³ Article 36-5 of the Infectious Diseases Control Law.

medical institutions. (MHLW)

- (x) Prefectural governments, etc., in collaboration with private transport operators, etc., shall secure means of transportation for patients and individuals who have recovered from symptoms to provide transportation between their homes and clinics for outpatients with fever, inpatient medical institutions, or accommodation-based recovery facilities, etc. Additionally, prefectural governments shall inform residents, etc., about the appropriate use of emergency vehicles, such as urging them to refrain from using ambulances in cases of minor symptoms. (MHLW; FDMA)
- (xi) Prefectural governments shall request that medical institutions, other than fever outpatient clinics, guide patients to the appropriate clinics for outpatients with fever or consultation center based on the patient's inquiry. (MHLW)
- (xii) Prefectural governments shall establish systems for securing designated medical institutions and hospital beds for patients requiring special consideration, as well as ensure coordination, etc., with related organizations, etc., based on the specific needs of these patients. (MHLW)
- (xiii) Prefectural governments, in cooperation with municipal governments, shall inform residents of the regional medical care delivery system, including the procedures for seeking medical care at medical institutions, such as consultation centers and clinics for outpatients with fever. (MHLW)
- (xiv) The national and prefectural governments shall request medical institutions to implement the necessary measures, such as introducing a rotation system, ensuring leaves of absence, and providing mental health support, to address the potential effects on the mind and body on health care workers involved in the response to novel influenza, etc. (MHLW)

3-2. Establishment of medical care delivery system according to stage

3-2-1. Initial stage of the epidemic

3-2-1-1. Ensuring medical care delivery systems based on agreements

- (i) The national government shall request prefectural governments, based on regional infection trends, to secure a system that ensures the provision of appropriate inpatient and outpatient medical care, not only at designated medical institutions for infectious diseases but also at medical institutions which have concluded agreements on measures to ensure medical levels at the initial period of an epidemic. Prefectural governments shall take the necessary measures in response to this request. (MHLW)

- (ii) Designated medical institutions for infectious diseases shall continue to play a central role as the core of regional medical care delivery systems for infectious disease, as they did during the initial phase. Medical institutions which have concluded agreements on measures to ensure medical care in the initial stages of the epidemic shall, in accordance with these agreements concluded with prefectural governments during the preparation phase¹⁸⁴, secure hospital beds or establish clinics for outpatients with fever upon request from prefectural governments. (MHLW)
- (iii) Prefectural governments shall request medical institutions to rapidly report to the public health center when a patient is determined to be a confirmed or suspected case of novel influenza, etc., based on the case definition (MHLW)
- (iv) Medical institutions shall rapidly report to the public health center when a patient is determined to be a confirmed or suspected case of novel influenza, etc., based on the case definition.¹⁸⁵ (MHLW)
- (v) In the event that there are patients with novel influenza, etc., prefectural governments, etc., shall rapidly coordinate hospital admissions. In accordance with the Infectious Diseases Control Law, prefectural governments shall transfer the patients to designated medical institutions for infectious diseases, or to medical institutions which have concluded agreements on measures to ensure medical levels at the initial period of an epidemic for securing hospital beds. The prioritization of admissions and the selection of receiving medical institutions, etc., shall be managed in close coordination with medical institutions, etc., based on the role-sharing established during the preparation phase. Additionally, prefectural governments may exercise the authority for comprehensive coordination and directive authority, as necessary, to ensure smooth admission coordination with cities that have established public health centers, etc. (MHLW)
- (vi) Prefectural governments, taking into account the regional spread of infection and the strain on the medical care delivery system, shall ensure that they are prepared to swiftly establish temporary medical facilities, if necessary, as outlined in 3-4 (ii). To this end, prefectural governments shall review the methods such as for establishing, operating, securing medical personnel for these temporary medical facilities, as organized during the preparation phase, and undertake the necessary arrangements. (MHLW)

3-2-1-2. Strengthening of consultation centers

¹⁸⁴ Article 36-3 of the Infectious Diseases Control Law.

¹⁸⁵ Article 12, paragraph (1) of the Infectious Diseases Control Law.

- (i) The national government shall request that prefectural governments, etc., strengthen consultation centers to receive consultation from returnees, etc., contacts, and symptomatic individuals (including guidance on clinics for outpatients with fever where they can be consulted). (MHLW)
- (ii) The national government shall inform the people that symptomatic individuals who meet the case definition should receive clinics for outpatients with fever through consultation centers. Additionally, the national government shall request that prefectural governments, etc., ensure that this information is communicated to residents, etc. (MHLW)
- (iii) Prefectural governments, etc., shall strengthen consultation centers to effectively respond to inquiries from symptomatic individuals, etc., and ensure that residents, etc. are well-informed. Prefectural governments shall also rapidly facilitate the referral of individuals suspected of being infected to clinics for outpatients with fever for appropriate medical attention. (MHLW)

3-2-2. After the initial stage of the epidemic

3-2-2-1. Ensuring medical care delivery system based on agreements

- (i) The national government shall request prefectural governments to ensure that, in consideration of the regional infection status, medical institutions are prepared to respond as necessary, including not only designated medical institutions for infectious diseases and medical institutions which have concluded agreements on measures to ensure medical levels at the initial period of an epidemic but also other medical institutions with which an agreement has been concluded. (MHLW)
- (ii) Prefectural governments, taking into account the regional infection status, shall request medical institutions which have concluded agreements to secure hospital beds, provide clinics for outpatients with fever and medical care for home care patients, etc., offer back-up support, or dispatch medical personnel as needed. In this case, as for securing hospital beds, the initial response shall start primarily by involving public medical institutions, etc.,¹⁸⁶ among the medical institutions with which an agreement has been concluded. Additionally, within approximately three months, the number of medical institutions which have concluded agreements will be expanded, etc., as needed and promptly to enhance the medical care delivery system progressively in accordance with regional

¹⁸⁶ Including medical institutions, other than public medical institutions, that are capable of responding to novel influenza, etc.

circumstances. (MHLW)

- (iii) The medical institutions which have concluded agreements during the preparation phase shall, based on those agreements with prefectural governments¹⁸⁷, secure hospital beds, establish clinics for outpatients with fever, provide medical care to home care patients, etc., offer logistical support, or dispatch medical personnel in response to requests from prefectural governments. (MHLW)
- (iv) In the event that there are patients with novel influenza, etc., prefectural governments shall rapidly coordinate hospital admissions and, in accordance with the Infectious Diseases Control Law, transfer the patient to designated medical institutions for infectious diseases or medical institutions which have concluded agreements securing hospital beds. The prioritization of admissions and the selection of receiving medical institutions, etc., shall be managed for response through appropriate coordination with the relevant medical institutions, etc., based on the role-sharing arrangements established during the preparation phase. Additionally, prefectural governments shall exercise the authority for comprehensive coordination and directive authority as necessary to ensure smooth admission coordination, including with cities with public health centers. (MHLW)
- (v) When the hospital bed occupancy rate is high, prefectural governments shall prioritize the hospitalization of patients who are likely to have severe symptoms, such as those with underlying diseases. Concurrently, prefectural governments shall strengthen the systems for home-based recovery, accommodation-based recovery, or care facilities for elderly people. Additionally, efforts will be made to transfer those who have recovered from their symptoms to medical institutions which have concluded agreements providing secondary support. In this context, the national government shall develop and provide indicators for identifying patients who are likely to have severe symptoms. (MHLW)
- (vi) Prefectural governments, as needed, shall request medical institutions which have concluded agreements to deploy medical personnel, including disaster and infectious disease healthcare workers, to medical institutions, etc. (MHLW)
- (vii) Prefectural governments, etc., shall ensure the establishment of a system for monitoring the status of symptoms in accordance with the characteristics of the infection during home-based recovery and accommodation-based recovery, etc.

¹⁸⁷ Article 36-3 of the Infectious Diseases Control Law.

This includes the provision of pulse oximeters for measuring the percutaneous oxygen saturation. (MHLW)

3-2-2-2. Strengthening of consultation centers

The initiatives described in 3-2-1-2 above shall continue. (MHLW)

3-2-2-3. Measures based on the characteristics of pathogens

- (i) In the event of the outbreak of novel influenza, etc., which poses a higher risk of infection and severe outcomes for specific groups, such as children, pregnant women, elderly people, and individuals with certain pre-existing conditions, the national government shall request prefectural governments to ensure a prioritized medical care delivery system tailored to these high-risk groups. (MHLW)
- (ii) The national government shall request prefectural governments to increase the availability of beds for severe cases at designated medical institutions for infectious diseases and medical institutions which have concluded agreements, particularly in scenarios where the pathogenicity exhibits high virulence, leading to a significant number of severe patients. Conversely, in cases where it shows high infectivity and transmissibility, the national government shall urge prefectural governments to expand the medical care delivery system as needed, including ensuring that all medical institutions which have concluded agreements are prepared to respond. Additionally, the national government will revise hospitalization criteria to prioritize hospitalization care for patients at high risk of severe outcomes. (MHLW)

3-2-3. Period of enhanced response capabilities through vaccines, therapeutics, etc.

- (i) The national government shall request prefectural governments to respond flexibly and swiftly, adjusting to regional circumstances, such as by reducing the number of medical institutions which have concluded agreements that take measures based on agreements, as the capacity to respond is enhanced through vaccines and treatments. Furthermore, in the event of a resurgence of infections due to the emergence of mutant strains, etc., the national government shall urge prefectural governments to increase the number of medical institutions which have concluded agreements, etc., taking measures under the agreements, adapting flexibly and swiftly according to the regional situation. (MHLW)
- (ii) The national government shall request prefectural governments to shift from a system where symptomatic individuals are directed to clinics for outpatients

with fever through consultation centers, to a system where symptomatic individuals can directly access clinics for outpatients with fever. In addition, the government shall inform the people of this. Prefectural governments, in response to this request, shall take the necessary measures and, in cooperation with municipalities, ensure that residents, etc., are adequately informed. (MHLW)

3-2-4. Stage for transitioning to basic infectious disease control measures not based on the Act on Special Measures

- (i) If there is a transition to basic infectious disease control measures not based on the Act on Special Measures, due to the progress of immunity acquisition through vaccination, etc., a decrease in pathogenicity, infectivity, transmissibility, etc., resulting from pathogen mutations, and the surpassing of a certain level of capacity to respond to novel influenza, etc., the national government shall present a policy shift toward basic infectious disease control measures to prefectural governments, etc. (CAICM; MHLW)
- (ii) Prefectural governments, in collaboration with the national government, shall gradually shift to the conventional medical care delivery system that was in place prior to the outbreak of novel influenza, etc. (MHLW; CAICM)

3-3. Response policy for situations significantly deviating from preliminary assumptions in the prevention plan and medical care plan

In the event of the outbreak of novel influenza, etc., if matters such as the characteristics of the novel influenza, etc., the acquisition of the latest knowledge regarding its response methods, or the status of securing infectious disease control supplies, etc. differ significantly from the preliminary assumptions established during the preparation phase of the medical care delivery system, the national government, in collaboration with JIHS and others, shall flexibly and swiftly assess the need to amend the content of the agreements concluded during the preparation phase or respond according to the situation, while considering a balance with conventional medical care. The national government shall then present a response policy to prefectural governments, etc. (MHLW)

3-4. Response policy for potential scenarios exceeding medical care delivery systems based on the prevention plan and medical care plan

In cases where the national and prefectural governments assess that the measures outlined in Sections 3-1 and 3-2 may prove to be insufficient, they shall undertake

the measures detailed in items (i) through (iii) below, as necessary.

- (i) In cases where the system established during the preparation phase is at risk of being overwhelmed due to strains on certain medical institutions or regions, the national and prefectural governments shall coordinate a flexible and swift deployment of medical personnel across broader areas and a transfer of patients to other facilities or regions, etc. The national and prefectural governments shall exercise the authority for comprehensive coordination¹⁸⁸ and directive authority¹⁸⁹. (MHLW)
- (ii) Prefectural governments, referencing data from the Gathering Medical Information System (G-MIS), shall establish temporary medical facilities and provide medical care as necessary, taking into account the regional spread of infection and strains on regional medical care delivery systems. (MHLW)
- (iii) The national and prefectural governments, while implementing the measures outlined in (i) and (ii) above, shall consider undertaking actions (A) through (C), listed below, if there is a risk of severe impact on the lives and health of the people. (CAICM; MHLW)
 - (A) Implement the measures outlined in Chapter 6, Section 3 (response phase during the “prevention of spread”), 3-1-2 and 3-1-3.
 - (B) Until appropriate medical care can be provided, the policy should be indicated regarding the provision of medical care in accordance with the degree of severity, urgency, etc., including conventional medical care.
 - (C) In cases where it is difficult to respond and there is an urgent need, request, etc.,¹⁹⁰ medical personnel to provide medical care.

¹⁸⁸ Article 44-5, paragraph (1) and Article 63-3 of the Infectious Diseases Control Law.

¹⁸⁹ Article 63-2 and Article 63-4 of the Infectious Diseases Control Law.

¹⁹⁰ Article 31 of the Act on Special Measures.

Chapter 9: Therapeutics

Section 1: Preparation phase

(1) Purpose

In the event of an outbreak of novel influenza, etc., ensuring the provision of medical care is essential to minimize health hazards and the impact on socioeconomic activities. It is crucial to swiftly secure effective therapeutic agents and establish therapeutic methods for nationwide dissemination. In normal times, it is necessary to build the required infrastructure, periodically verify the effectiveness of the therapeutic agent's distribution, etc., system through training, and continuously make the necessary revisions.

The national government shall undertake preparations to ensure the rapid availability of therapeutic agents and therapeutic methods in the event of an outbreak of novel influenza, etc. Regarding therapeutic agents, the national government aims to ensure that effective and safe therapeutic agents are readily accessible during such outbreaks. Furthermore, the government will designate priority infectious diseases for which MCM will be developed, thereby promoting research and development in research institutions such as universities, pharmaceutical companies, etc. Additionally, the national government will advance and implement measures to support the establishment of a series of ecosystems to be utilized.

(2) Required response

1-1. Designation of priority infectious diseases and development of information collection and analysis systems

- (i) The national government, in collaboration with JIHS, shall conduct analyses and evaluations from a crisis management perspective to identify infectious diseases that require the availability of drugs for infectious disease crisis within the country. Based on these assessments, such diseases shall be designated as priority infectious diseases. (MHLW)
- (ii) The national government and JIHS shall collect and analyze information on the research and development trends, stockpile status, and clinical information, etc., related to therapeutics for priority infectious diseases domestically and internationally. The analyzed data shall be utilized to advance the research and development of therapeutics, as well as to consider and improve plans for the allocation of therapeutic agents, thereby enhancing the nation's capacity to respond to infectious diseases crises. (MHLW; National Healthcare Policy Secretariat; MOFA; MEXT)

- (iii) The national government and JIHS shall establish a system for information sharing during crisis so that the obtained findings can be rapidly provided within the government, prefectural governments, medical institutions, AMED, etc. (MHLW; National Healthcare Policy Secretariat; MEXT)

1-2. Promotion of research and development of therapeutics

1-2-1. Organizing research and development directions

- (i) The national government and JIHS, in collaboration with AMED, shall promote and support the research and development of MCM and therapeutic methods, including the utilization of emerging technologies. (MHLW; National Healthcare Policy Secretariat)
- (ii) The national government shall review the direction of research and development on priority infectious diseases including unknown infectious diseases, by updating the concept and list of target priority infectious diseases, as necessary, among other approaches. The national government shall indicate policies and goals of research and development, taking into account the marketability and significance of therapeutic agents being developed, for example, by setting goals to be achieved according to the stage of development and a policy to be followed for each goal to be achieved. (MHLW; National Healthcare Policy Secretariat)

1-2-2. Establishment of research and development systems

- (i) The national government shall establish a system capable of rapidly evaluating the efficacy, etc., of existing therapeutic agents in the event of an outbreak of novel influenza, etc. (MHLW; National Healthcare Policy Secretariat)
- (ii) The national government, with JIHS at the center, shall establish a system for managing and consolidating clinical information, specimens, and pathogens in collaboration with designated medical institutions for infectious diseases specified by prefectural governments. (MHLW; National Healthcare Policy Secretariat)
- (iii) The national government and JIHS, in collaboration with AMED, shall establish a system in which JIHS functions as a hub for infectious disease research, from basic research to clinical research, such as clinical trials, in normal times in order to facilitate and support the rapid development and research of therapeutics from the initial stage, in the event of the outbreak of

novel influenza, etc. Support will be provided to establish a system that enables medical institutions treating infectious diseases to conduct joint research to generate scientific knowledge on infectious diseases and develop therapeutic agents, etc. Furthermore, efforts will be made to strengthen collaboration and networks with prefectural governments, domestic and international medical institutions, and research organizations, etc. Prefectural governments will actively cooperate with implementing clinical research on the research and development of therapeutics led by the national government through medical institutions, etc., that treat infectious diseases in their jurisdiction. (MHLW; National Healthcare Policy Secretariat)

1-2-3. Enhancement of funding functions to promote research and development

- (i) The national government, in collaboration with AMED and JIHS, will establish a foundation for the research and development of therapeutics regarding priority infectious diseases, as well as work on long-term and strategic support for research and development, including the establishment of systems for manufacturing drugs of clinical trials, etc., and the training and securing of human resources in normal times. (MHLW; National Healthcare Policy Secretariat)
- (ii) To promote the research and development of therapeutics that lack market demand in normal times, it is critically important to establish a mechanism that enhances the predictability of research and development so that pharmaceutical companies can undertake such development.

Additionally, in the case of conducting clinical trials for such therapeutics, it is difficult to estimate the development costs required for each fiscal year because the timing and scale, etc., of outbreaks of infectious diseases cannot be predicted. Therefore, the national government will establish a series of ecosystems for public health preparedness by ensuring market viability post-commercialization and promoting research and development in normal times and will secure both push type and pull type research and development supports for pharmaceutical companies, etc., as well as secure pharmaceuticals for public health measures. (MHLW; National Healthcare Policy Secretariat)

- (iii) The national government shall, taking into account international trends for pull type research and development support, comprehensively consider the necessity of public health procurement and stockpiling within the country, as well as needs abroad, etc., to proceed to consider the appropriate approach for

pull type research and development support for reaching conclusions. (MHLW)

- (iv) The national government and JIHS, in collaboration with related organizations, will examine and implement measures to ensure a stable securement of laboratory animals that are necessary for conducting research and development, such as primates. Additionally, the national government will examine and implement measures to establish and secure facilities and personnel capable of conducting non-clinical trials dealing with laboratory animals, including large primates. (MHLW; relevant ministries and agencies)

1-2-4. Development and promotion of research and development companies

- (i) The national government and JIHS, in collaboration with AMED and research institutions, etc., will undertake initiatives such as to foster and promote companies engaged in the research and development of therapeutics, including research test reagents, to support the development of domestically produced test reagents and promotion of domestic manufacturing, and to foster pharmaceutical ventures. (MHLW; National Healthcare Policy Secretariat; METI)
- (ii) JIHS will secure research funding with strategic foresight and provide the government with advice that will contribute to the implementation of research. (MHLW)
- (iii) Since there is no market demand for therapeutics in the applied development stage in normal times, the national government shall endeavor to ensure the predictability of business by examining and implementing support measures to realize market launch, and to ensure marketability after the market launch. (MHLW; National Healthcare Policy Secretariat)

1-2-5. Human resource development for basic research, clinical research, etc.

The national government and JIHS, in cooperation with universities and other research institutions, will conduct human resource development in the areas from basic research on infectious diseases to clinical research, such as clinical trials, etc., in order to ensure human resources in the research and development of therapeutics, and the national and prefectural governments, etc., will support universities and other research institutions.

Moreover, the government and prefectural governments, etc., by actively utilizing the trained human resources through support for their career development, shall enhance the implementation system for clinical research at medical institutions that promote research, clinical research core hospitals that participate in collaborative

networks with research institutions, designated medical institutions for infectious diseases, and other institutions. (MHLW; MEXT)

1-2-6. Promotion of DX

The national government and JIHS shall promote DX, including automation and labor-saving for information entry tasks, the centralization of information, and database linkage so that clinical information, genomic information, specimens, etc., can be shared promptly and contribute to the research and development of therapeutic agents and the establishment of therapeutic methods. Particularly, in the collection of clinical information for the purpose of establishing a foundation for the research and development of therapeutic agents, etc., a system should be established to enable more rapid response by DX, for example, through the extraction of information from electronic medical records. (MHLW)

1-3. Establishment of necessary pharmaceutical regulations

The national government, in collaboration with PMDA, shall establish the necessary pharmaceutical regulations, even during emergencies when there is only limited data available, to allow flexible regulatory reviews in light of the urgency of the situation based on the characteristics of MCM, which are not used in normal times when there are no patients. At the same time, the national government shall promote the international harmonization of pharmaceutical regulations to facilitate the early distribution of therapeutic agents in the event of the outbreak of novel influenza, etc. (MHLW)

1-4. Development for utilization of therapeutics

1-4-1. Establishment of a system for information provision and sharing with medical institutions

- (i) The government and JIHS shall establish a system to promptly provide and share information, etc., that contributes to the diagnosis and treatment of novel influenza, etc., to prefectures, medical institutions, health care workers, the people, etc. (MHLW)
- (ii) Prefectural governments shall, in the event of an outbreak of novel influenza or similar infectious diseases, establish a framework in collaboration with designated medical institutions for infectious diseases and medical institutions which have concluded agreements, etc., to ensure that therapeutics and treatment methods can be utilized, as indicated by the national government and JIHS.

