5-Year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices

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Ministry of Education, Culture, Sports, Science and Technology (MEXT)
Ministry of Health, Labour and Welfare (MHLW)
Ministry of Economy, Trade and Industry (METI)

○ Based on the nation's extensive R&D capabilities and by participating in the global development/delivery system of innovative pharmaceuticals/medical devices as well as expanding the global share of innovative drugs/devices developed in Japan, our goals are to boost the pharmaceutical/medical device industry to become the driving force of Japan's growth and swiftly provide our populace with access to the best pharmaceuticals/medical devices in the world.

○ In order to ensure consistency of the administrative policies with these goals, we will devise comprehensive 'policy packages' that will support the entire process from research to launch. In particular, in order to create an environment in which the development originating in Japan, simultaneous global development in which Japan participates, and international clinical trials all serve as the basics for pharmaceutical and medical device innovation, we will adopt appropriate and necessary measures related to the R&D and review stages. In addition, we will ensure a drug pricing and medical fee system that allows for the optimal assessment of innovative products as well as the latest domestic/overseas therapies while maintaining the balance with the healthcare insurance system.

○ Our 5-Year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices will be devised according to the perspectives described above.

1. Concentrated Research Financing

(1) Prioritization and expansion of budgets that will contribute to the development of pharmaceuticals and medical devices (Measures to be effectuated as of FY2007: MEXT, MHLW and METI)

- We will prioritize and expand life sciences-related budgets in the development of pharmaceuticals and medical devices. In particular, we will focus on the following areas:

  a. Clinical and practical application research (including bridging research to clinical research)

  b. Serious diseases, such as cancer, neuron-psychiatric disorders and incurable diseases, as well as rare diseases

  c. New technologies (biomarkers, tailor-made medicine, regenerative medicine, microdosing, etc.)

- Under the common themes, we will promote matching budgets among the concerned ministries.

- Based on the public-private discourse, we will create collaborative organizations comprised of concerned ministries, research institutes and industry in order to achieve consensus on the focal R&D in pharmaceuticals/medical devices, measures to nurture ventures, and development and improvement of the clinical research/trial environment.

- In addition, we will review the use of funds allocated for research according to the actual state of clinical research. (To be deliberated in FY2007: MHLW)

(2) Deliberations on the improvement and enhancement of taxation for R&D

- In consideration of the characteristics of pharmaceutical/medical device development, which requires large funds for R&D, we will engage in deliberations on the improvement and enhancement of tax issues related to R&D from the perspective of promoting innovation. (To be deliberated and decided in FY2007: MHLW and METI)

(3) Matters concerning medical devices (promotion of standardization)

- The promotion of standardizing methods of measuring the physical properties of medical materials will significantly contribute to swifter and more efficient development (R&D). Moreover, proceeding with these moves toward international standardization is critical in terms of promoting the seamless expansion of the medical device industry in Japan to the global market. We will promote strategic standardization, including an integrated approach toward advancing standardization and R&D projects. (To be implemented as needed as of FY2007: MHLW and METI)

2. Nurturing Ventures, etc.

(1) Improvement of corporate support measures

We will expand R&D financing targeting venture companies. (Measures to be effectuated as of FY2008: MHLW)

(2) Support of bridging research by ventures

We will promote bridging research by ventures that engage in the discovery of innovative drugs, including technologies in regenerative medicine, and/or the practical application of medical devices. (Measures to be effectuated as of FY2007: METI)

(3) Promotion of facility and equipment use

- Targeting venture companies, we will promote common use of facilities/equipment as well as joint research within the respective medical cluster (touched upon later). (Measures to be effectuated as of FY2008 or later: MHLW)
- We will support activities geared toward common use of facilities and equipment owned by independent administrative corporations, universities and the like. (Measures to be effectuated as of FY2007 or later: MEXT)

(4) Support measures to turn budding technologies into business

- Taking into full consideration the relatively large number of pharmaceutical-/medical device-related ventures originating in universities, we will endorse the development of systems specifically designed to support this area, while maintaining the utilization of the existing framework. In particular, we will develop a system that can provide the advice of specialists who are able to judge and commercialize budding technologies and/or support clinical research/trials all in order to allow for strategic and coordinated designing of intellectual property strategies, licensing negotiations and the like. (To be deliberated in FY2007 and effectuated as of FY2008:

MEXT and MHLW)

- We will develop a system within each of the nine Small Business Support Centers run by the Organization for Small & Medium Enterprises and Regional Innovation, JAPAN (SMRJ) that can aptly address a variety of consultations from regional drug discovery ventures and other issues such as patents. (Measures to be effectuated as of FY2007: METI) Moreover, we will configure a system that exploits retired human resources with expert knowledge on pharmaceuticals and medical devices in order to provide the advice to ventures. (To be deliberated in FY2007 and effectuated as of FY2008: MHLW) Based on the above, the SMRJ, METI and MHLW will collaborate and network in order to justly address the consultations for venture companies.

