

# Act on Promotion of Healthcare Policy

(Act No. 48 of May 30, 2014)

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## Chapter I General Provisions

### (Purpose)

Article 1 The purpose of this Act is to be able to build a society in which the people can enjoy long and healthy lives (referred to as, a "society in which people enjoy long and healthy lives" below), by promoting research and development in the medical care sector which contributes to the provision of medical care using cutting-edge science and technology, medical care using innovative pharmaceutical drugs, etc. (meaning pharmaceuticals prescribed in Article 2, paragraph (1) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960), medical devices prescribed in paragraph (4) of that Article, or regenerative medicine products prescribed in paragraph (9) of that Article; this also applies in Article 13, paragraph (1)), and other medical care using the world's most advanced technology (referred to as, the "world's most advanced medical care" below), and by improving the environment fostering that research and development and then disseminating those results, and also by generating and invigorating operations for the creation of new industry activities that contribute to building a society in which people enjoy long and healthy lives and improving the environment for those operations, and making plans to improve the environment fostering those operations (referred to as, "cutting-edge healthcare and medical research and development and the creation of new industries" below), all while keeping in mind the importance of promoting the growth of Japan's economy through this research and development, this Act aims to promote a plan (referred to as, the "Healthcare Policy" below) by prescribing basic principles, the responsibilities of the national government, etc., basic measures to cutting-edge healthcare and medical research and

development and the creation of new industries, as well as other fundamental matters, it also sets out a plan for the comprehensive and systematic promotion of measures that the government should take for cutting-edge healthcare and medical research and development and the creation of new industries, the establishment of a Headquarters for the Healthcare Policy, and other matters necessary for the promotion of the healthcare policy, and as a result, it will contribute to the building of a society in which people enjoy long and healthy lives.

(Basic Principles)

Article 2 Cutting-edge healthcare and medical research and development and the creation of new industries must be carried out for the purpose of contributing to the provision of the world's most advanced medical care in the world by promoting integrated medical research and development activities, from basic research and development to research and development for practical application, and by smoothly putting those results into practical application, as well as contributing to the Japan's economic growth while also contributing to the improvement of the quality of medical care abroad by promoting the creation and overseas expansion of new industries that contribute to the establishment of a society in which people enjoy long and healthy lives, and otherwise revitalizing those activities.

(Responsibilities of the National Government)

Article 3 The national government is responsible for formulating and implementing measures for cutting-edge healthcare and medical research and development and the creation of new industries in a comprehensive and systematic manner, in accordance with the basic principles prescribed in the preceding Article (referred to below as the "basic principles").

(Responsibilities of Local Governments)

Article 4 A local government is responsible for formulating and implementing autonomous measures that make use of the characteristics of the area of the relevant local government, as measures to be implemented by a local government for cutting-edge healthcare and medical research and development and the creation of new industries, under an appropriate division of roles with the national government, in accordance with the basic principles.

(Responsibilities of Research Institutions)

Article 5 (1) A university, research and development corporation (meaning the research and development corporation prescribed in Article 2, paragraph (9) of the Act on Activation of Scientific and Technological Innovation (Act No. 63 of

2008)), and other research institution (simply referred to below as the "research institution") must actively endeavor to carry out research and development in the medical care sector, disseminate the results of those, and develop personnel, in accordance with the basic principles.

(2) A research institution must endeavor to conduct cutting-edge, interdisciplinary, or comprehensive research in conducting research and development in the medical care sector,.

#### (Responsibilities of Medical Institutions)

Article 6 A medical institution must endeavor to cooperate with the measures implemented by the national government pursuant to the provisions of Article 3 and the measures implemented by local governments pursuant to the provisions of Article 4, in accordance with the basic principles.

#### (Responsibilities of Business Operators Engaged in Cutting-Edge Healthcare and Medical Research and Development and the Creation of New Industries)

Article 7 A business operator engaged in cutting-edge healthcare and medical research and development and the creation of new industries (simply referred to as the "business operator" in the following Article, Article 12, and Article 16) must endeavor to conduct its own research and development, and must endeavor to cooperate with the measures implemented by the national government pursuant to the provisions of Article 3 and the measures implemented by local governments pursuant to the provisions of Article 4, in accordance with the basic principles.

