

# Immunization Act

((Act No. 68 of June 30, 1948))

## Chapter I General Rules

(Purpose)

Article 1 The purpose of this Act is to contribute in maintaining the health of the people as well as promptly aiding adverse effects from vaccinations by implementing vaccinations and taking other necessary measures from the viewpoint of public health to prevent the outbreak and spread of infectious diseases.

(Definition)

Article 2 (1) The term "vaccination" as used in this Act means to inject or administer a vaccine that is known to be effective for the prevention of a particular disease as it effective immunity against that disease.

(2) The term "category A diseases" as used in this Act refers to the diseases as listed below:

- (i) diphtheria;
- (ii) pertussis;
- (iii) polio (acute myelitis);
- (iv) measles;
- (v) rubella;
- (vi) japanese encephalitis;
- (vii) tetanus;
- (viii) tuberculosis;
- (ix) Hib infection (Haemophilis influenza type B);
- (x) pneumococcal infectious disease (limiting to one that is of infants);
- (xi) human papilloma virus infection; and
- (xii) beyond the diseases listed in the preceding items, diseases provided for by Cabinet Order as diseases against which vaccinations are deemed a required necessity to prevent an outbreak and a spread from person to person, or to prevent a outbreak or a spreading as the condition of a person infected can become serious or will likely become serious.

(3) The term "category B diseases" as used in this Act means the diseases as listed below:

- (i) influenza; and
- (ii) Beyond the diseases listed in the preceding items, diseases provided for by Cabinet Order as diseases against which vaccinations are deemed a required

necessity to prevent individuals from developing the disease or the condition from getting worse, and to contribute to preventing the disease from spreading.

- (4) The term "routine vaccination" as used in this Act means the vaccination as listed below:
- (i) the vaccination under Article 5, paragraph (1); and
  - (ii) a vaccination that meets the standards specified by the Minister of Health, Labour and Welfare as a vaccination equivalent to the vaccination listed in the preceding item, and is performed by a person other than the mayor of municipality.
- (5) The term "temporary vaccination" as used in this Act means vaccinations as listed below:
- (i) vaccination under Article 6, paragraphs (1) or (3); and
  - (ii) a vaccination that meets the standards specified by the Minister of Health, Labour and Welfare as a vaccination equivalent to the vaccination listed in the preceding item, and is performed by a person other than the prefectural governor and the mayor of a municipality after the date on which designation under Article 6, paragraphs (1) or (3) was executed, and until the designated date or the date of expiration of their designated term.
- (6) The term "routine vaccination, etc." as used in this Act means a routine vaccination or a temporary vaccination.
- (7) The term "custodian" as used in this Act means a person who exercises a parental authority or a guardian.

## **Chapter II National Immunization Plan**

(National Immunization Plan)

Article 3 (1) In order to comprehensively and systematically promote measures for vaccination, the Minister of Health, Labour and Welfare must provide a basic plan for vaccination (hereinafter referred to as the "national immunization plan" in this Chapter and of Article 24, item (ii)).

- (2) The national immunization plan is to specify the following matters:
- (i) a basic direction on the comprehensive and systematic promotion of measures concerning vaccinations;
  - (ii) matters concerning the division of roles with respect to vaccination by national government, local government and other related organizations;
  - (iii) matters concerning targets related to comprehensive and systematic promotion of measures concerning vaccination;
  - (iv) basic matters to promote measures concerning the proper implementation of vaccinations;
  - (v) basic matters to promote measures for promoting research and development

- of vaccinations and securing the supply of vaccines;
  - (vi) basic matters to promote measures for improving the effectiveness and safety of vaccinations;
  - (vii) matters concerning the international cooperation regarding vaccinations; and
  - (viii) Other important matters concerning the comprehensive and systematic promotion of measures concerning vaccinations
- (3) The Minister of Health, Labour and Welfare is to review the national immunization plan at least every five years and if necessary, make any changes.
- (4) If the Minister of Health, Labour and Welfare intends to provide or change the national immunization plan, the Minister must consult with the head of the relevant administrative organ in advance.
- (5) If the Minister of Health, Labour and Welfare provides or changes the national immunization plan, the Minister must make it public without delay.

(Individual Vaccination Promotion Guideline)

Article 4 (1) Among category A diseases and category B diseases regarding the one specified by the Order of the Minister of Health, Labour and Welfare as particularly necessary to comprehensively promote vaccination, the Minister of Health, Labour and Welfare must provide a guideline to promote vaccination against the diseases by each relevant disease (hereinafter referred to as "individual vaccination promotion guideline" in this Article and Article 24, item (ii)) in accordance with the national immunization plan . .

- (2) The individual vaccination promotion guideline is to specify the following matters:
- (i) matters concerning the significance, effectiveness, and safety of the vaccination against the disease;
  - (ii) matters concerning enlightenment and dissemination of knowledge on the vaccination against the disease;
  - (iii) matters concerning measures for the proper implementation of vaccination against the disease;
  - (iv) matters concerning the promotion of research and development for vaccination against the disease and securing the supply of the vaccine; and
  - (v) other important matters concerning the promotion of vaccination against the disease.
- (3) If the guidelines for the prevention of specified infectious diseases are created pursuant to the provisions of Article 11, paragraph (1) of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 1998, referred to as the "Infectious Disease Act" in Article 6, paragraph (1) of the supplementary provisions), individual

- vaccination promotion guidelines must be included as an integral part of the aforementioned guidelines for the prevention of specified infectious diseases.
- (4) If the Minister of Health, Labour and Welfare provides or changes the individual vaccination promotion guidelines, the Minister must make it public without delay.

### **Chapter III Implementation of Routine Vaccination**

(Vaccination Implemented by the Mayor of Municipality)

- Article 5 (1) Among category A and category B diseases regarding the one specified by Cabinet Order, the mayor of municipality must administer a vaccination to a person who lives in the area of the relevant municipality and is provided for by Cabinet Order by designating a date or a period upon receipt of the direction by the head of a health center (or the prefectural governor in case of a special ward and the city provided for by Cabinet Order based on the provisions of Article 5, paragraph (1) of Community Health Act (Act No. 101 of 1947) (referred to as "the city where a health center is established" in Article 10)).
- (2) Among the diseases pursuant to the preceding paragraph regarding the disease specified by Cabinet Order, taking into account of the state of the outbreak, etc. of the relevant disease, the prefectural governor may designate a specified area within the prefecture where vaccination against the relevant disease is recognized as unnecessary.
- (3) If a designation has been made pursuant to the preceding paragraph, and the entire area of municipality is included in the area of the relevant designation, the mayor of the municipality does not need to implement vaccination against the designated disease irrespective of the provisions in paragraph (1).

(Temporary Vaccinations)

- Article 6 (1) If the prefectural governor finds an urgent need to prevent a disease spreading specified by the Minister of Health, Labour and Welfare among category A and category B diseases, the governor may designate recipients, the date or the period and implement a temporary vaccination or instruct the mayor of the municipality to do so.
- (2) If the Minister of Health, Labour and Welfare finds an urgent need to prevent the disease pursuant to the preceding paragraph from spreading, the Minister may instruct the prefectural governor to implement a vaccination set forth in the same paragraph pursuant to the provisions of Cabinet Order.
- (3) Among category B diseases, regarding the one specified by the Minister of Health, Labour and Welfare in consideration of the degree of the symptoms of the disease, if the Minister finds an urgent need to prevent a disease from

spreading, the Minister may designate recipients, the date or the period and direct the mayor of the municipality through the prefectural governor to implement a temporary vaccination pursuant to the provisions of Cabinet Order. In this case, the prefectural governor is to provide necessary cooperation with the mayor of the municipality involved in helping them to smoothly implement the relevant vaccination within the areas of the relevant prefecture.