- We will extend the efforts to improve the systems and measures to appropriately address consultations at every stage of development and clinical trials conducted by the Pharmaceuticals and Medical Devices Agency (PMDA). (To be deliberated and measures effectuated in order of precedence as of FY2007: MHLW)

(5) Fee support

We will deliberate on the support regarding application fees. (To be deliberated and decided in FY2007: MHLW and METI)

(6) Establishment of venues to discuss policies and measures to support ventures

We will collaborate with concerned ministries, research institutes and industry to establish venues for the deliberation of policies/measures to support the development of ventures, which play a pivotal role in innovative drug discovery and medical devices, including technologies in regenerative medicine. (Measures to be effectuated as of FY2007: MHLW and METI)

(7) Matters concerning medical devices (promotion of entry into the medical device industry)

- We will proceed with joint deliberation with related industries on measures to invigorate the delivery of materials and parts for implanted

medical devices and the like. (To be deliberated and decided in FY2007: MHLW and METI)

- We will devise socioeconomic guidelines that contribute to the development and growth of medical devices as well as examine the effects of such guidelines. (To be deliberated and decided in FY2007: METI)

3. Improvement of Clinical Research/Trial Environment

(1) Promotion of international clinical trials

- We will improve the environment that facilitates the participation of Japanese sites in international clinical trials by improving case series and reducing trial costs through the improvement of clinical research/trial environments in terms of networking with the medical clusters (provisional name) mentioned below, core hospitals and central medical centers.

- We will engage in activities to foster human resources able to conduct international clinical trials. (Measures to be effectuated as of FY2007: MEXT and MHLW)

- We will outline the basic policy in regard to the drug review involving international clinical trials. (Touched upon later)

(2) Development of medical clusters (provisional name)

- In order to develop and commercialize pioneering technologies, goods and systems for conditions (serious and rare diseases) that significantly affect the national populace, we will develop 'medical clusters (provisional name)' that promote clinical and practical research through close cooperation between business, academia and government, primarily centering on the National Center for Advanced and Specialized Medical Care (hereinafter referred to as the National Center). We will also ensure that the National Center is able to function appropriately in the respective field as it approaches its 2010 date for transition to an independent administrative organization. (Measures to be effectuated as of FY2008: MHLW)

- In order to enable close collaboration between business, academia and government, we will promote joint research and integration of research institutes, such as those operated by corporations and universities, by improving the availability of clinical research beds, experimental devices and the like primarily in medical clusters as well as accepting researchers from corporations and overseas.

(3) Improvement of translational research centers

- In terms of translational research centers that promote bridging research that links the promising basic research outcomes in the fields of medical and pharmaceutical engineering to clinical practice, we will promote the characterization (differentiation) of the respective field of development, and improve the organization and functions of each center. (Measures to be effectuated as of FY2007: MEXT)

- We will ensure that each of those translational research centers enhance their research activities in order to link innovative pharmaceuticals and medical devices to clinical practice. (To be deliberated in FY2007: MEXT)

(4) Development of the domestic clinical research system

Based on the new Five-Year Plan for National Clinical Trial Vitalization (announced by MEXT and MHLW on March 30, 2007), we will intensively place qualified clinical trial/research staff at some 40 trial sites, namely core hospitals and central medical centers, and engage in the following activities from the perspective of expertise integration and human resource development:

- We will subsidize 10 medical institutions in order to improve the infrastructure of core hospitals that function as clinical trial sites. (Measures to be effectuated as of FY2007: MHLW)

- We will subsidize 30 medical institutions in order to improve the infrastructure of central medical centers that function as clinical trial sites. (Measures to be effectuated as of FY2007: MHLW)

- We will deliberate on the support for medical institutions that meet the predetermined standards, such as diseases/conditions treated, number of trials conducted and number of investigators, in order to further collaboration with core hospitals and central medical centers in clinical trials. (To be deliberated and decided in FY2007: MHLW)

