

# Overview of the Healthcare Policy

## Introduction

- For Japan, which is becoming an ultra-aging society ahead of other countries, it is important to realize the world's most advanced medical technologies and services as a pioneer challenge solver and further extend the health expectancy in order to establish a society in which people enjoy long and healthy lives.
- While contributing to the improvement of the quality of medical care abroad by promoting the creation and overseas expansion of new industry activities that contribute to the establishment of a society in which people enjoy long and healthy lives, it is important for Japan to foster those industries as strategic ones that can contribute to its economic growth and expand them globally as an advanced medical and welfare country on the premise of the top level of safety and security in the world.

## 1. General outline

### 1) Position of the Healthcare Policy

- The Policy was formulated under Article 17 of the Act on Promotion of Healthcare Policy in accordance with the basic principles prescribed in Article 2 based on the basic measures prescribed in Articles 10 to 16 (promoting R&D, improving the R&D environment, ensuring fair and appropriate operation for R&D, establishing a better examination system for putting R&D results into practical application, promoting the creation and overseas development of new industry activities, promotion of education, securing personnel, etc.).

### 2) Basic principles of the Healthcare Policy (Article 2 of the Promotion Act)

- Provide medical care using the cutting-edge technologies  
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 application R&D and by smoothly putting the research outcomes into practical application.
- Contribute to economic growth  
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 a society in which people enjoy long and healthy lives.

### 3) Period covered by the Healthcare Policy

- Cover the five years from FY2014, foreseeing the next 10 years. Though the policy will be fully reviewed five years after its formulation, revisions may be made as necessary based on the results of follow-up reviews.

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

The government will take measures that will contribute to the provision of the top level of medical care in the world by promoting integrated R&D activities from basic R&D to practical application R&D and smoothly putting the research outcomes into practical application. Through these measures, the government will aim to enhance industrial competitiveness in the fields of drugs, medical devices, medical technologies, etc. and will promote international medical collaboration and international contributions. Based on Article 18 of the Act on Promotion of Healthcare Policy, the government will also formulate the Plan for Promotion of Medical R&D that prescribes basic principles for measures and specific measures that it should implement intensively and systematically, and will promote medical R&D based thereon.

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

- The government's function of strategic allocation of research funds will be concentrated at a new national R&D organization called the Japan Agency for Medical Research and Development (hereinafter referred to as "AMED"), in order to smoothly put the R&D research outcomes into practical application.
- Under management that takes advantage of the program director's expertise, seamless support will be provided for research activities from basic research to practical application, including research support for managing intellectual property.

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

- The Act to Partially Revise the Pharmaceutical Affairs Law and the Amending Law to the Related Acts for Securing Comprehensive Medical and Long-Term Care in the Community have been enacted in order to improve the medical research environment.
- The government will promote the improvement of the environment—including the system to conduct clinical research and trials, databases and ICT—that is necessary for smooth and effective implementation of medical R&D essential to the provision of the top level of medical care in the world.
- The headquarters functions of the Drug Discovery Support Network will be smoothly transferred to the AMED, and a network of universities and R&D institutions will be established in order to promote the development of medical device.

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

#### 3) Governmental measures to secure fair and appropriate operation for R&D

- To prevent research irregularities and deal with ethical challenges, such as the protection of people participating in clinical trials, the government will take measures to secure fair and appropriate operation for R&D in order to make sure that research institutions, etc. comply with laws and regulations and appropriately manage personal information when engaging in R&D.
- To restore trust in clinical research, a study will be conducted on systems related to clinical research, including the legal system, and a conclusion will be reached by autumn this year.
- In order to promote initiatives to prevent irregularities in basic and clinical research, a dedicated division for that purpose will be established at AMED so as to ensure fair and appropriate operation for medical R&D, accumulate knowhow on dealing with research irregularities and train professional personnel.

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

- To ensure that new drugs and medical devices are put into practical application in a prompt and safe manner, the Act to Partially Revise the Pharmaceutical Affairs Law has been enacted to obligate manufacturers and sellers of drugs and medical devices to submit an attached document prepared based on up-to-date knowledge and establish a system to grant conditional, limited-period approval to regenerative medicine products, among other measures.
- To enable prompt and appropriate implementation of procedures necessary for putting drugs and medical devices into practical application, the government will promote regulatory science by strengthening the organizational system of the Pharmaceuticals and Medical Devices Agency (PMDA) and enhancing its collaboration with universities, research institutions, etc.