Additionally, prefectural governments shall regularly verify the implementation system within these medical institutions. (MHLW)

1-4-2. Preparations for supply of therapeutics, etc., during crisis

- (i) The national government shall establish and organize the distribution methods, prioritization of allocation by type of medical institution, patient groups eligible for treatment, etc., and the framework for the smooth distribution of therapeutic agents to medical institutions and pharmacies in the event of supply limitations. Furthermore, the government shall conduct preparations and trainings, etc., in anticipation of crisis. (MHLW)
- (ii) The national government shall identify the domestic manufacturing bases for therapeutic agents, etc., and undertake the necessary measures to strengthen them. (MHLW; METI)
- (iii) The national government shall coordinate international frameworks for collaboration and cooperation to secure therapeutic agents. (MHLW; MOFA)

1-4-3. Establishment of stockpiling and distribution systems of MCM

- (i) The national government shall stockpile the necessary quantities of drugs for infectious disease crisis by the national which are deemed essential, both domestic and international, from the perspective of infectious disease crisis management. In determining the stockpiling quantities and timelines, the government will comprehensively consider factors, such as the development status of the necessary pharmaceuticals and the occurrence of infectious diseases. (MHLW)
- (ii) The national and prefectural governments shall plan and maintain stable stockpiles of anti-influenza virus drugs for influenza. This will be done with consideration of the latest stockpiling practices, medical knowledge, etc., from other countries, aiming to secure sufficient quantities necessary for patient treatment and other medical responses. In this process, current stockpiles, distribution conditions, and the management of severe cases, etc., will also be taken into account. (MHLW)
- (iii) The national government will collect information including the outbreak of drug-resistant viruses, and consider about new anti-influenza virus drugs whether stockpiling is necessary, including the ratio of anti-influenza virus drugs to the total stockpile of drugs. (MHLW)
- (iv) The national government, based on the distribution status of anti-influenza

virus drugs, will establish a system for a smooth supply in the event of a novel influenza outbreak, and will instruct medical institutions, pharmacies, and wholesale distributors of pharmaceutical products on the proper distribution of anti-influenza virus drugs. In addition, manufacturers and distributors should be requested to increase manufacturing as necessary¹⁹¹. (MHLW)

- (v) While taking into account the local legal systems and other relevant factors, the national government shall stockpile anti-influenza virus drugs for influenza at overseas diplomatic missions, as necessary. (MOFA)
- (vi) The national government shall require businesses engaged in the manufacturing, importation, or sale of therapeutics used for symptomatic treatment, etc., including antipyretic-analgesic, antitussive, and anti-inflammatory drugs (hereinafter referred to as “symptomatic treatment drugs”), to regularly report on their manufacturing, etc., status. Additionally, businesses involved in the manufacturing or importation of symptomatic treatment drugs will also be required to report on their manufacturing capacity, etc¹⁹². (MHLW)
- (vii) The national government shall monitor the stockpiled quantities of therapeutic agents, including those held by manufacturers and distributors, as necessary. (MHLW)

¹⁹¹ Article 53-16 of the Infectious Diseases Control Law.

¹⁹² Article 53-22 of the Infectious Diseases Control Law.

Section 2: Initial phase

(1) Purpose

In the event of an outbreak of novel influenza, etc., the established systems developed during the preparation phase shall be rapidly utilized to ensure the rapid development, approval, procurement, and distribution of effective therapeutic agents. Simultaneously, efforts shall be directed towards the establishment and nationwide dissemination of appropriate therapeutic methods to achieve the swift containment of the outbreak.

The national government and JIHS, in collaboration with AMED, shall rapidly transition to response system for crisis based on the arrangement made during the preparation phase. The government will swiftly designate the emerging novel influenza, etc. as a priority infectious disease. While closely monitoring international developments in the research and development of MCM, the national government will advance the research and development of therapeutics. Furthermore, a comprehensive approach will be taken to expedite the approval, manufacturing, allocation, distribution management, etc., of these therapeutic agents.

(2) Required response

2-1. Collection, analysis, and sharing of information on domestic and international research and development trends

The government and JIHS, in collaboration with domestic and international related organizations, including AMED, shall continuously gather and analyze information on research and development trends and clinical data, etc., related to therapeutics for emerging novel influenza, etc. Additionally, this knowledge will be shared interactively within the government and with related organizations, such as prefectures and medical institutions. (MHLW; National Healthcare Policy Secretariat; MOFA; MEXT)

2-2. Consideration of the Research and Development Policy, etc.

The national government, in collaboration with JIHS, AMED, and other related organizations, shall continuously review and assess the research and development policy for therapeutics for the novel influenza, etc. Additionally, the government will evaluate strategies for securing therapeutics. (MHLW; National Healthcare Policy Secretariat)

2-3. Rapid implementation of research and development

2-3-1. Early acquisition of pathogen and genomic information

The national government and JIHS, in collaboration with domestic and international organizations, will rapidly acquire information, such as pathogens and genomic sequence data, to advance the development of therapeutics. This information will be shared with related organizations such as relevant pharmaceutical companies and research institutions engaged in research and development. (MHLW; MOFA; MEXT)

2-3-2. Promotion of basic and bridging research

The national government and JIHS, in collaboration with AMED, will work with domestic and international related organizations to promote the research and development of new therapeutics. Utilizing the research and development infrastructure, etc., established during the preparation phase for priority infectious diseases, they will swiftly carry out basic and bridging research with the goal of early clinical application. (MHLW; National Healthcare Policy Secretariat; MEXT)

2-3-3. Rapid implementation of clinical research

The national government and JIHS, in collaboration with pharmaceutical companies and medical institutions, etc., will leverage the systems and personnel established during the preparation phase to swiftly initiate the necessary clinical research, etc., both domestically and internationally. Additionally, efforts will be made to gather and share scientific knowledge that supports the development of therapeutics and the establishment of therapeutic methods. (MHLW)

2-3-4. Collaboration and cooperation with research and development enterprises

- (i) The national government and JIHS, in collaboration with related organizations, including AMED and PMDA, will provide essential support to promote research and development enterprises involved in therapeutics, including those utilizing research reagents. This support will encompass the development of domestic reagents, the promotion of domestic manufacturing, and the advancement of drug discovery ventures, all aimed at accelerating research and development and achieving early practical applications. (MHLW; National Healthcare Policy Secretariat; METI)
- (ii) JIHS will secure research funding with a strategic focus and provide the national government with information that supports the setting of research

agendas and the allocation of research funds, etc. (MHLW)

- (iii) The national government and JIHS, in collaboration with AMED, will request pharmaceutical companies and related entities to rapidly verify the efficacy, etc., of existing therapeutic agents, compounds, and developmental seeds against novel influenza, etc. Additionally, they will provide research and development support, as necessary. (MHLW; National Healthcare Policy Secretariat)

2-4. Consideration of emergency approval, etc.

The government will initiate the examination of the feasibility of implementing emergency approval¹⁹³ or specified approval¹⁹⁴ to ensure the early acquisition of newly developed pharmaceuticals and medical devices, etc. (MHLW)

2-5. Establishment of systems for utilization of therapeutics

2-5-1. Establishment of clinical guidelines

The national government and JIHS, in collaboration with research institutions such as universities and pharmaceutical companies, etc., will rapidly verify the efficacy, etc., of existing therapeutics against novel influenza, etc. Concurrently, they will establish clinical guidelines for the initial stage of the epidemic. In doing so, they will utilize the research and development infrastructure established during the preparation phase to thoroughly assess the effectiveness, etc., of these therapeutics as needed. (MHLW)

2-5-2. Information provision and sharing with medical institutions, etc.

The national government and JIHS will rapidly provide and share information, etc., relevant to the diagnosis and treatment of novel influenza, etc. with prefectures, medical institutions, etc., health care workers, etc., and the people. (MHLW)

The prefectures will provide and share information with medical institutions, etc., including designated medical institutions for infectious diseases and medical institutions which have concluded agreements, etc., to ensure that they can utilize therapeutics that refer to clinical guidelines, etc., by the national government and JIHS during outbreaks of novel influenza, etc. (MHLW)

2-5-3. Securing of therapeutic agents

In the case where existing therapeutic agents are found to be effective in treating

¹⁹³ Article 14-2-2 of the Pharmaceutical Affairs Act

¹⁹⁴ Article 14-3 of the Pharmaceutical Affairs Act

novel influenza, etc. or when new therapeutics are developed, the national government will endeavor to secure the necessary quantities, including through the utilization of international cooperation frameworks. Additionally, for therapeutic agents that can be manufactured domestically, the government will promote increased manufacturing at domestic manufacturing facilities. (MHLW; METI)

2-5-4. Allocation of therapeutic agents

The national government, in collaboration with prefectural governments, etc., and other relevant entities, will ensure the timely and equitable distribution of therapeutic agents, particularly those with limited supply. This will be achieved by organizing matters such as the distribution framework, prioritizing the allocation to different types of medical institutions, and identifying patient groups eligible for treatment. The distribution system established during the preparation phase will be utilized to smoothly deliver these medications to designated medical institutions and pharmacies, ensuring that the necessary patients receive appropriate treatment in a fair and timely manner. (MHLW)

2-5-5. Management of distribution and appropriate use of therapeutic agents

The national government, in coordination with prefectural governments, etc., will request that medical institutions and pharmacies appropriately use therapeutic agents for fundamentally treating novel influenza, etc. Additionally, the government will provide guidance on the proper distribution of therapeutic agents, including measures to prevent excessive stockpiling. (MHLW)

2-5-6. Management of distribution and appropriate use of symptomatic treatment drugs

In the event of a potential shortage of symptomatic treatment drugs, the national government will, as necessary, request increased manufacturing, etc., from manufacturers and other relevant parties¹⁹⁵. Additionally, the government will support the strengthening of manufacturing systems from the perspective of securing personnel and facilities, etc. Furthermore, the government will provide guidance on the proper distribution of symptomatic treatment drugs. (MHLW)

2-6. Use of anti-influenza virus drugs (in the case of novel influenza)

- (i) The national and prefectural governments will monitor the stockpiles of anti-

¹⁹⁵ Article 53-16 of the Infectious Diseases Control Law.

influenza virus drugs, including those held in distribution reserves by manufacturers. (MHLW)

- (ii) The national government, in collaboration with prefectural governments, etc., will request medical institutions to administer prophylactic anti-influenza virus drugs, as necessary, to household members of patients, health care workers, emergency medical personnel, etc., and other transportation staff, etc., using the stockpiled antiviral drugs. (MHLW)
- (iii) Prefectural governments, etc., in coordination with the national government and with the cooperation of medical institutions, as necessary, will provide guidance on the prophylactic administration of anti-influenza virus drugs, as well as on the management of symptomatic cases, to close contacts with patients with novel influenza, such as household members, and to health care workers or emergency medical personnel, etc., who have been exposed without adequate protection. In the event where symptoms appear, these individuals will be transferred to designated medical institutions for infectious diseases, etc. (MHLW)
- (iv) The national government, in collaboration with prefectural governments, etc., will request medical institutions and pharmacies to appropriately use anti-influenza virus drugs in preparation for the potential spread of infection within the country. (MHLW)
- (v) The national government will provide guidance on the proper distribution of anti-influenza virus drugs (MHLW)

Section 3: Response phase

(1) Purpose

In the event of an outbreak of novel influenza, etc., efforts will be made to rapidly develop, approve, and secure effective therapeutic agents with the aim of containing the spread of the disease as quickly as possible. Additionally, therapeutic methods will be established to ensure that the necessary patients receive these therapeutics equitably.

The national government and JIHS, in collaboration with domestic and international related organizations, including AMED, will promote the expedited research and development of therapeutics and will strive to facilitate their widespread adoption.

(2) Required response

3-1. Response in situations where comprehensive risk is deemed high

In the situation where the overall risk to lives and health of the people is assessed as high due to the outbreak of novel influenza, etc., the national government will take the measures detailed below to ensure the early availability of therapeutics, including the rapid research and development and securing of the therapeutic agents.

3-1-1. Collection, analysis, and sharing of information on domestic and international research and development trends

The national government and JIHS, in collaboration with domestic and international related organizations, including AMED, will continuously gather information on the research and development trends, etc., related to therapeutics for the outbreaks of novel influenza, etc. This will include the collection of clinical data, as necessary. An analysis will be conducted on the effectiveness of existing drugs against the circulating pathogen. The findings will be shared within the national government, with prefectural governments, and other related organizations such as medical institutions, facilitating interactive information exchange. (MHLW; National Healthcare Policy Secretariat; MOFA; MEXT)

3-1-2. Consideration of research and development policies

The national government, in collaboration with JIHS, AMED, PMDA, etc., will continuously review and, if necessary, revise the policies regarding the research, development, and securing of therapeutics for outbreaks of novel influenza, etc.

Furthermore, if the national government identifies specific groups at high risk of severe outcomes from the emerging novel influenza, etc., such as children, pregnant women, elderly people, and individuals with certain preexisting conditions or

complications, it will collaborate with PMDA to prioritize the development of therapeutic agents, etc., specifically targeted at these groups. The government will provide the necessary support, etc., to research institutions such as universities, etc., and pharmaceutical companies to promote these efforts. (MHLW; National Healthcare Policy Secretariat; MEXT; METI)

3-1-3. Promotion of research and development of therapeutics

The national government will explore and implement both push type research and development support and pull type research and development support to further advance the development of therapeutics for novel influenza, etc. Through organizations such as AMED, the national government will promote research and development efforts. Additionally, the government will provide the necessary support, etc., to companies involved in drug development, offering assistance from the research and development phase through to marketing approval and commercialization, including tailored support for drugs with strong potential for practical application.

The national government and JIHS, in collaboration with domestic and international related organizations, including AMED, will provide support for the conducting of clinical trials during the development of therapeutics. (MHLW; National Healthcare Policy Secretariat; METI)

3-1-4. Coordination to secure therapeutic agents

Considering the potential for expanding the use of existing therapeutic agents and the development of new effective therapeutic agents for novel influenza, etc., the national government will coordinate with domestic and international related organizations, etc., to secure and supply these therapeutic agents.

Furthermore, the national government will rapidly consider the applicability of emergency approvals or specified approvals, etc., to ensure that these therapeutic agents can be used as quickly as possible. Additionally, if necessary, the national government will coordinate procurement, including negotiating purchase agreements, etc., with domestic and international pharmaceutical companies prior to marketing approval. (MHLW; MOFA; METI)

3-1-5. Coordination for symptomatic treatment drugs

In the event of a potential shortage of symptomatic treatment drugs, the national

government will request manufacturers, etc., to increase manufacturing, etc.¹⁹⁶, as necessary. Additionally, the government will provide coordination and support to strengthen manufacturing systems, focusing on securing personnel and facilities, etc. (MHLW; METI)

3-1-6. Utilization of therapeutics

3-1-6-1. Measures for early dissemination of developed therapeutics

The national government and JIHS will organize the obtained knowledge to contribute to the establishment of therapeutic methods using existing therapeutic agents and symptomatic treatment drugs, as well as newly developed and approved therapeutic agents. They will support the sharing of scientific knowledge by JIHS or relevant academic societies, etc., and assist in the formulation and revision of clinical guidelines, including the appropriate use thereof. (MHLW)

3-1-6-2. Follow-up after dissemination of therapeutics

The national government and JIHS will work to gather information on the effectiveness and safety of therapeutics, striving to enhance the level of evidence¹⁹⁷ for these therapeutic methods. Special attention will be given to therapeutic agents that have been granted specified approval or emergency approval, particularly considering the limited domestic and the national use cases, etc., with efforts to monitor the occurrence of adverse effects. Additionally, the government will consider the necessary support for revising, etc., clinical guidelines as needed. If adverse effects from therapeutic agents are reported, appropriate relief measures will be implemented in collaboration with related organizations. (MHLW)

3-1-6-3. Provision and sharing of information with medical institutions

The national government will continue to rapidly provide information relevant to the diagnosis and treatment of novel influenza, etc., as well as the formulated clinical guidelines, etc., to prefectural governments, medical institutions, health care workers, and the people. (MHLW)

3-1-6-4. Vigilance activities at medical institutions and pharmacies

The national government will guide and coordinate with prefectural police to

¹⁹⁶ Article 53-16 of the Infectious Diseases Control Law.

¹⁹⁷ This refers to the indicators used to assess the reliability of information serving as scientific evidence. The level of reliability is evaluated in a graduated manner by categorizing the methods used in the underlying research or studies.

conduct the necessary vigilance activities, etc., at medical institutions, pharmacies, and their surrounding areas to prevent confusion among the people, and unforeseen incidents. (NPA)

3-1-6-5. Distribution management of therapeutic agents

- (i) The national government will continue to collaborate with prefectural governments, etc., to request medical institutions and pharmacies to appropriately use therapeutic agents for fundamentally treating novel influenza, etc. Additionally, the government will monitor the distribution status of these therapeutics and provide guidance to ensure proper distribution, including preventing excessive stockpiling. (MHLW)
- (ii) The national government will also request the appropriate use of symptomatic treatment drugs, monitor their distribution status, and provide guidance to ensure proper distribution. (MHLW)
- (iii) When the number of patients decreases, the national government will, as necessary, request pharmaceutical companies and related entities to increase manufacturing, etc., in preparation for the next wave of infection¹⁹⁸. Additionally, the national and prefectural governments will secure the increased supply of therapeutic agents, as needed. (MHLW)
- (iv) If it is anticipated that the stable supply of therapeutic agents will be challenging, the national and prefectural governments will utilize the distribution system established during the preparation phase to ensure the timely and equitable allocation of these therapeutic agents to patients in need through medical institutions and pharmacies. Once the supply stabilizes, the distribution will transition to general commercial channels. (MHLW)

3-1-7. Identification of medium to long term prognosis and research on treatments for complications

The national government, in collaboration with JIHS and relevant academic societies, etc., will identify complications and medium to long term prognoses related to infections of novel influenza, etc., as necessary. The national government will also analyze treatments, etc., for these complications and conduct the necessary research. Insights gained from this research will be rapidly reflected in clinical guidelines, etc., and disseminated to prefectures, medical institutions, and the people. (MHLW)

¹⁹⁸ Article 53-16 of the Infectious Diseases Control Law.

3-1-8. Stockpiling and use of anti-influenza virus drugs (in the case of novel influenza)

- (i) The national government will monitor the stockpiles of anti-influenza virus drugs held by both the national and prefectural governments. The national government will also assess the distribution of anti-influenza virus drugs within each prefecture, ensuring that these drugs are being supplied to regions where they are needed based on the status of patient outbreaks. Additionally, in response to requests, etc., from prefectures, the national government will allocate anti-influenza virus drugs from its own stockpiles and coordinate distribution accordingly, etc. (MHLW)
- (ii) The national government, in coordination with prefectural governments, etc., in the event of a regional outbreak of infections, for prioritize the treatment of patients, as a general rule, will request medical institutions to refrain from the prophylactic use of anti-influenza virus drugs for those who have had close contact with patients (excluding household members). Furthermore, the continuation of prophylactic administration to household members of patients will be determined based on an evaluation of the expected effectiveness. (MHLW)
- (iii) The national and prefectural governments, when the number of patients has decreased, will replenish anti-influenza virus drugs as necessary in preparation for the next wave of infections. (MHLW)

3-2. Determination and revision of policy based on risk assessment

When the acquisition of immunity through vaccines and other means has progressed or when pathogenicity or infectivity and transmissibility, etc., has decreased due to pathogen mutation, etc., the national government will comprehensively assess the situation of the infectious disease crisis and the specific circumstances of each region, etc., and implement the measures that follow below. (MHLW)

3-2-1. Relaxation and prioritization of systems, etc.

Taking into account the overall situation of the infectious disease crisis, the specific circumstances of each region, etc., the national government will examine the relaxation of systems, etc., related to the procurement and distribution management of therapeutics. Where necessary, it will request increased manufacturing of

symptomatic treatment drugs¹⁹⁹ and support the strengthening of manufacturing systems, etc. Furthermore, the government will implement targeted measures to ensure that the necessary treatments are provided to specific groups at high risk of severe illness. (MHLW)

3-2-2. Enhancement of preparedness based on potential risk increase

The national government, recognizing the possibility of further risk increases due to factors, such as pathogens mutations that lead to greater pathogenicity or infectivity and transmissibility, unexpected shortages of therapeutic agents and related supplies, etc., or concurrent epidemic of other infectious diseases, will continue to collect and analyze relevant information. Based on the evolving situation, the national government will take appropriate actions to address these potential compound crises. (MHLW)

¹⁹⁹ Article 53-16 of the Infectious Diseases Control Law.

Chapter 10: Testing

Section 1: Preparation phase

(1) Purpose

The diagnosis of a patient is conducted based on various factors, including the patient's symptoms, history of contact with other infected individuals, etc., exposure to the pathogen, and the results of various testing, etc., that confirm the presence of the pathogen or the body's response to it. The testing used for diagnosing infectious diseases include a wide range of methods, from microscopic examination to tests that detect the pathogen's genetic material, such as PCR testing, etc., and testing that confirm the presence of antigens, such as quantitative antigen testing and qualitative antigen testing (rapid testing kits). There is also antibody testing that measure the antibodies produced by the body in response to the antigen and testing that detect the manufacturing of specific lymphocytes. Depending on the type of pathogen, the characteristics of the infectious disease, the context and purpose of the testing, and factors, such as the development status, attributes, and accuracy of the testing, it is necessary to select an appropriate, scientifically validated diagnostic method. In this chapter, the focus will be on PCR testing, etc., and testing for confirming the antigens of the pathogens, which have been utilized in the diagnosis of past outbreaks of novel influenza, etc., and measures related to these diagnostic methods will be outlined.

In the event of an outbreak of novel influenza, etc., it is essential to rapidly develop detection methods for the pathogen and establish appropriate sites and methods for collecting diagnostic samples. This will enable the rapid and accurate diagnosis of patients, ensuring timely treatment while accurately assessing the infection status and implementing appropriate countermeasures. Also, depending on the scale of the epidemic, it may be necessary to swiftly expand the implementation system for testing with guaranteed accuracy, underscoring the importance of establishing coordination mechanisms among relevant stakeholders. Additionally, it is crucial to ensure the procurement of testing supplies and personnel, as well as to secure the systems for sample collection and transport, etc., advancing a comprehensive and coordinated response.