(When Vaccinations Are Not to Be Implemented)

Article 7 If the mayor of the municipality or the prefectural governor implement vaccinations under Article 5, paragraph (1) or paragraphs (1) or (3) in the preceding article, they are to examine the health condition of the person who is to undergo the vaccination by the method provided for by Order of the Ministry of Health, Labour and Welfare, and if it is recognized that the person is a candidate who is not suitable for the vaccination under the relevant Order, the person must not be vaccinated.

(Recommendations for Vaccination)

Article 8 (1) The mayor of the municipality or the prefectural governor is to recommend a routine vaccination against category A diseases or temporary vaccination to the recipient of a vaccination against category A diseases pursuant to the provisions of Article 5, paragraph (1), or a vaccination pursuant to the provisions of Article 6, paragraphs (1) or (3).

(2) If the recipient of a vaccination in the preceding paragraph is under sixteen years of age or is an adult ward, the mayor of the municipality or the prefectural governor is to recommend the custodian to have the recipient undergo a routine vaccination against category A diseases or a temporary vaccination.

(Duty to Endeavor to Receive Vaccination)

Article 9 (1) The recipient of a vaccination against category A diseases pursuant to the provisions Article 5, paragraph (1) or a vaccination pursuant to the provisions of Article 6, paragraphs (1) must endeavor to undergo a routine vaccination against a category A diseases or a temporary vaccination (excluding those pertaining paragraph (3)of the same Article).

(2) If the recipient of a vaccination in the preceding paragraph is under sixteen years of age or an adult ward, the custodian must endeavor to take necessary measures to have the recipient undergo a routine vaccination against category A diseases or a temporary vaccination (excluding those pertaining to Article 6, paragraph (3))

(Delegation to Head of Health Center)

Article 10 The prefectural governor, or the mayor of the city or special ward where a health center is established may delegate administrative work for vaccination pursuant to the provisions of Article 5, paragraph (1) or Article 6, paragraphs (1) or (3) to the head of the health center.

(Delegation to Cabinet Order and Order of the Ministry of Health, Labour and Welfare)

Article 11 Beyond what is provided for in this chapter, necessary matters concerning public notices, public disseminations, records and reports on implementation of vaccinations are specified by Cabinet Order, and other necessary matters concerning the implementation of vaccinations by Order of the Ministry of Health, Labour and Welfare.

#### **Chapter IV Measures for Proper Implementation of Routine vaccinations**

(Report of Symptoms Suspected to Be Caused by Routine Vaccination)

Article 12 (1) If the establisher of a hospital, or clinic, or a medical doctor recognizes a person who underwent a routine vaccination shows symptoms of a disease that are suspected as a result of a routine vaccination, etc. pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, they must report the details to the Minister of Health, Labour and Welfare pursuant to the provisions of the relevant Order.

(2) If the Minister of Health, Labour and Welfare receives a report pursuant to the provisions of the preceding paragraph, the Minister is to notify the mayor of the municipality or the prefectural governor of the matter pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare without delay.

(Measures for Proper Implementation of Routine Vaccinations)

Article 13 (1) Each fiscal year, the Minister of Health, Labour and Welfare is to inform the Health and Science Council on the status of the report under the provisions of paragraph (1) of the preceding Article, and if necessary, hear the opinions of the council, and take other necessary measures and provide information on the safety of routine vaccinations, etc. for the proper implementation of routine vaccinations, etc.

(2) Beyond the measures under the provisions of the preceding paragraph, the Health Science Council may study and deliberate on measures for proper implementation of routine vaccination including provision of information on the safety of routine vaccinations, etc., and if necessary, give their opinions to the Minister of Health, Labour and Welfare.

- (3) In conducting a report or measures pursuant to the provisions of paragraph (1), the Minister of Health, Labour and Welfare is to compile the information pertaining to the report under the provisions of paragraph (1) of the preceding Article or conduct investigations concerning the report.
- (4) If the Minister of Health, Labour and Welfare finds it necessary for the proper implementation of routine vaccinations, etc., the Minister may seek cooperation necessary for the implementation of an investigation pursuant to the provisions of the preceding paragraph with the prefectural government, establishers of hospitals or clinics, medical doctors, vaccine manufacturers and sellers (those who are licensed to manufacture and sell pharmaceuticals for business under Article 12, paragraph (1) of the Pharmaceutical Affairs Act (Act No. 145 of 1960) and approved to manufacture and sell vaccines (meaning "manufacture and sell" as provided for in Article 2, paragraph (12) of the same Act; the same applies in Article 6, paragraph (1) of the supplementary provisions) under Article 14 of the same Act (including those who seek that approval); the same applies in Article 23, paragraph (5)), persons who have undergone a routine vaccination, etc. or their custodians, and other parties concerned.

(Compilation and Investigation of Information by an Organization)

- Article 14 (1) The Minister of Health, Labour and Welfare may allow the incorporated administrative agency of National Institute of Pharmaceutical and Medical Devices (hereinafter referred to as "the organization" in this Article) to compile the information provided for in paragraph (3) of the preceding Article.
- (2) If the Minister of Health, Labour and Welfare finds that the investigation pursuant to the provisions of paragraph (3) of the preceding Article is necessary for conducting a report or measures pursuant to the provisions of paragraph (1) of the same Article, the Minister may have the organization conduct it.
- (3) If the organization compiles information pursuant to the provisions of paragraph (1) or conducts an investigation pursuant to the provisions of the preceding paragraph, it must notify the Minister of Health, Labour and Welfare of the results of the compilation or the investigation, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare without delay.

## **Chapter V Remedial Measures of Damage to Health by Routine Vaccinations**

(Remedial Measures of Damage to Health)

- Article 15 (1) If a recipient who underwent a routine vaccination, etc. while living in an area of municipality that becomes infected with a disease, develops a disability, or dies, and the Minister of Health, Labour and Welfare certifies that the disease, disability, or death was caused by the relevant routine vaccination etc., the mayor of the relevant municipality is to as provide payment pursuant to the provisions of the following Article and Article 17.
- (2) When giving the certification set forth in the preceding paragraph, the Minister of Health, Labour and Welfare must hear the opinions of those persons who are provided for in Cabinet Order at the council, etc. (referred to as organs pursuant to Article 8 of the National Government Organization Act (Act No. 120 of 1948)).

(Scope of Payment)

- Article 16 (1) With regard to the disease, the disability or death caused by a routine vaccination against category A diseases or a temporary vaccination against category B diseases, the payments pursuant to the provisions of paragraph (1) of the preceding Article are to be as set forth in the following items and provided to persons specified in the respective items:
- (i) medical expenses and medical benefits: A person who undergoes a medical treatment of a disease due to a given vaccination;
  - (ii) child disability assistance pension: A person who takes care of those under eighteen years of age who are in a state of disability due to given vaccination, as specified by Cabinet Order;
  - (iii) disability pension: A person who is eighteen years of age or more, who is in a state of disability as determined by Cabinet Order as a result of being vaccinated;
  - (iv) lump sum payment: A surviving family of a person who died of a given vaccination, specified by Cabinet Order; and
  - (v) funeral rite expenses: A person who performs funeral rites for a person who died due to a given vaccination.
- (2) With regard to the disease, the disability or the death caused by a routine vaccination against category B diseases, the payments pursuant to the provisions of paragraph (1) of the preceding Article are to be as set forth in the following items and provided to persons specified in the respective items.
- (i) medical expenses and medical benefits: A person who undergoes a medical treatment of a disease due to a given vaccination, as determined by Cabinet Order;
  - (ii) child disability assistance pension: A person who cares for those under eighteen years of age who are in a state of disability as determined by Cabinet Order as a result of a given vaccination.;
  - (iii) disability pension: A person who is over eighteen years of age and in a

state of disability due to a given vaccination, as determined by Cabinet Order;

- (iv) pension for a surviving family or lump sum payment for a surviving family: A surviving family of a person who died due to a given vaccination, specified by Cabinet Order; and
- (v) funeral rite: A person who performs funeral rites for a person who died due to given vaccination.