(5) Centralization of clinical trial sites and creating of networks, centering on the medical clusters

- Regarding medical institutions, universities and other facilities selected

either as a medical cluster, core hospital/central medical center for clinical trials or bridging research facility by the MEXT and MHLW as part of their projects, we will establish a system capable of coordinating these medical institutions to form a common network and implement the respectively designated bridging research to clinical practice and/or clinical trials/research by cooperating with each other. (Measures to be effectuated as of FY2007: MEXT and MHLW)

- Regarding the medical clusters to be developed and improved as cited in items (2) through (4), we will attempt to create collaboration with knowledge clusters and industrial clusters as is possible in order to enhance fusion (exchange) of human resources and technologies. Moreover, we will strive toward enhancing collaborative efforts with medical institutions, universities and other facilities within the existing clusters as is deemed necessary. (MEXT, MHLW and METI)

(6) Development of centers to promote regenerative medicine

This is a field in which Japanese technologies lead the world. We will engage in the activities listed below in order to expand the horizons of researchers in this field and provide a more competitive practical research environment. (Measures to be effectuated as of FY2008: MEXT, MHLW and METI)

- Improvement and networking of key hospitals where the practical use of technologies is promoted
  We will engage in improvement of the current environment surrounding regenerative medicine, including clinical research beds and experimental and analytical equipment.

- Promotion of technological R&D that leads the world
  We will make efforts in advancing stem cell engineering technologies, developing stem cell banks and promoting collaborations with nanotechnology and material engineering all in order to achieve practical application of regenerative medicine.

(7) Development and securing of relevant human resources

- We will support the efforts of universities in terms of educational research that are implemented based on the collaboration among

faculties, including medicine, pharmacology, science and engineering and biostatistics. (Measures to be effectuated as of FY2007 or later: MEXT)

- We will strive to create and increase opportunities for clinical research education targeting medical professionals, such as physicians, pharmacists and nurses, who work at postsecondary educational institutions. (Measures to be effectuated by FY2011: MEXT and MHLW)

- We will engage in efforts to improve the assessment of clinical achievements by physicians and the like (including the setting of assessment standards that would contribute to improvement of the clinical research quality, i.e., the number of papers related to clinical research in Japan that are published in major overseas journals). (Measures to be effectuated as of FY2008: MEXT and MHLW)

- We will strive to foster specialists who can provide support for clinical research, such as clinical research coordinators (CRCs). In particular, we will develop 3,000 new CRCs. (Measures to be effectuated by FY2011: MEXT and MHLW)

- We will engage in the assessment of clinical research/trial achievements by researchers as well as the relative involvement of other specialists, such as biostatisticians, in conjunction with the adoption of clinical research to be funded by public funds. (Measures to be effectuated as of FY2008: MEXT and MHLW)

- In order to foster individuals that have the comprehensive knowledge and skill in medicine, pharmacology, and science and engineering required in the development of biomarkers, pacemakers and the like, we will strive to create collaborations between graduate schools and medical clusters, public research institutes, industries and the like. (To be deliberated and decided by FY2008: MEXT, MHLW and METI)

- In order to fully exploit the performance of medical devices, we will promote the development of training tools, such as simulators, that contribute to smooth and widespread use, along with R&D, of such devices. (To be implemented as needed as of FY2007: MHLW and METI)

(8) Rationalization of clinical research regulations

- We will review the status of the 'Ethical Guidelines for Clinical Studies (EGCS)' based on the current clinical environment and deliberations of the legislative issues. In order to ensure that this review does not hinder the promotion of clinical research, we will take into account that the current guidelines do not provide a system of public checks in regard to clinical research quality nor suffice in terms of trial subject protection. (To be deliberated and decided in FY2007: MHLW)

- We will review the EGCS also in order to contribute to the discussion and review of the cost burden associated with clinical research.

