

# **The Healthcare Policy**

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## Introduction

The whole of humanity aspires to the creation of a society with a high life expectancy; having achieved the world's highest average life expectancy, Japan has turned this into reality. This is the result of its outstanding health and medical care systems, including a universal public health insurance system, excellent public health measures, and advanced medical technology. From now on, it will be even more important to ensure that every member of the populace remains healthy from infancy to old age, and to build a society in which they can live vibrant, fulfilling lives in accordance with their preferred lifestyle, whether playing an active role in society or enjoying leisure pursuits. The desire to live a long, healthy life is shared by most of the populace. As such, while maintaining the basic principles of the medical care and welfare field, which seeks to protect the lives of the people and guarantee the livelihood of each individual, the establishment of a society in which the public can live even healthier lives and enjoy greater longevity (a society in which people enjoy long and healthy lives) is becoming a matter of urgency.

Japan's average life expectancy is growing, because the universal public health insurance system that has been in place since 1961 through to the present day allows all citizens to receive medical care. However, in 1970, the share of elderly people aged 65 or above among the population as a whole (aging rate) passed 7%, which is the threshold for being considered an aging society. Over the next 24 years, the aging of the population progressed at a rate without precedent worldwide and in 1994 the aging rate reached the 14% threshold for being considered an aged society. By 2012, the aging rate had risen to 24.1% and is projected to reach 39.9% by 2060.

As the aging of the population began to attract attention within Japan, the nation was faced with the challenge of how to achieve a "healthy life expectancy", a term that the World Health Organization (WHO) defined for the first time in 2000. With the highest average life expectancy and aging rate in the world, Japan was faced with the challenge of not simply how to live a long time, but also how to ensure a life that was both long and healthy.

As the aging of the population has progressed, the number of people receiving nursing care under the nursing care insurance system introduced around that time in 2000 has been increasing by the year. The main reasons for requiring nursing care are cerebrovascular disease (21.5%), dementia (15.3%), age-related weakness (13.7%), and joint disease (10.9%) (Ministry of Health, Labour and Welfare (MHLW), *Comprehensive Survey of Living Conditions (2010)*). Looking at elderly (aged 65 or above) patients by illness/injury, among those admitted to hospital, 16.2% were admitted for cerebrovascular disease, 10.1% for malignant neoplasm, and 5.4% for cardiac disease (excluding hypertensive heart disease). Among those attending as outpatients, 2.7% were seen for cerebrovascular disease, 3.1% for malignant neoplasm, and 3.1% for cardiac disease (as above) (MHLW, *Patient Survey (2011)*). Thus, effective medical care for these conditions is required in order to establish a society in which people enjoy long and healthy lives in Japan.

Amid this situation, under the universal public health insurance system, the Japanese market for pharmaceutical drugs (hereinafter "drugs") is worth approximately ¥9.5 trillion, while the market for medical device is worth about ¥2.6 trillion, and both markets are slowly growing (MHLW, *Statistics of Production by Pharmaceutical Industry (2012)*). On the other hand, the trade deficit in the drugs market amounts to around ¥1.8 trillion (Ministry of Finance (hereinafter "MOF"), *Trade Statistics (2013)*), while that in the medical device market has reached approximately ¥0.7 trillion (MHLW, *Statistics of Production by Pharmaceutical Industry (2012)*), and the deficits in both areas are on the increase. Although the international competitiveness of Japanese pharmaceutical companies

remains high, Japanese companies face the challenge of further enhancing their international competitiveness. For example, in 2012, Japanese companies were lagging behind in terms of the development of biopharmaceuticals such as antibody preparations, which account for seven of the ten highest-earning major drugs worldwide. Furthermore, from the perspective of company scale, Japanese manufacturers of drugs and medical devices have fewer risk-tolerant management resources than their counterparts in the West, so while companies are investing enormous sums in drug R&D, the gap between Japan and the U.S.A. in terms of R&D expenditure per company is widening, due to the difference in company scale.

Looking at the situation worldwide, the total world population is projected to grow from 6.89589 billion in 2010 to 9.61519 billion in 2060, while the aging rate is forecast to rise from 7.6% in 2010 to 18.3% in 2060. In particular, looking at Asian countries, it is estimated that the aging rate in countries including China, Singapore, and South Korea will be in excess of 30% by 2060 and the aging of the population is expected to progress rapidly in future, suggesting that issues similar to Japan's will emerge as a result of the rising aging rate.

In light of such changes in the global demographic structure, it is vital for Japan, which is becoming an ultra-aging society ahead of the rest of the world, as a pioneer challenge solver, to realize the cutting-edge medical technologies and services, with the aim of establishing a society in which people enjoy long and healthy lives, as well as further extending healthy life expectancy (the length of time for which people can live without health problems restricting their daily life). In addition, Japan must contribute to improving the quality of medical care overseas by promoting the creation and overseas expansion of new industrial activities that assist in the establishment of a society in which people enjoy long and healthy lives, such as the Health-care New Frontier initiative focused on health care and "ME-BYO" industries, and cutting-edge medical treatment and technologies being undertaken to this end in Kanagawa Prefecture. While doing so, it is important for Japan to foster these sectors as strategic industries that can contribute to its economic growth and to expand them globally as an advanced medical and welfare country on the premise of the top level of safety and security in the world.

To respond to these challenges, the government set forth its interim policy on June 14, 2013 in the Japan Revitalization Strategy and the Healthcare Policy (hereinafter "the previous Healthcare Policy"), which was based on mutual agreement among relevant Cabinet ministers. In addition, on January 22, 2014, the government compiled the Comprehensive Policy on Medical R&D (Report by the Expert Panel on Medical R&D).

The Act on Promotion of Healthcare policy (Act No. 48 of 2014. Hereinafter "the Promotion Act") and the Act on the Independent Administrative Agency of Japan Agency for Medical Research and Development (Act No. 49 of 2014. Hereinafter "the AMED Act") were enacted on May 23, during the 186th ordinary session of the Diet. As such, in accordance with the provisions of Article 17 of the Promotion Act, the government hereby prescribes this Healthcare Policy (hereinafter "the Healthcare Policy"), while also taking into account previous initiatives.

## 1. General outline

### (1) The Healthcare Policy

#### 1) Positioning of the Healthcare Policy

On June 14, 2013, the growth strategy that forms the third of the “Three Arrows” aimed at revitalizing the Japanese economy, entitled the “Japan Revitalization Strategy -JAPAN is BACK-”, was approved by Cabinet. This set out three action plans – Plan for the Revitalization of Japanese Industry, the Strategic Market Creation Plan, and the Strategy of Global Outreach – as concrete initiatives aimed at achieving growth. Of these, the Strategic Market Creation Plan took “Extending the nation’s ‘healthy life expectancy’” as one of its themes, stipulating that the government would aim to achieve the following ideal situations in 2030:

- ① A society where people are able to live a healthy life and get old, by enhancing effective preventive care services and health management
- ② A society which can provide the necessary medical care at the world’s most advanced level by activating medical-related industries
- ③ A society where people unable to work due to illness or injury can return to work as quickly as possible through access to better medical and nursing care

The previous Healthcare Policy, which was put together on the same day as the Cabinet approved the Japan Revitalization Strategy, was based on measures in the Five-Year Strategy for Medical Innovation compiled by the Medical Innovation Council on June 6, 2012. These measures were revised and put together based on an approach of implementing those that could be implemented without delay, and swiftly incorporating any additional measures that should be included.

More specifically, it was determined that the two should be developed in tandem to ensure consistency between them, by working closely with the team formulating the Japan Revitalization Strategy and including key items in both the Japan Revitalization Strategy and the previous Healthcare Policy. In particular, the new items included in the previous Healthcare Policy in light of the Japan Revitalization Strategy were as follows: (1) establishing control tower functions in medical R&D; (2) global outreach of the medical market; (3) creation of services to extend healthy life expectancy; and (4) promoting the use of ICT in the field of healthcare and medical care.

Regarding the establishment of control tower functions in medical R&D, the Japan Revitalization Strategy and the previous Healthcare Policy stated that the government would take such steps as:

- ① Establishing a “Promotion Headquarters” consisting of the Prime Minister, the ministers in charge, and relevant other Cabinet ministers to serve as the headquarters of the medical R&D control tower; and
- ② Establishing an incorporated administrative agency to ensure seamless research management, from basic research through to its practical application.

In response, the establishment of the Headquarters for Healthcare Policy was approved by Cabinet on August 2, 2013. The body was tasked with comprehensively coordinating requests for and allocation of budget funds for medical R&D, promoting the previous Healthcare Policy and serving as the headquarters for the control tower in this field.

It was decided that the incorporated administrative agency would be established on the basis of the scrap and build principle. Advisor's committee, which provides policy advice to the Headquarters for Healthcare Policy, and Expert Panel on Medical R&D discussed the specific functions that it should have as a specialized agency optimized for the distinctive nature of medical R&D.

Following this process, during the 186th ordinary session of the Diet, the government submitted the Healthcare Policy Promotion Bill and the Japan Agency for Medical Research and Development Bill to the Diet on February 12, 2014, having obtained Cabinet approval for them the same day.

While the bills were being debated in the House of Representatives and the House of Councillors, the clause "Within three years of this Act's entry into force, the government will consider the situation concerning improvements to the clinical research environment at medical institutions playing a core role and will take the necessary measures based on the outcome of its deliberations" was added to Article 2 (1) of the supplementary provision of the Healthcare Policy Promotion Bill, in light of various circumstances surrounding medical R&D in particular. In addition, to ensure that appropriate steps are taken, supplementary resolutions were adopted concerning the accumulation of know-how regarding the prevention of fraud in research and the cultivation of specialist personnel in this area, and measures to provide citizens with a deeper understanding of the importance of R&D in the medical field. The Promotion Act and the AMED Act were subsequently enacted on May 23, 2014.

The "Japan Revitalization Strategy (Revised in 2014) -Japan's challenge for the future-" was approved by Cabinet on June 24, 2014, detailing the steady progress being made through initiatives undertaken to date with the aim of extending the nation's "healthy life expectancy", and setting forth new measures to be implemented to activate service industry outside the public insurance system.

This policy has been formulated in accordance with the provisions of Article 17 of the Promotion Act pursuant to the basic principles prescribed in Article 2 of the Promotion Act, in keeping with the basic measures prescribed in Articles 10 to 16 of the Promotion Act.

## 2) Basic principles of the Healthcare Policy

Article 17 (1) of the Promotion Act stipulates that "The government shall prescribe a Healthcare Policy in keeping with the basic measures prescribed in the previous Chapter, pursuant to the basic principles."

Article 2 of the Promotion Act prescribes the following matters concerning the basic principles of this policy.

[Basic principles prescribed in Article 2 of the Promotion Act]

### ① Provide medical care using the cutting-edge technologies

To provide people with the top level of medical care in the world by promoting integrated medical R&D activities, from basic R&D to practical applications R&D , and by smoothly putting the research outcomes into practical application.

### ② Contribute to economic growth

To contribute to Japan's economic growth while helping to improve the quality of medical care abroad by promoting the creation and overseas expansion of industries that contribute to the establishment of a society in which people enjoy long and healthy lives.

This makes it clear that building a system that steadily links Japan’s advanced R&D capabilities into the practical application of drugs, medical devices, and medical technology (technology required to provide medical care; excludes drugs (drugs as stipulated in Article 2 (1) of the Act on Ensuring the Quality, Effectiveness, and Safety of Drugs and Medical devices, etc. (Act No. 145 of 1960. Hereinafter referred to in this policy as the “Drugs and Medical device Act”).) (Named the Pharmaceutical Affairs Act until the Act to Partially Revise the Pharmaceutical Affairs Act (Act No. 84 of 2013) entered into force. The same shall apply hereinafter)), medical device (medical device as prescribed in paragraph 4 of said Article), and regenerative medicine products, etc. (regenerative medicine products, etc. as prescribed in paragraph 9 of said Article). Apart from “medical technology” in 2 (5) (b), the same shall apply hereinafter), with a view to achieving a society in which people truly enjoy long and healthy lives, will enable the country to provide the world’s best medical care by feeding back the outcomes of R&D to citizens. In addition, from the perspective of contributing to the international community, promoting the overseas expansion of industries that assist in establishing new societies in which people enjoy long and healthy lives will lead to improvements in the quality of medical care overseas, while also enabling markets for related industries to expand globally, thereby contributing to the growth of the Japanese economy.

It is vital to promote the Healthcare Policy on the basis of an accurate understanding of the needs of stakeholders such as patients and other citizens.

Given that Japan is in the process of becoming an ultra-aging society ahead of the rest of the world, it is important, as a pioneer challenge solver, to ensure the global spread of its model for overcoming the difficulties inherent in an ultra-aging society.

## (2) Period covered by the Healthcare Policy

This policy covers the period of five years from FY2014, foreseeing the next ten years.

This policy will undergo a full review five years after its formulation, but revisions may be made as necessary, based on the results of follow-up reviews.