#### 5) Other necessary governmental measures

- The government will promote the development of original Japanese drugs, medical devices and medical technologies and promote their use to contribute to the improvement of medical care not only in Japan but also in other countries. At the same time, the government will train and secure personnel in all fields related to the enhancement of the potential of medical R&D.
- A division dedicated to performing support functions (A consultation window for intellectual property rights, support for planning an acquiring intellectual property strategy) to help research institutions acquire intellectual property will be established at AMED.

## 2. Details

### **(2) Measures related to the promotion of creation and overseas expansion of new industry activities related to healthcare and medical care**

For the development of drugs and medical device, technologies and services in Japan, a market that meets the specific domestic and foreign needs is necessary. On the domestic front, the government will seek to realize the world's most advanced high-quality medical care and create a new market for healthcare services not covered by public insurance, such as disease prevention and living support in the chronic phase. The government will also seek to crack open foreign markets by promoting overseas sales of new drugs and medical device and technologies as well as new healthcare and medical services while encouraging international medical cooperation.

#### 1) Creating new industry activities related to healthcare and medical care

To create industrial activities that contribute to the establishment of a society in which people enjoy long and healthy lives, mainly those related to services not covered by public insurance, the Next-Generation Healthcare Industry Council will (1) improve the environment to create new businesses, including by eliminating a gray zone where the application scope of existing regulations is unclear, (2) encourage the purchase and use by insured people and companies of services not covered by public insurance that contribute to health enhancement and disease prevention and (3) promote the establishment of a mechanism to evaluate the quality of products and services.

#### 2) Supporting business expansion of venture businesses, etc. in growth markets

To foster industries in the fields of healthcare and medical care, the Task Force for fund for Healthcare Policy will ensure appropriate management of public-private funds and make pioneering investments as a driving force of R&D, thereby supporting business expansion of venture businesses and small and medium-size enterprises.

#### 3) Promoting overseas expansion of healthcare and medical businesses

To provide drugs and medical device, technologies and services to emerging and developing countries while sufficiently taking account of individual countries' circumstances and to build mutually beneficial relationships with them, the Task Force for Global Reach of Japanese-style Medical Technology and Service, in cooperation with MEJ and relevant ministries and agencies, will promote the creation of businesses in the field of medical care and seek to realize universal health coverage. The government will promote support for the supply to developing countries of drugs to treat neglected tropical diseases (NTDs) through the Global Health Innovative Technology Fund (GHIT Fund).

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

In addition to the above measures, the government will implement measures to deal with the progress in aging of society and growing health consciousness, promote sports activities that contribute to health enhancement and create houses, towns and transportation systems that make it possible for elderly people to live a comfortable and healthy life.

## 2. Details

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

The government will promote securing and training of personnel necessary for promoting cutting-edge healthcare and medical R&D and creation of new industry activities, including clinical research coordinators who are necessary for efficiently implementing clinical research and trials, and such professional personnel as innovation personnel capable of matching medical needs with businesses. The government will also promote education and learning that deepen public interest in and understanding of the importance of medical R&D and will enhance public relations activities.

### **(4) Measures related to digitization and ICT use regarding medical, nursing and health care that are necessary for realizing the world's most advanced medical care**

To realize efficient and high-quality medical services and make Japan's medical care the world's most advanced intellectual infrastructure for creation of new drugs and medical device, technologies and services, the government will (1) promote advanced digitization of the frontlines of medical care, (2) establish the overall digital platform that enables sharing of various data collected from the frontlines of medical care among relevant people through standardization, etc., (3) use this digital platform to improve the efficiency of medical administration, provide advanced medical services and promote research and (4) establish rules and mechanisms concerning the use of medical information and the infrastructure for a numbering system like a personal-number system.

Specific measures are as follows:

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

The government will establish a mechanism for comprehensive analysis of data collected through different systems (including databases)—in other words, a framework for (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 (e.g. mechanism and rules to ensure the payment of the cost by people receiving benefits based on analysis)—in a comprehensive manner from a broad perspective (digital platform in the fields of medical, nursing and health care).

