

Basic Act on Hepatitis Control

(Act No. 97 of December 4, 2009)

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Today, there are many people who are infected with the hepatitis viruses or who suffer from hepatitis in Japan, and hepatitis is the most common infectious disease in Japan.

These people have immeasurable anxiety about the future, because hepatitis can become chronic and progress into more severe diseases such as cirrhosis or liver cancer if hepatitis is not treated properly.

Thanks to the advancement of medical treatment, accumulation of medical knowledge and advancement of science and technology in the post-war period, the way to overcome hepatitis has been paved, whereas there still are many problems to be solved in terms of early detection and accessibility to medical treatment. Furthermore, it is obvious that all Japanese citizens have not fully acquired a correct understanding of the hepatitis virus and hepatitis.

Some hepatitis B and hepatitis C infections have been caused due to reasons attributable to the national government, or due to the fact that the cause of those infections had not been determined. In the hepatitis infection cases caused by specific coagulation factor concentrates contaminated with the hepatitis C virus, which resulted in the infection of many and unspecified persons, and the victims were badly affected by hepatitis, for which the government admitted its responsibility to compensate for being unable to prevent the spread of hepatitis. Also, in the hepatitis infection cases due to collective vaccination in which hepatitis B viral infection occurred by using the same syringe needles for many,

the final judicial decision on government's liability for compensation has been made by the Supreme Court.

Under the circumstances, it is necessary for the government to further advance its efforts to overcome hepatitis by surely providing high-quality and appropriate medical treatment for the hepatitis carriers and hepatitis patients, while respecting for their human rights.

This Act is established to clarify the basic policies of the hepatitis control, and to advance those policies comprehensively.

Chapter I General Provisions

(Purpose)

Article 1 The purpose of this Act is to establish basic principles for hepatitis control, and clarify the responsibilities of the national government, local governments, medical insurers, citizens and physicians, etc., and provide for matters concerning the formulation of guidelines for the advancement of hepatitis control, and provide the basic matters for hepatitis control, and thereby advance the hepatitis control comprehensively.

(Basic Principles)

Article 2 The hepatitis control measures must be taken according to the following matters, which are the basic principles.

- (i) to advance specialized, interdisciplinary or comprehensive research on hepatitis, and to disseminate, use and further improve the advanced technologies for prevention, diagnosis, and treatment, etc. of hepatitis, and other outcomes of studies, etc.;
- (ii) to make hepatitis tests (hereinafter referred to as "hepatitis tests") accessible to any person regardless of which region the person resides;
- (iii) to make appropriate medical treatment for hepatitis (hereinafter referred to as "hepatitis medical treatment") accessible to any hepatitis carrier or patient (hereinafter referred to as "hepatitis patients, etc.") regardless of which region the person resides; and
- (iv) to give due consideration to hepatitis patients, etc., in implementing the policies under items (i) through (iii), so that the human rights of hepatitis patients, etc. are respected and the patients are not discriminated for being the hepatitis patient;

(Responsibilities of the National Government)

Article 3 The national government is responsible for formulating comprehensive

hepatitis control measures and implementing the measures in accordance with the basic principles prescribed in the preceding Article (hereinafter referred to as the "basic principles" in the following Article).

(Responsibility of Local Governments)

Article 4 The local governments have a responsibility to formulate measures for hepatitis control according to the regional characteristics while working together with the national government for the measures, in accordance with the basic principles.

(Responsibility of Medical Insurers)

Article 5 Medical insurers (meaning medical insurers prescribed in Article 7, paragraph (7) of the Long-Term Care Insurance Act (Act No. 123 of 1997)) must endeavor to cooperate for the measures taken for improving public awareness and disseminating knowledge concerning the prevention of hepatitis, and campaign to increase public awareness on hepatitis tests implemented by the national government and local governments.

(Responsibilities of Citizens)

Article 6 Citizens must strive to have correct knowledge of hepatitis, give due consideration to ensure that the hepatitis patients, etc. are not discriminated for being the hepatitis patients, etc., and to take necessary precautions to prevent hepatitis and endeavor to undergo a hepatitis test as necessary.