## 2. Details

### (1) Measures related to medical R&D, etc. that contribute to the provision of the world’s best medical care

The government will take measures that will contribute to the provision of the world’s best medical care by promoting integrated medical R&D activities, from basic R&D to R&D focused on practical applications, and by facilitating the practical application of the results of these activities. Through this, it will aim to improve industrial competitiveness in fields associated with drugs, medical devices, etc. and medical technology, as well as promoting international medical collaboration and contributing to the international community.

Regarding medical R&D, in addition to this policy, a Plan for Promotion of Medical Research and Development (hereinafter “the Promotion Plan”) will be prepared that prescribes the basic policy on measures and the measures to be implemented intensively and systematically by the government, based on Article 18 of the Promotion Act and



in keeping with this policy. Medical R&D will be promoted on the basis of the Promotion Plan.

#### 1) Governmental measures to promote medical R&D

The government will promote integrated medical R&D activities, from basic R&D to R&D focused on practical applications, through partnerships between the Japan Agency for Medical Research and Development (hereinafter “AMED”), universities, and research institutes. The objective of this will be to promote the medical R&D required to provide the world’s best medical care, as well as facilitating the practical application of the results of this R&D.

##### ○ Promoting “cyclical R&D” and achieving open innovation

• It is necessary to strengthen basic research and constantly generate groundbreaking seeds to sustain medical R&D. Accordingly, as well as promoting “cyclical R&D” that not only channels the results of basic research into clinical settings, but also feeds the challenges identified in clinical settings back into basic research, the government will develop initiatives aimed at achieving open innovation, while securing intellectual property. Systems for the transfer of R&D results achieved by research institutes will be developed and information about such results will be provided.

• The government will strengthen the partnerships forged by the Pharmaceuticals and Medical Devices Agency (PMDA) and National Institute of Health Sciences with universities, research institutes, medical institutions, and companies. In addition, it will seek to disseminate and enhance regulatory science in R&D by augmenting the pharmaceutical affairs consultation system, developing examination guidelines, and improving the specialist knowledge of examiners.

##### ○ Building new mechanisms for developing drugs, medical devices, etc. and medical technology

• To build a system for unearthing and adopting promising seeds from research institutes in Japan and link these into practical applications, the government will develop systems for promoting integrated R&D activities, from basic R&D to clinical research (medical research in which humans are the subjects, which is carried out for the purpose of improving strategies for treating illness in the context of medical care, understanding the causes of diseases, etc., and increasing the quality of life of patients; this excludes “clinical trials” as prescribed in Article 2 (17) of the Drugs and Medical devices Act (Article 2 (16) of the Pharmaceutical Affairs Act that was in force until the day on which the Act to Partially Revise the Pharmaceutical Affairs Act entered into force). The same shall apply hereinafter) and trials, and on to practical applications, as well as for assisting verification in clinical settings and the identification of new challenges.

• To advance the development of innovative drugs and medical devices in Japan, the government will seek appropriate evaluation of innovation within the prescription drug price system, etc.

##### ○ Toward the establishment of evidence-based medicine

• To achieve medical care based on evidence such as environment or genetic background, the government will

proceed with deliberations focused on developing the necessary infrastructure and information technology. Large-scale cohorts and banks not only of patients, but also healthy individuals will be networked and utilized effectively. To ensure effective use of clinical information and diseased tissue and other samples obtained from patients, government support will be provided in dealing with bioethical issues and disease specimen banks will be developed. In addition, consideration will be given to enabling companies, etc. to access anonymized data.

- Initiatives for achieving the world's best medical care

- As well as promoting initiatives aimed at regenerative medicine and genomic medicine, the government will promote the use of Japan's advanced science and technology to identify the clinical nature of diseases and the establishment of gene therapies and other new treatments based on these findings. It will also cultivate groundbreaking new seeds that offer substantial hope for future drugs, medical devices, and medical technology, including the development of drug delivery systems (DDS) and innovative drugs and medical devices, etc. It will seek to strengthen the development of biopharmaceuticals, the market for which is expected to expand in the future, as well as next-generation technologies, instruments, and systems for measurement, analysis, and evaluation.

Given the substantial impact that it will have on society in the future, consideration will be given to the handling of information, including specific ethical responses and the need for legal restrictions.

- New systems for promoting medical R&D

- To promote governmental R&D in the field of medicine, the government will consolidate in the hands of AMED its strategic research expenditure allocation functions in relation to medical R&D focused on drugs, medical devices, etc. and medical technology, ensuring the integrated allocation of funds. Regarding the medical R&D carried out by individual ministries, AMED will provide integrated research management from the basic to the applied stages, utilizing the expertise of program directors (PD), ensuring seamless support for research activities from basic research through to practical application, including intellectual property (IP) management by IP experts.

(Note) Pursuant to the provisions of the Act for Establishment of Laws and Regulations Related to the Enforcement of the Act to Partially Revise the Act on General Rules for Independent Administrative Agency (Act No. 67 of 2014), the Japan Agency for Medical Research and Development will change from an incorporated administrative agency to a national research and development corporation on April 1, 2015, with this change being reflected in AMED's Japanese name.

## 2) Governmental measures to improve the environment for R&D

The government is implementing the necessary initiatives to improve the medical R&D environment. To this end, it has enacted the Act to Partially Revise the Pharmaceutical Affairs Act, which extends the scope of the system of medical device certification by an accredited certification body to cover specially controlled medical devices, and establishes an approval system that takes into account the attributes of regenerative medicine products, etc. that differ from ordinary drugs and medical devices; the Act to Ensure the Safety of Regenerative Medicine, etc. (Act

No. 85 of 2013), which prescribes for the first time standards for medical institutions providing regenerative medicine, etc., and standards for facilities cultivating and processing cells, to ensure the safety of regenerative medicine, etc.; and the Act Concerning Improvement of Relevant Acts for Promoting Comprehensive Measures for Securing Regional Medical and Nursing Care (Act No. 83 of 2014), which positions hospitals playing a central role in world-class clinical research and physician-led clinical trials as core hospitals for clinical research.

The government will continue to promote improvements to the environment – including systems, databases, and ICT – to facilitate the clinical research and trials required for the smooth, effective implementation of the medical R&D essential to the provision of the world’s best medical care.

- Fundamentally improving the clinical research and trials environment

- The government will make comprehensive use of the centers being developed as part of the Innovative Medical Technology Creation Center Project, namely translational research support centers, centers for early and exploratory clinical trials, core hospitals for clinical research, and centers for Japan-led global clinical research (hereinafter “Innovative Medical Technology Creation Centers”), as well as the national centers for advanced and specialized medicine (National Centers). In addition, it will promote clinical research and trials by building up ARO (Academic Research Organization) functions centered on these. To advance clinical research and trials, the government will seek the consolidation of cases through collaboration between facilities, and will promote further improvements in function while making effective use of these resources, thereby building a mechanism to enable high-quality world-class clinical research and trials to be conducted without fail.

In addition, to promote the high-quality clinical research and trials required for Japan to develop innovative drugs, medical devices, etc. and medical technology, the government will lose no time in considering the requirements for core hospitals for clinical research, which are positioned in the Medical Care Act as playing a central role in conducting world-class clinical research and physician-led clinical trials, so that these hospitals can be established.

- Developing the research base

- The government will aim to ensure that information and samples are shared as widely as possible, including life science databases, nationwide databases of intractable diseases, Big Data databases, and the collection and preservation of high-quality samples. In addition, collaboration focused on the databases developed by individual ministries will be promoted. The government will develop the research base in such areas as samples from patients and will work in partnership with both existing large-scale advanced research infrastructure, such as synchrotron radiation facilities and supercomputers, and small-scale facilities with cutting-edge measurement and analysis instruments, seeking to make it easier to use common science and technology infrastructure, and to utilize it to further promote medical R&D.

All possible measures will be taken to ensure the smooth transition of duties relating to drug discovery from the National Institute of Biomedical Innovation to AMED, particularly the transfer of its functions as the headquarters of the Drug Discovery Support Network. Moreover, the government will build a network consisting of universities, research and development corporations, and other research institutes and companies, to promote the development of medical device.

○ ICT-related initiatives

• The government will consider and put in place technologies for increasing the number of cases accumulated, with a view to promoting efficient clinical research and trials, as well as technologies that will allow the flexible integration of citizens' medical information and various other data, taking into account the conditions for the handling of medical information, including the need for legal revisions. Moreover, in promoting greater application of ICT to health and medical information, practical database functions will be developed, including the use of big data via ICT, to ensure its effective use in R&D. As well as promoting R&D concerning the comprehensive application of ICT in medical care, the government will undertake initiatives aimed at ensuring interoperability between systems handling this medical information.

3) Governmental measures to ensure fair and appropriate operation of R&D

The government will seek to prevent research irregularities, such as the fraudulent manipulation of data or conflict of interests in research papers, and deal with ethical issues, such as the protection of test subjects participating in clinical research. To this end, it will conduct the initiatives required to ensure the fair, appropriate implementation of medical R&D, to make sure that any research institute, medical institution, or business operator conducting medical R&D complies with legislation and administrative guidelines concerning R&D, as well as managing ethical considerations and personal information appropriately.

○ Fair research mechanisms and improving the environment to ensure ethical, legislative, and regulatory compliance

• Steady progress will be made with the revision of the Ethical Guidelines for Clinical Studies, which are currently under review. In FY2014, a system for the accreditation of ethical review boards that meet standards prescribed by the government will be introduced. As well as ensuring the quality of reviews conducted by these ethical review boards, overall improvements in their quality will be sought. To restore trust in Japanese clinical research, the government will review systems relating to clinical research, including the legal system, aiming to reach a conclusion by the autumn of 2014.

• To promote initiatives to prevent irregularities in basic and clinical research, a dedicated division will be established at AMED to ensure fair and appropriate operation of research conducted using the research funds that it allocates. In addition, through its duties, it will strive to accumulate know-how concerning responses to irregularities in medical R&D and to cultivate personnel specializing in this area.

4) Governmental measures to establish a better review system for putting the results of governmental R&D to practical application

The Act to Partially Revise the Pharmaceutical Affairs Act has been enacted to ensure that the fruits of medical

R&D, namely new drugs and medical devices, etc., are swiftly and safely put to practical application. Among other measures, the Act obliges those manufacturing and selling drugs and medical devices, etc. to submit package inserts prepared on the basis of up-to-date knowledge. In addition, it expands the scope of medical device certification by accredited certification bodies (in the case of the medical device manufacturing / manufacturing and sale sector, the provisions are described in a separate chapter from those for drugs, etc.), and establishes a system for granting conditional approval for regenerative medicine products, etc. for a limited period. A review system will be put in place to ensure the appropriate operation of this new scheme and enable the swift, accurate implementation of the procedures required for the practical application of drugs and medical devices, etc., including reviews of approval for drugs and medical devices, etc. The government will seek the development of the systems required for promoting science focused on swift, appropriate forecasting, evaluation, and judgment based on scientific knowledge, concerning the quality, effectiveness, and safety of practical applications for medical R&D results. In addition, it will aim to secure and nurture relevant personnel, as well as improving their capabilities.

○ Strengthening the PMDA

- The pharmaceutical affairs consultation system will be enhanced and the necessary operational improvements will be made to the priority clinical trial consultation system, to strengthen partnerships between the PMDA and universities, research institutes, medical institutions, and companies, with a view to ensuring that research results are linked efficiently to pharmaceutical approval.

- To support the development of practical applications, the government will bolster the PMDA's systems for pharmaceutical affairs consultation, etc. In addition, it will formulate and provide advice concerning an exit strategy for promising seeds in partnership with the PMDA, and will strengthen business partnerships and collaboration support functions, including the provision of information to companies and business matching.

- Consideration will be given to further expanding the scope of acceptance of English-language materials among the supporting materials submitted when applying to the PMDA for approval for a new drug.

○ Promoting regulatory science

- The government will strengthen the partnerships forged by the PMDA and National Institute of Health Sciences with universities, research institutes, medical institutions, and companies. In addition, it will seek to disseminate and enhance regulatory science in R&D by augmenting the pharmaceutical affairs consultation system, developing examination guidelines, and improving the specialist knowledge of examiners. (Described above)

5) Other necessary governmental measures

As well as developing drugs, medical devices, etc. and medical technology originating in Japan, and promoting efforts to contribute to improving medical care not only at home, but also in other countries, the government will seek to secure and cultivate personnel in all relevant fields, in order to increase the potential for medical R&D. In

seeking to increase Japan's international competitiveness in the field of medical care, the government will promote strategic IP initiatives, such as enhancing IP education, and cultivating and utilizing experts in IP.