#### (Strengthening Collaboration)

Article 8 The national government is to take the necessary measures to strengthen collaboration among the national government, local governments, research institutes, medical institutions, and business operators, taking into consideration the fact that their mutual collaboration and cooperation will facilitate the effective implementation of cutting-edge healthcare and medical research and development and the creation of new industries.

#### (Legislative Measures)

Article 9 The national government is to take legislative or financial measures, or other measures necessary to implement measures for cutting-edge healthcare and medical research and development and the creation of new industries.

## **Chapter II Basic Measures**

#### (Promoting Research and Development)

Article 10 The national government is to promote integrated research and development, concerning research and development in the medical care sector, from basic research and development to research and development for practical application, establish a system for transferring the results of research and development at a research institution, provide information on the results of research and development, and take other measures, in order to promote research and development in the medical care sector that is necessary for providing the world's most advanced medical care and to ensure the smooth practical application of the results of those.

(Improving the Research and Development Environment)

Article 11 The national government is to, in order to ensure smooth and effective research and development in the medical care sector that is necessary for providing the world's most advanced medical care, take measures such as improving the clinical research environment in a medical institution that plays a core role in research and development in the medical care sector at research institutions and in clinical research.

(Ensuring Fair and Appropriate Operation for Research and Development)

Article 12 The national government is to take the necessary measures to ensure the fair and appropriate operation for research and development in the medical care sector so that a research institution, medical institution, or business operator complies with laws and regulations and the administrative guidance guidelines on research and development (meaning the administrative guidance guidelines referred to in Article 2, item (viii), (d) of the Administrative Procedure Act (Act No. 88 of 1993)), gives consideration to bioethics, and appropriately manages personal information, when conducting research and development in the medical care sector,

(Establishing a Better Examination System for Putting Research and Development Results into Practical Application)

Article 13 (1) The national government is to take measures such as establishing an examination system that enables the prompt and appropriate implementation of examinations for approval of pharmaceuticals, etc. pursuant to the provisions of Article 14, Article 23-2-5 or Article 23-25 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices and other procedures necessary for the practical application of pharmaceuticals, etc., in order to ensure the prompt and safe practical application of new pharmaceuticals, etc. that are the results of research and development in the medical care sector.

(2) The national government is to take measures to establish a system necessary

for the promotion of science to properly and promptly predict, evaluate, and judge the quality, efficacy, and safety of the results based on scientific knowledge, secure and train personnel, improve their qualities, and take other measures, when putting the results of research and development in the medical care sector into practical application.

(Promoting the Creation and Overseas Development of New Industries)

Article 14 The national government is to take the necessary measures to promote the commercialization of the results of research and development in the medical care sector and otherwise create new industrial activities, and to promote the expansion of those activities overseas in order to revitalize new industrial activities that contribute to the establishment of a society in which people enjoy long and healthy lives.

(Promotion of Education)

Article 15 The national government is to promote education and learning on cutting-edge healthcare and medical research and development and the creation of new industries, enhance public relations activities, and take other necessary measures so that the people will have a deeper interest in and understanding of cutting-edge healthcare and medical research and development and the creation of new industries.

(Securing Personnel)

Article 16 The national government is to take the necessary measures to secure, train, and improve the quality of personnel who has expert knowledge concerning cutting-edge healthcare and medical research and development and the creation of new industries in close collaboration and cooperation with local governments, research institutes, medical institutions, and business operators,.

### **Chapter III Healthcare Policy**

Article 17 (1) The government is to establish a healthcare policy based on the basic measures prescribed in the preceding Chapter, in accordance with the basic principles.

(2) The healthcare policy is to specify the following matters:

- (i) the outline of the measures for cutting-edge healthcare and medical research and development and the creation of new industries that the government should take comprehensively and over the long term;
- (ii) beyond what is stated in the preceding item, matters necessary for the government to comprehensively and systematically promote measures it should take for cutting-edge healthcare and medical research and

- development and the creation of new industries.
- (3) The Prime Minister is to seek a cabinet decision on the draft of healthcare policy prepared by the Headquarters for Healthcare Policy.
  - (4) When a cabinet decision under the provisions of the preceding paragraph has been made, the Prime Minister is to make public the healthcare policy without delay.
  - (5) The provisions of the preceding two paragraphs apply mutatis mutandis to changes in the healthcare policy.