(Responsibilities of Physicians)

Article 7 Physicians and other medical personnel must endeavor to cooperate for the measures for hepatitis control taken by the national government and local governments and contribute to the prevention of hepatitis, and also endeavor to deeply understand the situations that the hepatitis patients, etc. are in now and provide high-quality and appropriate hepatitis medical treatment.

(Legislative Measures)

Article 8 The national government must implement legislative, financial and other measures necessary to implement the hepatitis control measures.

Chapter II Basic Guidelines on Hepatitis Control

(Formulation of Basic Guidelines on Hepatitis Control)

Article 9 (1) The Minister of Health, Labour and Welfare must formulate the basic guidelines for the promotion of hepatitis control measures (hereinafter referred to as the "basic guidelines on hepatitis control measures") in order to

promote the integrated hepatitis control measures.

- (2) The Basic Guidelines on Hepatitis Control are to provide the following particulars:
- (i) the basic direction for promoting the prevention of hepatitis and hepatitis medical treatment;
 - (ii) matters concerning the preventive measures for hepatitis;
 - (iii) matters concerning the improvement of a system to perform hepatitis tests and its test capacity;
 - (iv) matters concerning securing of the system to provide hepatitis medical treatment;
 - (v) matters concerning the development of human resources for the prevention of hepatitis and hepatitis medical treatment;
 - (vi) matters concerning research and studies on hepatitis;
 - (vii) matters concerning the advancement of research and development of medicines for hepatitis medical treatment;
 - (viii) matters concerning the improvement of public awareness on and dissemination of knowledge of hepatitis and matters concerning respect for human rights of hepatitis patients, etc.; and
 - (ix) other important matters concerning the promotion of hepatitis control measures.
- (3) When intending to formulate the Basic Guidelines on Hepatitis Control, the Minister of Health, Labour and Welfare must consult with the heads of the relevant administrative organs and hear the opinions of the Council for Promotion of Hepatitis Control in advance.
- (4) When the Minister of Health, Labour and Welfare formulates the Basic Guidelines on Hepatitis Control, the minister must make this known to the public via the Internet or in any other appropriate manner without delay.
- (5) The Minister of Health, Labour and Welfare must conduct a review of the Basic Guidelines on Hepatitis Control at least every five years, taking into account the changes in the circumstances surrounding hepatitis medical treatment and based on the assessment of the effects of the hepatitis control measures, and when the minister finds it necessary, make changes to the Basic Guidelines on Hepatitis Control.
- (6) The provisions of paragraphs (3) and (4) apply mutatis mutandis to any changes to the Basic Guidelines on Hepatitis Control.

(Requests to Relevant Administrative Organs)

Article 10 The Minister of Health, Labour and Welfare may make a formal request to the heads of the relevant administrative organs to submit the materials for the formulation of the Basic Guidelines on Hepatitis Control or to implement the measures under their jurisdiction that are provided in the Basic

Guidelines on Hepatitis Control, when the minister finds it necessary.

Chapter III Basic Control Measures

Section 1 Advancement of Prevention and Early Detection of Hepatitis

(Advancement of Prevention of Hepatitis)

Article 11 The national government and the local governments is to take necessary measures to increase public awareness and disseminate knowledge about the prevention of hepatitis and to advance prevention of hepatitis.

(Improvement of Quality of Hepatitis Tests)

Article 12 In order to contribute to the early detection of hepatitis, the national government and local governments is to take measures for the improvement of the quality of hepatitis test methods, such as conducting a review of hepatitis test methods, assessing hepatitis test services and securing opportunities for medical personnel engages in hepatitis tests to receive the training, and to run a campaign for hepatitis test and other necessary measures so that the number of persons who undergo hepatitis test may increases.