○ Initiatives based on international perspectives

• Adequate consideration will also be given to international perspectives when setting R&D themes. As well as experts in individual fields, personnel with an international mindset will be cultivated and utilized. When selecting topics, the government will strive to ensure an adequate hearing for the opinions of both Japanese and foreign scientists in the relevant specialist discipline. Promoting international cooperation is also essential, so the government will strengthen support systems for conducting international collaborative research, such as the development of high-quality clinical research and trials, and the establishment of research networks. Through cooperation in the provision of medical services and development of systems suited to the circumstances and needs of the counterpart country, the government will seek to strengthen Japan's industrial competitiveness, while demonstrating an awareness of sustainable business development that truly contributes to medical care in the counterpart country. Positioning global health as a key issue in Japanese diplomacy, the government will mobilize knowledge from throughout Japan in its quest to ensure that everyone around the world can enjoy basic medical care services at an affordable price (universal health coverage (UHC)).

○ Human resource development

• The government will cultivate personnel who are well-versed in everything from basic research to clinical research and trials, have a record of world-class academic achievements, and can demonstrate strong leadership.

It will promote efforts to secure and cultivate experts in biostatistics, regulatory science, and other specialist fields.

Moreover, it will cultivate personnel capable of conducting multidisciplinary research and creating innovation, to ensure that innovative drugs, medical devices, etc. and medical technology reach clinical practice sooner.

Efforts will also be made to raise the nation's overall understanding (literacy) concerning health and disease.

○ IP management initiatives

• A dedicated department will be established in AMED to support research institutes in acquiring IP (IP management and advice desk, support for the formulation of IP acquisition strategies, etc.)

(2) Measures related to promoting the creation of new industries and facilitating overseas expansion in the healthcare and medical care sector

Markets that can respond to specific needs at home and abroad are required for the development of drugs and medical devices, technology, and services in Japan. On the domestic front, the government will seek to achieve the world's most advanced, highest-quality medical care, and to create new markets for healthcare services not covered by public insurance, focusing on such areas as disease prevention and chronic phase support for daily life. In addition, the government will develop overseas markets, while engaging in international medical cooperation, by

seeking the overseas expansion of new drugs, medical devices, etc. and medical technology, as well as new medical and healthcare services.

#### 1) Creation of new industries focused on healthcare and medical care

In creating a society in which people can enjoy healthier lives as they grow old, drugs, medical devices, etc. and medical technology are the foundation not only of the treatment of illnesses, but also of effective disease prevention, health management, and services that provide support for the daily lives of those affected by illness. As such, focusing primarily on such new healthcare services, it is essential to ensure that industrial activities contributing to the establishment of a society in which people enjoy long and healthy lives are coordinated with a variety of health promotion activities linked to the public insurance system and meet the various health-related needs of individuals and communities. This can be expected to “kill three birds with one stone”: (1) improving people’s health; (2) developing a new healthcare industry outside the public insurance system; and (3) as a result, optimizing expenditure on chronic medical care associated with lifestyle-related diseases, for example. Moreover, it will be important for local authorities and companies, along with insurers, to demonstrate a greater interest in the health of local citizens and employees and to make use of these industries when taking concrete actions.

At the same time, as the population declines in Japan’s regions, the development of new industrial activities that contribute to the establishment of a society in which people enjoy long and healthy lives is expected to play an important role in revitalizing local economies and communities. The use of this development to achieve local economic revitalization and ensure the sustainability of the public insurance system is a pressing issue and if sufficiently positive results can be achieved, it will become the world’s most advanced framework for complex healthcare.

The tasks required to achieve this include (1) rousing public awareness of health promotion and prevention; (2) visualizing the effects of disease prevention; (3) clarifying the various advantages and disadvantages of health promotion and prevention for individuals, companies, and local authorities; (4) using partnerships between medical institutions and companies to create scientifically-based services not covered by public insurance, including disease prevention and health management services; (5) utilizing local resources (collaboration between medicine, agriculture, commerce and industry) to create new industries; and (6) developing an environment in which high-quality clinical research and trials and cohort studies can be carried out smoothly at an appropriate cost, to generate scientifically-based services.

By taking on these challenges, the specific options for health promotion and disease prevention will become more diverse, making it possible to create a society in which, with reasonable effort, people can avoid contracting or aggravating diseases as far as possible. For example, in the case of diabetes and other lifestyle-related diseases, the use of health management services would enable people to routinely manage their own health, seeking a consultation at a medical institution if the possibility of a condition arose and using services to prevent disease or aggravation of a condition. Alternatively, insurers could conclude a contract with a service provider to supply the insured with a service.

To establish a proper care cycle and create industrial activities that will contribute to the establishment of a society in which people enjoy long and healthy lives, with a particular focus on services not covered by public

insurance, the Next-Generation Healthcare Industry Council established under the auspices of the Headquarters for Healthcare Policy will (1) improve the environment for creating new businesses, through such efforts as eliminating gray areas where the scope of application of existing regulations is unclear; (2) encourage the purchase and use by insurers and companies, etc. of services not covered by public insurance that will contribute to health promotion and disease prevention (hereinafter “investment in health”); and (3) promote the establishment of a mechanism for evaluating the quality of products and services. Moreover, to improve quality of life for elderly people and people with disabilities and create new manufacturing industries in Japan, the government will improve the environment to promote R&D focused on robotic care equipment and encourage its introduction.

(a) Improving the environment to create new business

○ Regional roll-out

• To develop industrial activities that will contribute to the establishment of a society in which people enjoy long and healthy lives in Japan’s regions, it is vital for diverse bodies such as service providers, medical institutions, local authorities, chambers of commerce and industry, and financial institutions to work in partnership with each other. Accordingly, the government will seek to roll out regional Next-Generation Healthcare Industry Councils nationwide, to nurture industries that make use of local resources, such as collaboration between medicine, agriculture, commerce and industry.

• The government will support model demonstration projects focused on new business, to promote regional collaboration between medicine, agriculture, commerce and industry.

• In order to develop dynamic industries focused on senior lifestyles and create a society in which elderly people can live healthy lives in their communities with peace of mind, the government will enhance the diverse range of living support services offered by elderly people themselves, NPOs, volunteers, social welfare service corporations, and private sector companies, based on the concept of self-help and mutual aid, while also striving to achieve appropriate partnerships and the division of roles with the local healthcare industry.

• The government will aim for local authorities to establish new social healthcare systems that incorporate service businesses (local healthcare that takes into account the existence of private sector services not covered by public insurance), creating a forum for the exchange of information concerning community health promotion based on an appropriate combination of not only medical care covered by public insurance and services within the scope of public benefit administration, but also community prevention and health management services.

○ Supplying funds for business

• In order to provide funding and management know-how for the healthcare industry and encourage the development and widespread adoption of new business models, the Regional Economy Vitalization Corporation of Japan (REVIC) will establish a Regional Healthcare Industry Support Fund (tentative name) to support the creation and expansion of the healthcare industry in Japan’s regions.



- The government will encourage effective use of the policy-based finance system to support the healthcare industry.

- Personnel

- Model projects focused on work and social participation by elderly people will be implemented, starting in the next fiscal year. In addition, starting in the next fiscal year, efforts will be made to promote public awareness of initiatives focused on the evaluation and verification of model projects, as well as awareness of initiatives aimed at promoting work and social participation by elderly people. These will subsequently be rolled out nationwide.

- The government will support matching projects focused on the effective use of local public health nurses and active senior personnel (people aged 65 or above who are capable of working).

- Improving ICT systems

- As well as promoting the development of systems that also share (visualize) relevant nursing and medical care information with the public, the government will promote information sharing and partnerships among diverse actors involved in integrated community care.

- The government will formulate the technical requirements and operational rules required for collaboration with patient-focused peripheral medical care services using information and communications technology, such as services in the medical cloud, and health management and monitoring. In addition, it will aim to standardize the process used for collaboration between medical institutions and private sector business operators, and verify the specific items that need to be shared.

- Other

- To offer health examinations and guidance based on the specific attributes of elderly people, with a view to further promoting efforts to prevent the need for nursing care, the government will work in partnership with medical institutions to undertake projects focused on preventing the exacerbation of underlying conditions for those suffering from lifestyle-related diseases, taking into account the opinions of experts and insurers concerning approaches to health services for elderly people.

- The government will develop a health guidance retreat program (tentative name) within the current fiscal year, which will focus on those suspected of having diabetes and will utilize hotels, traditional ryokan inns and other local tourism resources. Following pilot projects, the government will seek to promote the widespread adoption of this program.

- In addition to services focused on meals, exercise, and mobility support for elderly people and people with disabilities, the government will encourage the development and demonstration of new technologies and services

that promote the recovery of physical functions, such as improving and restoring the function of cranial nerves (neurorehabilitation). Establishing an initial market for these new technologies and services is particularly important, so the government will actively support overseas expansion efforts in this area.

(b) Encouraging investment in health by insurers and companies

○ Utilizing data such as medical receipts and health check information

• The government will formulate and announce a “data health program”, using data such as medical receipts and health check information provided by insurers to promote health programs based on data analysis. In addition, taking into account the results of large-scale verification of health creation models using ICT, it will seek to promote individual health-consciousness in projects positioned within the data health program. A collection of case studies of health programs based on insurers and business operators working together will be compiled and published, and collaboration between insurers and business operators (collaborative health) will be promoted.

• As a means of improving the take-up rate of special health check-ups among those insured with the Japan Health Insurance Association, the government will encourage initiatives to cultivate an awareness of the problem among business operators, to promote the provision of data to insurers by business operators. For example, these initiatives include lobbying of companies by insurers that use data, and the promotion of health management declarations by the senior management of SMEs.

• As a means of improving the take-up rate of special health check-ups among dependents of those insured via employees’ insurance, the government will add items to the special health check-up that will increase motivation to undergo the check-up and will implement measures to make health check-ups more convenient. Further measures to encourage dependents to undergo these check-ups may be implemented, depending on the implementation status of the aforementioned measures. Outsourcing to the National Health Insurance (NHI) program (municipal organizations) will also be promoted.

• The government will create next-generation healthcare services to support effective health programs by insurers, while promoting the integrated use of medical and nursing care information. To this end, it will aim to ensure that municipal NHI organizations make effective use of the NHI database (KDB) held by the All-Japan Federation of National Health Insurance Organizations, which brings together data from medical receipts and special health check-ups, with a view to analyzing regional medical expenses, gaining an understanding of local health issues, and implementing finely-tuned health programs.

• As well as promoting dental health initiatives within the context of the data health program, the government will verify the effects of dental health promotion services on lifestyle-related diseases. Based on the results, it will enhance dental promotion initiatives, such as further upgrading dental health promotion services.

• Using data from medical receipts held by insurers, the government will encourage initiatives to promote mental

health, by such means as supporting mental health measures undertaken by business operators.

○ Granting incentives

• With a view to granting incentives aimed at increasing the take-up rate of special health check-ups, the government will conduct demonstration projects concerning points-based healthcare incentive systems. Regarding systems for increasing or decreasing funding for older elderly people, the government will compile specific measures that take account of the opinions of relevant stakeholders and the verification of the effects of special health check-ups and special health guidance.

○ Evaluation of investment in health

• A new theme-based issue (Health-Management Stocks (tentative name)) will be established on the Tokyo Stock Exchange as a mechanism for evaluating companies that invest in health, and such companies will be encouraged to include details of their health management and disease prevention initiatives for employees in their corporate governance reports and CSR reports.

• The government will develop indicators that will allow investment in health by companies and health insurance societies to be evaluated and their health promotion initiatives to be compared. It will also encourage the use of these indicators by companies and health insurance societies in conjunction with the data health program.

○ Other

• The government will support good examples of projects such as initiatives focused on preventing the exacerbation of diabetes in diabetics, with a view to enabling the nationwide roll-out of such projects to begin during the current fiscal year.

• To encourage investment in health, the Next-Generation Healthcare Industry Council will publish and share examples of best practice by companies and insurers.

(c) Establishing a mechanism to evaluate the quality of products and services

• Regarding “healthy exercise services”, the government will undertake a trial of third-party certification by private sector organizations, and will encourage the use of certified services by local authorities and companies.

• The government will formulate standards for healthy meals that support the longevity of Japanese citizens and will develop a mechanism for encouraging widespread consumption of meals that meet these standards.

(d) Improving the environment to promote R&D focused on robotic care equipment and encourage its introduction

• To improve the quality of life of elderly people and people with disabilities and minimize the burden of nursing care, the government will promote improvements to the environment to facilitate R&D and practical applications in the field of robot technology.

- The government will seek to support the self-reliance of elderly people and people with disabilities, reduce the burden in frontline nursing care, and create a new manufacturing industry in Japan by ensuring the rapid adoption and widespread use of cheap robotic care equipment that meets the specific needs of elderly people and people with disabilities, as well as those on the frontline of nursing care. To this end, it will promote the Five-year Plan for Developing Nursing Care Robots, which began during the previous fiscal year and advocates using a contest format to encourage the development of cheap, convenient robotic care equipment, such as wearable transfer aids and monitoring systems. In addition, after large-scale introduction and demonstration begins this year, the government will aim for the full-scale introduction of such equipment in frontline nursing care from FY2015. Through this, it will seek to support the self-reliance of elderly people and people with disabilities, and alleviate the burden on care workers.