The primary objectives of testing are to prevent the spread of infection through early detection of patients, diagnosis and rapid initiate treatment for patients, and ascertain the actual situation of the epidemic. During the preparation phase, it is essential to establish a testing system to prepare for a potential outbreak of novel influenza, etc., as well as to train the necessary personnel. It is also important to regularly verify the effectiveness of the system through drills and other exercises, ensuring a smooth

establishment of the testing framework during crisis. This process should include periodic reviews of the testing system based on the prevention plans of prefectural governments, etc. Furthermore, in developing the testing system, preparations should be made in collaboration with entities, such as JIHS, public health institutes, etc., medical institutions, research organizations, private testing companies, and distribution business operators²⁰⁰, to enable the rapid implementation of the testing framework.

(2) Required response

1-1. Establishment of testing systems

- (i) The national government shall ensure the accuracy management of testing in normal times and establish and maintain the implementation system for the infectious disease surveillance, etc., in collaboration with prefectural governments, etc., based on the prevention plans formulated under the Infectious Diseases Control Law. This will facilitate the rapid expansion of testing systems during crisis. Furthermore, the government will request testing organizations to establish systems for managing testing accuracy. (MHLW)
- (ii) JIHS shall establish a system to support the enhancement of testing systems at domestic testing organizations, including private testing companies, etc., while strengthening its collaboration with public health institutes, etc. through routine examination and testings, etc. Furthermore, it will develop a framework to swiftly verify testing accuracy in cooperation with public health institutes, etc. and ensure access to testing reagents and other necessary materials during crisis. (MHLW)
- (iii) Prefectural governments, etc., shall advance the stockpiling and securement of testing supplies, such as sample collection containers, sample collection tools, and testing reagents, to ensure the smooth implementation of testing during crisis. (MHLW)
- (iv) In order to swiftly establish a testing framework during an outbreak of novel influenza, etc., the national government shall confirm the division of roles in normal times with institutions involved in testing during crisis, such as quarantine stations, public health institutes, etc., private testing companies, medical institutions, research institutions, and distribution businesses (hereinafter referred to as “testing-related organizations”). The national government will also prepare for the establishment of a testing system for crisis.

²⁰⁰ This refers to businesses involved in the manufacture and distribution of reagents and testing equipment, as well as distributors involved in the transportation of samples, etc.

Additionally, to enable rapid testing during such outbreaks, the national government will explore transportation methods for sample delivery, including using official vehicles and engaging distributors, etc., and make the necessary arrangements, such as concluding agreements in advance. (MHLW; relevant ministries and agencies)

- (v) Prefectural governments, etc., based on their prevention plans, shall identify the status of testing capacities at public health institutes, etc. and private testing companies that have entered into agreement on testing and other measures. Prefectural governments, etc., shall report this information to the national government annually and provide the necessary support in response to consultations or requests from these institutions, etc., regarding the enhancement and strengthening of their testing systems²⁰¹. (MHLW)
- (vi) In order to establish a testing system during an outbreak of novel influenza, etc., the national government will aim to maintain a certain level of PCR testing, etc., capacity, secured during the response to COVID-19, while strengthening infectious disease surveillance, ensuring testing capabilities, and maintaining testing equipment. Additionally, in collaboration with JIHS, the national government will provide technical training aimed at developing personnel necessary for the establishment of testing systems, enhancing the quality control of tests, and ensuring the accuracy of testing conducted by testing organizations. (MHLW)

1-2. Maintenance and strengthening of a testing system through training, etc.

- (i) The national government, in collaboration with JIHS, will conduct training, etc., involving public health institutes, etc. and organizations, etc. which have concluded agreements on testing and other measures to ensure the smooth establishment of a testing system during crisis. Prefectural governments, etc., based on the prevention plans, will regularly conduct verifications through trainings, etc., to ensure the ability to rapidly assess the status of testing capacity enhancements, the readiness of public health institutes, etc. and organizations, etc. which have concluded agreements on testing and other measures to implement testing during crisis. Public health institutes, etc. and organizations, etc. which have concluded agreements on testing and other measures, in cooperation with the national and prefectural governments, will work to

²⁰¹ This refers to the requests to prefectures, etc., to establish testing systems based on the prevention plans.

maintain the testing system by utilizing these trainings, etc.,. (MHLW; relevant ministries and agencies)

- (ii) Public health institutes, etc. and organizations, etc. which have concluded agreements on testing and other measures shall cooperate with testing-related organizations of relevant prefectures, etc., to ensure, through drills and trainings, that the transportation of samples and pathogens can be carried out smoothly in crisis. (MHLW; relevant ministries and agencies)
- (iii) JIHS shall conduct training to establish an initial response system from the acquisition of samples to the development of pathogen detection methods and the dissemination of those methods to testing organizations, in collaboration with prefectural governments, etc., public health institutes, etc., quarantine stations, research institutions, academic societies, and private companies, such as reagent and testing equipment manufacturers. (MHLW; relevant ministries and agencies)
- (iv) The national government shall conduct technical training, etc., on sample collection²⁰² for dentists in collaboration with related organizations, recognizing that the profession of individuals permitted to collect samples may be restricted depending on the site of sample collection. (MHLW)

1-3. Ensuring a system to identify the testing implementation status

The national government, in collaboration with JIHS, public health institutes, etc., private testing companies, medical institutions, and others, will establish methods and secure systems to efficiently identify the testing implementation status conducted during crisis, including the proportion of positive results. In doing so, the national government will promote DX to implement automated and streamlined systems, aiming to reduce the operational burden during such crisis. (MHLW)

1-4. Implementation of research and development support measures, etc.

1-4-1. Organizing research and development directions

- (i) The national government and JIHS, in cooperation with AMED, will advance discussions on establishing an integrated ecosystem that encompasses the designation of priority infectious diseases, the promotion of research and development, and the assurance of a system for the utilization in order to secure the possibility of using MCM in preparation for the outbreak of novel influenza,

²⁰² Article 31-2, Paragraph 1 of the Act on Special Measures. During the outbreak and epidemic of infectious diseases, dentists may perform sample collection only when the MHLW or other relevant authorities request cooperation from medical personnel.

etc. Additionally, they will promote research on new diagnostic technologies, and if their effectiveness is demonstrated, will consider their implementation and dissemination as countermeasures against novel influenza, etc. (MHLW; National Healthcare Policy Secretariat)

- (ii) The national government and JIHS, in collaboration with prefectural governments, domestic and international medical institutions, research organizations, etc., along with research organizations and testing organizations, etc., with research and development capabilities, will organize the policies for the development of diagnostic technologies. (MHLW)
- (iii) The national government and JIHS, in preparation for the outbreak of novel influenza, etc., will promote the research and development of new diagnostic technologies, in addition to existing technologies of molecular diagnostics, such as PCR testing, genome analysis, serological testing, and rapid testing kits, , etc. (MHLW)

1-4-2. Establishment of research and development system

The national government and JIHS, in collaboration with AMED, will support the establishment of a system enabling medical institutions involved in infectious disease treatment to conduct joint research on the development of diagnostic agents and testing equipment, etc., with the aim of rapidly advancing the research, development, and dissemination of diagnostic technologies, together with research institutes and testing organizations, etc., with research and development capabilities, when novel influenza, etc. emerge. Furthermore, efforts will be made to strengthen cooperation and networks with domestic and international research institutions, etc., as well as prefectural governments, etc. (MHLW; National Healthcare Policy Secretariat; MOFA)

1-4-3. Fostering and promotion of research and development enterprises

- (i) The national government and JIHS will support, etc., the fostering and promotion of research and development companies with the aim of advancing the research, development, and domestic manufacturing of diagnostic agents, testing equipment, and other diagnostic technologies. (MHLW; METI)
- (ii) The national government, in collaboration with JIHS and AMED, will establish research agendas for the development of diagnostic agents, testing equipment, and other diagnostic technologies while also securing research funding and strategically allocating research grants, etc. JIHS will provide the

government with relevant information, etc., to assist in the strategic formulation of research agendas and the allocation of research funding. (MHLW; National Healthcare Policy Secretariat)

1-4-4. Collaboration with testing related organizations

- (i) The government and JIHS, in order to facilitate the early development, manufacturing, and distribution of diagnostic agents, testing equipment, etc., shall verify and establish the necessary measures for the procurement and transportation systems related to samples, pathogens, genome sequence data, and other materials from overseas. (MHLW; relevant ministries and agencies)
- (ii) The government, in order to expedite the development, manufacturing, and distribution of diagnostic reagents and related products, shall review and streamline the procedures for examination and approval during the outbreak of novel influenza, etc. and take the necessary measures accordingly. (MHLW; relevant ministries and agencies)
- (iii) Prefectural governments, etc., shall actively cooperate with the clinical research conducted by medical institutions, etc., within their jurisdictions that provide infectious disease treatment in support of the research and development of diagnostic technologies led by the national government and JIHS. (MHLW)
- (iv) The national government shall endeavor to collect information on the research and development activities, etc., of WHO and foreign countries, facilitate international cooperation in research and development, etc., and coordinate, etc., with other nations and related organizations concerning the import or export of diagnostic agents and testing equipment in order to establish a framework for international collaboration and cooperation. (MHLW; National Healthcare Policy Secretariat; MOFA; METI)

1-5. Organizing basic policies for conducting inspections in crisis

The national government shall organize a testing implementation policy that outlines fundamental principles regarding which testing methods should be applied to specific target groups according to the purpose and prepare for crisis, considering various factors, such as the state of the epidemic, the status of the medical care delivery system, the testing implementation capacity, and the need to minimize the impact on the national life and the economy in the outbreak of novel influenza, etc. (MHLW)

Section 2: Initial phase

(1) Purpose

In the event of novel influenza, etc., the national government aims to swiftly obtain pathogens and other relevant materials from overseas as soon as the outbreak occurs abroad, establish testing methods, and rapidly organize the testing framework.

The national government, in the event of novel influenza, etc. within the country, will implement appropriate testing to detect patients, etc., at an early stage, ensuring appropriate medical care delivery and preventing further spread of the infection from patients. Simultaneously, the national government will monitor the epidemic situation to minimize the impact of the novel influenza, etc. on individuals and society.

(2) Required response

2-1. Establishment of testing systems

- (i) In order to ensure the rapid operation of clinics for outpatients with fever during the response phase, the national government will request prefectural governments, etc., to establish a robust testing framework based on the prevention plan. This will include confirming the status of testing capacities at public health institutes, etc. and organizations, etc. which have concluded agreements on testing and other measures to ensure that the target number of testing can be swiftly achieved in initial stage of the epidemic, and the national government will also provide support as needed. Additionally, based on the preparations made during the preparation phase, the national government will secure the necessary budget and personnel for testing, conduct training, etc., as required, and take further steps to strengthen personnel resources. (MHLW)
- (ii) Prefectural governments, etc., based on the prevention plan, shall confirm the status of testing capacity at public health institutes, etc. and organizations, etc. which have concluded agreements on testing and other measures, ensuring the enhancement and strengthening of the testing system. Furthermore, they will rapidly establish the necessary testing framework and regularly report to the national government on the status of testing capacity. (MHLW)
- (iii) The national government shall verify the status of testing supplies reserves and, if necessary, request private companies, including reagent and testing equipment manufacturers, etc., to increase the manufacturing of testing supplies. (MHLW; METI)
- (iv) In the event of a domestic outbreak of novel influenza, etc., if necessary, the national government shall establish agreements, etc., with distributors, etc., to

ensure the rapid transport of samples and pathogens while also assessing the need to expand the number of cooperating businesses. (MHLW; relevant ministries and agencies)

- (v) The national government, in collaboration with JIHS, shall conduct technical evaluations to enable the implementation of PCR testing, etc., at quarantine stations, etc., in line with the reinforcement of border measures, and establish a system that allows for the utilization of testing equipment available at these stations, etc. (MHLW)
- (vi) The national government, in cooperation with JIHS, will gather comprehensive information on novel influenza, etc., including data from abroad, and will use the acquired information to enhance the testing framework. (MHLW; MOFA)

2-2. Establishment and dissemination of versatile testing methods, such as PCR testing, etc., in Japan²⁰³

- (i) The national government, in collaboration with JIHS, will rapidly work to obtain samples and pathogens in the event of an outbreak of novel influenza, etc. abroad. Based on the obtained samples, the government will establish pathogen detection methods and disclose pathogen information. Furthermore, the government will swiftly establish testing methods based on the pathogen or pathogen related information. (MHLW; MOFA)
- (ii) JIHS will collect samples obtained from domestic sources, including quarantine stations, to secure pathogens, in addition to rapidly obtaining samples and pathogens from abroad. Furthermore, JIHS will also develop testing reagents and prepare testing manuals based on these samples. (MHLW; MOFA)
- (iii) The national government, in collaboration with JIHS, will assess and determine the feasibility of utilizing existing diagnostic reagents, testing equipment, etc. Additionally, the government will provide technical support by rapidly distributing testing reagents and manuals to public health institutes, etc., as well as organizations, etc. which have concluded agreements on testing and other measures. (MHLW)
- (iv) The government, in collaboration with JIHS, will work with research

²⁰³ Testing methods include not only microscopic examination but also tests that confirm the presence of pathogen genes, such as PCR testing, etc.; antigen testing, including quantitative antigen testing and qualitative antigen testing (rapid testing kits), which detect pathogen antigens; antibody tests, which measure antibodies produced by the human body in response to the antigen; and testing that confirm the production of specific lymphocytes. In developing these testing, it is essential to consider the pathogen detection system for each method, along with the appropriate sample collection site, collection method, and timing for clinical diagnosis.

institutions, testing organizations, and private testing companies with research and development capabilities, etc., from the early stages of the outbreak of novel influenza, etc. The goal is to rapidly develop optimal and versatile testing methods, such as PCR testing, etc., evaluate these methods through clinical research, and consolidate information on their usage. This information will be provided and shared with medical institutions and other relevant entities. (MHLW)

2-3. Establishment and dissemination of testing and diagnosis technologies by research and development enterprises

- (i) The national government will endeavor to collect and share scientific knowledge that contributes to the research, development, and establishment of diagnostic technologies. (MHLW)
- (ii) JIHS, in collaboration with the government, will swiftly isolate pathogens from samples and will distribute and provide these pathogens for research and development purposes in response to requests from related organizations such as research and development enterprises, research institutions, and academic societies capable of appropriate pathogen management. (MHLW)
- (iii) The national government and JIHS, in collaboration with AMED, will utilize the networks established during the preparation phase with prefectures, etc., domestic and international medical institutions, and research organizations, etc., to promote the research and development of diagnostic technologies. This will include providing the infectious disease sample panel²⁰⁴ that has been created for research institutions and testing organizations, etc., with research and development capabilities. Furthermore, the national government will evaluate the developed diagnostic technologies, ensuring quality maintenance. Additionally, guidelines for various testing methods will be consolidated and shared with public health institutes, etc., private testing companies, medical institutions, etc. (MHLW; National Healthcare Policy Secretariat; MOFA)
- (iv) Prefectural governments, etc., shall actively cooperate with clinical research conducted through medical institutions, etc., within their jurisdictions that provide infectious disease care in support of the research and development of diagnostic technologies led by the national government and JIHS. (MHLW)
- (v) The national government shall rapidly assess the applicability of emergency

²⁰⁴ This refers to a serum and plasma panel that collects samples of infectious diseases that are of particular public health importance.

approval, etc., mechanisms to ensure the early availability of newly developed diagnostic reagents and testing equipment, etc. Additionally, the national government shall swiftly provide and share information regarding diagnostic reagents and testing equipment that have obtained marketing approval with medical institutions and other relevant entities, including instructions on their use. (MHLW)

2-4. Coordination for procurement and supply of diagnostic agents, testing equipment, etc.

The national government shall coordinate with relevant domestic and international companies concerning the procurement of diagnostic reagents and testing equipment, etc., considering the potential for the development of effective testing methods for novel influenza, etc. abroad. Furthermore, in the event of a potential shortage of diagnostic reagents and testing equipment, etc., for conventional medical care other than novel influenza, etc., the national government will also undertake coordination to rectify supply-demand imbalances. (MHLW; MOFA; METI)

2-5. Consideration of testing implementation policy based on risk assessment²⁰⁵

- (i) The national government, in collaboration with prefectural governments, etc., and JIHS, will conduct a risk assessment based on factors such as the characteristics of the infectious disease and the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), as well as the status of the epidemic and the medical care delivery system, taking into account the fundamental principles of the testing implementation policy established during the preparedness phase. Based on this assessment, the national government will establish the testing implementation policy and will revise the policy in stages²⁰⁶. Furthermore, the national government will ensure that information on the testing implementation policy, etc., including the purpose of testing and the testing framework, is clearly communicated and shared with the people based on the status of the epidemic and risk assessment. (MHLW)
- (ii) The national government shall evaluate the appropriateness of utilizing testing

²⁰⁵ In the initial phase, depending on the infection situation, there may be instances where testing capacity is insufficient to meet testing demand. In such cases, priority shall, in principle, be given to implementing (i), and based on the status of its implementation, (ii) will subsequently be carried out.

²⁰⁶ The method for sample collection, including the site and timing of sample collection, is determined based on the characteristics of the infectious disease and the characteristics of the pathogen. Additionally, the prioritization of testing and the selection of individuals to be tested are considered based on the epidemic situation and other relevant factors.

to maintain the continuity of national life, taking into account the characteristics and transmission status of infectious diseases, such as novel influenza, as well as the nature and capacity of testing. In addition to technical considerations, the national government will assess the potential impact on the national life and economy, aiming to minimize adverse effects, etc. In the case where testing is utilized, the national government will also consider the potential development of rapid testing kits in determining the policy for implementing testing. (MHLW)

Section 3: Response phase

(1) Purpose

Taking into account the nationwide and regional outbreak and trends of novel influenza, etc., along with the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), as well as the appropriate timing and sites for sample collection and the methods of testing, the necessary testing infrastructure will be established to ensure smooth execution of tests. This will enable timely responses to evolving situations from the initial phase of an outbreak of novel influenza, etc. both domestically and internationally.

Following the initial phase, efforts will be made to rapidly detect patients through the implementation of appropriate testing. This will facilitate the provision of appropriate medical care, prevent the spread of infection from patients, monitor the epidemic situation, and minimize the impact on individuals and society caused by novel influenza, etc. Additionally, consideration will be given to factors such as the changes in the characteristics of the infectious disease and the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), shifts in the epidemiological situation, and the attributes of testing methods. The aim will also include supporting the recovery and maintenance of socioeconomic activities as part of the testing objectives.

(2) Required response

3-1. Expansion of testing systems

- (i) The national government, in accordance with the prevention plan, shall regularly receive reports from prefectural governments, etc., regarding the status of securing testing capacities and the number of tests conducted by public health institutes, etc. and organizations, etc. which have concluded agreements on testing and other measures. Based on these reports, the national government will request the enhancement and expansion of testing systems as necessary and provide support accordingly. Additionally, the national government will review and ensure the allocation of the necessary budget and personnel required for testing. (MHLW)
- (ii) Prefectural governments, etc., in accordance with the prevention plan, shall verify the status of securing testing capacities related to the enhancement and strengthening of testing systems at public health institutes, etc. and organizations, etc. which have concluded agreements on testing and other measures and regularly report the status of such capacities to the national government.

(MHLW)

- (iii) The national government shall confirm the status of securing testing supplies and, if necessary, request private companies, etc., such as reagent and testing equipment manufacturers, to increase the manufacturing volume of the testing supplies. (MHLW; METI)
- (iv) The national government, as necessary, shall conclude additional agreements, etc., with distributors, etc., to ensure the rapid transfer of samples and pathogens while assessing the need to expand the number of cooperating businesses and take appropriate actions accordingly. (MHLW; relevant ministries and agencies)
- (v) The national government, in cooperation with JIHS, shall gather information on testing systems both domestically and internationally and, as necessary, review measures to maintain or enhance the domestic testing infrastructure, etc. (MHLW; MOFA)

3-2. Establishment and dissemination of diagnosis technologies by research and development enterprises

- (i) The national government and JIHS, in collaboration with AMED and public-private research institutions, shall utilize the partnerships and networks established with testing related organizations during the preparation phase to promote clinical research and facilitate the collection and sharing of scientific knowledge that contributes to the development and establishment of testing methods. (MHLW; National Healthcare Policy Secretariat)
- (ii) When testing methods are developed domestically, the national government, in collaboration with JIHS, shall provide support for the implementation of clinical trials of the testing methods. (MHLW)
- (iii) The national government shall rapidly review the applicability of emergency approval, etc., mechanisms to ensure that the developed diagnostic agents and testing equipment, etc., can be made available for use at an early stage. (MHLW)
- (iv) The national government, in collaboration with JIHS, shall rapidly evaluate diagnostic agents and testing equipment, etc., including rapid testing kits and antibody tests, through clinical trials. Upon obtaining marketing approval, the government will swiftly provide and share information on these diagnostic tools, including their usage methods, with medical institutions and other relevant entities. (MHLW)
- (v) Prefectural governments, etc., shall actively cooperate in the implementation of clinical research conducted through medical institutions, etc., within their

jurisdiction regarding the research and development of diagnostic technologies led by the national government and JIHS. (MHLW)

- (vi) The national government shall verify the status of procurement and distribution of testing supplies at private testing companies, etc., including medical facilities, that have concluded the agreement on testing and other measures and, when necessary, request the increased manufacturing of testing supplies. Furthermore, the national government shall consider implementing purchase guarantees to ensure the availability of testing supplies. (MHLW; METI)
- (vii) In the event that new and safer testing methods or sample collection techniques are developed, the national government and JIHS shall rapidly work to disseminate these methods to medical institutions and other relevant entities. (MHLW)

3-3. Maintenance and review of accuracy of testing methods, etc.

The national government, in collaboration with JIHS, shall endeavor to collect information on the accuracy of testing methods that have not yet received marketing approval. In the event where issues are identified, the government will provide guidance on improving the accuracy, etc., of such methods or, if necessary, request the suspension of sales. Furthermore, in cases where labeling violations are found, the national government will provide guidance, etc., for corrective actions in compliance with relevant laws and regulations. (MHLW; Consumer Affairs Agency (CAA))

3-4. Coordination for procurement and supply of diagnostic agents, testing equipment, etc.