(Delegation to Cabinet Order)

Article 17 (1) Beyond what is provided for in the preceding Article, the amount of payments under the provisions of Article 15, paragraph (1), (hereinafter referred to as "payment"), the method of payment and other necessary matters concerning payments are to be specified by Cabinet Order.

(2) Cabinet Orders from paragraph (2), items (i) through (iv) of the preceding Article and Cabinet Orders based on the provisions of the preceding paragraph pertaining to the payment pursuant to the provisions of the same paragraph are to be provided for with reference to Cabinet Orders from Article 16, paragraph (1), items (i) through (iv) pertaining to the side effect relief payment provided for in Article 15, paragraph (1), item (i) of the Act on Pharmaceuticals and Medical Device Agency, Independent Administrative Agency (Act No. 192 of 2002) and Cabinet Orders based on the provisions of paragraph (3) of the same Article.

(Adjustment with Compensation of Damages)

Article 18 (1) If the person receiving payments receives compensation of damages for the same reasons, the mayor of the municipality may choose not to provide payment up to the amount of the payment.

(2) If the person who received a payment receives compensation of damages for the same reason, the mayor of the municipality may have a person return the amount equivalent to the received amount up to the amount of payment .

(Collection of Unjust Enrichment)

Article 19 (1) When the mayor of the municipality finds that there is a person who has received a payment through deception or other wrongful means, the mayor may collect all or a part of the amount equivalent to the received amount of payment using the same rules as those for the collection of national tax .

(2) The order of statutory liens on the amount collected pursuant to the provisions of the preceding paragraph comes after national taxes and local taxes.

(Protection of the Right to Receive Payments)

Article 20 The right for receiving payment may not be transferred, mortgaged or attached.

(Prohibition of Public Charges)

Article 21 Taxation and other public charges may not be imposed based on the money received as payments.

(Promotion of Health and Welfare Projects)

Article 22 The national government is to promote projects responding to consultations by families as well as health care and public aid projects concerning the medical treatment and nursing care ,etc. of persons who receive nursing care at their residence, and is a recipient of a payment listed in Article 16, paragraph (1), items (i) through (iii) or paragraph (2), items (i) through (iii) in the same Article.

## **Chapter VI Miscellaneous Provisions**

(Responsibility of the National Government)

- Article 23 (1) In order for the citizens to be vaccinated having the proper understanding, the national government is to strive to educate and disseminate knowledge regarding vaccinations.
- (2) In order to ensure smooth and proper implementation of vaccinations, the national government is to take necessary measures such as promoting the research of vaccines, and taking the necessary measures to secure the supply of vaccines.
- (3) In order to prevent damage to health caused by vaccinations, the national government is to take necessary measures, such as implementing training for persons engaged in administering vaccinations.
- (4) The national government is to conduct surveys on the status of the acquired immunity through vaccinations, the occurrence of damage to health, and other necessary investigations and research for improving the effectiveness and safety of vaccinations.
- (5) The establishers of a hospital or clinic, a medical doctor, a vaccine manufacturer and seller, a person who has undergone a vaccination or the custodian, and other parties concerned are to endeavor to offer necessary cooperation with the national government carrying out its responsibility in the preceding each paragraph.

(Hearing the Opinions of the Health Science Council)

Article 24 The Minister of Health, Labour and Welfare must hear the opinions of

the Health Science Council in advance for the following cases:

- (i) when intending to enact, revise or abolish the Cabinet Order under Article 2, paragraph (2), item (xii), paragraph (3), item (ii) and Article 5, paragraphs (1) and (2);
- (ii) when providing for or changing the national immunization plan and the individual vaccination promotion guideline;
- (iii) when providing for diseases prescribed in Article 6, paragraphs (1) and (3);
- (iv) when making an order pursuant to the provisions of Article 6, paragraphs (2) and (3); and.
- (v) when intending to enact, revise or abolish the Order of the Ministry of Health, Labour and Welfare of Article 7 that provides for a person who is not suitable to receive the vaccination, the Order of the Ministry of Health, Labour and Welfare of Article 11 (matters to be determined based on medical knowledge) and the Order of the Ministry of Health, Labour and Welfare of Article 12, paragraph (1) that provides for the symptoms of a disease that are suspected to be as a result of the routine vaccinations, etc.

#### (Payment of Expenses Required for Vaccinations)

Article 25 (1) The expenses required for vaccinations pursuant to the provisions of this Act are to be paid by municipalities (prefectures or municipalities for vaccination under the provisions of Article 6, paragraph (1)).

(2) The municipality pays the expenses required for a payment.

#### (Burden of Prefectural Government)

Article 26 (1) The prefecture is to bear two thirds of the amount to be paid by the municipality (limited to those pertaining to vaccination under the provisions of Article 6, paragraph (1)) pursuant to the provisions of paragraph (1) in the preceding Article, in accordance with Cabinet Order provisions.

(2) The prefecture is to bear three-fourths of the sum of amount to be paid by the municipality (limited to those pertaining to vaccinations under the provisions of Article 6, paragraph (3)) pursuant to the provisions of paragraph (1) in the preceding Article and the amount to be paid pursuant to the provisions of paragraph (2) in the preceding Article in accordance with Cabinet Order.

#### (Burden on the National Treasury)

Article 27 (1) The national treasury is to bear one-half of the amount to be paid by the prefecture pursuant to the provisions of Article 25, paragraph (1) and the amount the prefecture is to pay back pursuant to the provisions of paragraph (1) of the preceding Article in accordance with the provisions of Cabinet Order,.

(2) The national treasury is to bear two-thirds of the amount borne by the

prefecture pursuant to the provisions of paragraph (2) of the preceding Article.

(Collection of Actual Costs)

Article 28 Those who carried out a vaccination pursuant to the provisions of Article 5, paragraph (1) or Article 6, paragraph (3) may collect the actual costs from those who underwent the vaccination or their custodian to the provisions of Cabinet Order; provided, however, that this does not apply when the Minister finds that the person cannot bear the costs due to economic reasons.

(Classification of Processes)

Article 29 The administrative processes that are to be taken by the prefectural government pursuant to the provisions of Article 6 and the administrative processes that are to be taken by municipality pursuant to the provisions of paragraphs (1) and (3) in the same Article Article 15, paragraph (1), Article 18 and Article 19, paragraph (1) are to be Type 1 statutory entrusted functions as provided in Article 2, paragraph (9), item (i) of the Local Autonomy Act (Act No. 67 of 1947).

### **Supplementary Provisions [Extract]**

(Effective Date)

Article 1 This Act comes into force as of July 1, 1948; provided, however, that the effective dates of the provisions of Articles 13 and 14 are each provided for by Cabinet Order by June 30, 1949.

Article 5 (1) The smallpox vaccination Act (Act No. 35 of 1909) is to be abolished; provided, however, that prior Acts continue to govern the applicability of penal provisions to conduct that a person engages in before this Act comes into effect.

(2) The first dose of vaccination pursuant to the provisions of Article 1 of the smallpox vaccination Act prior to the enforcement of this Act is deemed to have been made pursuant to the provisions of Article 10, paragraph (1), item (i).