- The government will promote improvements to the environment aimed at the practical application of communication robot technology, including sensor technology, to facilitate its utilization in monitoring elderly people and people with disabilities, supporting daily life and nursing care, and healthcare.

## 2) Supporting business expansion of startup companies, etc. in growth markets

To develop the field of healthcare and medical care, it is vital to conduct R&D with a clear awareness of the market, restructure existing businesses, and establish new business models that will aid business development both within Japan and overseas. Accordingly, it is necessary to conduct both R&D and pioneering investment as integral halves of the same whole, and to offer support for business expansion by startup companies and SMEs in the field of healthcare and medical care.

### (a) Improving the environment for the supply of funds in the field of healthcare and medical care

- Compared with other fields, healthcare and medical care requires the investment of large sums of money and there is a tendency for the risks to be comparatively high as well. Accordingly, to ensure that investment and funding in this field is implemented and managed effectively, the Task Force on Healthcare Policy Funds established under the auspices of the Headquarters for Healthcare Policy will seek to ensure appropriate management in accordance with the attributes of the field in question, while exchanging and sharing information concerning such matters as the investment policies of public-private investment funds in this field, examples of investment, and the implementation status of relevant government policies. In doing so, consideration will be given to such guidelines as the Guidelines on the Management of Public-Private Investment Funds (approved on September 27, 2013 by the relevant Cabinet committee on promoting the use of public-private investment funds).

- To establish a virtuous circle in which public-private investment funds serve as pump-priming measures, with the startup companies thus cultivated then investing in new private sector startups, the government will compile examples of success in joint investment with the private sector from the initial stages of investment, and will seek

ongoing revitalization throughout the healthcare and medical care industry, while ensuring cooperation between the public and private sectors. In addition, to enhance the investment environment, the government will continue to develop and strengthen business support systems in the healthcare and medical care sector, such as the establishment of teams focused on healthcare and medical care at public-private investment funds and other businesses and the development of systems for this, with a view also to human resource development and the cultivation of private sector funds.

- Creating innovative drugs and medical devices, etc. while dealing with the diversification of medical needs and new technologies requires an environment in which private sector companies can actively engage in such endeavors as selection and concentration in areas of strength, and the promotion of open innovation that blends the company's own R&D and human resources with external seeds, technologies, and money. Accordingly, the government will continue to implement measures to encourage efforts to strengthen the R&D capabilities of private sector companies and develop drugs and medical devices, etc. that will contribute to increased international competitiveness.

(b) Support for industry development by startup companies and SMEs

- Collaboration between industry, academia and government

- Through collaboration between industry, academia and government, the government will utilize subsidies to realize innovations to support R&D that creates innovations by linking excellent seeds to practical applications.

- To promote business partnerships with startup companies and SMEs, the government will offer support for business matching forums with large corporations from both within Japan and overseas, as well as supporting overseas expansion. In conjunction with this, it will make effective use of gatherings, seminars, and exhibitions, etc. attended by companies, universities and other R&D organizations from across the globe, and will encourage startup companies and SMEs to form alliances with domestic and overseas pharmaceutical companies and medical device manufacturers.

- Starting from the pre-launch stage, the government will utilize the commercialization know-how of private sector venture capital companies and other private sector bodies to support the creation of university startups focusing on markets and outlets in their quest to commercialize high-risk seeds with a high potential for developing new markets.

- Regulation

- The PMDA's pharmaceutical affairs consultation program (including on-site consultation) will be enhanced, with the aim of offering advice concerning the development process (roadmap) for innovative drugs, medical devices, etc. and medical technology, and ensuring that they are put to practical application without delay. The primary focus of this advice will be universities, research institutes, business companies and SMEs.

- To promote the practical application of innovative medical device created by startup companies or SMEs, future approaches to examination fees will be explored.

### 3) Facilitation of overseas expansion in the healthcare and medical care sector

Boasting a universal public health insurance system and some of the world's most advanced drugs, medical device, etc. and medical technology, Japan's medical and nursing care system is one of the world's foremost, ranking among the top countries in the WHO's assessment of health care systems. On the other hand, in many emerging countries, there are growing expectations that economic growth will be accompanied by efforts to meet medical and nursing care needs and build sustainable systems. However, such countries have little experience of constructing insurance systems or medical and nursing care systems, as well as suffering from both a lack of sophisticated technology and personnel shortages.

Accordingly, giving adequate consideration to the situation in each country, Japan will provide specific drugs, medical devices, etc., medical technology, and medical services to emerging and developing countries, as well as providing cooperation in the construction of medical and nursing care systems, thereby building mutually-beneficial relationships in the field of medical and nursing care. Through this, Japan will ensure diversity in its methods of building diplomatic and economic relationships, thereby creating an environment that allows Japanese citizens to play an active role overseas with peace of mind. Furthermore, the government will aim to create a virtuous circle for both Japan and emerging and developing countries by using its efforts to encourage overseas expansion as a catalyst for creating cutting-edge medical and nursing care services in Japan as well.

#### (a) Appropriate operation of frameworks for international medical cooperation

- In forums such as the Task Force on International Expansion of Medical Businesses, which has been established under the auspices of the Headquarters for Healthcare Policy, relevant organizations (including Medical Excellence JAPAN (MEJ), the Japan International Cooperation Agency (JICA), the Japan Bank for International Cooperation (JBIC), the Japan External Trade Organization (JETRO), and the PMDA) and ministries will join forces to plan the overseas expansion of Japanese drugs, medical device, etc., medical technology, and medical services in a manner tailored to the needs of emerging and developing countries, sharing information and operating the PDCA cycle.

- In the process of operating frameworks for international medical cooperation, diplomatic missions overseas will work in partnership with JICA and other relevant government institutions to ascertain the health and medical care situation in emerging and developing countries and identify their needs. In addition, they will promote specific overseas expansion initiatives, such as collaboration and coordination with health authorities in the counterpart country.

#### (b) Building healthcare infrastructure in emerging countries

- Improving the environment in relation to health and medical care systems, technical standards, and regulatory requirements

- The government will seek the overseas expansion of medical and nursing care services based on an approach focused on both specific countries within each region and regions as a whole. To this end, it will provide emerging and developing countries in the ASEAN region and beyond with support for the establishment of health and welfare policies concerning measures to deal with the aging of the population, as well as sharing Japan's experience and knowledge concerning public medical insurance systems, and helping to improve the environment by offering personnel education systems. In addition, it will undertake cooperation with developed countries in the realm of measures against dementia.

- Based on cooperation between Japanese companies with overseas offices and relevant ministries and agencies, the government will promote exchanges that bring together the public and private sectors. More specifically, with a view to furthering the overseas expansion of high-quality drugs and medical devices, etc. originating in Japan, the government will strengthen dialogue with regulatory authorities in various countries and regions, focusing primarily on emerging and developing countries, in order to increase understanding of Japan's regulations, standards, and approval systems, thereby building and reinforcing relationships of trust at the national level.

- Japan will work in partnership with the countries of the West and Asia to improve understanding of Japan's regulations and standards around clinical trials and applications for approval of pharmaceuticals, as well as seeking to ensure international consistency in this area.

- The government will enhance research aimed at developing guidelines on evaluating the quality, effectiveness, and safety of drugs, medical devices, etc. and medical technology that utilizes cutting-edge technology. In addition, ahead of other countries, it will propose the formulation of international standards and criteria concerning methods of evaluating state-of-the-art drugs, medical devices, etc. and medical technology, and promote international standardization as a benchmark that can be used in regulation. At the same time, it will strengthen its efforts to disseminate information about Japanese drugs, medical devices, etc. and medical technology to the rest of the world. For example, it will take steps to ensure that the effectiveness of particle beam radiotherapy can be effectively explained to emerging countries on scientific grounds.

- The appropriate use of relevant international standards will be pursued to facilitate international distribution of Japanese drugs and medical devices, etc.

- In facilitating the overseas expansion of drugs, medical devices, etc., medical technology, and medical services, the government will promote the active use of telemedicine and other ICT.

- The government will verify and establish models for the practical application of medical device that uses information and communications networks. In addition, it will verify and establish communications standards for networks tailored to such equipment and will promote the overseas expansion of these models and communications standards.

- In pursuing the overseas expansion of drugs, medical devices, etc., medical technology, and medical services originating in Japan, the government will work with relevant countries to encourage the protection of IP rights, to achieve environmental improvements that will ensure that IP rights in regard to such products are properly secured and appropriate prices for them are set. In addition, it will promote improvements in market environments in these countries, conducting a study of systems for determining prices, including health technology assessments (HTA) for each country.

- Human resource development

- In terms of infrastructure for undertaking international medical projects, such as the overseas expansion of drugs, medical device, etc., medical technology, and medical services, the government will introduce foreign medical personnel to high-quality Japanese diagnostic and therapeutic techniques, providing them with ongoing opportunities to actually come into contact with them and strengthening educational functions in this area.

- The government will contribute to social stability in the Western Pacific Region in particular, by improving the standard of public health via the WHO's support programs. Maternal and child health and measures against infectious disease remain a high priority in emerging and developing countries, and they face a double disease burden in the form of lifestyle-related diseases and other non-communicable diseases (NCDs), so tackling these is a major challenge. However, the increase in the financial burden on the individual is also becoming a problem, so to achieve UHC, the government will strengthen support for human resource development in the field of health policy by sharing Japan's own experience and knowledge. Through this, it will improve the environment for Japanese companies to expand into these regions.

- (c) Overseas expansion through international medical projects

- Positioning MEJ as the core organization for promoting international medical projects, the government will support research, feasibility studies, demonstration projects, and finance focused on healthcare-related markets in each country, as well as conducting human resource development and accepting foreign patients, with a view to aiding the overseas expansion of drugs, medical devices, etc., medical technology, and medical services into markets in emerging and developing countries. Through this, it will support Japanese medical institutions and companies in establishing bases for offering medical services and undertaking related business initiatives overseas in a self-reliant, sustainable manner. At the same time, it will strengthen its efforts to disseminate information about Japanese drugs, medical devices, etc. and medical technology to the rest of the world. For example, it will take steps to ensure that the effectiveness of particle beam radiotherapy can be effectively explained to emerging countries on scientific grounds.

- Having gained an adequate understanding of the living and social environment in emerging and developing countries, particularly those in Asia, the government will encourage the deployment of drugs, medical devices, etc., medical technology, and medical services suited to the circumstances of each country and region, while improving



the environment for the supply of funds for integrated overseas expansion that unites these elements.

(d) Support via public-private partnerships focused on neglected tropical diseases (NTD) and malnutrition

- Via public-private partnership, the government will use the outstanding R&D capabilities of Japan's pharmaceutical industry to promote support for the provision of drugs to developing countries to fight diseases such as NTDs. In addition, it will continue to seek progress in partnership with the Global Health Innovative Technology Fund (GHIT Fund).

- The government will aim to ensure that Japan can demonstrate leadership in collaborative international clinical research and trials, so that high-quality evidence about the creation and use in clinical settings of innovative drugs, medical devices, etc. and medical technology originating in Japan can be disseminated. To this end, it will develop systems for global clinical research led by Japan that will facilitate the construction of international networks and support the systems of Japanese institutions participating in collaborative international clinical research and trials.

- To promote collaboration aimed at the discovery of innovative drugs, the government will support the Asia Partnership Conference of Pharmaceutical Associations (APAC) initiative, which aims to develop a platform for open innovation in the field of drug discovery involving industry, academia, and government throughout Asia.

- To contribute to the overseas expansion of drugs, medical devices, etc. and medical technology originating in Japan, the government will promote greater efficiency by such means as the digitalization of import and export procedures for such items using the Nippon Automated Cargo and Port Consolidated System (NACCS).

- In light of the fact that Japan and the UK affirmed in a joint statement their intention to strengthen worldwide initiatives to improve nutrition in the lead-up to the 2020 Tokyo Olympics and Paralympics, the government will make use of Japan's outstanding R&D capabilities in the field of fortified foods and promote the overseas expansion of inclusive business and other business initiatives via public-private partnerships focused on improving nutrition across the globe, including in emerging and developing countries. In addition, it will use the Sport for Tomorrow program and other opportunities to disseminate information about such initiatives.

(e) Use of Official Development Assistance (ODA) (support that utilizes drugs, medical devices, etc., medical technology, and medical services in which Japan has a comparative advantage, effective implementation of bilateral aid, and collaboration with global initiatives, based on the Strategy for Global Health Diplomacy, which positions initiatives in the field of international health as a key topic in Japan's diplomatic relations)

- In light of Japan's Strategy for Global Health Diplomacy, the government will position international health as a key topic in Japan's diplomatic relations and promote widespread adoption of UHC. It will strengthen initiatives focused on the achievement of the Millennium Development Goals (MDGs) and the formulation of post-2015 development targets, through collaboration with global initiatives and effective implementation of bilateral aid. While doing so, it will also contribute to encouraging adoption of UHC, mobilizing Japan's knowledge concerning

health and medical care systems and measures to deal with the aging of the population.