#### **Chapter IV Promotion of Research and Development in the Medical Care Sector**

(Promotion Plan for Research and Development in the Medical Care Sector)

- Article 18 (1) The Headquarters for Healthcare Policy is to prepare a plan for promoting measures for research and development in the medical care sector (referred to below as the "promotion plan for research and development in the medical care sector" in this Article, the following Article, and Article 21, item (ii)) in line with the healthcare policy, in order to intensively and systematically promote measures to be taken by the government for research and development in the medical care sector, improvement of the environment for the research and development, and dissemination of those results (referred to below as the "measures for research and development in the medical care sector").
- (2) The promotion plan for research and development in the medical care sector is to specify the following:
    - (i) the basic policy on measures for research and development in the medical care sector;
    - (ii) measures for research and development in the medical care sector that should be taken in an intensive and systematic manner;
    - (iii) beyond what is stated in the preceding two items, matters necessary to promote measures for research and development in the medical care sector in an intensive and systematic manner.
  - (3) Concerning measures for research and development in the medical care sector stated in item (ii) of the preceding paragraph, the specific goals of the relevant measures for research and development in the medical care sector and the period for achieving the goals are to be specified.
  - (4) When the Headquarters for Healthcare Policy has prepared a promotion plan for research and development in the medical care sector pursuant to the provisions of paragraph (1), it is to make public the plan without delay.
  - (5) The Headquarters for Healthcare Policy is to review the promotion plan for research and development in the medical care sector and make necessary

changes, taking into consideration changes in the circumstances surrounding research and development in the medical care sector and based on an evaluation of the effects of the measures for research and development in the medical care sector.

- (6) The provisions of paragraph (4) apply *mutatis mutandis* to changes to the promotion plan for research and development in the medical care sector.

(Core Role of the Japan Agency for Medical Research and Development,  
National Research and Development Agency)

Article 19 The promotion plan for research and development in the medical care sector is to be prepared so that the Japan Medical Research and Development Agency, National Research and Development Agency will play a core role in research and development in the medical care sector conducted by utilizing the capabilities of research institutions and the improvement of the environment of those, and in assisting research and development in the medical care sector and the improvement of the environment of those at research institutions.

## **Chapter V Headquarters for Healthcare Policy**

(Establishment)

Article 20 The Headquarters for Healthcare Policy (referred to below as the "Headquarters") is established in the Cabinet for the purpose of promoting healthcare policy.

(Affairs under the Jurisdiction)

Article 21 The Headquarters takes charge of the following affairs:

- (i) matters concerning the preparation of drafts of healthcare policy and the promotion of their implementation;
- (ii) matters concerning the preparation of the promotion plan for research and development in the medical care sector and the promotion of its implementation;
- (iii) matters related to the planning, drafting, and overall coordination of policies for the allocation of budgets, personnel, and other resources related to research and development in the medical care sector and the improvement of the environment of those;
- (iv) stating its opinions pursuant to the provisions of Article 8 or 20 of the Act on the Japan Agency for Medical Research and Development, National Research and Development Agency (Act No. 49 of 2014);
- (v) beyond what is stated in the preceding items, affairs related to the planning, drafting, and overall coordination of important measures for cutting-edge healthcare and medical research and development and the creation of new

- industries;
- (vi) beyond what is stated in the preceding items, affairs assigned to the Headquarters pursuant to the provisions of other laws and regulations.

(Organization)

Article 22 The Headquarters consists of the Director-General of the Headquarters for Healthcare Policy, the Vice Director-General of the Headquarters for Healthcare Policy, and the members of the Headquarters for Healthcare Policy.

(Director-General of the Headquarters for Healthcare Policy)

- Article 23 (1) The Headquarters is headed by the Director-General of the Headquarters for Healthcare Policy (referred to as the "Director-General" in the following paragraph, paragraph (2) of the following Article, and Article 25, paragraph (2)), and the Prime Minister serves in this capacity.
- (2) The Director-General takes overall control of the affairs of the Headquarters and directs and supervises the employees of the Headquarters.