Section 2 Promoting Equal Access to Hepatitis Medical Treatment

(Training and Education of Physicians and Other Medical Personnel with Specialized Knowledge and Skills)

Article 13 The national government and local governments is to take measures necessary to promote the training and education of physicians and other medical personnel having specialist knowledge and skills who engaged in anti-viral treatment, such as interferon therapy, liver supportive therapy and other hepatitis medical treatment.

(Establishment of Medical Institutions)

Article 14 (1) The national government and local governments is to take measures necessary to establish medical institutions capable of providing specialized hepatitis medical treatment, so that hepatitis patients, etc. may receive appropriate hepatitis medical treatment depending on the symptoms of the disease regardless of which region hepatitis patients, etc. reside.

(2) The national government and local governments is to take measures necessary to establish a system for coordination and cooperation between the medical institutions referred to in the preceding paragraph and other medical institutions, so that appropriate hepatitis medical treatment may be provided for hepatitis patients, etc.

(Financial Support for Medical Treatment of Hepatitis Patients)

Article 15 The national government and local governments is to take measures necessary to reduce the financial burden of hepatitis patients, so that the patients may receive appropriate hepatitis medical treatment as necessary.

(Securing Opportunities to Receive Hepatitis Medical Treatment)

Article 16 The national government and local governments is to take measures necessary to secure the system for coordination and cooperation among the medical institutions, employers of hepatitis patients and other related persons to enable hepatitis patients to stay in a hospital or see a doctor while receiving hepatitis medical treatment without any difficulties, and to secure opportunities for medical personnel to receive training concerning the maintenance and improvement of the quality of life of hepatitis patients.

(Development of Systems to Collect and Provide Information Concerning Hepatitis Medical Treatment)

Article 17 The national government and local governments is to take measures necessary to develop a system to collect and provide information concerning hepatitis medical treatment, and measures necessary to promote consultation, support or the like for hepatitis patients, etc., and their families, and the relevant persons thereof .

Section 3 Promotion of Research

Article 18 (1) The national government and local governments is to take measures necessary to advance the development of innovative methods to prevent, diagnose and treat hepatitis and the research concerning the matters contributing to a decline in mortality rate of hepatitis, and the outcome thereof may be shared with others.

(2) The national government and local governments is to take the necessary measures to develop an environment in which clinical testing of medicines and medical equipment that are particularly necessary to provide hepatitis medical treatment may be carried out in a prompt and reliable manner which may contribute to the early approval of their production and sale pursuant to the provisions of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960), and in which clinical research for the development of standard treatment methods of hepatitis medical treatment may be carried out smoothly.

Chapter IV Council for Promotion of Hepatitis Control

Article 19 In relation to the Basic Guidelines on Hepatitis Control, the Council for Promotion of Hepatitis Control (hereinafter referred to as the "Council") is established by the Ministry of Health, Labour and Welfare to handle the matters prescribed in Article 9, paragraph (3) (including as applied *mutatis mutandis* pursuant to the provisions of paragraph (6) of that Article).

Article 20 (1) The Council is composed of not more than 20 members.

(2) The Council members are appointed by the Minister of Health, Labour and Welfare from among hepatitis patients, etc. and their families or persons representing bereaved families, persons engaged in hepatitis medical treatment, and persons with relevant expertise.

(3) The Council members serve on a part-time basis.

(4) Beyond what is provided for in the preceding three paragraphs, necessary matters concerning the organization and operation of the Council are specified by Cabinet Order.

Supplementary Provisions [Extract]

(Effective Date)

Article 1 This Act comes into effect on January 1, 2010.

(Implementation of Measures for Cirrhosis and Liver Cancer)

Article 2 (1) The national government and local governments is to take the measures necessary to develop an environment in which clinical testing of medicines and medical equipment that are particularly necessary for treatment of cirrhosis and liver cancer is carried out in a prompt and reliable manner which may contribute to the early approval of their production and sale pursuant to the provisions of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, and in which the research and development of new treatment methods are promoted and the levels of treatment are improved.

(2) How the patients having cirrhosis or liver cancer caused by hepatitis may be supported are to be reviewed in the future, if necessary, by taking into account the circumstances surrounding medical treatment provided for the patients.