

健康・医療戦略推進法

Act on Promotion of Healthcare Policy

(平成二十六年五月三十日法律第四十八号)
(Act No. 48 of May 30, 2014)

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第一章 総則

Chapter I General Provisions

(目的)

(Purpose)

第一条 この法律は、国民が健康な生活及び長寿を享受することのできる社会（以下「健康長寿社会」という。）を形成するためには、先端的な科学技術を用いた医療、革新的な医薬品等（医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律（昭和三十五年法律第百四十五号）第二条第一項に規定する医薬品、同条第四項に規定する医療機器又は同条第九項に規定する再生医療等製品をいう。第十三条第一項において同じ。）を用いた医療その他の世界最高水準の技術を用いた医療（以下「世界最高水準の医療」という。）の提供に資する医療分野の研究開発並びにその環境の整備及び成果の普及並びに健康長寿社会の形成に資する新たな産業活動の創出及び活性化並びにそれらの環境の整備（以下「健康・医療に関する先端的研究開発及び新産業創出」という。）を図るとともに、それを通じた我が国経済の成長を図ることが重要となっていることに鑑み、健康・医療に関する先端的研究開発及び新産業創出に関し、基本理念、国等の責務、その推進を図るための基本的施策その他基本となる事項について定めるとともに、政府が講ずべき健康・医療に関する先端的研究開発及

び新産業創出に関する施策を総合的かつ計画的に推進するための計画（以下「健康・医療戦略」という。）の作成及び健康・医療戦略推進本部の設置その他の健康・医療戦略の推進に必要となる事項について定めることにより、健康・医療戦略を推進し、もって健康長寿社会の形成に資することを目的とする。

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.

（基本理念）

(Basic Principles)

第二条 健康・医療に関する先端的研究開発及び新産業創出は、医療分野の研究開発における基礎的な研究開発から実用化のための研究開発までの一貫した研究開発の推進

及びその成果の円滑な実用化により、世界最高水準の医療の提供に資するとともに、健康長寿社会の形成に資する新たな産業活動の創出及びその海外における展開の促進その他の活性化により、海外における医療の質の向上にも寄与しつつ、我が国経済の成長に資するものとなることを旨として、行われなければならない。

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.

(国の責務)

(Responsibilities of the National Government)

第三条 国は、前条に定める基本理念（以下「基本理念」という。）にのっとり、健康・医療に関する先端的研究開発及び新産業創出に関する施策を総合的かつ計画的に策定し、及び実施する責務を有する。

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").

(地方公共団体の責務)

(Responsibilities of Local Governments)

第四条 地方公共団体は、基本理念にのっとり、健康・医療に関する先端的研究開発及び新産業創出に関し、国との適切な役割分担の下、地方公共団体が実施すべき施策として、その地方公共団体の区域の特性を生かした自主的な施策を策定し、及び実施する責務を有する。

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.

(研究機関の責務)

(Responsibilities of Research Institutions)

第五条 大学、研究開発法人（科学技術・イノベーション創出の活性化に関する法律（平成二十年法律第六十三号）第二条第九項に規定する研究開発法人をいう。）その他の研究機関（以下単に「研究機関」という。）は、基本理念にのっとり、医療分野の研究開発及びその成果の普及並びに人材の育成に積極的に努めなければならない。

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 研究機関は、医療分野の研究開発を行うに当たっては、先端的、学際的又は総合的な研究に努めなければならない。

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

(医療機関の責務)

(Responsibilities of Medical Institutions)

第六条 医療機関は、基本理念にのっとり、第三条の規定に基づき国が実施する施策及び第四条の規定に基づき地方公共団体が実施する施策に協力するよう努めなければならない。

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.

(健康・医療に関する先端的研究開発及び新産業創出を行う事業者の責務)

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

第七条 健康・医療に関する先端的研究開発及び新産業創出を行う事業者（次条、第十二条及び第十六条において単に「事業者」という。）は、基本理念にのっとり、自ら研究開発に努めるとともに、第三条の規定に基づき国が実施する施策及び第四条の規定に基づき地方公共団体が実施する施策に協力するよう努めなければならない。

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.

(連携の強化)

(Strengthening Collaboration)

第八条 国は、国、地方公共団体、研究機関、医療機関及び事業者が相互に連携を図りながら協力することにより、健康・医療に関する先端的研究開発及び新産業創出の効果的な実施が図られることに鑑み、これらの者との間の連携の強化に必要な施策を講ずるものとする。

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.