Considering the possibility that effective testing methods for novel influenza, etc. may be developed abroad, the national government shall coordinate the procurement of diagnostic reagents and testing equipment, etc., with relevant domestic and international companies. Additionally, in the event of potential shortages of diagnostic reagents and testing equipment, etc., for conventional medical care other than novel influenza, etc., the national government will undertake measures to correct the supply and demand imbalance through the necessary adjustments. (MHLW; MOFA; METI)

3-5. Determination and revision of policy for conducting testing based on risk

assessment

- (i) The national government, in collaboration with prefectural governments, etc., and JIHS, shall conduct risk assessments based on the characteristics of the infectious disease and the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), as well as the epidemic situation and the state of the medical care delivery system, etc. Based on these assessments, the government will determine the testing implementation policy and review the policy in stages ²⁰⁷. Furthermore, the national government will provide and share information with the people in an easily comprehensible manner regarding the objectives of testing, the testing system, and the overall testing policy, etc., taking into account the epidemic status and risk assessment. (MHLW)
- (ii) The national government, taking into account the overall situation of the infectious disease crisis, including progress in immunity acquisition through vaccinations, etc., or a reduction in pathogenicity or infectivity and transmissibility, etc., due to pathogen mutations, as well as the actual conditions of each region, will comprehensively review and determine any necessary revisions, etc., to the policy on the implementation of testing in stages. (MHLW)
- (iii) The national government, considering the characteristics and infection status of novel influenza, etc., as well as the properties of testing and the testing framework, will determine whether to utilize testing for the purpose of maintaining national life. This decision will take into account not only technical aspects but also aspects such as the minimization of impacts on the national life and economy. Furthermore, in the case where testing is to be utilized, the government will establish a policy on testing implementation with the consideration that the use of rapid testing kits may be included. (MHLW)

²⁰⁷ As in the initial phase, the methods for sample collection, including the collection sites and timing, will be determined based on the characteristics of the infectious disease and the characteristics of the pathogen. Additionally, considering the epidemic situation, etc., the prioritization of testing will be assessed, leading to the determination of the target population for testing. During the response phase, in addition to these considerations, there may be instances where the target population for testing is expanded, taking into account the status of testing capabilities and the need to minimize impacts on the national life and economy.

Chapter 11: Health

Section 1: Preparation phase

(1) Purpose

In the event of an infectious disease crisis, public health centers play a central role in the information collection and analysis in the region and in the implementation of infectious disease countermeasures according to the actual conditions of each region. Public health institutes, etc., also play a central role in infectious disease crisis by fulfilling a scientific and technical role in the region's information collection and analysis, etc.

Prefectural governments, etc., shall establish a system in normal times to collect information on matters such as the infectious disease outbreaks and the state of medical care in the region through infectious disease surveillance and other methods. In addition, in order to ensure that institutions, such as public health centers and public health institutes, etc., are able to fulfill their function in crisis, prefectures, etc., should also prepare by conducting drills and training, developing human resources capable of prompt and appropriate crisis management for infectious disease crisis over the medium to long term, securing the necessary human resources, including the use of external personnel, estimating the workload, preparing the equipment and materials, etc., necessary for infectious disease crisis management, stockpiling supplies, and so on.

In doing so, the division of roles between the headquarters of prefectures, etc., and public health centers, etc., the coordination between the two in the event of a sudden increase in workload and systems to provide support and receive assistance, and the division of roles among the local governments involved should be clarified so that they can work closely with one another.

In addition, information on the infectious diseases that have been collected and analyzed should be actively shared with relevant parties and residents to form a common understanding of the situation of infectious disease outbreaks and countermeasures, thereby creating a foundation for prompt information provision and sharing and collaboration in crisis.

(2) Required response

1-1. Securing human resources

- (i) The national government shall develop a mechanism for dispatching support personnel ²⁰⁸ beyond prefectural areas in cooperation with the National

²⁰⁸ Article 44-5 (including situations when applied according to Article 44-8) and Article 51-4 of the Infectious Disease

Governors' Association, etc. (MHLW, CAICM)

- (ii) Prefectural governments shall establish a system to secure human resources, including specialists who can respond to infectious diseases, and to send and receive human resources, etc., from the national and local governments, etc. (MHLW)
- (iii) Prefectural governments, etc., should secure personnel for the infectious disease emergency system of public health centers, such as staff members of public health centers, support staff members from head offices, IHEAT personnel, and support dispatched from municipalities, etc., in order to cope with the workload expected during the first month of the epidemic (public announcement of the outbreaks, etc. of novel influenza, etc.) at the public health centers. (MHLW)

1-2. Establishment of a system including Business Continuity Plan

- (i) The national government shall request prefectural governments, etc., to confirm every fiscal year the status of the infectious disease emergency system (the number of personnel and the number of IHEAT personnel to be secured corresponding to the expected workload at public health centers during the first month of an epidemic) at public health centers as specified in the prevention plan, and prefectural governments, etc., should confirm the status of the infectious disease emergency system every fiscal year. (MHLW)
- (ii) The national government shall confirm with prefectural governments, etc., the achievement status of the target values of the testing system (testing implementation capacity) at public health institutes, etc., and private testing companies with which have been concluded the agreement on testing and other measures, as stipulated in the prevention plan. Prefectural governments, etc., shall ensure the testing system by public health institutes, etc., and other medical institutions or private testing companies with which they have concluded the agreement on testing and other measures, etc. (MHLW)
- (iii) Prefectural governments, etc., or public health centers shall formulate Business Continuity Plans for public health center operations. The business continuity plans shall also be formulated for public health institutes, etc., assuming in advance that the necessary systems for the continuity of operations should be prioritized.

Moreover, in formulating the Business Continuity Plan, the operations of prefectural governments, etc., public health centers and public health institutes, etc., in crisis should be organized. Furthermore, in order to enable a smooth transition to an operation system based on the Business Continuity Plans in crisis, business efficiency should be improved through the use of ICT, outsourcing in normal times, etc. (MHLW)

1-3. Development of human resources and establishment of cooperation system through training and drills, etc.

1-3-1. Implementation of drills and training

- (i) The national government shall request prefectural governments, etc., to conduct drills and training at least once a year for personnel (including IHEAT personnel) who are part of the infectious disease emergency system at public health centers. (MHLW)
- (ii) The national government, in cooperation with prefectural governments, etc., JIHS, and other organizations, should enhance regional expert human resources and improve their ability to respond to infectious disease crisis such as by developing human resources for crisis management leadership and support staff members, training epidemiology experts and promoting collaboration through the FETP-J, and conducting training related to IHEAT personnel. (MHLW)
- (iii) Prefectures should support human resource development at public health centers and public health institutes, etc. within their jurisdiction. (MHLW)
- (iv) Prefectural governments, etc., should prepare for outbreaks of novel influenza, etc., by actively utilizing national and prefectural training programs, etc., and striving to develop human resources at public health centers and public health institutes, etc. In addition, training for the outbreak and spread of novel influenza, etc., should be conducted at public health centers, public health institutes, etc. (MHLW; relevant ministries and agencies).
- (v) Prefectural governments, etc., should aim to improve their ability to respond to infectious disease crisis by conducting agency-wide drills and training, not limited to infectious disease crisis management departments, in order to promptly shift to infectious disease emergency system at the head office in addition to public health centers, public health institutes, etc. (CAICM; MHLW; relevant ministries and agencies)

1-3-2. Establishment of a system for collaboration with various entities

In preparation for the outbreak of novel influenza, etc., prefectural governments, etc., should utilize organizations, such as the Prefectural Coordination Council, to strengthen coordination with not only public health centers and public health institutes, etc., but also municipalities and other related organizations, such as fire departments and professional associations, through opinion exchanges and coordination, etc., as required in normal times. (MHLW; relevant ministries and agencies)

In addition, at the Prefectural Coordination Council, etc., matters such as the method of hospitalization coordination, securing medical personnel, public health center system, testing system and policies for conducting testing, how information should be shared, transfers of patients with infectious diseases, etc., and emergency transportation of injured and sick people with other diseases, etc., should be discussed, based on which prefectural governments, etc., should formulate or modify their prevention plans. During the formulation or modification of the prevention plan, consistency should be ensured with prefectural action plans, municipal action plans, medical care plans, and health crisis response plans prepared by public health centers and public health institutes, etc. based on the basic guidelines for the promotion of community health measures²⁰⁹. (MHLW; relevant ministries and agencies)

In doing so, prefectures should confirm with related organizations, etc., in advance how to secure the medical care delivery system while utilizing their authority for comprehensive coordination²¹⁰ as necessary. (MHLW; relevant ministries and agencies)

Furthermore, during crisis, when people who have tested positive are treated at home or in an accommodation-based recovery facility²¹¹ due to factors such as the characteristics of the infectious disease, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), the epidemic situation, or the shortage of hospital beds, it is necessary to provide meals, etc.²¹², and secure accommodation facilities, etc., for the people who have tested positive. Therefore, prefectural governments, etc., shall establish a system to prepare for infectious disease crisis within the entire region by building a cooperative system

²⁰⁹ The basic guidelines established under Article 4 of the Community Health Act (Ministry of Health and Welfare Notification No. 374 of 1994).

²¹⁰ Article 63-3 of the Infectious Diseases Control Law.

²¹¹ Refers to the accommodation facilities specified in Article 44-3, paragraph (2) and Article 50-2, paragraph (2) (including the cases where it is applied *mutatis mutandis* pursuant to Article 44-9) of the Infectious Diseases Control Law. The same shall apply hereinafter.

²¹² Article 44-3, paragraphs (7), (9), and (10) of the Infectious Diseases Control Law.

with the municipalities and private lodging business operators²¹³, etc., with whom they have concluded agreements. (MHLW; relevant ministries and agencies)

1-4. Development of systems of public health centers and public health institutes, etc.

- (i) Prefectural governments, etc., shall establish a system for efficient information aggregation and flexible work allocation, cooperation, and coordination, assuming an increase in the volume of information and workload when there is an infectious disease outbreak in order to appropriately implement identification of infection routes, active epidemiological investigation²¹⁴ for ascertaining people in close contact with patients of infectious diseases, collection and analysis of pathogens, etc. In addition, the personnel system and facilities at public health centers and public health institutes, etc. should be improved, including for shift personnel, and the necessary measures should be taken, such as mental health support for staff members, etc., engaged in infectious disease response work. Furthermore, a system should be established to conduct health observation²¹⁵ by utilizing outsourcing²¹⁶ and cooperation from municipalities. (MHLW)
- (ii) Public health centers should formulate a health crisis response plan to systematically prepare for outbreaks, etc., of infectious diseases, such as novel influenza, etc., in normal times, secure personnel to handle the estimated workload, conduct education and training, improve work efficiency through the use of ICT, etc., and strengthen cooperation with related organizations such as regional professional associations, and educational institutions such as universities. (MHLW)
- (iii) JIHS shall establish a cooperative system that includes information sharing with public health institutes, etc., and provide the necessary support to maintain and strengthen the functions of prompt testing and epidemiological investigation. (MHLW)
- (iv) Public health institutes, etc., should formulate a health crisis response plan, develop and maintain facilities and equipment, improve the accuracy management of testing, utilize systems for managing information on infectious

²¹³ Article 36-6, paragraph (1) of the Infectious Diseases Control Law.

²¹⁴ Infectious Disease Control Law, Article 15.

²¹⁵ This means to request a person who has justifiable grounds to suspect that they are suffering from the said infectious disease or a patient of the said infectious disease to report on their health condition pursuant to the provisions of Article 44-3, paragraph (1) or paragraph (2) of the Infectious Diseases Control Law. The same shall apply hereinafter.

²¹⁶ Article 44-3, paragraphs (4) and (5) of the Infectious Diseases Control Law.

diseases, etc., enhance surveys and research, establish a system for cooperation with JIHS and other related organizations, and develop a system for appropriate response on holidays and during nighttime hours. (MHLW)

- (v) In order to maintain and strengthen the function of prompt testing and epidemiological investigations, the public health institutes, etc., and other organizations, etc. which have concluded agreements on testing and other measures will participate in training, etc., conducted by the government in cooperation with JIHS. In addition, these institutions shall maintain the testing system in cooperation with the national government and prefectures by utilizing training, etc., in normal times. (MHLW)
- (vi) Public health institutes, etc., and organizations, etc. which have concluded agreements on testing and other measures shall cooperate with prefectural governments, etc., and other related organizations in normal times and confirm through trainings that specimens can be transported without delay in crisis. (MHLW; relevant ministries and agencies)
- (vii) JIHS, in cooperation with prefectural governments, etc., public health institutes, etc., quarantine stations, research institutes, academic societies, etc., and private companies, such as reagent and testing equipment manufacturers, will conduct training to establish an initial response system from obtaining specimens to establish pathogen detection methods and disseminating these methods to testing organizations so that a prompt testing system can be established in crisis. (MHLW; relevant ministries and agencies)
- (viii) The national government, JIHS, prefectural governments, etc., public health centers, and public health institutes, etc., should establish a system to promptly grasp the epidemic status (including pathogen genome surveillance) of seasonal influenza and novel coronavirus in normal times by utilizing the infectious disease surveillance system. (MHLW)
- (ix) The national government, prefectural governments, etc., and public health centers shall utilize the Gathering Medical Information System (G-MIS) to grasp the preparation status of the agreements (e.g., confirmation of measures, such as securing hospital beds and outpatient fever treatment, drills and training, and the stockpiling of supplies) of the medical institutions with which an agreement has been concluded. (MHLW)
- (x) The national government, prefectural governments, etc., public health centers, and livestock public health centers shall ascertain the status of outbreaks of avian influenza, etc., in Japan and other regions based on notifications from

veterinarians in accordance with the Infectious Diseases Control Law or the Act on the Prevention of Infectious Diseases in Livestock (Act No. 166 of 1951)²¹⁷ or surveys of wild birds, etc. In addition, when information is provided or shared by medical institutions to public health centers regarding people suspected of being infected with avian influenza, a system for providing or sharing information will be established. (MHLW; MAFF; MOE)

- (xi) Prefectural governments, etc., should actively cooperate in research and studies led by the national government and JIHS to clarify the characteristics of the infectious diseases and the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), etc., as well as in the research and development of therapeutic agents, etc. (MHLW)

1-5. Promotion of DX

The national government will utilize the infectious disease surveillance system and the Gathering Medical Information System (G-MIS) in normal times and establish a system to ensure that these systems can continue to be utilized during crisis. In addition, through training in cooperation with prefectural governments, etc., public health centers, public health institutes, etc., the national government will improve issues related to the operation of various systems so that prefectural governments, etc., public health centers, public health institutes, etc., and medical institutions, etc., can efficiently carry out their operations. (MHLW)

1-6. Providing and sharing of information and risk communication in the region

- (i) The national government, in cooperation with institutions such as JIHS, should provide prefectural governments, etc., with basic information on infectious diseases and basic infectious disease measures (ventilation, cough etiquette, such as wearing masks, hand washing, avoiding crowds, etc.), information on outbreaks of infectious diseases, etc., information on novel influenza, etc., and measures to be taken in the event of an outbreak, in normal times. (CAICM; MHLW)
- (ii) Prefectural governments, etc., will provide and share information to residents in a manner appropriate to regional conditions while utilizing information and media provided by the national government. In addition, the method of providing and sharing information with residents, the method of developing a consultation

²¹⁷ Article 13, paragraph (1) of the Infectious Diseases Control Law and Article 13, paragraph (1) of the Act on the Prevention of Infectious Diseases in Livestock.

system for residents, including the establishment of call centers, etc., for residents, and the approach of risk communication, etc., should be discussed in advance so that a system for providing and sharing information on the infectious diseases to residents can be established promptly in crisis. (CAICM; MHLW)

- (iii) Prefectural governments, etc., should grasp the information required by residents, etc., and organize methods, etc., for further provision and sharing of information so that risk communication based on interactive communication with residents, etc., who are the recipients of information, can be carried out appropriately as much as possible. (CAICM; MHLW)
- (iv) Prefectural governments, etc., should raise awareness that anyone can be infected with infectious diseases and that prejudice and discrimination, etc., against infected people, their families, affiliated institutions, health care workers, and other personnel is unacceptable and can lead to legal liability, and can also hinder infectious disease control measures, such as by refraining patients from seeking medical consultation²¹⁸. (CAICM; MOJ; MEXT; MHLW; relevant ministries and agencies)
- (v) Prefectural governments, etc., in cooperation with municipalities, shall give appropriate consideration to the sharing of information on infectious diseases in normal times so that information can be shared in a timely and appropriate manner in crisis, even with those who require special consideration regarding information sharing, such as elderly people, children, foreign nationals with insufficient Japanese language skills, and people with visual or hearing impairments, etc. (MHLW)
- (vi) Public health centers, in cooperation with public health institutes, etc., shall collect information necessary for infectious disease countermeasures, and as a regional center for the dissemination of comprehensive information on infectious diseases, shall provide risk communication such as information sharing and consultation about the infectious diseases. (MHLW)

²¹⁸ Article 13, paragraph (2) of the Act on Special Measures.

Section 2: Initial phase

(1) Purpose

The initial phase is the period during which residents, etc., begin to feel anxious, and it is important to proceed with preparations promptly from the initial phase.

Based on the prevention plans established by prefectural governments, etc., and the health crisis response plan established by public health centers and public health institutes, etc., public health centers and public health institutes, etc., should be able to prepare for the transition to crisis system so that they can respond promptly after the public announcement of the outbreak, etc. of novel influenza, etc.

In addition, risk communication to the residents based on the assumption of a domestic outbreak of an infectious disease that could be classified as novel influenza, etc., will be initiated to reduce the risk of the spread of infection with the cooperation of the regional community.

(2) Required response

2-1. Preparation for shifting to emergency system

- (i) The national government shall quickly and appropriately ascertain the preparation status of the transition of the infectious disease emergency system at public health centers based on the prevention plan (the number of personnel and the number of IHEAT personnel secured corresponding to the expected workload at public health centers during the first month since the epidemic starts) and the testing system during crisis at public health institutes, etc. In addition, the national government shall provide requests or advice, according to necessity, for prefectural governments, etc., to prepare for responses (A) to (E), as follows below, in preparation after the public announcement of the outbreak, etc. of novel influenza, etc. (MHLW)
 - (A) When a patient is identified through a physician's report²¹⁹, etc., measures to be taken for the patient (hospitalization recommendations and measures, active epidemiological investigation, etc.) and to close contacts with patients, including those living with patients (requests of voluntary restraint, requests to undergo health observation, guidance on how to address symptoms²²⁰, etc.).
 - (B) Identification of outbreaks (clusters) through active epidemiological investigation, etc.
 - (C) Requesting IHEAT personnel to engage in measures, such as regional health

²¹⁹ Article 12 of the Infectious Disease Control Law.

²²⁰ Article 44-3, paragraph (2) of the Infectious Disease Control Law.

countermeasures in the areas under the jurisdiction of prefectural governments, etc.

- (D) Improving operational efficiency of public health centers such as by centralizing or outsourcing operations at the time of an expansion of infection.
- (E) Rapid development of testing systems at public health institutes, etc., medical institutions, and private testing companies with which have been concluded agreements on testing and other measures.
- (ii) Prefectural governments, etc., based on requests and advice from the national government, should grasp the status of preparations for the transition to infectious disease emergency system at public health centers and the crisis testing systems at public health institutes, etc., in a timely and appropriate manner based on the prevention plan, and promptly launch the testing system. In addition, preparations will be made to secure personnel, including replacement personnel, such as by dispatching support staff members from the head offices of prefectural governments, etc., requesting municipalities to dispatch support, and requesting support for IHEAT personnel. (MHLW)
- (iii) The national government shall request prefectures to promptly ensure a system to provide appropriate medical care to patients with infectious diseases at designated medical institutions for infectious diseases. (MHLW)
- (iv) Prefectural government shall ensure a system for accepting patients with infectious diseases at designated medical institutions for infectious diseases, as well as promote the establishment of a system for hospitalization coordination in cooperation with public health centers, medical institutions, fire departments, etc., and promptly establish the flow from counseling and consultation to admission and discharge, which was organized by the Prefectural Coordination Council, etc., during the preparation phase. In addition, requests shall be made to medical institutions to ensure that the status, such as the number of secured beds, occupancy status, the utilization rate of beds, utilization rate of beds for severely ill patients, and outpatient shortage status, are entered into the Gathering Medical Information System (G-MIS). (MHLW)
- (v) Based on the health crisis response plan, public health centers should prepare for the transition to the infectious disease emergency system in cooperation with the head offices of prefectural governments, etc., by gathering personnel for the infectious disease emergency system, preparing to receive assistance, and preparing for the procurement of the necessary supplies and equipment based on the characteristics of the infectious diseases and the characteristics of the

pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), etc. (MHLW)

- (vi) Prefectural governments, etc., shall make efforts to establish a testing system at an early stage, including cooperation with private testing companies with which they have concluded the examination, etc., measures agreement and other measures, and consultation centers as described in 2-2 below, by utilizing technical support, etc., provided by JIHS to public health institutes, etc. (MHLW)
- (vii) Based on the health crisis response plan, the public health institutes, etc., shall prepare for the transition to infectious disease emergency system in cooperation with the head offices of prefectures, etc., by gathering personnel for the infectious disease emergency system, preparing for receiving assistance, and preparing for procurement of the necessary supplies and equipment, etc., based on the characteristics of the infectious diseases and the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.). In addition, efforts will be made to collect information on infectious diseases in cooperation with JIHS, etc. (MHLW)
- (viii) Prefectural governments, etc., should actively cooperate in research and studies led by the national government and JIHS to clarify the characteristics of the infectious diseases and the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), etc., as well as in the research and development of therapeutics agents, etc. (MHLW)

2-2. Start of sending and sharing information with residents

- (i) The national government, in cooperation with JIHS, shall promptly ascertain the status of outbreaks of infectious diseases that may be positioned as novel influenza, etc., in Japan and abroad, and support prefectural governments, etc., by providing and sharing the information necessary for risk communication, etc., from prefectural governments, etc., to residents, including the characteristics and effective infection prevention measures of such infectious diseases. (MHLW; CAICM)
- (ii) The national government shall request prefectural governments, etc., to promptly establish consultation centers to receive consultation from returnees, etc. returning from outbreak countries or regions and symptomatic people. (MHLW)
- (iii) Prefectural governments, etc., shall establish consultation centers in

accordance with requests from the government and inform returnees, etc., returning from outbreak countries or regions and symptomatic people so that they can receive consultation at designated medical institutions for infectious diseases in a timely manner, if necessary. (MHLW)

- (iv) Prefectural governments, etc., shall establish a system to promptly provide and share information to residents such as by publicizing websites, etc., established by the government for providing and sharing information, publishing Q&As, and setting up call centers, etc., for residents, and also communicate interactively to share risk information, including information on how to interpret the said information, and the significance of countermeasures. (MHLW; CAICM)

2-3. Actions to be taken when infection is confirmed in the jurisdiction prior to the public announcement of the outbreak, etc. of novel influenza, etc.