(3) At the time of enforcement of this Act, if the person receiving the vaccine is a person enrolled in elementary school who has not yet received the second dose of the vaccination pursuant to the provisions of Article 1 of the smallpox vaccination Act, the mayor of the municipality must designate the due date and have them vaccinated

(Indemnity Agreement)

Article 6 (1) If it recognized that a new type of influenza, etc. infectious diseases vaccine (meaning a "vaccine" against infectious diseases such as a new type of influenza prescribed in Article 6, paragraph (7) of the Infectious Disease Act,

the same applies hereinafter) is urgently needed to secure the life and health of the people, as there is a chance of a significant shortage in the supply and demand of the vaccine on a global scale or a likely shortage of the vaccine within five years from the date of the enforcement of the Act partially amending the Immunization Act and Act on Special Measures concerning relief, etc. of health hazards by the new type of influenza vaccination (Act No. 85 of 2011), the Minister of Health, Labour and Welfare as a counterparty to the manufacturer and seller of a purchase contract of the new type of influenza, etc. infectious disease vaccine (limiting to a person who is granted permission to be engaged in the business of manufacturing and sales of pharmaceuticals in Article 12, paragraph (1) of the Act concerning the security of the quality, availability, and safety, etc. of pharmaceuticals, medical devices, instruments, machinery, etc.), and also approved to manufacture and sell the new type of influenza, etc. infectious diseases vaccine in Article 14 of the same Act, pursuant to the provisions of paragraph (1), Article 14-3 of the same Act (including a person who is trying to be approved) the government may enter into a contract (hereinafter referred to as the "indemnity agreement") to the effect that the government promises to compensate for a necessary losses that the national government needs to compensate for, based on damages that have arisen as a result of the new type of influenza, etc. infectious diseases vaccine causing damages to health and losses occurred based on the nature of the relevant new type of influenza, etc. infectious diseases vaccine of the relevant purchase contract.

- (2) When the Minister of Health, Labour and Welfare concludes a purchase contract set forth in the preceding paragraph (limited to the purchase contract in the case of concluding an indemnity agreement on the new type of influenza etc., infectious disease vaccine relevant to the purchase contract), the decision must be made in advance by Cabinet Order.
- (3) The Government must get the approval of the Diet over the conclusion of the relevant indemnity before concluding the indemnity agreement; provided, however, that when urgently required, the government may conclude the relevant indemnity (limited to the approval of the Diet under the provisions of the preceding paragraph to which the conditions take effect) without getting the approval of the Diet.
- (4) If the Government has concluded the indemnity agreement without getting the approval of the Diet pursuant to the provisions of the proviso in the preceding paragraph, it must immediately get the approval of the Diet over the conclusion of the relevant indemnity agreement.

**Supplementary Provisions [Act No. 96 of March 31, 1951] [Extract]**

(Effective Date)

- (1) This Act comes into force as of April 1, 1951.

**Supplementary Provisions [Act No. 120 of April 2, 1951]**

This Act comes into force as of the date of promulgation.

**Supplementary Provisions [Act No. 213 of August 15, 1953] [Extract]**

- (1) This Act comes into force as of September 1, 1953.
- (2) Permissions, approvals, and other dispositions, applications, notifications and other procedures that were implemented under the provisions of precedent laws and regulations before the enforcement of this Act are to be deemed as dispositions or procedures, respectively implemented on the basis of the corresponding provisions after the amendment.

**Supplementary Provisions [Act No. 136 of June 1, 1954] [Extract]**

(Effective Date)

- (1) This Act comes into force as of the date of promulgation.

(Transitional Provision Concerning Penal Provisions)

- (4) Prior Acts continue to govern the applicability of penal provisions to conduct that a person engages in before this Act comes into effect.

**Supplementary Provisions [Act No. 66 of April 19, 1958] [Extract]**

(Effective Date)

- (1) This Act comes into force as of July 1, 1958.

**Supplementary Provisions [Act No. 7 of March 28, 1961] [Extract]**

(Effective Date)

- (1) This Act comes into force as of April 1, 1961.

**Supplementary Provisions [Act No. 60 of April 16, 1964] [Extract]**

(Effective Date)

- (1) This Act comes into force as of the date of promulgation.

**Supplementary Provisions [Act No. 169 of July 11, 1964] [Extract]**

(Effective Date)

(1) This Act comes into force as of April 1, 1965.

(Transitional Provisions)

(5) Beyond what is provided for in the preceding three paragraphs, transitional measures that need to be set in place for enforcing this Act are provided for by Cabinet Order.

### **Supplementary Provisions [Act No. 111 of June 1, 1970]**

(Effective Date)

(1) This Act comes into force as of the date of promulgation.

### **Supplementary Provisions [Act No. 69 of June 19, 1976] [Extract]**

(Effective Date)

Article 1 (1) This Act comes into force as of the date of promulgation; provided, however, that the provisions of Article 2, Article 3 and Articles 3 through 5 of supplementary provisions come into effect as of the date specified by Cabinet Order within a period not exceeding one year from the day of promulgation.

(2) The provisions of Article 16, paragraph (1) of the Immunization Act after its amendment pursuant to the provisions of Article 2 and the provisions of Article 21-2, paragraph (1) of the Tuberculosis Control Act after its amendment pursuant to the provisions of Article 3, apply to symptoms, disablement, and death caused by the vaccination implemented after the date specified by Cabinet Order in the preceding paragraph.

(Transitional Measures Concerning Penal Provisions)

Article 2 Prior Acts continue to govern the applicability of penal provisions to conduct that a person engages in before this Act comes into effect.

(Measures Concerning Relief of Damage to Health Caused by Vaccination Then in Force)

Article 3 (1) If a person was vaccinated pursuant to the provisions of the Immunization Act or the Tuberculosis Control Act or was vaccinated with a vaccine which the Minister of Health, Labour and Welfare provided for as equivalent thereto before the date provided for by Cabinet Order in the proviso to Article 1, paragraph (1) of the supplementary provisions becomes infected with a disease, becomes disabled or dies on or after the date of the vaccination, and the Minister of Health, Labour and Welfare certifies that the relevant

disease, disablement, or death was caused by the vaccination, the mayor of the municipality in which the person resided at the time of the relevant vaccination, as provided for by Cabinet Order, makes a payment equivalent to the payment pursuant to the provisions of Article 16, paragraph (1) of the Immunization Act to the person.

- (2) The provisions of Article 15, paragraph (2), Articles 18 through Article 21, Article 25, paragraph (2), Article 26, paragraph (2), and Article 27, paragraph (2) of Immunization Act apply mutatis mutandis to the payment pursuant to the provisions in the preceding paragraph.

#### **Supplementary Provisions [Act No. 55 of May 23, 1978] [Extract]**

(Effective Date)

- (1) This Act is to come into force as of the date of promulgation; provided, however, that the provisions set forth in the following items are to come into effect as from the date specified in each of the relevant items:
- (i) the provisions in Article 49 to amend Article 16-3, paragraph (3), and paragraph (4) of the Mental Health Act and the provisions in Article 59 to amend Article 70 of the Forest Act: the day when a period of six months has passed from the date of promulgation; or
  - (ii) the provisions of Article 1 (excluding the part concerning the council for measures for areas susceptible to typhoons) and the provisions of Article 6 through Article 9, the provisions in Article 10 to amend Article 7, paragraph (1) of the Act on Special Measures for the Amami Islands Promotion and Development, the provisions Article 11, Article 12 and Articles 14 through 32: the date prescribed by Cabinet Order within a period until March 31, 1979.

#### **Supplementary Provisions [Act No. 66 of July 16, 1982]**

This Act comes into force as of October 1, 1982.

#### **Supplementary Provisions [Act No. 51 of June 29, 1994] [Extract]**

(Effective Date)

Article 1 This Act comes into force as of October 1, 1982.

Article 2 Deleted.

Article 3 Deleted.