- While making effective use of ODA and other public funds, the government will support efforts to facilitate human resource development and the construction of medical insurance systems in emerging and developing countries, integrating these endeavors with initiatives focused on expanding exports of Japanese drugs, medical devices, etc., medical technology, and medical services.

- The government will promote proactive use of Special Terms for Economic Partnership (STEP) in Japanese ODA loans and overseas investment and lending by JICA.

#### 4) Other measures that contribute to the establishment of a society in which people enjoy long and healthy lives

The government will promote the following measures to assist in the creation of new industrial activities that will contribute to the establishment of a society in which people enjoy long and healthy lives, as well as encouraging overseas expansion.

- Responding to the escalation in the aging of the population and growing health-consciousness

- The government will support initiatives at every stage from food production to consumption, to encourage consumers to maintain a healthy diet. In addition, it will support activities aimed at providing a deeper understanding of food and the agriculture, forestry and fishery industry, developing food education as a national movement.

- Having been awarded Intangible Cultural Heritage status by UNESCO, Japanese cuisine is attracting growing attention not only from within Japan, but also from various other countries. However, although it is deemed to be highly effective in maintaining and promoting health, there is little scientific evidence to support this. Accordingly, the government will evaluate its functions in maintaining and promoting health, as well as its effects on stress resistance and motor function, and will publicize this information at home and overseas.

- During the current fiscal year, the government will implement new measures that will enable companies, etc. to label (at their own risk) so-called health foods and other processed foods and agricultural, forestry, and fisheries produce with information about their functionality, based on scientific evidence.

- The government will create a new industry focused on so-called health foods and other functional foods that will contribute to efforts to promote health. To this end, it will promote the sharing of information with nutritional guidance and meal delivery services that hope to use such foods, as well as encouraging interaction among business operators in this realm.

- Focusing on functional ingredients in agricultural, forestry, and fisheries produce, the government will promote

R&D focused on such produce and foods with high added value. In addition, it will establish supply systems tailored to the health of individuals, such as the guidance provided by national registered dietitians at Nutritional Care Stations established in partnership with Kanagawa Prefecture. Through such initiatives, it will aim to improve the eating habits of citizens, thereby contributing to efforts to build a rich, healthy diet.

- The government will promote the establishment of new markets by the private sector by promoting initiatives based on partnerships between the medical, welfare, food, and agriculture sectors. Examples of these include initiatives focused on improving awareness of nursing care food, support for initiatives aimed at establishing systems for the provision of new nursing care food developed using local agricultural, forestry, and fisheries produce, and development of industrial infrastructure to support new market development based on foods and services that promote a healthy life expectancy.

- As an initiative aimed at creating new demand for agricultural and livestock products through the use of such products in drugs and medical devices, the government is promoting the development of such products as rice containing cedar pollen protein, blood vessel prostheses made from silk yarn, and dressings made from collagen. In due course, the government will share the results of this initiative with private sector business operators and undertake trials of their safety and effectiveness in humans, with a view to their practical application.

- The government will undertake R&D focused on next-generation functional agricultural, forestry, and fisheries produce and foods aimed at maintaining and improving brain function and physical and motor function. In addition, as well as verifying their synergistic effect with sport and exercise, it will develop systems that make it simple to measure their effects in humans.

- Encouraging sports activities that contribute to health promotion

- Taking the opportunity offered by the decision to hold the 2020 Olympics and Paralympics in Tokyo, the government will aim to cultivate a nationwide awareness of health promotion through sport. To this end, based on collaboration between industry, academia and government, it will improve the environment with a view to enabling everyone – including women and people with disabilities – to enjoy sport from infancy through to old age, and will promote effective use of the results of research in the fields of sports medicine and science. Sports tourism in Japan's regions will also be promoted in conjunction with this.

- Improving the environment so that foreign residents can receive medical services in Japan with peace of mind

- The government will steadily promote various measures aimed at improving the environment so that foreign residents can receive medical services in Japan with peace of mind.

- Creating homes, towns, and transport systems that allow elderly people to live a comfortable and healthy life

- To enable people to live independently and comfortably at home for as long as possible into old age, the government will strive to build an advanced model based on using ICT, making homes more energy-efficient, and

promoting greater use of wood. In addition, it will use PPP/PFI to turn particularly old and dilapidated public rental housing estates (public housing and UR rental housing) in Japan's regions into welfare centers and develop serviced housing for elderly people. Moreover, the creation of multi-generational housing and communities adapted to people's life cycles (Smart Wellness Housing and Cities) will be promoted.

- To encourage elderly people to either renovate their home with a view to continuing to live there or to move to a home better suited to their needs in old age, based on an appropriate appraisal of housing assets, the government will encourage efforts to revitalize the market for used houses and renovation. To this end, it will promote such measures as the revision of appraisal techniques for used houses, the effective use of the assets of elderly people and other citizens, including via reverse mortgages, and the upgrading of existing housing to create houses that remain in excellent condition in the long term.

- With a view to the utilization of healthcare REITs to promote effective use of private sector funds, the government will develop guidelines and raise awareness concerning the acquisition and use of hospitals and housing for the elderly (including municipal hospitals).

- The government will construct systems that offer comprehensive support to local governments formulating site rationalization plans in accordance with the Act on Special Measures concerning Urban Reconstruction and local public transport restructuring plans in accordance with the Act on Revitalization and Rehabilitation of Local Public Transportation Systems. In addition, it will promote compact urban development based on consolidation of urban functions such as medical care and welfare, and residence along public transport routes, and will seek to expand opportunities for relocation through the enhancement of public transport. In conjunction with this, the government will further promote the introduction of barrier-free design in passenger facilities and vehicles, and will ensure thorough implementation of barrier-free measures along whole lines and throughout entire districts, rather than adopting a piecemeal approach focused on individual sites. Moreover, in promoting local industries focused on extending healthy life expectancy and constructing new regional social healthcare systems, the government will implement pioneering initiatives aimed at ensuring widespread adoption of super-compact mobility devices to complement public transport.

### (3) Measures for promotion of education and securing of personnel related to cutting-edge healthcare and medical R&D and the creation of new industries

In promoting advanced R&D in the field of healthcare and medical care and the creation of new industries, the government will implement the necessary measures to secure and cultivate personnel with expertise, and to further enhance their skills. In addition, it will promote education and learning aimed at deepening people's interest and understanding, and will also enhance PR activities in this area.

#### 1) Securing and cultivating the personnel required to promote cutting-edge healthcare and medical R&D

The government will promote the necessary initiatives to secure personnel with the expertise required to promote advanced R&D in the field of healthcare and medical care, as well as cultivating their abilities and enhancing their skills.

- Securing and cultivating the personnel required for efficient, effective promotion of clinical research and trials
  - The government will secure and cultivate the personnel required for efficient, effective promotion of clinical research and trials. Moreover, in doing so, it will seek to secure and expand the educational opportunities related to clinical research and trials that are offered to staff involved in associated duties, including further development of education, training, and e-learning.

- i. Specialist physicians, etc. who can play a leading role in clinical research and trials

- ii. Personnel who can carry out or support duties associated with clinical research and trials (clinical research coordinators (CRC), data managers (DM), biostatisticians, project managers, etc.)

- Utilizing personnel in the field of bioinformatics to respond to new needs
  - Medical data and information is growing exponentially and personnel working in the field of bioinformatics are indispensable to efforts to ensure its effective use, as well as to the future development of R&D in the life sciences. As such, the government will nurture personnel working in the field of bioinformatics.

- Promoting exchange and cultivation of personnel well-versed in innovative technologies and evaluation techniques for encouraging the practical application of innovative drugs, medical devices, and regenerative medicine products, etc.

- The government will support research that contributes to the establishment of techniques for evaluating the safety and effectiveness of innovative drugs, medical devices, and regenerative medicine products, etc. In addition, it will promote the exchange and cultivation of personnel with a view to encouraging the practical application of innovative drugs, medical devices, and regenerative medicine products, etc. Universities will also cultivate such personnel.

- Cultivating personnel with specialist skills in the specific handling methods required for regenerative medicine products, etc.

- The government will promote human resource development, developing training facilities where personnel can learn techniques essential to researchers investigating the clinical application of regenerative medicine, such as cell culture and processing.

## 2) Securing and cultivating the specialist personnel required to promote the creation of new industries

The government will promote efforts to secure and cultivate specialist personnel, such as innovative personnel who can provide integrated management of everything from the practical application of the drugs, medical devices, etc. and medical technology required to promote the creation of new industries, close collaboration and matching

between industry, academia, and government, and the identification and planning of medical care needs, to the formulation of business plans.

- Cultivating personnel who can match medical and nursing care needs and seeds as a viable business
  - Vision and knowledge concerning interdisciplinary medicine and engineering are required to develop medical device. Accordingly, the government will upgrade the medical device technology development environment by utilizing the results of research focused on development and appraisal methods, and encouraging partnerships between universities, the industrial sector, and medical institutions. Moreover, it will promote the cultivation of personnel who can formulate and commercialize plans and designs for medical device originating in Japan, pharmaceutical matters, intellectual property strategy, and business plans, as well as personnel who can demonstrate leadership in managing all of these in an integrated manner. In addition, the government will strive to encourage universities to offer education in interdisciplinary medicine and engineering.

- To cultivate innovative personnel in the field of medical care, the government will actively promote the introduction of advanced programs and people-to-people exchange.

- Cultivating personnel to support entrepreneurship
  - Strengthening partnerships with public and private sector personnel offering support for entrepreneurship, including venture capital funds, financial institutions, and certified public tax accountants and other accountants, the government will offer thorough management support (hands-on support) to business ideas and seeds with high growth potential, and promote awareness of examples of success and know-how in this area, thereby cultivating personnel capable of supporting entrepreneurship.

- The government will encourage exchange and cultivation of the personnel who are essential to the provision of peripheral medical and nursing care services and the internationalization of medical care.

- To enable Japan to respond to the simultaneous worldwide development of innovative drugs, medical devices, and regenerative medicine products, etc., the government will promote the strengthening of systems and efforts to secure and educate personnel at medical institutions actively involved in collaborative international clinical research and trials, to ensure that they are capable of dealing with linguistic and regulatory differences between countries.

3) Advancing education and learning, and enhancing PR activities concerning cutting-edge R&D and the creation of new industries

The government will promote PR activities and other initiatives to deepen public interest in and understanding of the importance of medical R&D and ensure wide-ranging cooperation in this area.

○ Disseminating information to promote understanding of the significance, benefits, and risks of clinical research and trials

• To enhance websites providing information concerning clinical research and trials, including those already underway, the government will actively endeavor to disseminate information that is easier for patients and the public as a whole to understand, in order to promote understanding of the significance, benefits, and risks of clinical research and trials. It will also promote more widespread awareness of these websites, with a view to deepening interest and understanding among the public concerning the importance of clinical research and trials and other medical R&D. Furthermore, it will conduct active PR campaigns to raise awareness of the significance of clinical research and trials.

(4) Measures related to digitization and ICT use associated with the medical, nursing and health care required to achieve the world's most advanced medical care

To promote comprehensive use of ICT in the field of medicine, nursing care, and health, the government will aim to establish efficient, high-quality medical services, and will seek to ensure that Japan's medical and nursing care and healthcare industries themselves become the world's best intellectual infrastructure, generating new medical technology and services. It will be most effective to divide the specific ICT promotion measures into three levels and adopt a phased approach to their implementation.

Level 1 is the digitization of frontline medical, nursing and health care

Level 2 is digitization throughout medical, nursing and health care (digital infrastructure)

Level 3 is the effective use of medical, nursing and health information

More specifically, it will be important to ensure that the diverse data collected from frontline digitized medical settings is standardized and structured to consolidate it into an overall digital infrastructure that can be shared among relevant parties and that this digital infrastructure is utilized to (1) achieve greater efficiency in the administration of medical care; (2) provide more advanced medical services; and (3) stimulate research through greater efficiency in clinical research and trials. To facilitate this, it is necessary not only to pursue technical integration through standardization and structuring of data collection and analysis, but also to develop mechanisms that make digitization economically sustainable, by such means as granting incentives for supplying data to the digital infrastructure, and creating rules for ensuring that the bodies using the digital infrastructure bear the cost of its maintenance. In conjunction with this, it will be necessary to establish rules and mechanisms for the handling of medical information, as well as the infrastructure for a numbering system, such as the Social Security and Tax Number system. Furthermore, it will be vital to create a virtuous circle in which the results of the use of information at Level 3 are fed back to frontline medical care, to promote greater efficiency and more advanced practices in frontline medical care through digitization and greater use of ICT, with this in turn promoting further improvements in the digital infrastructure (Level 2) and more advanced use of information (Level 3).