(法制上の措置等)

(Legislative Measures)

第九条 国は、健康・医療に関する先端的研究開発及び新産業創出に関する施策を実施するため必要な法制上又は財政上の措置その他の措置を講ずるものとする。

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.

第二章 基本的施策

Chapter II Basic Measures

(研究開発の推進)

(Promoting Research and Development)

第十条 国は、世界最高水準の医療の提供に必要な医療分野の研究開発の推進及びその成果の円滑な実用化を図るため、医療分野の研究開発に関し、基礎的な研究開発から実用化のための研究開発までの一貫した研究開発の推進、研究機関における研究開発の成果の移転のための体制の整備、研究開発の成果に係る情報の提供その他の施策を講ずるものとする。

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.

(研究開発の環境の整備)

(Improving the Research and Development Environment)

第十一条 国は、世界最高水準の医療の提供に必要な医療分野の研究開発が円滑かつ効果的に行われるよう、研究機関における医療分野の研究開発及び臨床研究において中核的な役割を担う医療機関における臨床研究の環境の整備その他の施策を講ずるものとする。

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.

(研究開発の公正かつ適正な実施の確保)

(Ensuring Fair and Appropriate Operation for Research and Development)

第十二条 国は、研究機関、医療機関又は事業者が、医療分野の研究開発を行うに当たっては、法令及び研究開発に関する行政指導指針（行政手続法（平成五年法律第八十八号）第二条第八号ニの行政指導指針をいう。）を遵守し、生命倫理への配慮及び個人情報管理の適切な管理を行うよう、医療分野の研究開発の公正かつ適正な実施の確保に必要な施策を講ずるものとする。

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,

(研究開発成果の実用化のための審査体制の整備等)

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

第十三条 国は、医療分野の研究開発の成果である新たな医薬品等の実用化が迅速かつ安全に図られるよう、医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律第十四条、第二十三条の二の五又は第二十三条の二十五の規定による医薬品等の承認のための審査その他の医薬品等の実用化のために必要な手続の迅速かつ的確な実施を可能とする審査体制の整備その他の施策を講ずるものとする。

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 国は、医療分野の研究開発の成果の実用化に際し、その品質、有効性及び安全性を科学的知見に基づき適正かつ迅速に予測、評価及び判断することに関する科学の振興に必要な体制の整備、人材の確保、養成及び資質の向上その他の施策を講ずるものとする。

(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.

(新産業の創出及び海外展開の促進)

(Promoting the Creation and Overseas Development of New Industries)

第十四条 国は、健康長寿社会の形成に資する新たな産業活動の活性化を図るため、医療分野の研究開発の成果の企業化の促進その他の新たな産業活動の創出及びその海外における展開の促進に必要な施策を講ずるものとする。

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.

(教育の振興等)

(Promotion of Education)

第十五条 国は、国民が広く健康・医療に関する先端的研究開発及び新産業創出に対する関心と理解を深めるよう、健康・医療に関する先端的研究開発及び新産業創出に関する教育及び学習の振興、広報活動の充実その他の必要な施策を講ずるものとする。

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.

(人材の確保等)

(Securing Personnel)

第十六条 国は、地方公共団体、研究機関、医療機関及び事業者と緊密な連携協力を図りながら、健康・医療に関する先端的研究開発及び新産業創出に関する専門的知識を有する人材の確保、養成及び資質の向上に必要な施策を講ずるものとする。

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,.

第三章 健康・医療戦略

Chapter III Healthcare Policy

第十七条 政府は、基本理念にのっとり、前章に定める基本的施策を踏まえ、健康・医療戦略を定めるものとする。

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 健康・医療戦略は、次に掲げる事項について定めるものとする。

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

一 政府が総合的かつ長期的に講ずべき健康・医療に関する先端的研究開発及び新産業創出に関する施策の大綱

(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;

二 前号に掲げるもののほか、政府が講ずべき健康・医療に関する先端的研究開発及び新産業創出に関する施策を総合的かつ計画的に推進するために必要な事項

(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 内閣総理大臣は、健康・医療戦略推進本部の作成した健康・医療戦略の案について閣議の決定を求めるものとする。

(3) The Prime Minister is to seek a cabinet decision on the draft of healthcare policy prepared by the Headquarters for Healthcare Policy.