Article 4 A person (including a person who is deemed to have been vaccinated (by the relevant vaccine) pursuant to the provisions of Article 5, Article 8 or Article 10 of the Old Immunization Act) who was vaccinated pursuant to the provisions of Article 4, Article 7, Article 10 of the Immunization Act (hereinafter referred to as the "Old Immunization Act" in this Article) before its amendment pursuant to the provisions of Article 1 before this Act comes into effect is deemed as a person who underwent the routine vaccination provided for in Article 2, paragraph (4) in the same Act or the temporary vaccination (excluding Article 6, paragraph (3) in the same Act) provided for in Article 5 in the Act with regard to the application of the provisions of Article 15, paragraph (1) of the Immunization Act, and is deemed as a person who underwent the temporary vaccination, the routine vaccination against category A disease provided for in the same paragraph or the temporary vaccination against category B disease provided for in the same paragraph with the application of the provisions in Article 16, paragraph (1) in the same Act.

(Transitional Measures Concerning Penal Provisions)

Article 6 Prior Acts continue to govern the applicability of penal provisions to conduct that a person engages in before this Act comes into effect.

(Other Transitional Measures Delegated to Cabinet Order)

Article 9 Beyond what is provided for in these supplementary provisions, transitional measures that need to be set in place for enforcing this Act are provided for by Cabinet Order.

### **Supplementary Provisions [Act No. 84 of July 1, 1994] [Extract]**

(Effective Date)

Article 1 This Act comes into force as of the date of its promulgation; provided, however, that the provisions in Article 3 to amend Article 18 of the Maternal and Child Health Act (excluding the part in which "or a city in which a health center is established" is revised to "a city or special ward in which a health center is established") are to come into force as of January 1, 1995, and the provisions of Article 2, Article 4, Article 5, Article 7, Article 9, Article 11, Article 13, Article 15, Article 17, Article 18 and Article 20, the provisions in Article 21 to amend Article 22 of the Eugenic Protection Act (excluding the part in which "and a city where a health center is established" is revised to "a city or a special ward where a health center is established") the provisions to amend Article 30 in the same Act, Articles 3 through 11, and Articles 23 through 37 of the supplementary provisions, and the provisions of Article 39 of supplementary provisions and the provisions in Article 41 of supplementary

provisions to amend Article 6 of the Act of Establishment of the Ministry of Health, Labour and Welfare (limited to the part deleting "authorizing the establishment of a eugenic maternity and child counselor's office, and") come into force as of April 1, 1997.

### **Supplementary Provisions [Act No. 87 of July 16, 1999] [Extract]**

(Effective Date)

Article 1 This Act comes into force as of April 1, 2000; provided, however, that the provisions listed in the following items are to come into force as from the date specified in each of the relevant items:

(i) the provisions in Article 1 to add five articles, the Section title, and two subsections and the titles thereof following Article 250 of the Local Autonomy Act (limited to the part concerning Article 250-9, paragraph (1) of the relevant Act (limited to the part concerning the requirement of consent of both Houses)), the provisions in Article 40 to amend paragraph (9) and paragraph (10) of the supplementary provisions of the Natural Parks Act (limited to the part concerning paragraph (10) of the supplementary provisions of the same Act), the provisions of Article 244 (excluding the part concerning the provisions to amend Article 14-3 of the Agricultural Improvement and Promotion Act), and the provisions of Article 472 (excluding the part concerning the provisions to revise Article 6, Article 8, and Article 17 of the Act on Special Provisions Concerning Merger of Municipalities), and the provisions of Article 7, Article 10, Article 12, proviso of Article 59, paragraph (4) and paragraph (5), Article 60, Article 73, Article 77, paragraphs (4) through (6), Article 157, Article 160, Article 163, Article 164, and Article 202 of the supplementary provisions: the date of promulgation.

(Transitional Measures Concerning Processes. Pursuant to the Provisions then in Force)

Article 69 The processes, powers, or authority of a prefectural governor related to the matter for which the provisions then in force remain applicable pursuant to the provisions of Article 32, paragraph (1), Article 78, paragraph (1) and Article 87, paragraphs (1) and (13), supplementary provisions of the Act Partially Amending the National Pension Act (Act No. 34 of 1985) (hereinafter referred to as "processes, etc." in this Article), are regarded as processes or powers of the Minister of Health, Labour and Welfare or the Director-General of a Social Insurance Agency, who is required to administer or exercise the processes or powers corresponding to the processes, etc. pursuant to the provisions of National Pension Act, the Employees Pension Act, and the

Marines Insurance Act, as amended by this Act, or the provisions of any order thereunder, or of the head of a local social insurance bureau delegated by the foregoing or the head of a social insurance office delegated by the head of a local social insurance bureau.

(Special Provisions for Application of Article 156, paragraph (4) of New Local Autonomy Act)

Article 70 With regard to the local social insurance secretariat and social insurance offices in Article 14 of the Act of Establishment of the Ministry of Health, Labour and Welfare after amendment by provisions of article 166, that are placed in the same position as prefectural organs (limited to those handling procedures related to social insurance) that were responsible for procedures in Article 8 of the supplementary provisions of the old Local Autonomy Act (if a local social insurance bureau, limited to those placed in a cities, (including special wards) where prefectural government agencies are located) when this Act comes into force, the provisions of Article 156, paragraph (4) of the New Local Autonomy Act do not apply.

(Transitional Measures Concerning Local Official Related to Social Insurance)

Article 71 A person who is an official prescribed by Article 8 of the supplementary provisions of the old Local Autonomy Act at the time of the enforcement of this Act (limited to a person appointed by the Minister of Health, Labour and Welfare or by any person delegated by the relevant minister; referred to as a "local official related to social insurance" in Article 158 of the supplementary provisions) is to become an official of the corresponding local social insurance bureau or social insurance office unless a separate appointment is issued for the relevant person.

(Transitional Measure Concerning Local Social Insurance Medical Council)

Article 72 A local social insurance medical care council, its chairman, members and expert advisors under the provisions of the Social Insurance Council Act before its amendment by the provisions of Article 169 are to continue in same capacity as the corresponding local social insurance medical council of regional social insurance bureaus, its chairman, members and expert advisors.

(Preparatory Actions)

Article 73 Designation under the provisions of Article 92-3, paragraph (1), item (ii) of the National Pension Act and public notice under the provisions of paragraph (2) of the same Article after its amendment by the provisions of Article 200 may be made even prior to the enforcement of the provisions of Article 200.

(Transitional Measures Concerning Re-examination-Claim to the Minister of Health, Labour and Welfare)

Article 74 With regard to requests for re-examination based on the provisions of Article 59-4 paragraph (2) of the Child Welfare Act, Article 12-4 of the Act on Massage and Finger Pressure Practitioners, Acupuncturists, Moxibustion Practitioners, etc., Article 29-4 of the Food Sanitation Act, Article 9-3 of the Inns and Hotels Act, Article 7-3 of the Public Bath Houses Act, Article 71-3 of the Medical Care Act, Article 43-2, paragraph (2) of the Act on Welfare of Persons with Physical Disabilities, Article 51-12, paragraph (2) of the Act on Mental Health and Welfare for Persons with Mental Disabilities, Article 14-2, paragraph (2) of the Laundries Act, Article 25-2 of the Rabies Prevention Act, Article 83-2, paragraph (2) of the Social Welfare Services Act, Article 69 of the Tuberculosis Prevention Act, Article 20 of the Slaughterhouse Act, Article 27-2 of the Dental Technicians Act, Article 20-8-2 of the Act on Clinical Laboratory Technicians, Public Health Laboratory Technicians, etc., Article 30, paragraph (2) of the Act on Welfare of Persons with Intellectual Disabilities, Article 34, paragraph (2) of the Act on Social Welfare for the Elderly, Article 26, paragraph (2) of the Maternal and Child Health Act, Article 23 of the Judo Therapists Act, Article 14, paragraph (2) of the Act on Maintenance of Sanitation in Buildings, Article 24 of the Waste Management and Public Cleaning Act, Article 41, paragraph (3) of the Poultry Slaughtering Business Control and Poultry Meat Inspection Act, or Article 65 of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases before those provisions' amendment pursuant to the provisions of Articles 149 through 151, Article 157, Article 158, Article 165, Article 168, Article 170, Article 172, Article 173, Article 175, Article 176, Article 183, Article 188, Article 195, Article 201, Article 208, Article 214, Articles 219 through 221, Article 229 or Article 238 pertaining to dispositions implemented by administrative agencies before the date of enforcements, provisions then in force remain applicable.