#### 2) Using the digital platform

In addition to expanding businesses related to receipt data, which have already been analyzed and used, the government will promote the creation of businesses that collect and analyze unused test data on a large scale as well as the creation of high-quality, efficient medical care services and healthcare services not covered by public insurance based on the use of ICT and the digital infrastructure.

#### 3) Advanced digitization of the frontlines of medical care

The government will implement R&D programs to promote the application of ICT and create an environment to do so (e.g. establishing a mechanism to evaluate and verify new technologies and systems).

#### 4) Systems concerning the use of medical and personal information

The government will formulate rules on the use of the infrastructure for a numbering system like a personal-number system in the field of medical care and on the handling of medical information.

### 3. Implementing measures

#### (1) System to implement the Healthcare Policy (cutting-edge healthcare and medical R&D and creation of new industry activities )

- 1) Five perspectives for implementing the policy : “prioritization of measures,” “adoption of efficient and effective policy steps,” “PDCA cycle reviewing system,” “utilization of private-sector vitality” and “execution capability”
- 2) Establishment of the Headquarters for Healthcare Policy(chairman; the prime minister; vice chairmen: Chief Cabinet Secretary and the Minister of State for Healthcare Policy)
- 3) The Japan Agency for Medical Research and Development: responsible for playing the central role in medical R&D, etc. and providing seamless, integrated research support from basic research to practical application.

#### (2) Roles of relevant parties and cooperation and collaboration

In order to execute the Healthcare Policy, relevant parties will implement measures suited to their respective roles, including cooperation and collaboration between relevant ministries and agencies, promotion and coordination of unique and pioneering activities of local governments, establishment of a framework of collaboration between industry, academia and government that involves universities and other research institutions and promotion of high-quality clinical research by Clinical Research Core Hospitals.

#### (3) Implementing measures based on the Healthcare Policy

- 1) Implementing measures based on the Healthcare Policy : The government will implement measures included in the Healthcare Policy and will also promote necessary private-sector activities.
- 2) Implementing measures in light of the needs of various segments of Japanese society  
The Headquarters will accurately identify the needs of relevant parties, including academic experts, the industrial world, relevant medical organizations, the general public and patients and will implement measures included in the Healthcare Policy and the Plan for Promotion of Medical R&D in cooperation with various segments of Japanese society while paying attention to the opinions of the Council of Healthcare Policy Advisors and the Expert Study Panel on Promotion of Healthcare Policy.
- 3) Promoting domestic and external public relations activities  
The government will promote the understanding and cooperation of various segments of Japanese society regarding the Healthcare Policy and measures included in the policy by disclosing, via the Internet and other media, background information concerning the policy and the measures in an appropriate manner and will also disseminate English-language information so as to promote accurate understanding of the measures abroad.
- 4) Promoting activities to strengthen collaboration between organizations implementing measures  
With a view to steady implementation of medical R&D, the government will establish cooperative relationships between universities and other research institutions and secure intellectual property so as to smoothly put the research outcomes of their basic research into practical application. In addition, the government will study a framework for promoting clinical research and trials using funds provided by private companies and organizations.
- 5) Monitoring and disclosing the progress status of measures  
The progress status of measures will be monitored by the Cabinet Secretariat under the supervision of the Headquarters and the results will be disclosed via the Internet and other media in an appropriate manner.
- 6) Implementation of the PDCA cycle of the Healthcare Policy by the Headquarters  
The progress management based on the PDCA cycle will be implemented by the Cabinet Secretariat under the supervision of the Headquarters. As for the monitoring of the measures, their effectiveness and efficiency will be verified based on evidence and their contents will be reviewed as necessary based on the verification results.
- 7) Reviewing the organization, budget, etc. in light of the PDCA results  
In light of the PDCA results, the government will conduct a study and take necessary measures with regard to the relationship between the Headquarters, AMED and relevant ministries and agencies as well as what the budget and organization should be like.

# Key Performance Indicators [KPIs]

※The following are KPIs to be achieved by around 2020 unless specified otherwise.