The information expected to be used via the digital infrastructure includes everything from data available from medical receipts, which has comparatively simple content (patient data, data concerning the name of the illness or injury, etc.) through to more complex data, including data from prescriptions, examinations, questionnaires,

operative notes, lifestyle records, reports, and death certificates.

Currently, the digitization of some data from clinical practice (Level 1), such as data from medical receipts, has been more or less completed; the MHLW has built the digital infrastructure (Level 2), and it has begun to be used by those working in health administration (Level 3).

In future, the government will promote the use of ICT throughout the fields of medical, nursing, and health care, to facilitate the integrated use of this infrastructure in all fields.

#### 1) Establishing digital infrastructure in the fields of medical, nursing and health care

The government will build mechanisms that facilitate the integrated collection and analysis of data gathered from different systems (including databases). More specifically, it will build a framework for a comprehensive package capable of (1) implementing technical collaboration and coordination; (2) implementing cross-sectoral coordination between system operators; and (3) continuously securing funds to cover the cost of maintaining the digital infrastructure (for example, mechanisms and rules to ensure that those benefiting from the analysis bear the cost of maintenance) (digital infrastructure in the fields of medical, nursing, and health care).

##### ○ Framework for deliberations

- In partnership with the IT Strategic Headquarters, which is in charge of considering the handling of personal data, particularly medical information, the government, medical institutions, academic societies in the field of medicine, research institutes, and industrial sectors will establish a forum for comprehensive deliberations and coordination. More specifically, the Task Force for Next-Generation Medical ICT established under the auspices of the Headquarters for Healthcare Policy will be progressively reorganized into the Council for Next-Generation Medical ICT Infrastructure (tentative name).

##### ○ Technical collaboration and coordination

- The government will conduct cross-sectoral coordination with a view to the efficient, effective use of ICT in existing programs focused on data collection and analysis. More specifically, the government will group together databases, etc. (consolidating purpose-specific databases and information concerning their data structure into a single catalog, which will also encompass local information-sharing infrastructure) and integrate them as far as necessary and possible (improving the environment to facilitate data exchange using common data structure rules and analysis of data from several different databases).

- The MHLW has established the Healthcare Information Specifications and Standards (MHLW Specifications and Standards), and will seek the adoption of these specifications and standards by project implementing bodies involved in data collection and analysis. In addition, standard specifications will be formulated in areas where these have not yet been prescribed.

- CSV text data file formats such as HL7, which is a standard used for the exchange of medical information, make it technically possible to collect information from several different databases, but issues still remain regarding the



standardization of methods of testing (for example, the fact that the use of different reagents in blood tests leads to different interpretations of the figures in the results, and the question of the degree to which peripheral information (such as whether the patient was standing or sitting when their blood pressure data was recorded) can be incorporated) and the lack of homogeneity in the structuring of expressions used in findings from history taking. The government will seek to resolve these problems.

- While conducting data collection and analysis, the government will improve the environment to facilitate greater interoperability and portability of databases.

- Making use of the outcomes of the Tohoku Medical Megabank program, which is conducting regional medical collaboration and cohort studies, the government will roll out its digital infrastructure in each region, as part of its efforts to implement the standardization required for sharing the medical and lifestyle data that will form the digital infrastructure for regional medical collaboration.

- To ensure integrated community care (collaboration between home medical care and nursing care), the necessary standardization will be carried out to facilitate the sharing of medical and nursing care data.

- With a view to building digital infrastructure, the government will seek appropriate ICT enhancement of projects including the Medical Information Database Infrastructure Development Project, medical information system backup projects undertaken by national university hospitals to assist with disaster countermeasures, cancer registration database projects, demonstration projects focused on standardization of dental care information, and database projects being undertaken by academic societies.

## 2) Using digital infrastructure in the fields of medical, nursing and health care

Data from medical receipts are already being analyzed and the results are beginning to be used. In addition to enhancing projects in this area, the government will promote the creation of projects focused on the large-scale collection, analysis and use of currently-unused test data, as well as the creation of high-quality, efficient medical services and healthcare services not covered by public insurance that are based on the utilization of ICT and the digital infrastructure.

- Comprehensive efforts aimed at ensuring reasonable medical expenses and health promotion among the public

- The MHLW has completed the standardization of data from medical receipts, so it has begun collating and analyzing it, and using the results. In addition to the information contained in medical receipts, the MHLW is gathering and analyzing Diagnosis Procedure Combination (DPC) data to which information has been added concerning the name of the illness or injury to which the largest amount of medical resources were devoted, along with certain information about the treatment received, focusing primarily on acute care hospitals. However, this information is not currently submitted to the MHLW online, so consideration will be given to the online submission

to the MHLW of DPC data via the examination and payment organizations at the same time as details of medical receipts are submitted, with the aim of alleviating the burden on medical institutions. Moreover, the submission of DPC data from chronic hospitals as well as acute care hospitals has been evaluated in terms of medical service fees, so the MHLW will also attempt to use DPC data to collect and analyze data regarding chronic hospitals.

- The government will promote the integrated use of medical and nursing care information through effective use by municipal NHI organizations of the KDB system operated by the All-Japan Federation of National Health Insurance Organizations, which brings together data from medical receipts and special health check-ups, with a view to analyzing regional medical expenses, gaining an understanding of local health issues, and implementing finely-tuned health programs.

- Preventing the exacerbation of lifestyle-related diseases

- The government will create projects focused on large-scale collection and analysis of test data, gathering the minimum amount of information necessary to obtain useful results. More specifically, with the aim of preventing the exacerbation of lifestyle-related diseases, the government will clearly stipulate such matters as targets for preventing the exacerbation of conditions, as well as the scale of the anticipated reduction in medical expenses. At the same time, it will collect and analyze the relevant test data from various databases, consider the potential for its secondary use in clinical research and trials and cohort studies, and generate concrete results while enhancing the digital infrastructure.

- Providing high-quality medical services at a low cost

- ICT will be used to promote the provision of sustainable medical services, such as critical care and telemedicine.

- Providing healthcare services not covered by public insurance

- The use of ICT in next-generation healthcare services and other industries outside the public insurance framework will be promoted.

- The government will aim to establish models that enable insurers, local authorities, and companies to use data and systems for the purpose of health promotion.

- Overseas expansion of efficient, high-quality medical care

- In facilitating the overseas expansion of drugs, medical devices, etc., medical technology, and medical services, the government will promote the active use of telemedicine and other ICT. (Described above)

- The government will verify and establish models for the practical application of medical device that uses information and communications networks. In addition, it will verify and establish communications standards for networks tailored to such equipment and will promote the overseas expansion of these models and communications standards. (Described above)

### 3) Advanced digitization of frontline medical, nursing and health care

The government will promote R&D focused on the application of ICT and the establishment of the requisite environment (for example, building mechanisms for evaluating and demonstrating new technologies and systems).

#### ○ R&D and practical applications focused on next-generation medical ICT

- As well as promoting R&D aimed at further digitization of clinical practice and seeking the practical application of the results, the government will consider approaches to interoperability and portability, with a view to the overseas expansion of these new systems.

- The government will promote R&D aimed at creating integrated systems capable of simultaneously analyzing a variety of medical information. The focus of this R&D will include the development of a platform incorporating a diagnostic aid system capable of associating and organizing information held in multiple systems, including electronic medical records and other hospital information systems (HIS), and picture archiving and communication systems (PACS) used for CT and other images.

- The government will develop operating theaters that offer highly efficient treatment. To this end, it will network various information about the patient undergoing surgery and the operating status of the diagnostic and therapeutic apparatus to be used in surgery, with the aim of building a surgical environment that dramatically increases the efficiency of treatment by facilitating the exchange of information both within the operating theater and outside it.

- To strengthen infrastructure for using supercomputer-based simulation techniques to make medical care and drug discovery processes more sophisticated and to encourage their use by pharmaceutical companies, the government will develop cutting-edge supercomputers that will assist in promoting efficient drug discovery.

#### ○ Demonstrating next-generation medical care systems

- It is hoped that next-generation medical care systems will actually support efforts to ensure greater operational efficiency in medical care, rather than being medical care systems that have evolved from medical accounting systems solely for the purpose of the digitization, storage, and sharing of information. In medical institutions that have introduced such next-generation medical care systems, teams will be established to (1) verify the performance of these systems; (2) establish techniques for their evaluation; (3) consider approaches to the necessary standards and common rules; and (4) examine measures for encouraging their practical application as medical software systems, thereby constructing a mechanism for substantiating improvements in the quality of medical care.

### 4) Systems associated with the use of medical and personal information

The government will formulate rules for the handling of medical information and the use of the My Number system or other numbering system infrastructure.

- Considering systems

- In medical-related fields, public acceptance is the prerequisite for developing the use of medical information that includes personal information. As such, as well as considering effective use of the My Number system or other numbering system infrastructure in the medical field, and clarifying the social rules for the use of medical information, the government will design sustainable data usage systems that utilize the dynamism of the private sector.

(5) Key Performance Indicators (KPIs)

The Key Performance Indicators (KPIs) for the measures set out in this policy in sections (1) to (4) of “2. Details” are as follows. These will be subject to further examination and verification as the measures in this policy are implemented, and will be revised if necessary.

a) Measures related to medical R&D, etc. that contribute to the provision of the top level of medical care in the world

- Drug discovery

[KPIs to be achieved by around 2020]

- Consulting and evaluation of seeds: 1,500 cases
  - Drug discovery support for promising seeds: 200 cases
  - Licensing-out to companies: 5 cases
  - Identification of drug discovery targets: 10 cases

- Development of medical device

[KPIs to be achieved by around 2020]

- Double the value of medical device exports (from approx. ¥500 billion in 2011 to approx. ¥1 trillion)
  - Put at least 5 types of innovative medical device to practical application
  - Expand the scale of the domestic market for medical device to ¥3.2 trillion

- Innovative Translational and Clinical Research Core Centers

[KPIs to be achieved by around 2020]

- Number of physician-led clinical trials notified: 40 cases per year
  - First in Human (FIH) studies (including company-initiated clinical trials): 40 cases per year

- Regenerative medicine

[KPIs to be achieved by around 2020]

- Develop clinical applications for new therapeutic drugs manufactured using iPS cell technology
  - Increase the number of pharmaceutical approvals granted for regenerative medicine products, etc.
  - Expand the scope of target diseases that transition into the clinical research or trial stage: approx. 15 cases

- Put peripheral equipment and apparatus related to regenerative medicine into practical application
- Present a proposal for international standardization of a method for evaluating drug cardiotoxicity using iPS cell technology

○ Genomic personalized medicine

[KPIs to be achieved by around 2020-2030]

- Dramatically improve therapies for lifestyle-related diseases (diabetes, stroke, myocardial infarction, etc.)
- Establish predictive diagnosis of cancer incidence, and of reactions to and adverse side-effects from anticancer drugs
- Start clinical research concerning genome therapy for depression and dementia
- Develop innovative methods of diagnosing and treating incurable neuromuscular diseases

○ Disease-specific research <Cancer>

[KPIs to be achieved by around 2020]

- License out at least 10 types of drug for clinical trial within 5 years, with a view to developing innovative anticancer drugs based on Japanese technology
- License out at least 6 types of drug for clinical trial, with a view to establishing practical applications for therapeutic drugs to treat pediatric, refractory, and rare cancers, including unapproved and off-label drugs
- Obtain approval or additional indications for at least 1 type of drug to treat pediatric and rare cancers, etc.
- Eliminate the so-called drug lag and device lag
- Establish standards of care for cancers that affect pediatric and elderly patients, and for rare cancers (formulate at least 3 sets of guidelines)

○ Disease-specific research <Psychiatric and Neurological Diseases/Disorders>

[KPIs to be achieved by around 2020]

- Start clinical trials of drug candidates originating in Japan for radical treatment of dementia, depression, and other psychiatric disorders
- Establish objective diagnostic techniques for psychiatric disorders
- Establish appropriate drug therapies for psychiatric disorders
- Complete maps of the structure and activity of all neural circuits in the brain

○ Disease-specific research <Emerging and re-emerging infectious diseases>

[KPIs to be achieved by around 2020]

- Identify drug target sites based on whole-genome databases obtained for pathogens (influenza, dengue fever, infectious diarrhea, drug-resistant bacteria); develop and put new rapid diagnosis methods into practical application
- Conduct non-clinical and clinical trials of a norovirus vaccine and a nasal influenza vaccine, and apply for pharmaceutical approval for these

\*KPI to be achieved by 2030

- Develop new vaccines

(E.g. versatile influenza vaccines)

- Develop new antibiotics and antivirals, etc.

• Eradicate/eliminate infectious diseases such as polio and measles, working in partnership with the WHO and various other countries

(KPI to be achieved by 2050 in the case of tuberculosis)

○ Disease-specific research <Rare/Intractable diseases>

[KPIs to be achieved by around 2020]

- Approve new drugs and additional indications for existing drugs in at least 11 cases

(amyotrophic lateral sclerosis (ALS), distal myopathy, etc.)