(Transitional Measures Concerning Orders for Suspension of Projects or Other Dispositions by the Minister of Health and Welfare or Prefectural Governor or Other Local Government Organ)

Article 75 Orders for suspension of projects or other dispositions issued or made by the Minister of Health and Welfare or a prefectural governor or other local government organ pursuant to the provisions of Article 46, paragraph (4) or Article 59, paragraphs (1) or (3) of the Child Welfare Act, Article 8, paragraph (1) of the Act on Massage and Finger Pressure Practitioners, Acupuncturists, Moxibustion Practitioners, etc. (including the cases where applied mutatis

mutandis pursuant to Article 12-2, paragraph (2) of the same Act), Article 22 of the Food Sanitation Act, Article 5, paragraph (2) or Article 25, paragraph (1) of the Medical Care Act, Article 17, paragraph (1) of the Poisonous and Deleterious Substances Control Act (including the cases where applied mutatis mutandis pursuant to Article 22, paragraphs (4) and (5) of the same Act), Article 100, paragraph (1) of the Employees' Pension Insurance Act, Article 39, paragraph (1) of the Water Supply Act, Article 106, paragraph (1) of the National Pension Act, Article 69, paragraph (1) or Article 72 of the Pharmaceutical Affairs Act, or Article 18, paragraph (1) of the Judo Therapists Act, prior to amendment by this Act are deemed as orders of suspension of projects or other dispositions issued or made by the Minister of Health and Welfare or a local government pursuant to the provisions of Article 46, paragraph (4) or Article 59, paragraphs (1) or (3) of the Child Welfare Act, Article 8, paragraph (1) of the Act on Massage and Finger Pressure Practitioners, Acupuncturists, Moxibustion Practitioners, etc. (including the cases where applied mutatis mutandis pursuant to Article 12-2, paragraph (2) of the same Act), Article 22 or Article 23 of the Food Sanitation Act, Article 5, paragraph (2) or Article 25, paragraph (1) of the Medical Care Act, Article 17, paragraphs (1) or (2) of the Poisonous and Deleterious Substances Control Act (including the cases where applied mutatis mutandis pursuant to Article 22, paragraphs (4) and (5) of the same Act), Article 100, paragraph (1) of the Employees' Pension Insurance Act, Article 39, paragraphs (1) or (2) of the Water Supply Act, Article 106, paragraph (1) of the National Pension Act, Article 69, paragraphs (1) or (2) or Article 72, paragraph (2) of the Pharmaceutical Affairs Act, or Article 18, paragraph (1) of the Judo Therapists Act, as amended by this Act, respectively.

(Processes of the national government)

Article 159 Beyond what is provided for in the respective Acts prior to amendment by this Act, processes of the national government, other local governments, and other public entities that are, prior to the enforcement of this Act, managed or executed by a local government organ in accordance with an Act or a Cabinet Order thereunder (in Article 161 of the supplementary provisions referred to as the "processes of the national government, etc.") are to be, after the enforcement of this Act, administered by the local government as its own processes in accordance with an Act or a Cabinet Order thereunder.

(Transitional Measures Concerning Dispositions, Applications)

Article 160 (1) Dispositions such as permission and other acts rendered prior to the Enforcement this Act( with regard to provisions listed in each item of Article 1 of the supplementary provisions: each relevant provision; the same

applies in this Article and Article 163 of the supplementary provisions) pursuant to the provisions of respective laws prior to the amendment (hereinafter referred to in this Article as the "Acts of Disposition, etc."), or application for permission other acts that are actually made at the time of enforcement of this Act pursuant to the provisions of respective laws prior to the amendment (hereinafter referred to in this Article as the "Acts of applications, etc." for which different persons will undertake the administrative processes pertaining to such Acts on the date of enforcement of this act, are deemed as the Acts of Disposition ,etc. or the Acts of Application ,etc. that are made pursuant to the corresponding provisions of the respective laws after the amendment respect of the application of respective laws after the amendment on and after the date of enforcement of this Act, except for those provided for in the provisions of Article 2 through the preceding Article of the supplementary provisions or in the provisions for transitional measures of respective laws(including orders based on these laws)after the amendment.

- (2) With respect to matters for which reports, notification, submission or other procedures are to be conducted before the organs of the national government or local government prior to the enforcement of this Act, pursuant to the respective Acts prior to the amendment, if these procedures have not yet been conducted by the date of enforcement of this Act, the provisions of the respective Acts amended by this Act apply to the procedures, except those otherwise provided by this Act or Cabinet Order enacted thereunder, on the assumption that reports, notification, submission or other procedures have not yet been conducted with respect to matters for which the procedures are to be conducted before the organs of the national government or local government pursuant to the relevant provisions of the respective amended Acts.

(Transitional Measures Concerning Appeals)

Article 161 (1) With regard to an appeal the Administrative appeal Act, which is a disposition pertaining to processes of the national government, etc. made prior to the date of enforcement in the case where the administrative agency which made the disposition (hereinafter referred to in this Article as " agencies of disposition" ) had a higher administrative agency as prescribed in the same Act (hereinafter referred to in this Article as a "higher administrative agency" ),prior to the date of enforcement, it is deemed that the Agency of Disposition continues to have a Higher Administrative Agency even after the date of enforcement, and the provisions of the Administrative Appeal Act are applicable

- (2) In the case referred to in the preceding paragraph, where the administrative agencies that are deemed to be higher administrative agencies are local

governments organs, the processes to be handled by the relevant organs pursuant to the provisions of the Administrative Appeal Act are to be Type 1 statutory entrusted functions prescribed in Article 2, paragraph (9), item 1 of the new Local Autonomy Act,

(Transitional Measures Concerning Commissions)

Article 162 Prior Acts continue to govern any fees which should have been paid pursuant to the provisions of respective Acts (including orders pursuant thereto) prior to amendment by this Act before the Effective Date, except as otherwise specified in this Act or Cabinet Order based thereon.

(Transitional Measures Concerning Penal Provisions)

Article 163 Prior Acts continue to govern the applicability of penal provisions to conduct that a person engages in before this Act comes into effect.

(Other Transitional Measures Delegated to Cabinet Order)

Article 164 (1) Beyond what is provided for in these supplementary provisions, transitional measures that need to be set in place for enforcing this Act (including transitional measures concerning penal provisions) are provided for by Cabinet Order.

(2) The matters required for the application of the provisions of Article 18, Article 51, and Article 184 of the supplementary provisions are provided for by Cabinet Order.

(Review)

Article 250 The establishment of Type1 statutory entrusted functions provided for in Article 2, paragraph (9), item (i) of the new Local Autonomy Act is to be restricted as much as possible, while those listed in Appended Table 1 of the new Local Autonomy Act and those specified in Cabinet Order under the new Local Autonomy Act is to be appropriately reviewed from the viewpoint of the promotion of decentralization,

Article 251 To enable local governments to execute their processes and projects autonomously and independently, the government is to, while taking account of trends in financial circumstances, review means of enhancing and securing local tax revenues in accordance with the distribution of roles between the national government and local governments, and is to take necessary measures based on the results of the review.