(Vice Director-General of the Headquarters for Healthcare Policy)

- Article 24 (1) The Vice Director-General of the Headquarters for Healthcare Policy (referred to as the "Vice Director-General" in the following paragraph and paragraph (2) of the following Article) is established in the Headquarters, and the Chief Cabinet Secretary and the Minister for Healthcare Policy (meaning the Minister of State whose duty is to assist the Prime Minister concerning healthcare policy, as ordered by the Prime Minister) serve in this capacity.
- (2) The Vice Director-General assists the duties of the Director-General.

(Members of the Headquarters for Healthcare Policy)

- Article 25 (1) Members of the Headquarters for Healthcare Policy (referred to as the "members" in the following paragraph) are assigned to the Headquarters.
- (2) The Members are appointed from all Ministers of State other than the Director-General and the Vice Director-General.

(Submission of Materials and Other Forms of Cooperation)

- Article 26 (1) When the Headquarters finds it necessary for executing the affairs under its jurisdiction, it may request the heads of relevant administrative organs, local governments, incorporated administrative agencies (meaning the incorporated administrative agencies prescribed in Article 2, paragraph (1) of Act on General Rules for Incorporated Administrative Agencies (Act No. 103 of 1999)) and local incorporated administrative agencies (meaning the local



incorporated administrative agency prescribed in Article 2, paragraph (1) of the Local Independent Administrative Agency Act (Act No. 118 of 2003)), and the representatives of special corporations (meaning corporations directly incorporated by law or corporations incorporated by a special act of incorporation pursuant to a special law, to which the provisions of Article 4, paragraph (1), item (viii) of the Act for Establishment of the Ministry of Internal Affairs and Communications (Act No. 91 of 1999) apply) to submit materials, express opinions, give explanations and provide other necessary cooperation.

(2) When the Headquarters finds it particularly necessary for executing the affairs under its jurisdiction, it may ask for necessary cooperation from persons other than those prescribed in the preceding paragraph.

(Affairs)

Article 27 Affairs concerning the Headquarters are handled by the Cabinet Office.

(Competent Minister)

Article 28 For matters concerning the Headquarters, the Prime Minister is to be the competent minister as referred to in the Cabinet Act (Act No. 5 of 1947).

(Delegation to Cabinet Order)

Article 29 Beyond what is provided for in this Act, necessary matters concerning the Headquarters are specified by Cabinet Order.

## **Supplementary Provisions**

(Effective Date)

Article 1 This Act comes into effect on the date of promulgation; provided, however, that the provisions of Chapters III through V come into effect on the day specified by Cabinet Order within a period not exceeding three months from the date of promulgation.

(Review)

Article 2 (1) Within three years after the enforcement of this Act, the government is to review the status of the development of the clinical research environment in a medical institution that plays a core role in clinical research, and take necessary measures based on the results of the review.

(2) Beyond what is provided for in the preceding paragraph, within five years after the enforcement of this Act, the government is to review the status of enforcement of this Act and take the necessary measures based on the results

of the review.

(Replacement of Terms until the Day Preceding the Date of Enforcement of the Act Partially Amending the Pharmaceutical Affairs Act)

Article 3 If the date of promulgation of this Act is before the date of enforcement of the Act Partially Amending the Pharmaceutical Affairs Act, etc. (Act No. 84 of 2013), concerning the application of the provisions of Article 1 and Article 13, paragraph (1) until the day before the date of enforcement, the term "the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices" in Article 1 is deemed to be replaced with "the Pharmaceutical Affairs Act," the term "paragraph (4) of that Article" is deemed to be replaced with "or paragraph (4) of that Article," the term ", or regenerative medicine products provided in paragraph (9) of that Article" is deemed to be replaced with " , " and the term "Article 14, Article 23-2-5 or Article 23-25 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices" in Article 13, paragraph (1) is deemed to be replaced with "Article 14 of the Pharmaceutical Affairs Act.

(Replacement of Terms until the Establishment of the Japan Agency for Medical Research and Development, Independent Administrative Agency)

Article 4 Concerning the application of the provisions of Article 21, item (iv) until the establishment of the Japan Agency for Medical Research and Development, Independent Administrative Agency, the term "Article 8 or" in that item is deemed to be replaced with "Article 8 of that Act or that Act, as applied mutatis mutandis pursuant to Article 4 of the Supplementary Provisions".