If prefectural governments, etc., learn of the outbreak of a suspected disease carrier in their jurisdiction prior to the public announcement of the outbreak, etc. of novel influenza, etc., through the suspected case surveillance, etc., initiated in Chapter 3, Section 2 (initial phase in “Surveillance”), 2-2-1, public health centers, etc., should conduct active epidemiological investigation and specimen collection²²¹ on such a patient, and seek cooperation from designated medical institutions for infectious diseases for hospitalization as necessary to prevent an outbreaks infectious diseases. (MHLW)

²²¹ Article 16-3, paragraphs 1 and 3 of the Infectious Disease Control Law.

Section 3: Response phase

(1) Purpose

In the event of the outbreak of novel influenza, etc., based on the prevention plan established by prefectural governments, etc., the health crisis response plan established by public health centers and public health institutes, etc., and the division of roles and coordination system with local governments, medical institutions, etc., and other related organizations and professional organizations that were organized during the preparation phase, public health centers and public health institutes, etc., shall establish a system necessary for the required tasks and fulfill their respective roles, as well as cooperate with the relevant regional institutions to respond to infectious disease crisis, thereby protecting the lives and health of the people.

In doing so, the characteristics of the infectious diseases, the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), and the infection situation, etc., should be taken into account to enable a flexible response according to the actual conditions of the region.

(2) Required response

3-1. Shifting to emergency system

- (i) Prefectural governments, etc., shall establish an infectious disease emergency system at public health centers by dispatching support staff members from the head office, requesting support dispatch to municipalities, requesting support for IHEAT personnel, etc., without delay, and promptly setting up a testing system at public health institutes, etc. (MHLW)
- (ii) The national government shall confirm the status of the transition to an infectious disease emergency system and expansion of the system at public health centers and public health institutes, etc. in prefectural governments, etc., and the status of their response to infectious diseases, and provide the necessary advice and support, etc., to prefectural governments, etc. (MHLW)
- (iii) Prefectural governments shall support cities with public health centers, etc., by consolidating information, coordinating among local governments, and centralizing operations, etc., in the event of the outbreak of novel influenza, etc. In addition, in cooperation with the national government, other prefectural governments, and cities with public health centers, etc., within their jurisdiction, etc., the coordination of overall health activities and support to health activities shall be made, including collecting information on infection routes and those of close contact with patients, and cooperation with medical institutions and

welfare service organizations.

Furthermore, the authority for comprehensive coordination and instructions²²² to the cities with public health centers, etc., within their jurisdiction shall be exercised, as necessary. (MHLW)

- (iv) Prefectural governments shall share the necessary information with municipalities in order to improve residents' understanding of the status of the outbreak of novel influenza, etc.²²³ (MHLW)
- (v) Prefectural governments, etc., shall actively cooperate in research and studies led by the national government and JIHS to clarify the characteristics of the infectious diseases and the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), etc., as well as in the research and development of therapeutics agents, etc. (MHLW)

3-2. Implementation of major response operations

Prefectural governments, etc., public health centers, and public health institutes, etc., shall cooperate with each other based on the prevention plan, health crisis response plan, and the organizational and operational structure and division of roles, etc., established and organized during the preparation phase, and shall implement the infectious disease response operations described in 3-2-1 to 3-2-7 below in cooperation with related organizations, such as municipalities, medical institutions, and fire departments.

3-2-1. Carry out consultation

Prefectural governments, etc., shall strengthen consultation centers that respond to consultations from people, such as symptomatic people, and promptly refer those who may have been infected to clinics for outpatients with fever as necessary, based on the severity of their symptoms and the risk of serious infection from their underlying diseases, etc. In operating the consultation centers, outsourcing or centralizing, etc., the operation in prefectures in a timely manner should be considered in order to improve operational efficiency. (MHLW)

3-2-2. Testing and surveillance

- (i) In cooperation with prefectural governments, etc., and JIHS, the national government shall conduct a risk assessment based on matters such as the characteristics of the infectious diseases, the characteristics of the pathogens

²²² Article 63-3 and 63-4 of the Infectious Disease Control Law.

²²³ Article 16, paragraphs (2) and (3) of the Infectious Diseases Control Law.

(pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), and the outbreak status to determine the policy for the implementation of testing and review the policy for the implementation of testing in stages. Furthermore, based on the outbreak status and the risk assessment, information such as on the purpose of testing and the policy for the implementation of testing, including the testing system, shall be provided and shared with the people in an easy-to-understand manner. (MHLW)

- (ii) The national government shall improve the efficiency and reduce the burden of infectious disease response work performed by prefectural governments, etc., by utilizing the infectious disease surveillance system. (MHLW)
- (iii) Prefectural governments, etc., shall determine the scope of the testing based on the factors such as the necessity of infectious disease countermeasures and the testing systems at public health institutes, etc., and organizations, etc., which have concluded agreements on testing and other measures, according to the actual conditions of each region. (MHLW)
- (iv) Public health institutes, etc., in cooperation with public health centers, shall conduct the necessary testing until the testing system, including private testing companies, etc., with which they have concluded the agreement on testing and other measures, is sufficiently expanded. In addition, the public health institutes, etc., shall exercise their surveillance function in the region through collecting knowledge on domestic novel influenza, etc., in cooperation with JIHS and utilizing the network with other public health institutes, etc., providing and sharing information, such as the regional infection status to JIHS, analyzing the status of mutant strains in the region, providing and sharing information to the head offices and public health centers of prefectural governments, etc., providing technical support, accuracy control, etc., for testing at private testing companies with which it has concluded agreements on testing and other measures, etc. (MHLW)
- (v) The national government, in cooperation with prefectural governments, etc., and JIHS shall request submission of notifications of discharge, etc., in order to grasp information such as the characteristics of novel influenza, etc., and clinical features of patients. In addition, the national government, in cooperation with prefectural governments, etc., and JIHS, and other related organizations, shall conduct surveillance on matters, such as outbreaks and trends of novel influenza, etc., in Japan, the characteristics of the infectious diseases, the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility,

etc.), and clinical features, etc., according to the outbreak status.

Additionally, when the number of patients in Japan increases, information and scientific knowledge on matters such as the characteristics of novel influenza, etc., and the clinical features of patients have been accumulated, the significance of notifiable disease surveillance will decrease, and the burden on prefectural governments, etc., and medical facilities will also become severely excessive.

Therefore, when it becomes possible to ascertain infection trends through sentinel surveillance based on patient reports from medical institutions, the national government shall reevaluate the necessity of notifiable disease surveillance, taking into consideration the workload of medical institutions and public health centers as the number of patients increases, and consider an appropriate implementation system for infectious disease surveillance, including sentinel surveillance, and make the transition at an appropriate time.

In addition to the infectious disease surveillance conducted by the national government, prefectural governments, etc., shall conduct infectious disease surveillance based on their own judgment according to regional infection trends, as necessary. (MHLW; MAFF; MOE)

3-2-3. Active epidemiological investigation

- (i) In order to estimate the source of infection (retrospective active epidemiological investigation) and identify people in close contact with patients (prospective active epidemiological investigations), etc., prefectural governments, etc., shall conduct an active epidemiological investigation of infected people or groups to which infected people belong, at public health centers, etc., based on the guidelines, etc., provided by JIHS. (MHLW)
- (ii) The national government shall review the scope of active epidemiological investigation of novel influenza, etc., based on the characteristics of the infectious diseases and the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), and shall inform prefectural governments, etc., of the details of such investigation. When the characteristics of an infectious disease are found to be significantly different from those of other infectious diseases, such as infection from asymptomatic pathogen carriers, the scope of coverage and survey items should be reviewed, taking into consideration the effects acquired by active epidemiological investigation and the workload of public health centers, and the details should be made known to prefectural governments, etc. (MHLW)

- (iii) Prefectural governments, etc., shall review the scope and items of active epidemiological investigation according to the regional conditions after the initial stage of the epidemic (approximately one month after the public announcement of the outbreak, etc., of novel influenza, etc. ; the same shall apply hereinafter in this chapter), taking into consideration the characteristics of the infectious diseases, the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), outbreak status, and workload at public health centers, as well as the policy presented by the national government. (MHLW)

3-2-4. Hospitalization recommendation and measures, hospitalization coordination, coordination of home and accommodation-based recovery, and transfers

- (i) When prefectural governments, etc., identify a patient, etc., with novel influenza, etc., based on a notification from a physician, they shall promptly determine the medical treatment facility and coordinate hospitalization recommendations and measures and hospitalization, home-based recovery or accommodation-based recovery, taking into account the factors including the following: the degree of symptoms and risk of serious illness of underlying diseases of the patient as determined by the physician, the number of beds, occupancy status, and utilization rate of beds available at the medical institutions which have concluded agreements to be ascertained through the Gathering Medical Information System (G-MIS), the characteristics of the infectious diseases and the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), and the outbreak status. If the characteristics of the infectious disease or the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.) are not clear, prefectural governments, etc., shall consult with the national government and JIHS as necessary regarding measures to be taken based on the knowledge obtained, and take action based on the results of such consultation. In determining matters, such as the priority level of hospitalization and the medical institution to which the patient should be admitted, appropriate measures shall be taken in cooperation with medical institutions based on the division of roles established and organized during the preparation phase. (MHLW)
- (ii) Prefectures shall take into account factors such as the outbreak status and the need for wide-area coordination, and in order to ensure smooth coordination of hospitalization within their jurisdiction, including cities with public health

centers, establish organizations and departments (Prefectural Coordination Headquarters) with the function of coordinating patient acceptance within their jurisdiction in a timely manner, centralize the coordination of hospitalization within their jurisdiction, and exercise the authority for comprehensive coordination and instruction²²⁴, as necessary. When patients require transfer to medical institutions²²⁵ for hospitalization, to their homes, or to accommodation-based recovery facilities, the cooperation of private patient, etc., transport operators will be sought as necessary to reduce the workload of public health centers. (MHLW; relevant ministries and agencies)

- (iii) Prefectures shall request medical institutions which have concluded agreements that provide medical care to home care patients, etc., to make doctor visits and house calls, provide telephone and online medical care, dispense and deliver prescriptions and guidance on medication, and provide home nursing care, as needed, and to respond appropriately according to the conditions of the home care patients, etc. (MHLW)
- (iv) Prefectures shall operate accommodation-based recovery facilities after determining the role of each facility and the people eligible for admission according to the actual conditions of each region. (MHLW)

3-2-5. Health observation and provision of foods and daily necessities

- (i) In the case of prefectural governments, etc., identifying patients, etc., with novel influenza, etc., based on notifications from physicians and requesting the cooperation of the said patients to recuperate at home or at accommodation-based recovery facilities, taking into consideration matters, such as the degree of symptoms as determined by the physician, the characteristics of the infectious diseases and the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug sensitivity, etc.), outbreak status, the prefectures shall request voluntary restraint²²⁶ or working restrictions²²⁷ to the patient, etc., and close contacts with patient, and conduct health observations during the specified period of time, utilizing outsourcing and the cooperation from municipalities. (MHLW)

²²⁴ Articles 63-3 and 63-4 of the Infectious Diseases Control Law.

²²⁵ Article 21 as applied *mutatis mutandis* pursuant to Article 26, paragraph (2) (including cases where it is applied *mutatis mutandis* pursuant to Article 44-9) and Article 47 of the Infectious Diseases Control Law.

²²⁶ Article 44-3, paragraphs (1) and (2) and Article 50-2, paragraphs (1) and (2) of the Infectious Diseases Control Law.

²²⁷ Article 18, paragraphs (1) and (2) of the Infectious Diseases Control Law (including the cases where it is applied *mutatis mutandis* pursuant to Article 44-9 and it is applied pursuant to Article 53).

- (ii) Prefectural governments, etc., in cooperation with municipalities as necessary, shall share information, etc., on the said patients and their close contacts with patients with municipalities and endeavor to provide the services necessary for the said patients and their close contacts to lead their daily lives, such as the provision of meals, or to provide goods, such as pulse oximeters²²⁸. (MHLW)
- (iii) Prefectural governments, etc., shall improve the work efficiency and reduce the workload of public health centers by utilizing the health status reporting function of the infectious disease surveillance system for health observation of mildly ill patients or asymptomatic pathogen carriers and close contacts with patients. (MHLW)

3-2-6. Health monitoring

- (i) Upon notification from the quarantine station, prefectural governments, etc., shall conduct health monitoring at public health centers for people staying in Residences, etc., who may have been infected with novel influenza, etc.²²⁹ (MHLW)
- (ii) The national government shall conduct health monitoring on behalf of prefectural governments, etc., when requested by such prefectural governments, etc., and when it is deemed necessary in order to prevent the outbreak of novel influenza, etc., taking into consideration the systems of such prefectural governments, etc.²³⁰. (MHLW)

3-2-7. Providing and sharing of information and risk communication

- (i) Prefectural governments, etc., shall provide and share information in an easy-to-understand manner to residents, etc., in order to deepen their understanding of information on novel influenza, etc., and countermeasures against novel influenza, etc., such as actions to be taken in the event of an outbreak, during periods when an infection is spreading. (CAICM; MHLW)
- (ii) Prefectural governments, etc., in cooperation with municipalities in their area of jurisdiction, shall provide public information on infectious disease countermeasures and various support measures with easy-to-understand contents and methods while giving appropriate consideration to the needs of those who require consideration in sharing information, such as elderly people, children,

²²⁸ Article 44-3, paragraphs (7), (9) and (10) of the Infectious Diseases Control Law.

²²⁹ Article 15-3, paragraph (1) of the Infectious Disease Control Law.

²³⁰ Article 15-3, paragraph (5) of the Infectious Disease Control Law.

foreign nationals with insufficient Japanese language skills, and people with visual and hearing impairments, etc. (CAICM; MHLW)

3-3. Efforts according to the infection situation

3-3-1. Initial stage of the epidemic

3-3-1-1. Transition to a rapid response system

- (i) The national government shall monitor the status of the transition to an infectious diseases emergency system and response to infectious diseases at public health centers and public health institutes, etc. in prefectural governments, etc., in a timely and appropriate manner and provide advice and support as necessary to enable a smooth transition. (MHLW)
- (ii) Prefectural governments, etc., shall switch to the infectious disease emergency system by the start of an epidemic and monitor in a timely and appropriate manner the status of transition to the infectious disease emergency system at public health centers and the testing system during crisis at public health institutes, etc., based on the prevention plan. In addition, prefectural governments, etc., shall dispatch support staff members from their head office, request municipalities to dispatch support staff members, and request IHEAT personnel to support them, etc., as necessary, in order to secure personnel, including shift personnel. (MHLW)
- (iii) When the national government receives a request from a prefecture for coordination of wide-area dispatch based on the provisions for comprehensive coordination by the MHLW under the Infectious Diseases Control Law, etc., it shall coordinate with other prefectures so that public health nurses and other local government officials are dispatched to local governments with an increased workload, such as public health centers. (MHLW)
- (iv) Upon request from prefectures, etc., JIHS shall consider the dispatch of personnel, such as experts in the field of epidemiology, according to the actual situation of infection in the region, etc., and implement it, as necessary. (MHLW)
- (v) Prefectural governments, etc., shall promote the efficiency of operations at public health centers and public health institutes, etc., by utilizing ICT tools, such as the national infectious disease surveillance system and centralizing and outsourcing operations, etc., at the prefectural level. (MHLW)
- (vi) Prefectural governments, etc., shall conduct epidemiological surveys, health observation, and other infectious disease response operations in cooperation with related organizations based on the organizational and operational structure and

role assignments, etc., developed and organized during the preparation phase at public health centers, etc. (MHLW)

- (vii) Public health centers shall switch to the infectious disease emergency system, gather personnel for the infectious disease emergency system, procure the necessary supplies and equipment, etc. (MHLW)
- (viii) Prefectural governments, etc., should actively cooperate in research and studies led by the national government and JIHS to clarify the characteristics of the infectious diseases and the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), etc., as well as in the research and development of therapeutic agents, etc. (MHLW)

3-3-1-2. Expansion of testing systems

- (i) The national government, in cooperation with prefectural governments, etc., and JIHS, shall conduct a risk assessment based on matters, such as the characteristics of the infectious diseases, the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), and the epidemic status, and determine policies for implementation of testing. (MHLW)
- (ii) Prefectural governments, etc., based on the prevention plan, shall expand the testing system at public health institutes, etc., and institutions with which they have concluded the examination, etc., measures agreement and other measures based on the policy on testing implementation decided by the national government and the actual situation of the epidemic in the region. (MHLW)
- (iii) Public health institutes, etc., shall conduct testing based on the policies for implementation of testing, etc.
- (iv) If prefectural governments, etc., determine that testing of asymptomatic pathogen carriers is necessary based on the evaluation of matters, such as the characteristics of the infectious diseases and the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), they shall inform related organizations of the people to be tested, etc. (MHLW)

3-3-2. After the initial stage of the epidemic

3-3-2-1. Review of the system in accordance with the epidemic situation and workload

- (i) The national government shall, appropriately and in a timely manner, grasp the status of the expansion of the system of public health centers and public health institutes, etc., in prefectural governments, etc., and their response to infectious diseases, and provide advice and support to prefectural governments,

etc., as necessary to help them prevent severely excessive workloads. In addition, the national government shall consider changes in response policies for infectious disease response operations conducted by prefectural governments, etc., such as focusing on or reviewing the notifiable disease surveillance and active epidemiological investigation based on the characteristics of the infectious diseases, the characteristics of the pathogens (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), and the outbreak status, and will present policies to prefectural governments, etc., as necessary. (MHLW)

- (ii) JIHS will continue to consider the dispatch of personnel, such as experts in the field of epidemiology, based on requests from prefectural governments, etc., according to the actual situation of infection in the region and implement it, as necessary. (MHLW)
- (iii) Prefectural governments, etc., shall continue to dispatch support personnel from their head offices, request municipalities to dispatch support staff members, and request IHEAT personnel to support them, etc., as necessary, in order to secure personnel, including shift personnel. (MHLW)
- (iv) When the national government receives a request from a prefecture for coordination of wide-area dispatch based on the provisions, etc., for comprehensive coordination by the MHLW under the Infectious Diseases Control Law, it shall continue to coordinate with other prefectures so that public health nurses and other local government officials are dispatched to local governments with an increased workload, such as public health centers. (MHLW)
- (v) Prefectural governments, etc., shall continue to promote operational efficiency through centralization of operations in prefectures and outsourcing, etc., when workloads are expected to become severely excessive at public health centers. (MHLW)
- (vi) Prefectural governments, etc., shall conduct infectious disease response operations at public health centers, etc., in cooperation with related organizations based on the organizational and operational system and role assignments, etc., established and organized in the preparation phase. In addition, in cases where the national government indicates a change in the response policy based on the characteristics of the infectious diseases, the pathogen characteristics (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), the outbreak status, etc., the personnel system of public health centers and testing system of public health institutes, etc., should be reviewed, and the response to

infectious diseases should be changed in a timely and appropriate manner, taking into account regional conditions and the workload of the main offices, public health centers and public health institutes, etc. (MHLW)

- (vii) When the hospital bed occupancy rate is high, prefectural governments shall prioritize the hospitalization of patients who are likely to have severe symptoms, such as those with underlying diseases. Concurrently, prefectural governments shall strengthen the system for home-based recovery, accommodation-based recovery, or care facilities for elderly people. Additionally, efforts will be made to transfer those who have recovered from their symptoms to medical institutions which have concluded agreements providing secondary support. (MHLW)
- (viii) Prefectural governments, etc., shall implement home-based recovery based on the implementation system and medical care delivery system, such as the provision of meals, including in municipalities established in the preparation phase. (MHLW)

3-3-2-2. Ensuring stable testing and surveillance functions

- (i) The national government shall continue to implement measures at the initial stages of the epidemic and will support efforts to improve the testing system in prefectural governments, etc., and public health institutes, etc., by providing advice to prefectural governments, etc., and public health institutes, etc., in addition to obtaining information on the status of securing testing capabilities for improving and strengthening the testing systems²³¹ in public health institutes, etc., and private testing companies which have concluded an agreement on testing and other measures, based on prevention plans of prefectural governments, etc. (MHLW)
- (ii) The national government shall review the policy for implementation of testing in stages based on risk assessment, taking into comprehensive consideration the situation of infectious disease and actual conditions in each region, etc., such as cases where immunity has been acquired through vaccines, etc., or where pathogenicity or infectivity and transmissibility has decreased due to the mutation of pathogens, and review the testing system, and present the policy to the prefectural governments, etc. (MHLW)
- (iii) Public health institutes, etc., shall analyze the status of mutant strains in the region and provide and share information with entities, such as the head offices

²³¹ The “testing system” means a request to prefectural governments, etc., for the development of testing systems, etc., based on a prevention plan.

of prefectural governments, etc., and public health centers, while maintaining the expanded testing system throughout the response phase. (MHLW)

3-3-3. Period to shift to basic measures against infectious diseases not based on the Act on Special Measures

- (i) The national government requests prefectural governments, etc., to consider gradual downsizing of the crisis systems, etc., based on the characteristics of the infectious diseases, the characteristics of the pathogen (pathogenicity, infectivity, transmissibility, drug susceptibility, etc.), and the outbreak status, etc. (MHLW)
- (ii) Prefectural governments, etc., based on the request from the national government, shall consider and implement a phased reduction of the crisis systems, etc., at public health centers and public health institutes, etc., according to the actual conditions of each region. In addition, information should be carefully provided and shared with residents regarding points to be noted in the transition to basic infectious disease countermeasures not based on the Act on Special Measures (such as a review of the medical care delivery system and infectious disease measures) and the accompanying downsizing of the response at public health centers, etc. (MHLW)

Chapter 12: Supplies

Section 1: Preparation phase

(1) Purpose

Infectious disease control supplies, etc., are indispensable for the smooth implementation of quarantines, medical care, testing, etc., in crisis. Therefore, the national government and local governments, etc., shall make the necessary preparations, such as by promoting the stockpiling of infectious disease control supplies²³² so that the necessary infectious disease control supplies, etc., can be secured in crisis.