Article 252 Along with various reforms such as the medical insurance system reform and the pension system reform, the government is to consider the ideal

administrative system for social insurance and a desirable personnel system therefor from the viewpoint of ensuring convenience for the insured and increasing efficiency in administration, and takes measures as required based on the results if necessary.

**Supplementary Provisions [Act No. 151 of December 8, 1999] [Extract]**

(Effective Date)

Article 1 This Act comes into force as of April 1, 2000.

Article 4 Prior Acts continue to govern the applicability of penal provisions to conduct that a person engages in before this Act in to effect.

**Supplementary Provisions [Act No. 160 of December 22, 1999] [Extract]**

(Effective Date)

Article 1 This Act (excluding Article 2 and Article 3.) comes into force as of January 6, 2001.

**Supplementary Provisions [Act No. 9 of March 30, 2001]**

(Effective Date)

Article 1 This Act comes into force as of the date of promulgation.

**Supplementary Provisions [Act No. 116 of November 7, 2001] [Extract]**

(Effective Date)

Article 1 This Act comes into force as of the date of promulgation.

(Review)

Article 2 After approximately five years from the enforcement of this Act, the government is to review the status of influenza outbreaks and vaccination rates among the elderly, the research results on the efficacy of vaccination against influenza and consider the circumstances of the enforcement of the provisions of the Immunization Act amended by this Act, and is to comprehensively review the method routine vaccinations and take necessary measures based on the results of the review.

(Special Provisions Concerning Routine Vaccination against Influenza)

Article 3 (1) In the case of conducting vaccination against influenza pursuant to the provisions of Article 5, paragraph (1) of the Immunization Act, for the time

being, "the person who resides within the area of the municipality and is provided for by Cabinet Order" in the same paragraph is deemed to be "an elderly person who resides within the area of the municipality and is provided for by Cabinet Order.

(2) The provisions of Article 16, paragraph (2), item (ii) of the Immunization Act do not apply to the payment of the relief from health damage caused by an influenza vaccination pursuant to the provisions of Article 5, paragraph (1) of the same Act that are replaced pursuant to the provisions of the preceding paragraph.

### **Supplementary Provisions [Act No. 192 of December 20, 2002] [Extract]**

(Effective Date)

Article 1 This Act comes into force as of April 1, 2016. However, Article 39, Article 4 of supplementary provisions, Article 12 to Article 14 of supplementary provisions and Article 33 of supplementary provisions comes into force as of October 1, 2003.

(Delegation to Cabinet Order)

Article 33 Beyond what is provided for in Article 3, Article 4, Article 6 through Article 20, Article 22 through Article 24 and Article 27 of the supplementary provisions, necessary transitional measures associated with the establishment of the organization and other transitional measures necessary for the enforcement of this Act are provided for by Cabinet Order.

### **Supplementary Provisions [Act No. 106 of December 8, 2006] [Extract]**

(Effective Date)

Article 1 This Act comes into effect as from the date specified by Cabinet Order within a period not exceeding six months from the day of promulgation; provided, however, that the provisions in Article 1 to amend the table of contents of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (limited the part amending "Article 26" to "Article 26-2" and Chapter VII "New Infectious Diseases (Article 45 to Article 53)" to "Chapter VII New Infectious Diseases (Article 45 to Article 53) Chapter VII-2 Tuberculosis (Article 53-2 to Article 53-15)"), the provisions to amend Article 6, paragraphs (2) through (6) of the same Act (limited to the part pertaining to paragraph (3), item (ii) in the same Act), the provisions to amend paragraph (11) in the same Article, the provisions to add eight paragraphs to the same Article (limited to the parts of paragraph (15), paragraph (21), item (ii), and paragraph (2), item (x) in the same Article), the provisions to delete

Article 10, paragraph (6) in the same Act, the provisions to amend Article 18 through Article 20, Article 23 and Article 24 of the same Act, the provisions to add one article after Article 24, the provisions to amend Article 26 of the same Act, the provisions to add one article after Article 26, the provisions to add one article after Article 37 of the same Act, the provisions to amend Article 38 through Article 44 and Article 46 of the same Act, the provisions to add one article after Article 49 of the same Act, the provisions to add one chapter after Chapter VII of the same Act, the provisions to amend Article 57 and Article 58 of the same Act, the provisions to add two articles after Article 58, the provisions to amend Article 59 through Article 62 and Article 64 of the same Act, the provisions to add one article after Article 64 and the provisions to amend Article 65, Article 65-2 (excluding the part of pertaining to Chapter III) and Article 67, paragraph (2) of the same Act, the provisions of Article 2, the provisions of the following Article through Article 7 of the supplementary provisions, Article 13 of the supplementary provisions(excluding the part of pertaining to Chapter III among the provisions to amend the part regarding the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases(Act No. 114 of 1998), in Appended Table 1 of the Local Autonomy Act(Act No. 67 of 1947) and the provisions of Article 14 through Article 24 of the supplementary provisions come into force as of April 1, 2007.

- Article 7 (1) A person who was vaccinated pursuant to the Old Tuberculosis Preventive Act before the date on which this Act partially comes into force was regarded as a person who underwent the routine vaccination pursuant to the provisions of Article 2, paragraph (4) in the same Act with regard to the application of the provisions of Article 15, paragraph (1) of the Immunization Act or the temporary preventive vaccination pursuant to the provisions of paragraph (5) in the same Act (excluding the part of Article 6, paragraph (3) in the same Act), and with regard to the application of Article 16, paragraph (1) in the same Act, the person is regarded as a person who underwent a routine vaccination against category A disease pursuant to the same paragraph.
- (2) If the Minister of Health, Labour and Welfare certifies that the sickness or disability was a result of the vaccination received prior to the date of partial enforcement pursuant to the provisions of Article 21-2, paragraph (1) of the Old Tuberculosis Preventative Act, it is deemed to have been confirmed by the Minister of Health, Labour and Welfare pursuant to the provisions of Article 15, paragraph (1) of the Immunization Act respectively.

(Transitional Measures Concerning Application of Penal Provisions)

Article 24 Prior Acts continue to govern the applicability of penal provisions to conduct that a person engages in before this Act (or with regard to the

provisions of the proviso to Article 1 of these supplementary provisions, the relevant provisions) comes into effect and to conduct that a person engages in after the provisions of the proviso to this Article come into effect in cases which, pursuant to these supplementary provisions, are to continue to be governed by the Acts previously in force.

(Other Transitional Measures Delegated to Cabinet Order)

Article 25 Beyond what is provided for in these supplementary provisions, transitional measures that need to be set in place for enforcing this Act are provided for by Cabinet Order.

### **Supplementary Provisions [Act No. 85 of July 22, 2011] [Extract]**

(Effective Date)

Article 1 This Act comes into force as of the date of promulgation; provided, however, that the provisions in Article 1 to amend add two paragraphs to Article 6 of the Immunization Act, the provisions to amend Article 7 of the same Act, the provisions to add one article after Article 7 of the same Act and the provisions to amend Article 8, Article 9, paragraph (2), Article 22, Article 24 and Article 25 of the same Act, the provisions in Article 2 to delete Article 5, paragraph (2) of the Act on Special Measures Concerning the Relief, etc. of Health Hazards Caused by the New Type of Influenza Vaccination, the provisions to amend Article 2, paragraph (2) of the supplementary provisions of the same Act, and the provisions of Article 3 and Article 4 of the supplementary provisions come into effect as of the date specified by Cabinet Order within a period not exceeding three months from the date of promulgation.