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

### Drug discovery

- Consult/Evaluate seeds. 1500 cases
- Support promising seeds. 200 cases
- License out 5 cases
- Identify drug targets 10 cases

### Medical Devices

- Double medical device exports (approx. 500billion in FY2011 to approx. 1 trillion yen)
- Implement more than five innovative medical devices
- Expand the domestic medical device market: 320 million yen.

### Translational and Clinical Research Core Centers

- Investigator-initiated clinical trials 40 cases per year
- FIH clinical trials 40 cases per year

### Regenerative Medicine

- Clinical application of new drugs using iPS cell technologies
- Increase the number of official approvals
- Expand target diseases in clinical research/trials to approximately 15 subjects. \*
- Implement medical devices regarding regenerative medicine
- Proposal of methods for cardiac safety assessment using iPS cell derived cardiomyocytes toward international harmonization

\*Includes 10 subjects in Goals by 2015

### Genomic Medicine

- Drastically reduce prevalence of adult-onset diseases (diabetes, stroke, myocardial infarction, etc.).
- Establish precision medicine on carcinogenesis and adverse reactions to anti-cancer agents, etc.
- Initiate clinical research on genomic medicine for dementia, etc.
- Develop innovative diagnostics and therapeutics in neuromuscular diseases/disorders, etc.

\*KPIs to be achieved by 2020-2030

### Disease-specific research <Cancer>

- Within five years, start 10 clinical trials in innovative anti-cancer agents
- Initiate more than six clinical trials on new anti-cancer agents, including unapproved and off-label drugs, in pediatric, intractable, and rare cancers, etc.
- Obtain at least one additional PMDA approval and clinical indication in drugs for pediatric and rare cancers, etc.
- Resolve so-called 'device-lags' and 'drug-lags'.
- Establish standard treatments in pediatric, geriatric and rare cancers (draw at least three guidelines).

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

- Initiate clinical trials on innovative drug candidates in psychiatric disorders including dementia
- Establish objective diagnostic methods in psychiatric disorders
- Establish proper drug interventions in psychiatric disorders
- Draw maps of structures and functions of the entire brain network

# Key Performance Indicators [KPIs]

※The following are KPIs to be achieved by around 2020 unless specified otherwise.

## 1) Measures related to medical R&D that contribute to the provision of the top level of medical care in the world

### Disease-specific research <Emerging/Re-emerging Infectious Diseases>

- Identify drug target sites and develop rapid diagnostic methods based on the whole genome database in the obtained pathogens (influenza, dengue fever, diarrheal diseases, drug-resistant bacteria, etc.)
- Conduct clinical research/trials and apply for PMDA approval of norovirus vaccine and intranasal influenza vaccine

\*KPIs to be achieved by around 2030: Develop new vaccines (e.g. universal vaccines for influenza); Develop new antibiotics, antiviral agents, etc.; Eradicate polio and measles etc. (tuberculosis by 2050) through cooperation with WHO and other countries.

### Disease-specific research <Rare/Intractable Diseases>

- Expand indication of new drugs and existing drugs in more than 11 diseases (ALS, distal myopathy etc.)
- Promote international collaboration in clinical research/trials with European and U.S. databases

## 2) Measures related to the promotion of creation and overseas expansion of new industry activities related to healthcare and medical care

- Expand the size of markets of industries related to health enhancement, disease prevention and living support (from ¥4 trillion to ¥10 trillion)
- Raise the ratio of projects receiving joint investments from public-private funds and private companies in the fields of healthcare and medical care to 100%
- Establish Japanese medical care bases abroad (from three bases to around 10 bases)
- Expand the size of foreign market shares captured by Japanese medical technologies and services to ¥5 trillion \*A KPI to be achieved by 2030.

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

- Extend the nation's health expectancy by one year or more
- Reduce the number of citizens with metabolic syndrome by 25% from FY2008
- Increase the health screening rate (for the 40-74 age range) to 80% (including specified health checkups)

## 4) Measures related to digitization and ICT use regarding medical, nursing and health care necessary for realizing the world's most advanced medical care

Create a digital infrastructure for medical nursing and health care that includes unused test data as well as receipt data and utilize medical information (which is not available for use now) in clinical research and trials, cohort research, etc.