(2) Required response

1-1. Establishment of systems

- (i) The national government shall establish the necessary systems to grasp the supply-demand situation of infectious disease control supplies, etc., in crisis, utilize the emergency approval system, etc., request and instruct relevant business operators, etc., to produce or import, request shipment coordination, and instruct sales, lending, transportation, and storage, etc. In addition, the national government shall establish a system for liaison and information sharing with prefectures, etc., and related organizations in order to smoothly grasp the supply-demand situation, stabilize supply, and make requests, etc. for production, etc. (MHLW; relevant ministries and agencies)
- (ii) The national government shall adjust the production facilities for infectious disease control supplies, etc., of which it has supported introduction, so that they can be used in the event of future outbreaks of novel influenza, etc. (METI)

1-2. Stockpiling of infectious disease control supplies, etc.²³³

- (i) The national government, prefectural governments, municipalities, and designated (local) public institutions shall stockpile, etc., infectious disease control supplies, etc., necessary for implementing measures against novel influenza, etc., in accordance with the government action plan, prefectural action plan, municipal action plan, or business plan, and shall periodically check the stockpile status, etc.²³⁴. In addition, the above stockpiling may be mutually combined with the stockpiling of supplies and materials under Article 49 of the

²³² In stockpiling, etc., the recommended expiration date for use must be carefully noted.

²³³ For the stockpiling of vaccines, therapeutic drugs and laboratory supplies, see the description in the chapter on the respective countermeasure items.

²³⁴ Article 10 of the Act on Special Measures.

Basic Act on Disaster Management (Act No. 223 of 1961)²³⁵. (MHLW; all other ministries and agencies)

- (ii) The national government shall periodically check the stockpile status of infectious disease control supplies, etc., in prefectures using systems, etc., and shall request prefectures to promote and maintain stockpiles of personal protective equipment as specified in the prevention plan, and shall provide the necessary support and advice, etc. (MHLW)
- (iii) The national government shall establish stockpile items necessary for personal protective equipment and stockpile levels, and prefectures should stockpile based on these items. (MHLW)
- (iv) The national government and prefectures should request fire departments to stockpile personal protective equipment for emergency personnel, etc., and other transport workers who may first come in contact with infected people and provide the necessary support. (FDMA)

1-3. Stockpiling of infectious disease control supplies, etc., at medical institutions, etc.

- (i) Prefectures shall promote the stockpiling of personal protective equipment, etc., at medical institutions with which agreements have been concluded in the region based on the prevention plan and shall confirm the stockpile and deployment status of the necessary infectious disease control supplies, etc., at such medical institutions from the perspective of compatibility with conventional medical care during crisis, while considering the numerical targets of the medical care plan formulated by each prefecture. (MHLW)
- (ii) Medical institutions with which agreements have been concluded shall systematically stockpile personal protective equipment based on the prevention plan, in accordance with the stockpile items and stockpile levels specified by the national government. The national government and prefectures shall support medical institutions with which agreements have been concluded in establishing storage facilities for personal protective equipment. (MHLW)
- (iii) The national government and prefectures shall request medical institutions, with which agreements have been concluded, to make efforts to stockpile and arrange the necessary infectious disease control supplies, etc., other than personal protective equipment. (MHLW)
- (iv) The national government and prefectures shall also request medical

²³⁵ Article 11 of the Act on Special Measures.

institutions, etc., that have not concluded agreements to stockpile and deploy the necessary infectious disease control supplies, etc. (MHLW)

- (v) The national government and prefectures shall periodically check the stockpiling and deployment of infectious disease control supplies, etc., at the medical institutions with which they have concluded an agreement, using systems, etc.²³⁶. (MHLW)
- (vi) The national government and prefectures shall call on social welfare facilities to stockpile the necessary infectious disease control supplies, etc., as much as possible. (MHLW; Child and Family Affairs Agency)

1-4. Understanding the supply and demand situation of infectious disease control supplies, etc.

The national government shall request business operators engaged in the production, import, sale, or lending of infectious disease control supplies, etc., to report on the status of production and other matters on a regular basis in normal times and shall also request business operators engaged in the production or import of infectious disease control supplies, etc., to report on their production capacity, etc., in order to grasp their supply capacity²³⁷. (MHLW; relevant ministries and agencies)

1-5. Requests to business operators engaged in the production, import, sale, or lending of infectious disease control supplies, etc.

The national government will request business operators that produce, import, sell, or lend infectious disease control supplies, etc., to take the necessary measures to ensure, as much as possible, that a stable supply of infectious disease control supplies, etc., will not be disrupted in the event of crisis, for example, through efforts to develop a system to secure personnel, etc., in preparation for the spread of infection at their business sites. (MHLW; relevant ministries and agencies)

²³⁶ Article 36-5 of the Infectious Disease Control Law.

²³⁷ Article 53-22 of the Infectious Disease Control Law.

Section 2: Initial phase

(1) Purpose

It is important to prevent impacts on the lives and health of the people due to a shortage of infectious disease control supplies, etc., which would delay quarantine, medical care, testing, etc. The national government shall secure infectious disease control supplies, etc., necessary during crisis by appropriately checking the supply and demand situation of infectious disease control supplies, etc., and making production requests, etc.

(2) Required Response

2-1. Confirmation of the stockpiling of infectious disease control supplies, etc.

- (i) The national government shall confirm the stockpiling of personal protective equipment, etc., at prefectures and medical institutions with which it has concluded agreements by using system, etc. (MHLW)
- (ii) The national government and prefectures shall use systems, etc., to confirm the stockpile and deployment status of the necessary infectious disease control supplies, etc., taking into account the characteristics of the novel influenza, etc., at the medical institutions with which agreements have been concluded²³⁸. (MHLW)
- (iii) Prefectural governments shall request medical institutions with which they have concluded agreements to confirm the stockpile and deployment status of the necessary infectious disease control supplies, etc., based on the characteristics of the novel influenza, etc. (MHLW)

2-2. Confirmation of demand for infectious disease control supplies, etc.

The national government shall request prompt reports on the status of supply and demand of infectious disease control supplies, etc., from business operators engaged in production, import, sales, or lending, and shall confirm whether there are any shortages, etc., in the supply of infectious disease control supplies, etc., based on the reports from such business operators and past experience in infectious disease crisis management, etc.²³⁹ (MHLW; relevant ministries and agencies)

2-3. Preparations for smooth supply

- (i) When there is a risk of shortages in the supply of infectious disease control

²³⁸ Article 36-5 of the Infectious Disease Control Law.

²³⁹ Article 53-22 of the Infectious Disease Control Law.

supplies, etc., and other situations, the national government shall consider the necessary measures²⁴⁰, such as requesting production from industry associations and business operators, etc., engaged in the production, import, sales, or lending of infectious disease control supplies, etc., and shall implement them as necessary²⁴¹. (MHLW; relevant ministries and agencies)

- (ii) The national government shall request prefectures to conduct a survey on the necessary infectious disease control supplies, etc., at medical institutions with which agreements have been concluded and to secure sufficient quantities. (MHLW; relevant ministries and agencies)
- (iii) The national government shall request medical institutions, etc., to secure the necessary quantities of infectious disease control supplies, etc., in a stable manner by placing orders systematically in advance to distributors of infectious disease control supplies, etc., when there is a risk of shortage of such supplies, etc. (MHLW)
- (iv) In situations such as when a shortage of infectious disease control supplies, etc., is anticipated at medical institutions and other entities, prefectures shall work to secure the necessary amount in cooperation with the national government and business operators engaged in the production, import, sale, or lending of infectious disease control supplies, etc. (MHLW)
- (v) The national government shall prepare for the distribution of personal protective equipment to medical institutions and other entities and for emergency distribution using the system, etc. (MHLW)

²⁴⁰ In the countermeasures against COVID-19 from 2020 onward, the government purchased needles and syringes for vaccination. For ventilators, pulse oximeters, test kits, and PCR test reagents, the government requested an increase in production on the premise that unsold items would be purchased, and the government purchased unsold items. Oxygen concentrators were borrowed by the government.

²⁴¹ Article 53-16 through Article 53-20 of the Infectious Disease Control Law.

Section 3: Response phase

(1) Purpose

It is important to prevent the impact on the lives and health of the people due to a shortage of infectious disease control supplies, etc., which would delay quarantine, medical care, testing, etc. Following the initial phase, the national government shall continue to appropriately confirm the supply and demand situation of infectious disease control supplies, etc., and make production requests, etc., to secure the necessary infectious disease control supplies, etc., during crises.

(2) Required Response

3-1. Confirmation of the stockpiling of infectious disease control supplies, etc.

- (i) The national government shall confirm the stockpiling, etc., of personal protective equipment at prefectures and medical institutions with which it has concluded agreements by using the system, etc. (MHLW)
- (ii) The national government and prefectures shall use the system, etc., to confirm the stockpile and deployment status of the necessary infectious disease control supplies, etc., taking into account the characteristics of novel influenza, etc., at the medical institutions with which agreements have been concluded²⁴². (MHLW)
- (iii) The national government shall request medical institutions, etc., to appropriately confirm the stockpiling and deployment, etc., of infectious disease control supplies, etc., necessary for the provision of medical care. Furthermore, the national government shall request medical institutions to secure the necessary quantities of infectious disease control supplies etc., in a stable manner such as by systematically placing orders in advance with distributors of infectious disease control supplies etc., taking into account the possibility that such supplies may be needed over a long period of time. (MHLW)

3-2. Confirmation of the supply and demand of infectious disease control supplies, etc.

The national government shall confirm the supply and demand situation of infectious disease control supplies, etc., by requesting business operators engaged in the production, import, sales, or lending of infectious disease control supplies, etc., to report, etc., on their production, distribution, inventory status, and future production plans, etc.,²⁴³. (MHLW; relevant ministries and agencies)

²⁴² Article 36-5 of the Infectious Disease Control Law.

²⁴³ Article 53-22 of the Infectious Disease Control Law.

3-3. Requests to business operators engaged in the production, import, sale, or lending of infectious disease control supplies, etc.

The national government shall request business operators that produce, import, sell, or lend infectious disease control supplies, etc., to take the necessary measures to ensure the stable and prompt delivery of infectious disease control supplies, etc., to target regions, taking into account the possibility of a sharp increase in demand and distribution volume of infectious disease control supplies, etc., due to the spread of infection of novel influenza, etc. (MHLW; relevant ministries and agencies)

3-4. Appropriate supply of insufficient supplies

- (i) In cases where there is a shortage or is likely to be a shortage of infectious disease control supplies in the future, the national government shall request, etc., business operators, etc., engaged in the production, import, sale, or lending of such infectious disease control supplies, etc., to promote production and import, etc., or give instructions on sale, lending, transportation, or storage, etc.²⁴⁴ (MHLW; relevant ministries and agencies)
- (ii) In cases where there is still a risk of a shortage of personal protective equipment despite based on the stockpiling of personal protective equipment by prefectures and medical institutions with which agreements have been concluded as confirmed in 3-1 (i) and the above production requests, etc., to manufacturers, etc., the national government shall distribute the necessary personal protective equipment to regions and medical institutions that are in short supply. (MHLW)

3-5. Support for producers and importers for smooth supply

The national government shall take the necessary financial measures and other measures for business operators, etc., who conduct production, import, sales, or lending businesses to which it has made production requests, etc.²⁴⁵ (MHLW; relevant ministries and agencies)

3-6. Mutual cooperation in supplying stockpiled supplies, etc.

In the event of a shortage of the necessary supplies and materials in a state of emergency of novel influenza, etc., outbreak, the national government shall endeavor

²⁴⁴ Article 53-16 through Article 53-20 of the Infectious Disease Control Law.

²⁴⁵ Article 53-21 of the Infectious Diseases Control Law.

to mutually cooperate in the supply of supplies and materials, including the mutual exchange of supplies and materials stockpiled by ministries and agencies, local governments, designated (local) public institutions, and other related organizations²⁴⁶. (MHLW; all other ministries and agencies)

3-7. Transportation of emergency supplies, etc.

- (i) When it is urgently necessary to implement emergency measures, the national government and prefectural governments shall request designated (local) public institutions, which are carrier business operators, to transport emergency supplies, such as infectious disease control supplies, etc. In addition, when it is urgently necessary to implement emergency measures, designated (local) public institutions that are distributors of medicines, etc., shall be requested to deliver medicine, medical equipment, or regenerative medical products²⁴⁷. (MHLW; MLIT)
- (ii) If there is no response to the above request without justifiable reasons, designated (local) public institutions will be instructed to transport or deliver the products only when it is deemed particularly necessary to implement emergency measures²⁴⁸. (MHLW; MLIT)

3-8. Request for the sale of supplies, etc.

- (i) Prefectural governments shall, when they find it necessary to implement emergency measures, request the owners of goods, such as medicines necessary for the implementation of emergency measures, which are managed by a person engaged in the business of production, collection, sale, distribution, storage or transportation (hereinafter referred to as “specified supplies”), to sell the said specified supplies²⁴⁹. (MHLW; relevant ministries and agencies)
- (ii) When prefectural governments secure supplies necessary for the implementation of measures, prefectural governments shall generally obtain the owner’s consent to the request for the sale of the supplies in advance. In the event that the owner, etc., does not respond to the request without any justifiable reasons, such as when the supplies, etc., are unusable due to a state of emergency of novel influenza, etc., or when the supplies are already subject to expropriation by other prefectural governments, etc., the said specified supplies shall be

²⁴⁶ Article 51 of the Act on Special Measures.

²⁴⁷ Article 54, paragraphs (1) and (2) of the Act on Special Measures.

²⁴⁸ Article 54, paragraph (3) of the Act on Special Measures.

²⁴⁹ Article 55, paragraph (1) of the Act on Special Measures.

expropriated only when it is deemed particularly necessary²⁵⁰. (MHLW; relevant ministries and agencies)

- (iii) In implementing emergency measures, when there is an urgent need to secure specified supplies, prefectural governments shall order business operators to store the specified supplies as necessary²⁵¹ (MHLW; relevant ministries and agencies).
- (iv) The national government shall take measures (i) through (iii), listed above, on its own when it finds it urgently necessary to support emergency measures taken by prefectural governments or when requested to do so by prefectural governments²⁵². (MHLW; relevant ministries and agencies)

²⁵⁰ Article 55, paragraph (2) of the Act on Special Measures.

²⁵¹ Article 55, paragraph (3) of the Act on Special Measures.

²⁵² Article 55, paragraph (4) of the Act on Special Measures.

Chapter 13: National life and economy

Section 1: Preparation phase

(1) Purpose

In the event of the outbreak of novel influenza, etc., the lives and health of the people may be harmed, and the national life and socioeconomic activities may be significantly affected by the novel influenza, etc., and measures to prevent the outbreak of the novel influenza, etc. The national government and local governments shall provide and share appropriate information to business operators and the people and encourage them to make the necessary preparations while the national government and local governments make their own necessary preparations. In addition, designated (local) public institutions and registered business operators should make the necessary preparations, such as formulating business plans in order to contribute to the stability of the national life and socioeconomic activities by implementing measures against novel influenza, etc., and continuing their own businesses in the event of the outbreak of novel influenza, etc. By making these necessary preparations, a system and an environment shall be established to ensure the stability of the national life and socioeconomic activities in the event of the outbreak of novel influenza, etc.

(2) Required response

1-1. Establishing an information-sharing system

In order to collect information on the impact on the national life and socioeconomic activities when a novel influenza epidemic occurs, the national government shall establish an information-sharing system by designating a department and a person in charge as a liaison among relevant ministries and agencies and between the national government and prefectures. In addition, each ministry and agency shall establish a liaison department and person in charge with the industry associations of the industries under their jurisdiction and establish an information-sharing system.

Furthermore, prefectural governments and municipalities shall establish the necessary information-sharing system for cooperation with related organizations and among internal departments in implementing measures against novel influenza, etc. (CAICM; all other ministries and agencies)

1-2. Development of a system for the implementation of support

The national government, prefectural governments, and municipalities shall promote DX and develop appropriate systems for administrative procedures related

to the implementation of support in the event of the outbreak of novel influenza, etc., and the provision and delivery of support funds, etc. In doing so, attention should be paid to ensure that information reaches the target of support promptly and comprehensively, including elderly people, people unfamiliar with digital devices, and foreign nationals. (All ministries and agencies)

1-3. Preparation for the flexible operation of laws and regulations

From the viewpoint of ensuring the stability of the national life and socioeconomic activities, the national government shall organize specific response policies for laws and regulations, etc., that need to be flexibly applied in the event of the outbreak of novel influenza, etc. (All ministries and agencies)

1-4. Preparation for business continuity in the event of the outbreak of novel influenza, etc.

1-4-1. Recommendation and Support for the Planning of Business Continuity Plan

- (i) The national government shall, to the extent possible, recommend and provide the necessary support for the formulation of business continuity plans in the event of the outbreak of novel influenza, etc., through relevant industry associations, etc., in order for businesses to implement infectious disease measures and continue their business operations. (CAICM; ministries and agencies with business jurisdiction)
- (ii) The national government and prefectural governments shall request designated (local) public institutions to make sufficient preparations in advance, such as formulating business plans for infectious disease measures in the workplace, health management of employees, continuation of important operations and a reduction of certain operations in preparation for the outbreak of novel influenza, etc., support the formulation of such business plans, and confirm their status. (CAICM; ministries and agencies with designated public agency jurisdiction)

1-4-2. Recommendation of preparation for the introduction of flexible work styles, etc.

The national government shall inform business operators of the possibility that, in the event of the outbreak of novel influenza, etc., initiatives that reduce opportunities for human contact, such as the use of online meetings, etc., telework, and staggered work hours, may be recommended, and recommend that they consider preparations for such a situation. It should also be noted that consideration may need to be given

to employees who are legal guardians of children in the event of temporary suspension of their children's schools, etc. (CAICM; ministries and agencies with business jurisdiction)

1-5. Development of a system for transportation of emergency supplies, etc.

The national government, in cooperation with prefectural governments, to ensure the distribution and transportation of emergency supplies such as medicines and foodstuffs in the outbreak of novel influenza, etc., shall request designated (local) public institutions that manufacture, sell, and transport emergency supplies to establish a system to ensure the business continuity of distribution and transportation of emergency supplies, such as medicines and food supplies, in the event of the outbreak of novel influenza, etc. (MHLW; MLIT; relevant ministries and agencies)

1-6. Stockpiling of supplies and materials²⁵³

(i) In accordance with the National Action Plan, Prefectural Action Plan, Municipal Action Plan, or Operation Plan, the national government, prefectural governments, municipalities, and designated (local) public institutions shall stockpile not only the infectious disease control supplies, etc., as described in Chapter 12, Section 1 (Preparation phase in "supplies"), 1-2 but also other necessary food, daily necessities, etc., in implementing the measures for novel influenza, etc., pertaining to the affairs or operations under their jurisdiction²⁵⁴.

The above stockpiles may be mutually combined with the stockpiling of supplies and materials under Article 49 of the Basic Act on Disaster Management²⁵⁵. (CAICM; all other ministries and agencies)

(ii) The national government, prefectural governments, and municipalities shall recommend that businesses and the people stockpile sanitary supplies, such as masks and disinfectants, food supplies, and daily necessities, etc., in preparation for the outbreak of novel influenza, etc. (CAICM; ministries and agencies with business jurisdiction)

1-7. Preparation of support for those in need of provision of food and daily necessities

The national government shall request municipalities to cooperate with prefectural governments to identify those in need of assistance and determine specific procedures

²⁵³ For the stockpiling of vaccines, therapeutic drugs, laboratory supplies and infectious disease control supplies, etc., refer to the description in the chapter of each countermeasure item.

²⁵⁴ Article 10 of the Act on Special Measures.

²⁵⁵ Article 11 of the Act on Special Measures.

for the provision of food and daily necessities (patrols, long-term care, home-visit medical care, provision of meals, etc.), transportation, and response in the event of death, etc., to elderly people, people with disabilities, etc., and other people in need of assistance in the event of the outbreak of novel influenza, etc. (MHLW)

1-8. Identification of cremation capacity, etc., and development of cremation systems

Prefectural governments, in cooperation with the national government and municipalities, shall confirm and examine the cremation capacities of crematoriums and facilities to be used as temporary morgues, etc., and establish a system to facilitate cremations and burials. (MHLW)

Section 2: Initial phase

(1) Purpose

The national government and local governments shall prepare the necessary measures, etc., in preparation for the outbreak of novel influenza, etc., and call on business operators and the people to prepare infectious disease measures and other measures that may be necessary for business continuity. In the event of the outbreak of novel influenza, etc., the necessary measures shall be promptly taken to ensure the stability of the national life and socioeconomic activities.