(Review)

Article 6 (1) The government is to comprehensively review the method of a vaccinations of an outbreak of a disease that is contagious and may spread, while taking into consideration the circumstances, etc. of the enforcement of the provisions of the Immunization Act amended by the provisions of Article 1, , and take any necessary measures based on the results of its reviews.

(2) Within five years from the date of enforcement of this Act, the government is to comprehensively review the role of the State, manufacturers and sellers, ( persons approved to manufacture and sell pharmaceuticals in Article 12, paragraph (1) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices) (Act No. 145 of 1960) and other related persons securing vaccines in an emergency, and take necessary measures based on the results of the review.

(Delegation to Cabinet Order)

Article 7 Beyond what is provided for in the supplementary provisions, transitional measures that need to be set in place for enforcing this Act are provided for by Cabinet Order.

### **Supplementary Provisions [Act No. 8 of March 30, 2013] [Extract]**

(Effective Date)

Article 1 This Act comes into force as of April 1, 2013; provided, however, that Article 6 and Article 19 of the supplementary provisions come into force as of the date of promulgation.

(Review)

Article 2 After approximately five years from the enforcement of this Act, the government is to review the situation of the spread of contagious diseases, the situation regarding vaccination rates, the damage to health caused by vaccinations, and the conditions of the provisions of the Immunization Act after its amendment (hereinafter referred to as the "New Act" in Article 7 of the supplementary provisions from this Article) and if necessary, the government is to review the provisions of the New Act and take necessary measures based on the results of the review.

(Transitional Measures Concerning Guidelines)

Article 3 At the time of the enforcement of this Act, guidelines established pursuant to the provisions of Article 20, paragraph (1) of the Immunization Act before the amendment by this Act (referred to as the "Old Act" in following Article and Article 5 and Article 7 of the supplementary provisions) are deemed as guidelines established pursuant to the provisions of Article 4, paragraph (1) of the New Act.

(Transitional Measures Concerning Reports)

Article 4 Routine vaccinations or temporary vaccinations prescribed in Article 7-2, paragraph (1) of the Old Act conducted prior to the enforcement of this Act applies to the application of the provisions of Article 12 of the New Act, deemed as vaccinations, etc. prescribed in Article 2, paragraph (6) of the New Act.

(Transitional Measures Concerning Relief of Damage to Health)

Article 5 (1) A person who underwent a routine vaccination against category I diseases provided for in paragraph (1), Article 7-2 of the Old Act or underwent a temporary vaccination provided for in the same paragraph before this Act

comes into force, is deemed as a person who underwent the routine vaccination provided for in Article 2, paragraph (4) of the New Act or a person who underwent the temporary vaccination provided for in paragraph (5) in the same Article with regard to the application of the provisions in Article 15, paragraph (1) of the New Act, and is deemed as a person who underwent the routine vaccination against category A disease provided for in the same paragraph or a person who underwent the temporary vaccination against category B diseases provided for in the same paragraph with regard to the application of Article 16, paragraph (1) of the New Act.

- (2) A person who underwent a routine vaccination of a category II disease provided for in Article 7-2, paragraph (1) of the Old Act before this Act comes into force is deemed as a person who underwent the routine vaccination provided for in Article 2, paragraph (4) of the New Act with regard to the application of the provisions of Article 15, paragraph (1) of the New Act, and is deemed as a person who underwent the routine vaccination against category B disease provided for in the same paragraph with regard to the application of the provisions in Article 16, paragraph (2) of the New Act.

(Hearing the Opinions of the Health Science Councilors)

Article 6 In the cases listed in each item of Article 24 of the New Act, the Minister of Health, Labour and Welfare may hear the opinions of the Welfare Science Council even before the enforcement of this Act.

(Special Provisions Concerning Routine Vaccination against Infectious Diseases Including New-Type Influenza,)

Article 7 With regard to the application of the provisions of Article 3 of the supplementary provisions to the Act Partially Amending the Immunization Act after its revision (Act No. 116 of 2001) pursuant to the provisions of Article 12 of the supplementary provisions regarding the vaccination pursuant to the provisions of Article 5, paragraph (1) of the New Act on the type of influenza listed below, "influenza" in paragraph (1) in the same Article is replaced with "influenza (the Act Partially Amending the Immunization Act (Act No. 8 of 2013) to each item, excluding those listed in Article 7 of the supplementary provisions; the same applies in the following paragraph)" and "the same paragraph" is replaced with "Article 5, paragraph (1) of the Immunization Act":

- (i) diseases that its outbreak of which the Minister of Health, Labour, and Welfare publicizes information on, pursuant the provisions of Article 44-2, paragraph (1) of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases, as diseases falling under the new type of influenza on April 28, 2009 (referred to as the "specific-type new influenza" in the next item) listed in Article 6, paragraph (7), item (1) of the

Infectious Disease Act (Act No. 114 of 1998, hereinafter referred to "Infectious Disease Act" in this Article);

- (ii) before this Act comes into force, diseases that the Minister of Health, Labour and Welfare prescribes, as category II diseases pursuant to Article 6, paragraph (1) or (3) of the Old Act or category B diseases pursuant to Article 6, paragraph (1) or (3) of the New Act from among diseases the outbreak of which the Minister publicizes information on (excluding specific-type new influenza), pursuant to the provisions of Article 44-2, paragraph (1) of the Infectious Disease Act, as diseases falling under the new type of influenza, etc. provided for in Article 6, paragraph (7) of the Infection Disease Act; and
- (iii) after this Act comes into force, diseases that the Minister of Health, Labour and Welfare prescribes, as category B diseases pursuant to Article 6, paragraph (1) or (3) of the New Act from among diseases the outbreak of which the Minister publicizes information on, pursuant to the provisions of Article 44-2, paragraph (1) of the Infectious Disease Act, as diseases falling under the new type of influenza, etc. provided for in Article 6, paragraph (7) of the Infection Disease Act.

(Delegation to Cabinet Order)

Article 19 Beyond what is provided for in these supplementary provisions, transitional measures that need to be set in place for enforcing this Act are provided for by Cabinet Order.

### **Supplementary Provisions [Act No. 84 of November 27, 2013] [Extract]**

(Effective Date)

Article 1 This Act comes into effect as from the date specified by Cabinet Order within the period not exceeding one year from the date of promulgation; provided, however, that the provisions of Article 64, Article 66 and Article 102 of the supplementary provisions come into force as of the date of promulgation.

(Review)

Article 66 After approximately five years from the enforcement of this Act, the government is to take into account the situation of the enforcement of the provisions amended by this Act, review the relevant provisions, and take any necessary measures based on the results of the review, if necessary.

(Effect of Dispositions)

Article 100 Any dispositions, procedures or other acts conducted prior to the enforcement of this Act pursuant to the provisions of respective Acts prior to the amendment (including orders issued thereunder; hereinafter the same

applies in this Article), for which corresponding provisions exist in the respective Act after the amendment are deemed to have been conducted pursuant to the corresponding provisions of the respective Acts after the amendment, except as otherwise provided for by the supplementary provisions.

(Transitional Measures Concerning Penal Provision)

Article 101 Prior Act continue to govern the applicability of penal provisions to conduct that a person engages in before this Act comes into effect and to conduct that a person engages in after this Act comes into effect but which, pursuant to this Act, is to continue to be governed by the Act previously in force.

(Delegation to Cabinet Order)

Article 102 Beyond what is provided for in these supplementary provisions, transitional measures that need to be set in place for enforcing this Act (including transitional measures concerning penal provisions) are provided for by Cabinet Order.

### **Supplementary Provisions [Act No. 103 of December 13, 2003] [Extract]**

(Effective Date)

Article 1 This Act comes into effect as from the day specified by Cabinet Order, within a period not exceeding six months from the date of promulgation.