4 内閣総理大臣は、前項の規定による閣議の決定があったときは、遅滞なく、健康・医療戦略を公表するものとする。

(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 前二項の規定は、健康・医療戦略の変更について準用する。

(5) The provisions of the preceding two paragraphs apply mutatis mutandis to changes in the healthcare policy.

第四章 医療分野の研究開発の推進

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

(医療分野研究開発推進計画)

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

第十八条 健康・医療戦略推進本部は、政府が講ずべき医療分野の研究開発並びにその環境の整備及び成果の普及に関する施策（以下「医療分野研究開発等施策」という。）の集中的かつ計画的な推進を図るため、健康・医療戦略に即して、医療分野研究開発等施策の推進に関する計画（以下この条、次条及び第二十一条第二号において「医療分野研究開発推進計画」という。）を作成するものとする。

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 医療分野研究開発推進計画は、次に掲げる事項について定めるものとする。

(2) The promotion plan for research and development in the medical care sector is to specify the following:

一 医療分野研究開発等施策についての基本的な方針

(i) the basic policy on measures for research and development in the medical care sector;

二 集中的かつ計画的に講ずべき医療分野研究開発等施策

(ii) measures for research and development in the medical care sector that should be taken in an intensive and systematic manner;

三 前二号に掲げるもののほか、医療分野研究開発等施策を集中的かつ計画的に推進するために必要な事項

(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 前項第二号の医療分野研究開発等施策については、当該医療分野研究開発等施策の具体的な目標及びその達成の期間を定めるものとする。
- (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 健康・医療戦略推進本部は、第一項の規定により医療分野研究開発推進計画を作成したときは、遅滞なく、これを公表するものとする。
- (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 健康・医療戦略推進本部は、医療分野の研究開発を取り巻く状況の変化を勘案し、及び医療分野研究開発等施策の効果に関する評価を踏まえ、医療分野研究開発推進計画の見直しを行い、必要な変更を加えるものとする。
- (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 第四項の規定は、医療分野研究開発推進計画の変更について準用する。
- (6) The provisions of paragraph (4) apply mutatis mutandis to changes to the promotion plan for research and development in the medical care sector.

(国立研究開発法人日本医療研究開発機構の中核的な役割)

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

第十九条 医療分野研究開発推進計画は、国立研究開発法人日本医療研究開発機構が、研究機関の能力を活用して行う医療分野の研究開発及びその環境の整備並びに研究機関における医療分野の研究開発及びその環境の整備の助成において中核的な役割を担うよう作成するものとする。

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.

第五章 健康・医療戦略推進本部

Chapter V Headquarters for Healthcare Policy

(設置)

(Establishment)

第二十条 健康・医療戦略の推進を図るため、内閣に、健康・医療戦略推進本部（以下「本部」という。）を置く。

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.

(所掌事務)

(Affairs under the Jurisdiction)

第二十一条 本部は、次に掲げる事務をつかさどる。

Article 21 The Headquarters takes charge of the following affairs:

一 健康・医療戦略の案の作成及び実施の推進に関すること。

(i) matters concerning the preparation of drafts of healthcare policy and the promotion of their implementation;

二 医療分野研究開発推進計画の作成及び実施の推進に関すること。

(ii) matters concerning the preparation of the promotion plan for research and development in the medical care sector and the promotion of its implementation;

三 医療分野の研究開発及びその環境の整備に関する予算、人材その他の資源の配分の方針の企画及び立案並びに総合調整に関すること。

(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;

四 国立研究開発法人日本医療研究開発機構法（平成二十六年法律第四十九号）第八条又は第二十条の規定により意見を述べること。

(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);

五 前各号に掲げるもののほか、健康・医療に関する先端的研究開発及び新産業創出に関する施策で重要なものの企画及び立案並びに総合調整に関すること。

(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;

六 前各号に掲げるもののほか、他の法令の規定により本部に属させられた事務

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

(組織)

(Organization)

第二十二條 本部は、健康・医療戦略推進本部長、健康・医療戦略推進副本部長及び健康・医療戦略推進本部員をもって組織する。

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.