(2) Required response

2-1. Request for preparations, etc., for business continuity

- (i) In preparation for the outbreak of novel influenza, etc., from the perspective of reducing opportunities for contact with potentially infected people, the national government shall request business operators to take the necessary measures to prevent the spread of infection, including thorough health management of employees as necessary, encouraging employees who show symptoms of suspected infection, etc., to take leave, using online meetings, etc., promoting telework and staggered working hours, etc. (CAICM; MHLW; ministries and agencies with business jurisdiction)
- (ii) Designated (local) public institutions, etc., shall make preparations for business continuity in cooperation with the national government and prefectures based on their business plans. The national government shall request registered business operators to make the necessary preparations for business continuity, etc. (Ministries and agencies with designated public agency jurisdiction; ministries and agencies with business jurisdiction)
- (iii) In addition to the above, the national government shall, as necessary, request business operators to prepare for outbreaks of novel influenza, etc., and to take the necessary measures, etc., to prevent the spread of infection based on their own business conditions. (CAICM; MHLW; ministries and agencies with business jurisdiction)

2-2. Call on the people and business operators for a stable supply of daily commodities, etc.

The national government shall call on the people to take appropriate actions as consumers when they purchase daily necessities, etc., (meaning food supplies, daily necessities, and other goods that are highly related to the national life or goods that

are important to the national economy; the same shall apply hereinafter), and also requests business operators to prevent prices of daily necessities from soaring, and to avoid hoarding and speculative stocking. (CAA; MHLW; MAFF; METI; relevant ministries and agencies)

2-3. Flexible application of laws and regulations

The national government shall disseminate information on the flexible operation of laws and regulations, etc., to ensure the stability of the national life and socioeconomic activities. In addition, the necessary measures shall be promptly considered and taken for other systems that have become difficult to comply with laws and regulations, etc., due to the outbreak of novel influenza, etc. (All ministries and agencies)

2-4. Cremation and placement of remains

The national government, through the prefectural governments, shall request municipalities to make preparations to secure facilities where bodies can be temporarily laid to rest, etc., in preparation for a situation where the cremation capacity of crematoriums exceeds its limit. (MHLW)

Section 3: Response phase

(1) Purpose

The national government and local governments shall take action to ensure the stability of the national life and socioeconomic activities based on the measures taken in the preparation phase. In addition, the necessary support and measures will be provided to mitigate the impact caused by the novel influenza, etc., and measures to prevent the outbreak of the novel influenza, etc. Designated (local) public institutions and registered business operators shall endeavor to ensure the stability of the national life and socioeconomic activities by implementing measures against novel influenza, etc., and continuing their own businesses in the event of the outbreak of novel influenza, etc.

Each entity shall ensure the stability of the national life and socioeconomic activities by fulfilling their respective roles.

(2) Required response

3-1. Measures to ensure the stability of the national life

3-1-1. Call on the people and business operators for a stable supply of daily necessities, etc.

The national government shall call on the people to take appropriate actions as consumers when they purchase daily necessities, and also requests business operators to prevent prices of daily necessities, etc. from soaring and to avoid hoarding and speculative stocking. (CAA; MHLW; MAFF; METI; relevant ministries and agencies)

3-1-2. Measures for mental and physical effects

The national government, prefectural governments, and municipalities shall take the necessary measures (e.g., measures against suicide, mental health, loneliness and isolation, prevention of frailty among elderly people, and measures against impacts on children's development and growth) in consideration of the possible physical and mental effects of the novel influenza, etc., and measures to prevent the outbreak of the novel influenza, etc. (MHLW; relevant ministries and agencies)

3-1-3. Support for those in need of provision of food and daily necessities

The national government shall request municipalities to provide food and daily necessities (patrols, long-term care, home-visit medical care, provision of meals, etc.),

transportation, and response in case of death, as necessary, to elderly people, people with disabilities, and other people in need of assistance, etc. (MHLW)

3-1-4. Support for continuing education and learning

In the event that restrictions on the use of schools²⁵⁶ or other requests for a temporary suspension of schools for a long period of time, etc., are made as measures against novel influenza, etc., the national, prefectural, and municipal governments shall provide the necessary support, including measures, etc., for continuing education and learning, as needed. (MEXT)

3-1-5. Notification to the people regarding service standards

The national government shall commence the grasping of the situation concerning service provision standards of business operators and, if necessary, endeavor to inform the people about the possibility of a considerable decline in service provision standards at the time of the spread of infection, such as the novel influenza, etc., and obtain their understanding. (CAICM; ministries and agencies with business jurisdiction)

3-1-6. Prevention and control of crime

In order to prevent various crimes that are expected to occur due to confusion, the national government shall endeavor to consolidate information on crimes, promote public information and awareness activities, and guide and coordinate prefectural police to ensure strict control of malicious crimes. (NPA)

3-1-7. Request for sale of supplies, etc.

- (i) When prefectures secure supplies necessary for the implementation of countermeasures, prefectures shall generally obtain the consent of the owner of the supplies to request the sale of the supplies in advance. If the said owner, etc., does not respond to the request without justifiable reasons, such as when the supplies, etc., are unusable due to a state of emergency of novel influenza, etc., or when the supplies are already subject to expropriation by other prefectural governments, the prefectural governments shall expropriate the said specified supplies only when it is deemed particularly necessary²⁵⁷. (CAICM; relevant ministries and agencies)

²⁵⁶ Article 45, paragraph (2) of the Act on Special Measures.

²⁵⁷ Article 55, paragraph (2) of the Act on Special Measures.

- (ii) In implementing emergency measures, when there is an urgent need to secure specified supplies, prefectures shall order business operators to store the specified supplies as necessary²⁵⁸. (CAICM; relevant ministries and agencies)

3-1-8. Stabilization of prices of daily supplies, etc.

- (i) In order to stabilize the national life and economy, it is necessary for the national, prefectural, and municipal governments to stabilize prices and ensure an adequate supply of daily necessities, etc. Therefore, they shall investigate and monitor prices of daily supplies, etc., to prevent them from soaring, as well as prevent hoarding and the speculative stocking of such commodities, and request relevant industry associations, etc., to ensure supply and prevent price gouging, as necessary. (CAA; MHLW; MAFF; METI; relevant ministries and agencies)
- (ii) The national government, prefectural governments, and municipalities shall endeavor to share information promptly and accurately to the people on the supply and demand balance and price trends of daily necessities, etc., and the details of measures taken, and if necessary, improve consultation and information collection services for the people. (CAA; MHLW; MAFF; METI; relevant ministries and agencies)
- (iii) When a shortage of rice, wheat, etc., occurs or is likely to occur, the national government shall consider the use of stockpiled supplies and take the necessary measures. (MAFF; relevant ministries and agencies)
- (iv) When price hikes or supply shortages of daily necessities, etc., have occurred or are likely to occur, the national, prefectural and municipal governments shall take appropriate measures in accordance with their respective action plans. (CAA; MHLW; MAFF; METI; relevant ministries and agencies)
- (v) In a state of emergency of novel influenza, etc., when there is a price hike or shortage of supplies or services that are highly related to the national life or important to the national economy, or when there is a risk of such a shortage occurring, the national, prefectural, and municipal governments shall take appropriate measures based on the Act on Emergency Measures against Acts of Buying Up or Holding Back Sales of Goods Related to Everyday Life (Act No. 48 of 1973), the Act on Emergency Measures for Stabilizing Living Conditions of the Public (Act No. 121 of 1973), the Price Control Ordinance (Imperial Ordinance No. 118 of 1946), and other laws and regulations, and take other

²⁵⁸ Act on Special Measures, Article 55, paragraph 3.

appropriate measures²⁵⁹. (CAA; MHLW; MAFF; METI; relevant ministries and agencies)

3-1-9. Special provisions for burial and cremation, etc.

The national government shall continue to take the measures described in Section 2 (initial phase) 2-4, and the national government and prefectural governments shall take measures (i) to (iv) below, as necessary.

- (i) The national government, through the prefectural governments, shall request municipalities to have crematorium operators operate cremation furnaces as much as possible. (MHLW)
- (ii) The national government, through the prefectural governments, shall request municipalities to immediately secure facilities, etc., to temporarily store remains when it becomes clear that the number of deaths will increase and exceed the limit of cremation capacity. (MHLW)
- (iii) In a state of emergency of novel influenza, etc., when it is difficult to smoothly conduct burial or cremation, and it is deemed urgently necessary, the national government shall establish special exceptions for burial and cremation procedures, such as permission for burial or cremation by municipalities other than the municipality concerned²⁶⁰. (MHLW)
- (iv) Prefectural governments shall promptly collect information related to cemeteries, crematoriums, etc., on burial and cremation of remains in a wide area and make arrangements for the transportation of the remains, etc.

3-1-10. Preservation of rights and interests of patients with novel influenza, etc.

In a state of emergency of novel influenza, etc., the national government shall examine the necessity of measures based on the Act on Special Measures concerning Preservation of Rights and Interests of Victims of Specified Disaster (Act No. 85 of 1996) and if necessary, shall designate measures that should be applied to the state of emergency of novel influenza, etc., among special measures to extend the expiration date of administrative rights and interests, to exempt from obligations not fulfilled within the time limit²⁶¹ and the like. (All ministries and agencies)

3-2. Measures to ensure the stability of socioeconomic activities

²⁵⁹ Act on Special Measures Article 59.

²⁶⁰ Act on Special Measures Article 56.

²⁶¹ Article 57 of the Act on Special Measures.

3-2-1. Requests to business operators, etc., for business continuity

- (i) The national government shall request all business operators nationwide to ensure the health management of their employees and to implement infection prevention measures at their offices and workplaces. (CAICM; MHLW; ministries and agencies with business jurisdiction)
- (ii) The national government shall provide information that contributes to business continuity (e.g., information related to infection prevention measures at workplaces and the necessary measures for employees who may have been infected) to business operators while updating the information in a timely manner. In addition, the national government, in cooperation with industry associations, shall support the preparation of infection prevention guidance for business operators, as necessary. (CAICM; ministries and agencies with business jurisdiction)
- (iii) Designated (local) public institutions, etc., shall initiate the necessary measures to properly implement their operations based on the operation plan. Registered business operators shall take measures for the continuous implementation of their services that contribute to the provision of medical care and the stability of the national life and socioeconomic activities. (Ministries and agencies with designated public institution jurisdiction; ministries and agencies with business jurisdiction)

3-2-2. Support for business operators

The national, prefectural, and municipal governments shall take the necessary financial and other necessary measures to support the affected businesses in an effective manner while paying attention to fairness in order to mitigate the impact of the novel influenza, etc., and measures to prevent the spread of novel influenza, etc., on their business operations and the national life, and to stabilize the national life and economy²⁶². (Ministries and agencies with business jurisdiction)

3-2-3. Measures taken by local governments and designated (local) public institutions to stabilize the national life and economy

Prefectural and municipal governments, or designated (local) public institutions that are entities listed under (i) through (v) below, shall take the necessary measures

²⁶² Article 63-2, paragraph (1) of the Act on Special Measures.

in accordance with their respective prefectural or municipal action plans and business plans in a state of emergency of novel influenza, etc.²⁶³

- (i) Designated (local) public institutions that are electric and gas utilities: Measures necessary for stable and appropriate supply of electricity and gas.
- (ii) Prefectural governments, municipalities, and designated (local) institutions that are water utilities, water supply business operators, and industrial water supply business operators: Measures necessary to ensure a stable and adequate supply of water.
- (iii) Designated (local) public institutions that are distributors: Measures necessary for the appropriate transport of passengers and cargo.
- (iv) Designated (local) public institutions as telecommunications business operators: Measures necessary to secure communications and to give priority to communications necessary for the implementation of emergency measures.
- (v) Designated (local) public institutions that are postal service operators and general correspondence delivery operators: The necessary measures to secure postal and letter services.

In addition, the national government or prefectural governments shall request designated (local) public institutions that are distributors to transport emergency supplies when urgently necessary for the implementation of emergency measures. In addition, the national government or prefectural governments shall request designated (local) public institutions that are distributors of pharmaceuticals, etc., to deliver the pharmaceuticals, medical care equipment, or regenerative medical care products necessary for the implementation of emergency measures²⁶⁴. (Ministries or agencies with designated public institution jurisdiction)

3-3. Measures to ensure stability of both the national life and socioeconomic activities

3-3-1. Flexible application of laws and regulations

The national government shall disseminate information on the flexible operation of laws and regulations to ensure the stability of the national life and socioeconomic activities. In addition, for other systems that have become difficult to comply with laws and regulations, etc., due to the outbreak of novel influenza, etc., the necessary measures shall be promptly considered and taken as required. (All ministries and agencies)

²⁶³ Article 52 and 53 of the Act on Special Measures.

²⁶⁴ Article 54 of the Act on Special Measures.

3-3-2. Deferment of payment of monetary obligations, etc.

The national government shall promptly examine countermeasures against possible disruption of economic order in a state of emergency of novel influenza, etc., and take the necessary measures²⁶⁵. (CAICM; relevant ministries and agencies)

3-3-3. Loans for state of emergency of novel influenza, etc.²⁶⁶

- (i) Government-affiliated financial institutions, etc., shall endeavor in advance to establish a business continuity system, etc., and shall endeavor to take appropriate measures in response to actual conditions in a state of emergency of novel influenza, etc., such as extending maturities or grace periods, refinancing old bonds, and reducing interest rates when necessary. (MOF; MHLW; MAFF; METI)
- (ii) Japan Finance Corporation, etc., shall endeavor to take appropriate measures in response to actual conditions, such as providing special loans to support the maintenance and stabilization of the business operations of affected small and medium-sized enterprises and agriculture, forestry, and fishery businesses, etc., in a state of emergency of novel influenza, etc. (MOF; MHLW; MAFF; METI)
- (iii) In a state of emergency of novel influenza, etc., when the competent minister has granted approval as prescribed in Article 11, paragraph (2) of the Japan Finance Corporation Act (Act No. 57 of 2007), Japan Finance Corporation shall conduct crises response facilitation operations so that the designated financial institutions stipulated in the same paragraph will be able to promptly and smoothly conduct crises response operations, such as lending funds and discounting bills necessary to deal with damage due to the said emergency. (MOF; MHLW; MAFF; METI)
- (iv) The national government shall take the required response, such as requesting government-affiliated financial institutions, etc., to take adequate measures, etc., as necessary. (MOF; MHLW; MAFF; METI)

3-3-4. Currency and financial stability

In a state of emergency of novel influenza, etc., the Bank of Japan, as Japan's central bank, shall take the necessary measures to contribute to the maintenance of credit orders by issuing banknotes and conducting monetary and financial adjustments as well as ensure smooth fund settlement among banks and other

²⁶⁵ Article 58 of the Act on Special Measures.

²⁶⁶ Article 60 of the Act on Special Measures.

financial institutions, in accordance with its operational plan²⁶⁷. (MOF, Financial Services Agency)

3-3-5. Support regarding the impact on employment

The national government shall provide the necessary support for employment, taking into consideration the impact on employment caused by the novel influenza, etc., and measures to prevent the outbreak of the novel influenza, etc. (MHLW)

3-3-6. Other support to mitigate the impact on the national life and socioeconomic activities

In addition to the support measures described in this chapter, the national government shall provide support as necessary to mitigate the impact on the national life and socioeconomic activities caused by the novel influenza, etc., and measures to prevent the outbreak of the novel influenza, etc. When the national government is considering support measures, it should be noted that those whose livelihoods are vulnerable, etc., will be particularly affected. (All ministries and agencies)

²⁶⁷ Article 61 of the Act on Special Measures.

Glossary

Term	Contents
Gathering Medical Information System (G-MIS)	G-MIS (Gathering Medical Information System) is a system that provides centralized monitoring and support to nationwide medical institutions, etc., regarding matters such as the operation status of medical institutions, etc., the status of hospital beds and medical care staff members, the number of patients, the number of testing, and the availability of medical care equipment (ventilators, etc.) and medical care materials (masks, protective clothing, etc.).
Medical care plan	A plan to ensure the medical care delivery system established by prefectural governments based on the provisions of Article 30-4, paragraph (1) of the Medical Care Act.
Medical care agreements	An agreement between a prefectural government and a medical institution located in the area under the jurisdiction of the said prefectural governor, as stipulated in Article 36-3, paragraph (1) of the Infectious Diseases Control Law.
Negative pressure room	A room in which the air pressure is set lower than the ambient pressure to control airflow as a measure against infectious diseases.
Epidemiology	The study of the distribution and determinants of health-relevant conditions and events in populations, as well as the application of the results of such studies to the prevention and control of health problems.
Ecosystem	A system in which various stakeholders, such as companies and universities, cooperate with each other and divide labor and collaborate.
Isolation	Admitting patients to a medical institution and separating them from the others in order to attempt to prevent the outbreak of novel influenza, etc., based on the provisions under Article 14, paragraph (1), item (i) and Article 15, paragraph (1) of the Quarantine Act (including cases where these provisions are applied according to Cabinet Order pursuant to Article 34, paragraph (1) or implemented pursuant to Article 34-2, paragraph (3) of the same Act).
Patient	People suffering novel influenza infection, etc. (including those with suspected novel influenza infection, etc., with a justifiable reason to suspect that they have such an infectious disease, and

	those who are asymptomatic pathogen carrier), people with designated infectious diseases, or those with findings of a new infectious disease.
Patients, etc.	Patients and people who may be infected.
Infectious disease intelligence	Activities to systematically and comprehensively collect, analyze, and interpret data on infectious diseases from all sources in order to detect and evaluate public health risks from infectious diseases, determine prevention and control methods, and provide this information (intelligence) for use in policy decision-making and practical decisions.
Infectious disease crisis	A situation in which novel influenza, etc., spreads rapidly throughout Japan and seriously affects the lives and health of the people, as well as the national life and economy because the majority of the population has not yet acquired immunity to the disease, etc.
Medical countermeasures	In public health crisis management, medicines and medical care devices, etc., that are of high importance and provide medical countermeasures to crises, such as saving lives, controlling epidemics, and maintaining social activities.
Infectious disease surveillance system	A system used to compile and return information, etc., reported in accordance with the provisions under Articles 12 and 14 of the Infectious Disease Control Law. The system also has a health observation function that was used in response to COVID-19.
Designated medical institutions for infectious diseases	In this National Action Plan, this term refers only to “designated medical institutions for specified infectious diseases,” “designated medical institutions for Class I infectious diseases,” and “designated medical institutions for Class II infectious diseases” among the designated medical institutions for infectious diseases stipulated in Article 6, paragraph (12) of the Infectious Diseases Control Law.
Infectious disease control supplies, etc.	As defined in Article 53-16, paragraph (1) of the Infectious Disease Control Law, medicines (medicines as defined in Article 2, paragraph (1) of the Pharmaceutical Affairs Act), medical care devices (medical care devices as defined in paragraph (4) of the same Article), personal protective equipment (personal tools to prevent exposure to pathogens, etc., by being worn), and other supplies and materials deemed essential for the production of these

	supplies.
Returnees, etc.	People returning to or entering Japan.
Seasonal influenza	An infectious disease mainly characterized by respiratory symptoms caused by influenza viruses type A, which have small antigenic changes and cause an epidemic in Japan every year, especially during the winter season, or influenza viruses type B, which do not undergo annual antigenic mutations like influenza type A viruses do.
Basic action policy	The basic policy for responding to novel influenza, etc., is based on the provisions of Article 18 of the Act on Special Measures.
Medical institutions which have concluded agreements	Medical institutions that conclude medical care agreements as stipulated in Article 36-3, paragraph (1) of the Infectious Disease Control Law. The medical institution shall implement one or more of the following medical care measures: “securing hospital beds,” “clinics for outpatients with fever,” “providing medical care to home care patients, etc.,” “logistical support,” or “dispatching medical personnel.”
Business Continuity Plan (BCP)	A plan that outlines policies, systems, procedures, etc., to ensure that important business operations are not interrupted in the event of an unforeseen event or that they can be restored in the shortest possible time, even if interrupted.
Instructions to stay in Residences, etc.	Instructions are given by the quarantine station chief to those who have received request to stay in Residences, etc., and who do not respond to the request without justifiable reasons, pursuant to the provisions of Article 14, paragraph (1), item (iv) and Article 16, paragraph (3), item (i) of the Quarantine Act (including cases where these provisions are applied according to Cabinet Order pursuant to the provisions in Article 34, paragraph (1) of the same Act), not to leave their Residences or equivalent places until the confirmation that they are not carrying pathogens, such as novel influenza, etc.
Request to stay in Residences, etc.	The quarantine station chief giving requests to a possibly infected person not to leave their residence or equivalent for a certain period (a period specified in consideration of the incubation period of such infectious disease), pursuant to the provisions of Article 14, paragraph (1), item (iii) and Article 16-2, paragraph (2) of the

	Quarantine Act (including cases where these provisions are applied according to Cabinet Order pursuant to Article 34, paragraph (1) of the same Act).
Declaration of a state of emergency	A declaration of a state of emergency of novel influenza, etc., as stipulated in Article 32, paragraph (1) of the Act on Special Measures. When it is recognized that novel influenza, etc., has occurred in Japan and that the nationwide and rapid outbreak of the novel influenza, etc., has had or is likely to have a serious impact on the national life and economy, a public announcement shall be made of the occurrence of such a situation and the period, area and details of emergency measures to be implemented, in accordance with the provisions of the same paragraph.
Emergency measures	A state of emergency measures for novel influenza, etc., as stipulated in Article 2, paragraph (4) of the Act on Special Measures. Measures taken by the national government, local governments, designated public institutions, and designated public institutions in accordance with the provisions of the Act on Special Measures to protect the lives and health of the people and to minimize the impact on the national life and economy. For example, they include requesting people not to leave their residences, etc., without permission except when necessary to maintain their livelihood, and requesting people to restrict or suspend the use of facilities used by many people.
Emergency approval	The approval system for medicines, medical care devices, in vitro diagnostic products and regenerative medical products (hereinafter in this paragraph referred to as “medicines, etc.”) prescribed in Article 14-2-2, paragraph (1), etc., of the Pharmaceutical Affairs Act. In the case where diseases that may seriously affect the lives and health of the people are breaking out, etc., the emergency approval is an approval of medicines, etc., which is urgently required to be used to prevent the outbreak of a disease likely to seriously affect the lives and health of the people and other health hazards, and along with this, when there is no appropriate method other than the use of the said medicines, etc., approval of a medicines, etc., which is presumed to have efficacy or effectiveness against the said disease.