- Promote collaborative international clinical research and trials in partnership with U.S. and European databases

b) Measures related to promoting the creation and overseas expansion of new industry activities related to healthcare and medical care

[KPIs to be achieved by 2020]

• Expand market scale in industries related to health promotion and prevention and living support (from ¥4 trillion to ¥10 trillion)

• Raise the proportion of projects in receipt of joint investment from public-private investment funds and private sector companies in the field of healthcare and medical care to 100%

[KPI to be achieved by 2020]

- Establish Japanese medical centers overseas (increase from 3 to around 10 centers)

\*KPI to be achieved by 2030

- Expand the scale of overseas markets captured by Japanese medical technologies and services to ¥5 trillion

c) Measures for promotion of education and securing of personnel associated with cutting-edge healthcare and medical R&D and the creation of new industries

[KPI to be achieved by 2020]

- Extend the nation's healthy life expectancy by at least one year

[KPI to be achieved by 2020]

- Reduce the number of citizens with metabolic syndrome by 25% from the figure for FY2008

[KPI to be achieved by around 2020]

- Increase the health check-up take-up rate (in the 40-74 age range) to 80% (including special health check-ups)

d) Measures related to digitization and ICT use associated with the medical, nursing and health care required to achieve the world's most advanced medical care

[KPI to be achieved by 2020]

- Create a digital infrastructure in the fields of medical, nursing, and health care that includes both hitherto-unused test data and data from medical receipts, and utilize medical information (that is not currently available for use) in clinical research and trials, cohort studies, etc.

### 3. Implementing measures

#### (1) System for implementing the Healthcare Policy

The Headquarters for Healthcare Policy and AMED will work together to promote the Healthcare Policy in a comprehensive and systematic manner.

The measures described in the Healthcare Policy will be promoted on the basis of the following five perspectives.

- **Prioritization of measures**

In implementing policy measures, the government will clearly identify the key fields to which the allocation of resources should be prioritized, and will set targets for the outcomes to be achieved from the input of these resources.

- **Adoption of effective, efficient policy instruments**

To achieve these outcome targets, the government will adopt the most effective, efficient policy instruments, using everything from regulatory and institutional reforms to budgets, the tax system, and policy-based finance.

- **Thorough operation of the PDCA review cycle**

The government will ensure thorough operation of the PDCA review cycle. As well as using evidence to verify the effects and efficiency of policies, the government will ensure that the results of this verification are used to revise policy measures.

- **Utilization of private sector dynamism**

The measures implemented will be based on the approach of utilizing the creativity and ingenuity of the private sector to generate new dynamism. From this perspective, the government will seek an appropriate division of roles between the public and private sectors. In addition, where there is public sector involvement, the government will clarify the grounds for this.

- **Executive ability**

The tasks involved in promoting the Healthcare Policy are clearly defined. Industry, academia, and government will work together to promote the various policy measures, as well as swiftly implementing the policy measures that should be implemented without delay.

## 1) Establishment of the Headquarters for Healthcare Policy

June 10, 2014 marked the full-scale entry into force of the Promotion Act, resulting in the abolition of the Headquarters for Healthcare and Medical Strategy Promotion, which had been established by Cabinet decision on August 2, 2013. In its place, the Headquarters for Healthcare Policy (hereinafter “the new Headquarters”) was established in law within the Cabinet, to serve as a control tower for medical R&D and efforts to create and revitalize industrial activities that contribute to the establishment of a society in which people enjoy long and healthy lives, with a view to establishing such a society in accordance with the Act on Promotion of Healthcare Policy. The new Headquarters has been established within the Cabinet, with all Cabinet ministers serving as members. The Prime Minister is the Director-General, while the Chief Cabinet Secretary and Minister for Healthcare Policy serve as Vice Directors-General. The new Headquarters will formulate policies and plans for the following and will promote measures based on these.

### ① The Healthcare Policy

The new Headquarters will stipulate the basic principles concerning advanced R&D and the creation of new industries in the field of healthcare and medical care, as well as prescribing the duties of the government and others, the basic measures to be implemented to promote these activities, and other fundamental matters. In addition, it will draft a plan – the Healthcare Policy – for the comprehensive and systematic promotion of the measures that the government should implement concerning advanced R&D and the creation of new industries in the field of healthcare and medical care, and will seek approval for the Healthcare Policy from the Cabinet.

### ② The Plan for Promotion of Medical Research and Development

To intensively and systematically promote the measures that the government should implement concerning medical R&D, the improvement of the environment for this, and the widespread adoption of the outcomes thereof, the new Headquarters will formulate a Promotion Plan concerning the promotion of measures focused on medical R&D, in accordance with the Healthcare Policy. This plan will specify the areas to be promoted strategically as a priority, such as regenerative medicine and cancer therapy.

### ③ Policy on budget allocation

In accordance with the Healthcare Policy and the Promotion Plan, the new Headquarters will draw up a policy on the allocation of budget funds for medical R&D and efforts to improve the environment for this. Relevant ministries and agencies will submit budgetary requests based on this policy.

### ④ Basic policy on business operations

The Cabinet Office will be positioned as the ministry with supervisory authority over AMED. As such, it will prepare a basic policy on operational management, covering such matters as the setting of AMED’s medium- to long-term goals and efforts to clarify the division of roles between competent ministers in the evaluation of AMED’s performance of its duties.

## 2) The Japan Agency for Medical Research and Development

Medical R&D has peculiarities not found in other research fields, such as the fact that it requires clinical research on human subjects that could have an adverse impact on their health, as well as the need for applications for



approval under the Drugs and Medical devices Act.

Accordingly, research support by people with expert knowledge and integrated research management functions that take into account the goal of obtaining approval in accordance with the Drugs and Medical device Act are essential in order to ensure effective, efficient R&D with a view to practical application.

As such, the government has decided to consolidate medical R&D programs into a specialized agency optimized for the specific characteristics of medical R&D by establishing a new incorporated administrative agency that can offer seamless support from the basic research stage through to practical application.

In the Promotion Plan, AMED is positioned as an institution playing a core role in medical R&D and efforts to implement and support improvements to the environment for this. With the consolidation of budgets relating to medical R&D (research funds allocated to researchers and research institutes for conducting top-down research based on national government policy), AMED will undertake the following in relation to the medical R&D that has hitherto been undertaken by individual ministers, and it will facilitate the integrated provision of seamless research support from the stage of basic medical R&D through to its practical application:

- ① integrated research management from the basic research stage through to practical application, crossing the boundaries between individual ministries and making effective use of the Program Directors (PD) and Program Officers (PO) allocated to each realm;
- ② IP management by IP experts, support for the formulation of strategies for the acquisition of IP, and research support by expert personnel such as staff specializing in supporting clinical research and trials; and
- ③ provision of a one-stop service for research funds, etc. through the integration of points of contact and procedures for applying for research funds.

To guarantee the steady implementation of the Promotion Plan by AMED, the new Headquarters will be involved in the appointment of AMED's president and/or auditors by the competent minister in accordance with the law, and in the setting of AMED's medium- to long-term goals.

## (2) Roles of relevant parties, and partnership and cooperation among them

To promote the Healthcare Policy in a comprehensive and systematic manner, it is vital for the government, local governments, universities and other research institutes, medical institutions, and business operators to cooperate on the basis of mutual partnership, actively implementing measures in accordance with their respective roles.

### 1) Partnership and cooperation among relevant national government administrative organs

In promoting the Healthcare Policy, the new Headquarters will pursue adequate partnership and cooperation with the control towers for other policy realms, including the IT Strategic Headquarters, the Intellectual Property Strategy Headquarters, the Council for Science, Technology and Innovation, and the Council for Regulatory Reform, as well as relevant ministries and agencies. Thus, the whole government will work together to promote the measures described in the Healthcare Policy, while striving to ensure consistency.

## 2) The role of local governments and partnership and cooperation involving them

It is important for local governments to plan, formulate, and implement the measures required in their regions to establish a society in which people enjoy long and healthy lives, tailoring these efforts to the characteristics and circumstances of the local economy, society, and industry, based on the division of roles between national and local government. Local governments are beginning to undertake various pioneering initiatives tailored to specific local circumstances.

### ① Pioneering initiatives in Kanagawa Prefecture

The following pioneering initiatives are being undertaken in Kanagawa Prefecture.

#### ○ Cutting-edge life sciences research

- Promotion of cutting-edge research focused on personalized medicine, preventive medicine, regenerative medicine, and other next-generation medical care, as well as research focused on next-generation regulatory science; improvement of the quality of clinical research and trials

- i. Establishment of the Life Innovation Center (tentative name) to offer integrated support for everything from research to commercialization in the field of regenerative and cellular medicine, in which substantial growth is anticipated in future

- ii. Establishment of the Medical Device Regulatory Science Center (tentative name) to undertake research and field trials aimed at building a new form of regulatory science to facilitate swift market development and evaluation criteria for medical device that uses cutting-edge technology

#### ○ Field trials, development, and introduction of personal care robots

- Initiatives undertaken in partnership with the Sagami Robot Industry Special Zone, aimed at field trials of nursing care robots, medical care robots and other personal care robots, as well as their development and introduction, with a view to their use in monitoring elderly people, supporting their self-reliance, alleviating the burden in frontline nursing care, and improving QOL

#### ○ Cultivating international medical and innovative personnel for the next generation

- Construction of systems based on international partnerships with the U.S.A. and Singapore, to cultivate international personnel who can become leaders in next-generation healthcare

#### ○ Deploying global strategies

- Initiatives to support overseas expansion by companies and promote collaboration with government institutions and universities, etc. in various countries, with which the prefecture and the Global Collaboration Center for Life Innovation (GCC) have concluded memorandums of understanding (MOU) concerning cooperation in the field of the life sciences

- Initiatives to support overseas expansion by companies and promote the conclusion of new MOU and collaboration with government institutions and universities, etc. in various European countries

- Promoting ICT in healthcare
  - Development of infrastructure for information gathering, accumulation, and analysis through the introduction of ICT to the field of health and medical care using PHR (personal health records)
    - i. Initiatives aimed at building up big data through the promotion of widespread adoption of systems such as electronic medical records and the “*My Karte*” personal health record (medication notebook), and the gathering, accumulation, and analysis of the health information contained therein
    - ii. Proposals concerning the development of guidelines concerning the handling of personal information required to promote initiatives more effectively
  
- Establishing medical informatics using data mining technology
  - Initiatives to create communities in which clinical trials can be provided more easily, focused on the introduction in medical institutions of data sharing and exchange technologies that enable data to be linked and shared between data systems with different specifications, the verification of the results and effectiveness of clinical trials using electromagnetic records, and the strengthening of the prefecture’s systems for conducting clinical trials
  
- Creating an industry focused on “ME-BYO” (presymptomatic states)
  - Promotion of efforts to create a new industry focused on “*ME-BYO*” through the construction of systems that use cutting-edge diagnostic techniques to make it simpler to ascertain an individual’s health status

\*What is “*ME-BYO*”?

Rather than regarding health and illness as being mutually exclusive, the concept of *ME-BYO* views a person’s mental and physical condition as continuously changing along a spectrum between health and illness, expressing the process of all of those changes. In the process of this series of changes, the treatment of these presymptomatic states referred to as *ME-BYO* is not confined to the prevention and treatment of specific complaints, but focuses on bringing the whole body closer to a healthy condition.

## ② Pioneering initiatives in the Kansai region

In the Kansai region, the procedures for obtaining a Yakkan certificate for the import of unapproved drugs, etc. have been digitized for the first time at Kansai International Airport. In due course, initiatives focused on digitizing procedures for the import and export of drugs and medical device throughout Japan will be implemented. The West Japan branch of the PMDA (PMDA-WEST) is now able to deal with pharmaceutical affairs consultations and GMP surveys in the Kansai region and West Japan as a whole, thereby contributing to the creation and revitalization of medical innovation. Making use of the results of this trailblazing initiative in Kansai, the following pioneering initiatives are being undertaken to further promote medical innovation.

- Translating into reality R&D focused on drugs, medical device, and regenerative medicine products, etc. originating in Japan

- Initiatives to achieve more rapid evaluation of advanced medical care at core hospitals for clinical research and at centers for early and exploratory clinical trials in the Kansai region, and to promote R&D focused on innovative drugs, medical device, and regenerative medicine products, etc. originating in Japan in such fields as the treatment of cancer and cardiovascular diseases, and iPS cells and other regenerative medicine.

- Translating innovative clinical research into reality

- Initiatives to promote innovative clinical research by establishing medical centers promoting the practical application of cutting-edge medical technology such as retinal regeneration therapy, which is the world's first clinical research project using iPS cells.