(健康・医療戦略推進本部長)

(Director-General of the Headquarters for Healthcare Policy)

第二十三條 本部の長は、健康・医療戦略推進本部長（次項、次条第二項及び第二十五条第二項において「本部長」という。）とし、内閣総理大臣をもって充てる。

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 本部長は、本部の事務を総括し、所部の職員を指揮監督する。

(2) The Director-General takes overall control of the affairs of the Headquarters and directs and supervises the employees of the Headquarters.

(健康・医療戦略推進副本部長)

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

第二十四條 本部に、健康・医療戦略推進副本部長（次項及び次条第二項において「副本部長」という。）を置き、内閣官房長官及び健康・医療戦略担当大臣（内閣総理大臣の命を受けて、健康・医療戦略に関し内閣総理大臣を助けることをその職務とする国務大臣をいう。）をもって充てる。

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 副本部長は、本部長の職務を助ける。

(2) The Vice Director-General assists the duties of the Director-General.

(健康・医療戦略推進本部員)

(Members of the Headquarters for Healthcare Policy)

第二十五条 本部に、健康・医療戦略推進本部員（次項において「本部員」という。）

を置く。

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 本部員は、本部長及び副本部長以外の全ての国務大臣をもって充てる。

(2) The Members are appointed from all Ministers of State other than the Director-General and the Vice Director-General.

(資料の提出その他の協力)

(Submission of Materials and Other Forms of Cooperation)

第二十六条 本部は、その所掌事務を遂行するため必要があると認めるときは、関係行政機関、地方公共団体、独立行政法人（独立行政法人通則法（平成十一年法律第百三号）第二条第一項に規定する独立行政法人をいう。）及び地方独立行政法人（地方独立行政法人法（平成十五年法律第百十八号）第二条第一項に規定する地方独立行政法人をいう。）の長並びに特殊法人（法律により直接に設立された法人又は特別の法律により特別の設立行為をもって設立された法人であつて、総務省設置法（平成十一年法律第九十一号）第四条第一項第八号の規定の適用を受けるものをいう。）の代表者に対して、資料の提出、意見の表明、説明その他必要な協力を求めることができる。

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 本部は、その所掌事務を遂行するために特に必要があると認めるときは、前項に規定する者以外の者に対しても、必要な協力を依頼することができる。

(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.

(事務)

(Affairs)

第二十七条 本部に関する事務は、内閣府において処理する。

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

(主任の大臣)

(Competent Minister)

第二十八条 本部に係る事項については、内閣法（昭和二十二年法律第五号）にいう主任の大臣は、内閣総理大臣とする。

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).

(政令への委任)

(Delegation to Cabinet Order)

第二十九条 この法律に定めるもののほか、本部に関し必要な事項は、政令で定める。

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

附 則

Supplementary Provisions

(施行期日)

(Effective Date)

第一条 この法律は、公布の日から施行する。ただし、第三章から第五章までの規定は、公布の日から起算して三月を超えない範囲内において政令で定める日から施行する。

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.

(検討)

(Review)

第二条 政府は、この法律の施行後三年以内に、臨床研究において中核的な役割を担う医療機関における臨床研究の環境の整備の状況について検討を加え、その結果に基づいて必要な措置を講ずるものとする。

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 政府は、前項に定める事項のほか、この法律の施行後五年以内に、この法律の施行の状況について検討を加え、その結果に基づいて必要な措置を講ずるものとする。

(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.

(薬事法等の一部を改正する法律の施行の日の前日までの間の読替え)

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

第三条 この法律の公布の日が薬事法等の一部を改正する法律（平成二十五年法律第八十四号）の施行の前日である場合には、同日の前日までの間における第一条及び第十三条第一項の規定の適用については、第一条中「医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律」とあるのは「薬事法」と、「同条第四項」とあるのは「又は同条第四項」と、「又は同条第九項に規定する再生医療等製品をいう」とあるのは「をいう」と、第十三条第一項中「医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律第十四条、第二十三条の二の五又は第二十三条の二十五」とあるのは「薬事法第十四条」とする。

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.

(独立行政法人日本医療研究開発機構が成立するまでの間の読替え)

(Replacement of Terms until the Establishment of the Japan Agency for

Medical Research and Development, Independent Administrative Agency)

第四条 独立行政法人日本医療研究開発機構が成立するまでの間における第二十一条第四号の規定の適用については、同号中「第八条又は」とあるのは、「附則第四条において準用する同法第八条又は同法」とする。

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".