Emergency supplies	Supplies and materials necessary for the implementation of a state of emergency measures for novel influenza, etc., as stipulated in Article 54 of the Act on Special Measures.
Genomic information	Refers to all genetic information contained by pathogens. By analyzing genomic information, it is possible to understand the status of mutations, etc.
Health observation	Under the provisions of Article 44-3, paragraph (1) or (2) of the Infectious Diseases Control Law, the prefectural governor or the mayor with a public health center shall request a person who has a justifiable reason to suspect that they are suffering from the said infectious disease or a patient of the said infectious disease to report on their health condition.
Health monitoring	The director of the quarantine station, pursuant to the provisions of Article 18, paragraph (2) of the Quarantine Act (including cases where it is applied according to Cabinet Order pursuant to Article 34-2, paragraph (1) of the same Act, or where it is implemented pursuant to Article 34-2, paragraph (3) of the same Act) or the prefectural governor or the mayor of a city with a public health center, etc., pursuant to the provisions of Article 15-3, paragraph (1) of the Infectious Diseases Control Law (including cases where it is applied according to Cabinet Order pursuant to Article 44-9, paragraph (1) of the Infectious Diseases Control Law), shall request a report on the subject's temperature and other health conditions, or ask questions.
Health crisis response plan	<p>A plan formulated by public health centers and public health institutes, etc., to systematically prepare for health crises in normal times based on the basic guidelines for the promotion of community health measures (MHLW Notification No. 374, 1994).</p> <p>In formulating the plan, it is necessary to take into account the guidelines stipulating wide-area health crisis management measures at the prefectural level, the guidelines stipulating wide-area health crisis management measures in cities with public health centers and special wards, prevention plans based on the Infectious Disease Control Law, prefectural action plans and municipal action plans based on the Act on Special Measures, and so on.</p>
Agreement on	Agreements concluded with organizations that conduct testing for

testing and other measures	pathogens, etc., and accommodation facilities, etc., in order to take prompt and appropriate measures, such as securing a system for providing testing for novel influenza, etc., and securing accommodation facilities as stipulated in Article 36-6, paragraph (1) of the Infectious Disease Control Law.
Organizations, etc., which have concluded agreements on testing and other measures	This refers to organizations that conduct testing for pathogens, etc., (private testing companies, medical institutions, etc.) and accommodation facilities that have concluded an agreement on testing and other measures as stipulated in Article 36-6 of the Infectious Disease Control Law.
Request of refraining from using public transportation	Article 14, paragraph (1), item (iii) and Article 16-2, paragraph (2) of the Quarantine Act (including cases where these provisions are applied according to Cabinet Order pursuant to Article 34, paragraph (1) of the same Act), the quarantine station chief shall request the non-use of public transportation when the returnees, etc., travels as part of measures to prevent the outbreak of infectious diseases.
Health, Labour and Welfare Sciences Research	The research supported as important and pioneering in terms of administration while creating a competitive research environment, which ensures the scientific promotion of administrative measures and improves the level of technology with regards to the people's health and medical care, welfare, living hygiene, occupational safety and health, etc., in order to obtain a new scientific foundation for solving various problems for which there is a strong social demand.
Japan Institute for Health Security (JIHS)	The Japan Institute for Health Security (JIHS) will be established in April 2025 under the Act for the Japan Institute for Health Security as a new expert organization to provide high-quality scientific knowledge to the CAICM and the MHLW. It will integrate the National Institute of Infectious Diseases and the National Center for Global Health and Medicine to provide integrated and comprehensive services, including information analysis, research, crisis response, human resource development, international cooperation, and the provision of medical care for infectious diseases and other diseases.

Personal protective equipment	Protective equipment, such as masks, goggles, gowns, gloves, etc., are created and designed to protect individuals from damage caused by contact with various pathogens, chemical substances, radioactive materials, and other hazardous factors.
Surveillance	Infectious disease surveillance refers to the identification of levels and trends in infectious disease occurrence (patients and pathogens).
Disaster Medical Assistance Team (DMAT)	DMAT (Disaster Medical Assistance Team) is a medical care team that has received specialized training and education to support the necessary medical care delivery system and protect the lives of the injured and sick in the event of a disaster or an outbreak or spread of emerging infectious diseases, etc. In addition to having the mobility to operate in the acute phase (approximately within 48 hours) at the scene of a large-scale disaster or an accident involving many injured or sick people, etc., the team also works with infectious disease specialists to coordinate hospitalization, support infection control at elderly people care facilities, etc., where outbreaks of infectious diseases have occurred, and support for the continuity of operations, etc., in the event that the number of patients with emerging infectious diseases increases and it is difficult to maintain the functions of the normal prefectural medical care delivery system, upon request by the prefectural government.
Disaster Psychiatric Assistance Team (DPAT)	DPAT (Disaster Psychiatric Assistance Team) is a disaster psychiatric assistance team with specialized training who, in the event of a disaster or the outbreak or spread of emerging infectious diseases, etc., assess the mental health medical care needs of the affected area, collaborate with other health medical care systems, manage various related organizations, etc., provide highly specialized psychiatric care, and support mental health activities. When the number of patients related to infectious diseases increases, and it is difficult to maintain the normal functioning of the mental health medical care delivery system in a prefecture, the team, together with specialists in infectious diseases, at the request of the prefectural government, coordinates the hospitalization of patients with mental disorders, supports infection control and continuation of operations at psychiatric medical institutions where

	mass infection has occurred, and so on.
Oxygen saturation	The percentage of hemoglobin in the red blood cells of blood that is bound by oxygen.
Questionnaire	Used by the quarantine station chief to inquire about a returnee's history of stay and health condition, etc., pursuant to Article 12 of the Quarantine Act.
Field Epidemiology Training Program (FETP-J)	FETP-J (Field Epidemiology Training Program) is a practical training program conducted by JIHS with the aim of training core field epidemiologists to rapidly detect infectious disease crisis management cases and establish a nationwide network of such experts to implement appropriate responses.
Designated (Local) Public Institutions	Designated public institutions as stipulated in Article 2, paragraph (7) and designated local public institutions as stipulated in Article 2, paragraph (8) of the Act on Special Measures. It includes business operators related to social infrastructure, such as electricity, gas, and railroads, as well as medical care, finance, and telecommunications.
Priority infectious disease	In public health crisis management, these are infectious diseases designated by the MHLW as those for which it is necessary to ensure the availability of highly important medical countermeasures (MCM) to save lives, control epidemics, maintain social activities, etc., and otherwise provide medical countermeasures to the crises. Under this National Action Plan, in order to serve as the basis for countermeasures against the outbreak of novel influenza, etc., under the Act on Special Measures, measures for medicines, etc., targeting priority infectious diseases will be implemented in normal times.
Priority areas	Areas that the government has publicly designated as requiring intensive measures on a priority basis to prevent the spread of infection based on the provisions of Article 31-6, paragraph (1) of the Act on Special Measures.
Resident vaccination	In accordance with Article 27-2 of the Act on Special Measures, when it is deemed urgently necessary to prevent novel influenza, etc., from causing serious damage to the lives and health of the people and undermining the stability of the national life and economy, the target population and period are specified, and the vaccinations are administered in accordance with Article 6, paragraph (3) of the Immunization Act.

Requests to stay in accommodation	<p>The quarantine station chief requesting not to exit from the accommodation facility during the following periods:</p> <ul style="list-style-type: none"> • The period until the patient is confirmed to not be carrying any pathogens, such as novel influenza, etc., based on Article 14, paragraph (1), item (iii) and Article 16-2, paragraph (1) of the Quarantine Act (including cases where these provisions are applied according to Cabinet Order pursuant to Article 34, paragraph (1) of the same Act); or • A certain period (period determined considering the incubation period of the infectious disease) for those who may have been infected, based on Article 14, paragraph (1), item (iii) and Article 16-2, paragraph (2) of the Quarantine Act (including cases where these provisions are applied according to Cabinet Order based on the provisions of Article 34, paragraph (1) of the same Act).
Syringe	In this National Action Plan, the cylinder portion of a syringe is used to administer vaccines.
Novel influenza, etc.	This refers to novel influenza infection, etc., prescribed in Article 6, paragraph (7) of the Infectious Diseases Control Law, designated infectious diseases prescribed in paragraph (8) of the same Article (limited to those pertaining to reporting under Article 14 of the Infectious Diseases Control Law) and new infectious disease prescribed in Article 6, paragraph (9) of the Infectious Diseases Control Law (limited to those that are likely to break out rapidly, nationwide). In this National Action Plan, this terminology will be used from the stage of detecting information on the occurrence of infectious diseases that may be classified as novel influenza, etc.
Public announcement of the outbreak, etc., of novel influenza infection, etc.	The Minister of Health, Labour and Welfare publicizing information, etc., specified in Article 16, paragraph (1) of the Infectious Diseases Control Law, pursuant to the provisions of Article 44-2, paragraph (1), Article 44-7, paragraph (1), or Article 44-10, paragraph (1) of the same law.
State of emergency of novel influenza,	A situation in which novel influenza, etc., as defined in Article 32 of the Act on Special Measures, has outbreaked in Japan and the nationwide and rapid spread has had or is likely to have an

etc.	enormous impact on the national life and economy, and meets the requirements specified by Cabinet Order.
Emerging infectious disease	An infectious disease that is unknown, newly recognized, and of public health concern locally or internationally.
Rapid testing kit	A testing kit that is easy to perform and allows rapid determination of results. Generally, antigen qualitative testing is used, and results can be obtained more easily and quickly than PCR or antigen quantitative testing.
Active epidemiological investigation	Investigations that are conducted on patients, suspected disease carriers, asymptomatic pathogen carriers, etc., in accordance with Article 15 of the Infectious Disease Control Law to clarify the status, trends, and causes of the occurrence of infectious diseases.
Notifiable disease surveillance	In accordance with Article 12 of the Infectious Disease Control Law, all physicians are required to report the occurrence of infectious diseases (total coverage).
Zoning	Separating areas contaminated by pathogens (contaminated areas) from uncontaminated areas (clean areas).
Consultation center	A telephone contact point for consultations from returnees, etc. who have returned from countries or regions where novel influenza, etc., has occurred, or from people who have been in close contact with patients and have a fever, respiratory symptoms, etc.
Interactive communication	Communication that not only provides one-way information by the national government but also utilizes various means to grasp and share the reactions and interests of the recipients of information so that the people, including local governments, medical institutions, and business operators, etc., can make appropriate decisions and take appropriate actions.
Basic Guidelines for the Promotion of Community Health Measures	Guidelines established by the Minister of Health, Labor and Welfare for the smooth implementation and comprehensive promotion of community health measures, based on the provisions of Article 4 of the Community Health Act.
Public health institutes, etc.	An organization of prefectures, etc., that conducts services, such as investigation or research, experiment or testing, information collection and analysis or provision, training and guidance, as

	prescribed in Article 26 of the Community Health Act (when the said prefectures, etc., have other organizations conduct the said services, refer to as the said organizations, etc.).
Sentinel surveillance	A method of ascertaining the outbreak of patients with infectious diseases for which only medical institutions designated by prefectures are notified pursuant to the provisions of Article 14 of the Infectious Diseases Control Law.
Detention	The quarantine station chief confining a possibly infected person in a medical institution, accommodation facility or vessel for a certain period of time (the period specified by Cabinet Order considering the respective incubation period for each infectious disease), pursuant to the provisions of Article 14, paragraph (1), item (ii) and Article 16, paragraph (2) of the Quarantine Act (including cases where these provisions are applied according to Cabinet Order pursuant to Article 34, paragraph (1) of the same Act, or implemented pursuant to Article 34-2, paragraph 3 of the same act.
Dual-use facilities	Facilities that can produce biopharmaceuticals according to the needs of companies in normal times and switch to vaccine production during crisis.
CAICM	The Cabinet Agency for Infectious Disease Crisis Management. In crisis due to an infectious disease crisis, the Cabinet Agency will strongly supervise the response of each ministry and agency, etc., under the Government Countermeasures Headquarters while utilizing the scientific knowledge provided by JIHS to formulate government-wide policies related to the response to an infectious disease crisis and to implement comprehensive coordination among the ministries and agencies.
Registered business operators	Business operators that provide medical care services as stipulated in Article 28 of the Act on Special Measures or businesses that contribute to the stability of the national life and economy and that have been registered by the Minister of Health, Labour and Welfare as stipulated by the Minister of Health, Labour and Welfare.
Specified measures against novel influenza, etc.	The specified measures for novel influenza, etc., as stipulated in Article 2, paragraph 2-2 of the Act on Special Measures. Measures taken by local governments pursuant to the provisions of the Act on Special Measures and the Infectious Diseases Control Law, which

	are prescribed in Article 1 of the Enforcement Order of the Act on Special Measures against Novel Influenza, etc., as particularly necessary to prevent the outbreak of novel influenza, etc.
Specified vaccination	Vaccinations given on a temporary basis in accordance with Article 28 of the Act on Special Measures when the national government deems it urgently necessary in order to ensure the provision of medical care and the stability of the national life and economy.
Specified supplies	Supplies necessary for the implementation of emergency measures prescribed in Article 55 of the Act on Special Measures (limited to medicines, food supplies, and other supplies specified by Cabinet Order), which are handled by a person engaged in the business of production, collection, sale, distribution, storage, or transportation.
Specified approval	The approval system for medicines, etc., as stipulated in Article 14-3, paragraph (1), etc., of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. An approval of medicine, etc., which is necessary to be used urgently to prevent the outbreak of diseases that may seriously affect the lives and health of the people and other health hazards in situations where such diseases are spreading, etc., and which is approved for sale, etc., in foreign countries (countries specified by Cabinet Order as having an approval system, etc., of equivalent standard to Japan's).
Prefectural coordination headquarters	An organization or department that coordinates the acceptance of patients within its jurisdiction and also coordinates the acceptance of patients in a wide area beyond the prefectural area (the name is set by each prefecture).
Prefectures, etc.	Prefectures, cities with public health centers (cities stipulated in Article 1 of the Enforcement Order of the Community Health Act (Cabinet Order No. 77 of 1948), and special wards.
Prefectural Coordination Council	An organization established by prefectures to strengthen coordination between prefectures and cities and special wards with public health centers, as stipulated in Article 10-2 of the Infectious Diseases Control Law, with its members including cities and special wards with public health centers, designated medical institutions for infectious diseases, fire departments and other related organizations within its jurisdiction.

Close contact with patients	A person who has justifiable reason to suspect that they are suffering from novel influenza, etc., through close or prolonged contact with an infected person.
Bridging research	Research to link the results of excellent basic research to practical applications, such as the development of new medicines, medical care devices, etc.
Pulse oximeter	A medical care device that measures oxygen saturation by measuring the absorption value of light through the skin.
Pandemic vaccines	Vaccines developed and manufactured to prevent the onset and severity of illness caused by novel influenza, etc.
Push-type research and development support	Research and development support up to the point of market launch, such as support for research and development with public research funds and accompanying support for practical application.
Pull-type research and development support	Research and development support by setting up market incentives to motivate companies to promote research and development by increasing the predictability of post-launch profits.
Frailty	A high-risk condition in which a person is prone to multiple problems, such as mental or psychological vulnerability and social vulnerability as well as physical vulnerability, which may lead to health problems, including disabilities related to independence in daily and social life and death.
Pre-pandemic vaccine	A vaccine developed and manufactured using a virus strain that is highly likely to cause a future pandemic and for which it is desirable to stockpile vaccines in advance. Pre-pandemic vaccines for novel influenza are manufactured based on avian influenza viruses that are highly likely to mutate into novel influenza at a stage before novel influenza occurs.
Intensive measures for prevention of the spread of infection	Intensive measures for prevention of the spread of infection of novel influenza, etc., as stipulated in Article 2, paragraph (3) of the Act on Special Measures. Measures to be taken by prefectures with jurisdiction over a certain area during the period publicly announced by the national government when it is recognized that a situation that meets the requirements specified by Cabinet Order has occurred, which are required to be intensively implemented in order

	to prevent the spread of novel influenza in a specific area where there is a risk of serious impact on the livelihood of the people and the national economy, in accordance with the provisions of Article 31-8, paragraph (1). For example, it includes requesting those who operate businesses in business categories that are deemed necessary to take measures to change their business hours, etc.
Asymptomatic pathogen carrier	A person who carries an infectious disease-causing pathogen prescribed in Article 6, paragraph (11) of the Infectious Diseases Control Act and does not present symptoms of the said infectious disease.
Modalities	This refers to the methods used to manufacture vaccines, such as live vaccines, attenuated vaccines, inactivated vaccines, recombinant protein vaccines, and mRNA vaccines.
Marketing approval	Approval granted by the Minister of Health, Labour and Welfare for the manufacturing and sale of medicines, etc., on an item-by-item basis, based on Article 14 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, etc.
Crisis	The period from the detection of information of the occurrence of an infectious disease that may be classified as novel influenza, etc., to the abolition of the Government Countermeasures Headquarters as stipulated in Article 21 of the Act on Special Measures.
Prevention plan	A plan for the implementation of measures for the prevention of infectious diseases specified by prefectures and cities with public health centers, etc., as stipulated in Article 10 of the Infectious Diseases Control Law.
Lead time	The time required from the start of a process to the completion of the entire process at a production, distribution, development, or other site. It refers not only to the period of actual work but also to the entire period from order placement to delivery. It also includes the period before work is started, waiting time, and the period for testing, transportation, etc.
Risk communication	An activity that aims to share risk information and perspectives through the exchange of information and opinions among individuals, institutions, and groups. The general concept emphasizes the interaction of various involved parties, etc., for

	appropriate risk response (decision-making based on the necessary information, behavior change, trust building, etc.).
Clinical features	A general term for the incubation period, route of infection, period with infectivity, transmissibility, symptoms, complications, etc.
Measures to ensure medical care levels at the initial period of an epidemic	A measure stipulated in Article 36-9, paragraph (1) of the Infectious Diseases Control Law, whereby prefectures provide expenses for securing medical care levels at the initial period of the epidemic to medical institutions that hospitalize patients and provide the necessary medical care by securing hospital beds or provide medical care to patients in outpatient fever clinics.
Core Clinical Research Hospital	A hospital approved by the Minister of Health, Labour and Welfare under Article 4-3 of the Medical Care Act to play a central role in international-level clinical research and investigator-initiated clinical trials in order to promote high-quality clinical research necessary for the development of innovative drugs and medical care devices originating in Japan.
Strategy for Strengthening Vaccine Development and Production System	This was determined by the Cabinet on June 1, 2021 as a national strategy for the national government to work together to rebuild the necessary systems and to make long-term, continuous efforts in order to identify the factors that have stalled vaccine development in Japan in the wake of the pandemic caused by a novel coronavirus and to make a national effort to resolve these issues.
One health approach	A collaborative effort by concerned parties to address cross-sectoral issues related to human and animal health and the environment.
AMED	Japan Agency for Medical Research and Development (AMED) is a national research and development corporation established in April 2015 as an organization that plays a central role in research and development in the medical care field and the establishment of its environment. In order to comprehensively and effectively promote consistent research and development in the medical care field from basic research to practical application, smooth practical application of the results, and the improvement of the environment for research and development in the medical care field, it conducts research and development in the medical care field, the improvement of its environment and subsidies based on the plan for promoting research and development in the medical care field

	prepared by the Headquarters for Healthcare Policy.
EBPM	Abbreviation for Evidence-Based Policy Making. It is an initiative to clarify the “basic policy framework” by (1) clarifying policy objectives, (2) clarifying the logical linkage between policy measures and objectives, such as which policy measures are truly effective in achieving those objectives, and (3) seeking as much data and other evidence as possible to support this linkage.
FF100	Abbreviation for the First Few Hundred Studies. The first few hundred or so cases are rapidly collected to obtain epidemiological and clinical information and knowledge on the characteristics of the pathogen, etc., through analysis of specimens, which is then used to determine the isolation or waiting period, medical therapeutic methods, etc.
ICT	Abbreviation for Information and Communication Technology. A general term for technologies related to information and communication. It includes devices and terminals that serve as contact points for users, networks provided by telecommunications business operators and broadcast business operators, cloud data centers, content and services, such as video and music distribution, as well as security and AI.
IHEAT personnel	Operational support personnel as defined in Article 21 of the Community Health Act. *“IHEAT” refers to a system in which regional public health nurses and other professionals support the operations of public health centers and other facilities during an infectious disease outbreak.
PCR	Polymerase Chain Reaction (PCR) is a principle for amplifying DNA, which can selectively amplify only specific DNA fragments (several hundred to several thousand base pairs).
PDCA	One of the methods to improve operations and efficiency by repeating a series of processes: Plan (planning), Do (execution), Check (evaluation), and Action (improvement).
PHEIC	Abbreviation of Public Health Emergency of International Concern. Specifically, PHEIC means an extraordinary event which is determined, as provided in the International Health Regulations (IHR): (1) to constitute a public health risk to other States through the

	international spread of disease; and (2) to potentially require a coordinated international response.
PMDA	Abbreviation of Pharmaceuticals and Medical Devices Agency. The PMDA was established on April 1, 2004 to contribute to the improvement of national health. It provides prompt relief for adverse drug reactions and health damage caused by infection via biological products, etc., (health damage relief), provides guidance and review of the quality, efficacy, and safety of medicines and medical care devices, etc., from pre-clinical trials to approval (approval review), and collects, analyzes, and provides information on safety after the market launch (safety measures).
SCARDA	Abbreviation of Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response. Based on the “Strategy for Strengthening Vaccine Development and Production System,” the Center was established on March 22, 2022 as a system to lead research and development in normal times in order to rapidly promote vaccine development as a national policy in the event of an infectious disease crisis. In normal times, the system will implement information collection and analysis on vaccine development, leading to the funding of strategic research expenses in anticipation of an infectious disease crisis. It also implements the Program on R&D of New Generation Vaccine Including New Modality Application and the Japan Initiative for World-leading Vaccine Research and Development Centers, and is responsible for management and comprehensive coordination throughout both normal times and crisis.
Category 5 Infectious Disease	Infectious diseases as defined in Article 6, paragraph (6) of the Infectious Disease Control Law. COVID-19 was positioned as a category 5 infectious disease on May 8, 2023.