- Future initiatives

- Promotion of global people-to-people exchange in team-based medicine in Japan through the establishment of a center for medical research into BNCT (boron neutron capture therapy), regarding which the world's first clinical trials have begun, and through the export of particle beam therapy instruments and endoscopes, such as the heavy ion radiotherapy that Japan pioneered ahead of the rest of the world.

In addition, new initiatives utilizing the National Strategic Special Zones are being promoted through partnerships between the national government, local governments, and the private sector. In future, specific projects will be detailed in the Zone Plans formulated by the Zone Council established in each Zone, and will be implemented with the approval of the Prime Minister.

In planning and formulating the Healthcare Policy and promoting the measures therein, the government will encourage such initiatives by local governments by maintaining close partnerships and cooperation with pioneering initiatives by the local governments in question, striving to reflect in measures at the national level those initiatives that are achieving outstanding results.

### 3) The role of research institutes at universities, etc. and partnership and cooperation involving them

Wide-ranging basic research based on innovative thinking by researchers is crucial to the promotion of the Healthcare Policy. It is anticipated that the Innovative Translational and Clinical Research Core Centers and National Centers will be involved in partnership and cooperation, to ensure that the results of basic research lead smoothly into clinical research and trials.

In planning and formulating the Healthcare Policy and promoting the measures described therein, the government will strive to encourage partnership and cooperation between these institutions.

Measures to prevent fraud in both basic and clinical research must be actively implemented not only by the government, but also by universities and other research institutes. Accordingly, it is necessary for universities and other research institutes to develop an environment that prevents fraud and to strengthen ethics education for researchers, while complying with the government's guidelines on research fraud.

In addition, universities and other research institutes are expected to endeavor to contribute to the creation of new

industries and human resource development in the field of healthcare and medical care through the construction and effective use of frameworks for collaboration between industry, academia and government. Accordingly, the government will strive to encourage such initiatives.

#### 4) Partnership and cooperation with medical institutions and business operators

It is vital for medical institutions and business operators involved in advanced R&D and the creation of new industries in the field of healthcare and medical care to cooperate with measures implemented by the national government and local governments to promote the Healthcare Policy.

It is anticipated that medical institutions – above all, the core hospitals for clinical research and centers for early and exploratory clinical trials that will play a central role in clinical research at the international level and physician-led clinical trials – will promote high-quality clinical research and trials aimed at the development of innovative drugs, medical devices, etc. and medical technology. Accordingly, the government will strive to encourage such initiatives.

Moreover, it is expected that business operators involved in advanced R&D and the creation of new industries in the field of healthcare and medical care will actively undertake R&D and establish pioneering practical applications for innovative drugs, medical devices, etc. and medical technology ahead of the rest of the world. As such, the government will endeavor to encourage such initiatives.

### (3) Implementation of measures based on the Healthcare Policy

The government will implement the following measures to comprehensively and systematically promote the measures described in the Healthcare Policy.

#### 1) Implementing measures based on the Healthcare Policy

As well as efficiently and effectively implementing the measures described in the Healthcare Policy, in accordance with the provisions of Article 9 of the Promotion Act, the government will make use of legislation, fiscal measures, and the tax system, and take any other steps deemed necessary to encourage the private sector to engage in the activities required for the steady promotion of these measures.

At the time for budgetary request, the new Headquarters will draw up a policy on the allocation of budget funds for medical R&D and efforts to improve the environment for this, and will present these to the relevant ministries and agencies. Having undertaken the necessary coordination with the Cabinet Secretariat to ensure the steady implementation of the Promotion Plan in accordance with this policy, the relevant ministries and agencies will submit a joint budgetary request with the Cabinet Secretariat for budgetary funds for medical R&D. Thus, the new Headquarters will strive to secure the necessary budget each fiscal year on the basis of comprehensive coordination of the allocation of budgetary funds, taking into account the country's fiscal situation.

## 2) Implementing measures that take account of the needs of all segments of Japanese society

Pursuing partnership and cooperation at all levels of society, the new Headquarters will promote the measures described in the Healthcare Policy and the Promotion Plan, based on an accurate understanding of the needs of stakeholders including people with relevant knowledge and experience, industry, medical institutions, and patients and other citizen, while also taking into account the opinions of the Council of Healthcare Policy Advisors and the Expert Panel on Promotion of the Healthcare Policy.

## 3) Promoting PR activities at home and abroad

The new Headquarters will use appropriate methods to publish information via the Internet, etc. concerning the background, necessity, and content of the Healthcare Policy and the measures described therein, and will promote understanding of and cooperation with these measures at all levels of society.

In conjunction with this, the new Headquarters will disseminate information in English to ensure a proper understanding of these measures overseas.

## 4) Promoting activities to strengthen collaboration between implementing agencies

In steadily implementing medical R&D in accordance with the Healthcare Policy, it will be vital to ensure that the results of basic research carried out at universities and other research institutes lead smoothly into practical applications. Accordingly, the new Headquarters will seek to build partnerships and cooperative relationships between universities, research and development corporations, other research institutes, medical institutions, and companies, etc., as well as encouraging the acquisition and use of IP and the matching of seeds with company needs. In addition, it will consider the development of frameworks for promoting clinical research and trials using funding provided by private sector companies and organizations.

## 5) Monitoring and disclosing the progress status of measures

Under the supervision of the new Headquarters, the Cabinet Secretariat will follow up on the implementation status of the measures described in the Healthcare Policy (conducting surveys regarding the implementation status of measures) and will use appropriate methods to publish the results via the Internet, etc.

## 6) Implementation of the PDCA cycle for the Healthcare Policy by the Headquarters

Under the supervision of the new Headquarters, the Cabinet Secretariat will conduct progress management of the Healthcare Policy based on the PDCA review cycle. In follow-up activities focused on the measures described in the Healthcare Policy, evidence will be used to verify the effects and efficiency of the measures. Where necessary, the content of the measures will be revised based on the results of this verification.

7) Reviewing the organization, budget, etc. in light of the PDCA results

The PDCA review cycle will be thoroughly implemented in regard to the Healthcare Policy and, in order to facilitate more comprehensive, systematic promotion of the measures described in the Healthcare Policy in light of the results of such reviews, consideration will be given to relationships between the new Headquarters, AMED, relevant ministries and agencies, and relevant incorporated administrative agencies, as well as to approaches to budgets and organization, with the necessary steps being taken in light of the results of these deliberations.

## Glossary

\*Organized in order of first appearance

P4

- Biopharmaceuticals

Drugs in which the active ingredient has been created from biological agents, such as proteins derived from cells, viruses, bacteria or other organisms (e.g. growth hormones, insulin, antibodies, etc.)

P5

- ICT: Information and Communication Technology

P8

- Open innovation

The resolution of problems through the use of external development capabilities and ideas, creating entirely new value.

- PMDA: Pharmaceuticals and Medical Devices Agency

With the aim of helping to improve the health of the public, the PMDA offers rapid redress for health hazards due to side-effects from drugs; reviews the quality, effectiveness, and safety of drugs and medical devices, etc.; and gathers, analyzes, and disseminates information concerning safety once these items become commercially available.

- Regulatory science

A branch of science that aims to make accurate, evidence-based projections, appraisals, and judgments, in order to ensure that the fruits of science and technology take the most desirable form from the perspective of their harmonization with people and society, with the objective of ensuring that the results of R&D in this area benefit people and society as a whole (Fourth Science and Technology Basic Plan). In particular, in the fields of drugs and medical devices, etc., science focused on swift, appropriate forecasting, evaluation, and judgment based on scientific knowledge, concerning the quality, effectiveness, and safety of practical applications for medical R&D results. (Article 13 (2) of the Act on Promotion of Healthcare Policy)

- Clinical trial

Clinical trials are implemented with the aim of gathering data that can be submitted as test results, along with other materials that must be submitted when applying for approval to manufacture or sell a drug or item of medical device, etc.

P9

- Cohort (study)



A follow-up study concerning the state of health or disease over the long term among a certain group of the population.

- Bank (biobank)

A collection of biological specimens and related information.

- Genome

A word created from a combination of the words gene and chromosome, meaning all genetic information in DNA.

- DDS: Drug Delivery System

A system that controls the delivery of drugs within the body in terms of quantity, space, and time.

P10

- ARO: Academic Research Organization

An organization equipped with functions that universities, etc. with research institutes and medical institutions can use to support drug development.

P13

- UHC: Universal Health Coverage

A situation in which all people can access the appropriate healthcare and medical services – including prevention, treatment, and rehabilitation – at a reasonable cost in times of need.

P15

- Investment in health

The purchase and use by companies or individuals, etc. of services not covered by public insurance that contribute to health promotion and disease prevention, for the purpose of extending healthy life expectancy, improving productivity, and curbing increases in medical expenses.

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- Data health program

A business plan formulated by insurers to implement efficient, effective health programs via the PDCA review cycle, based on the analysis of data from medical receipts and health check-ups.

P18

- Corporate Governance Report

A report compiled in order to provide investors with a clear understanding of a company's corporate governance situation, which a securities exchange requires all companies listed on that exchange to prepare.

- CSR Report

A voluntary report concerning a company's corporate social responsibility (CSR). Based on an approach aimed at gaining the trust of the various stakeholders surrounding a company, CSR refers to the behavior of companies that take responsibility for the effects of their activities, with the aim of enabling the company to coexist with society and the environment, and achieve sustainable growth.

## P23

- HTA: Health Technology Assessment

According to the International Network of Agencies for Health Technology Assessment, HTA is defined as “a multidisciplinary field of policy analysis that studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology.” However, in practice, HTA processes do not always consider the wide range of social, ethical and economic implications of the use and diffusion of new technologies and instead focus on health and organisational impacts. The main objective of HTA is to inform decisions of health insurance coverage, but it can also inform clinical guidelines. (2011 OECD Health Policy Studies: Value for Money in Health Spending)

## P24

- NTD: Neglected Tropical Diseases

A group of parasitic and bacterial diseases that are especially endemic in low-income populations in tropical regions and affect more than 1 billion people worldwide. These infectious diseases not only trap individuals in a cycle of poverty and disease, but also exacerbate and prolong the poverty of their local communities.

- Inclusive business

A business model promoted by the United Nations and the World Bank Group, which seeks to achieve compatibility between development objectives and company profits by including the poor in the business process.

- SFT: Sport for Tomorrow

An initiative designed to promote the value of sport and promote the Olympic Movement to people of all ages – especially the young people who will be the leaders of tomorrow – to achieve a better future worldwide, targeting more than 10 million people in more than 100 countries, including developing countries, over the seven years from 2014 to 2020

- Strategy for Global Health Diplomacy

Positioning initiatives in the field of international health as a key topic in Japan's diplomatic relations, this was approved by relevant Cabinet ministers as a means of increasing the international community's trust in Japan through efforts that bring relevant ministries and the public and private sectors together in an effort to resolve global health challenges. It positions health as a field that is essential in order to achieve human security and seeks to realize a world in which every person can receive basic healthcare services, making use of Japan's comparative

advantage as a society in which people enjoy the longest and healthiest lives in the world.

P27

- PPP: Public Private Partnership

An approach aimed at achieving greater efficiency in public services by introducing market mechanisms to such services, by such means as outsourcing to the private sector, the creation of incorporated administrative agencies, or privatization, depending on the nature of the service concerned.

- PFI: Private Finance Initiative

A technique for providing public services more efficiently and effectively than direct provision by the national government or local governments, via the introduction of private sector money, managerial skills, and technical capabilities to public services (construction, maintenance and management, and operation, etc. of public facilities).

- Healthcare REIT

Real estate investment trusts in which healthcare facilities are the target of investment.

P28

- CRC: Clinical Research Coordinator

A person who assists with tasks associated with clinical research and trials, such as dealing with test subjects and coordination with those in other occupations, to ensure that clinical research and trials are carried out smoothly at medical institutions.

- Bioinformatics

A field of study focused on using techniques from computer science to analyze biological data, and the technologies used for this analysis.

P31

- HL7: Health Level 7

A set of standards used for the exchange of medical information by HL7 (Health Level Seven International).

- CSV: Comma Separated Value

A format in which the fields in individual database records are separated only by commas.

P32

- Medical Information Database Infrastructure Development Project

Implemented in 10 medical institutions nationwide, the Medical Information Database Infrastructure Development Project is a project currently focused on using SS-MIX2 to build up a store of both data from electronic medical records (data concerning illness/injury, prescriptions and injections, and laboratory tests, radiological examinations,

and physical examinations, etc.) and medical receipt and Diagnosis Procedure Combination (DPC) data (data concerning illness/injury, admission and discharge, treatment, etc.) This data will be used to compile a database at each medical institution, which will then be used to analyze such matters as the frequency of adverse events, in order to develop safety measures for drugs and medical devices, etc.

\* SS-MIX2: Standardized Structured Medical record Information eXchange 2

The generic term for a system aimed primarily at standardized storage, developed via an MHLW project to promote the storage of standardized medical information.

• DPC: Diagnosis Procedure Combination

A classification system used in the fixed payment system for medical expenses.