- We will engage in deliberations concerning the ideal state of medical device delivery to physicians in order to smoothly promote the practical application of achievements and the like as a result of medicine-engineering collaborations. (To be deliberated as of FY2007: MHLW)

(9) Other efforts

- In order to expedite clinical trials and reduce the cost, we will strive to create networks between trial sites and standardize (integrate) the forms required in clinical trials by utilizing IT. (Measures to be effectuated by FY2011: MEXT, MHLW and METI)

- The MEXT, MHLW, METI will co-sponsor clinical research forums in an effort to provide venues to acquire knowledge/information, exchange (share) information and network that are necessary to conduct clinical research. (To be deliberated as of FY2007: MEXT, MHLW and METI)

4. Collaboration with Asia

In terms of participation in and implementation of simultaneous global development, it is important to collaborate with Asian counties because of their large population base and market size as well as the relative racial similarity as opposed to those in the West. Accordingly, we will make the following efforts:

- We will engage in activities to promote joint research with Asian countries

regarding pharmaceuticals and medical devices used for important diseases/conditions such as cancer. (Measures to be effectuated as of FY2007: MHLW)

- We will engage in joint research in regard to the methods of assessing and utilizing clinical data gathered in East Asia. (Measures to be effectuated as of FY2007: MHLW)

5. Faster and Better Reviews

(1) Shortening of the time to launch a new drug by 2.5 years. (Measures to be effectuated within 5 years: MHLW)

- We will create a work schedule by which to shorten the time from the initiation of trials to NDA and foster human resources. (Measures to be effectuated in FY 2007: MHLW)

(2) Expansion and improvement of review staff (MHLW)

- We will double the number of new drug review staff in 3 years (236 additional staff). (Measures to be effectuated by FY2009)
- We will improve the quality and number of clinical trial consultations. [The timing will be noted on the work schedule mentioned in Item (1).]
- We will strengthen and improve the overall review service by accelerating the review process through, for example, adopting a prior assessment system and establishing more review teams. In doing so, we will explore the ideal state of a rational review system, including the so-called 2-track system where there are separate teams for priority reviews and normal reviews. [The timing will be noted on the work schedule mentioned in Item (1).]
- We will deliberate on how best to exploit the talents of private sector individuals. (To be decided in the summer of FY2007: MHLW)

(3) Clarification of the approval review and standards

- We will advance the study on product assessment methods that incorporate new technologists (e.g., microdosing, biomarkers) in an effort to design review standards that aptly address such new technologies. (To be initiated as of FY2007: MHLW)
- We will clarify the safety assessment standards for medical devices and pharmaceuticals that involve the use of cells/tissue. (To be decided and effectuated in the summer of FY2007: MHLW)

(4) Enhanced efforts to address international clinical trials in relation to the approval review

- We will formulate a basic stance concerning international clinical trials in relation to the approval review. (Measures to be effectuated in FY2007: MHLW)
- We will place priority on consultation regarding international clinical trials in which sites are located in more than one country. (Already implemented as of FY2006)
- We will deliberate on the introduction of joint consultation by review authorities in Japan, Europe and the U.S. (To be deliberated as of FY2008: MHLW)

(5) Intensified collaboration with review authorities in Europe, the U.S. and Asia, etc.

- We will promote the exchange of opinions and human resources among review authorities concerning regulatory matters and the review process. (Measures to be effectuated as of FY2007: MHLW)

(6) Improved operation of GCP for pharmaceuticals

- In consideration of the comparison with the international standard (ICH-GCP), we will improve the operation of 'Ministerial Ordinance on Standards for Conducting Clinical Trials on Pharmaceuticals' to facilitate smooth clinical trials in Japan. (To be deliberated and decided in FY2007: MHLW)

(7) Matters concerning medical devices

We will engage in the following activities in order to rationalize and simplify the review process, while maintaining the safety of medical devices:

- We will proceed with (a) devising guidelines that increase the efficiency of the development of feasible and innovative medical devices for which there are great needs in medicine. (Continued to be implemented in FY2007 and beyond: METI) We will also proceed with (b) devising

indexes for evaluation. (Continued to be implemented in FY2007 and beyond: MHLW)

- We will promote acceleration of the review process by, for example, devising review standards for medical devices. (Continued to be implemented in FY2007 and beyond: MHLW)
- We will examine the state of regulations by, for example, reviewing the handling of minor improvements within the appropriate range. (To be deliberated and decided in the summer of FY2007: MHLW)
- We will consider the rationalization of the range at which clinical trials are required. (To be deliberated as of FY2007: MHLW)
- We will attempt to improve upon and train review staff. (Measures to be effectuated as of FY2007: MHLW)
- We will conduct deliberation toward promoting international clinical trials. (To be deliberated as of FY2007: MHLW)
- We will improve the operation of 'Ministerial Ordinance on Standards for Conducting Clinical Trials on Medical Devices' in order to facilitate clinical trials, including investigator-sponsored trials. (To be deliberated as of FY2007: MHLW)

6. Appropriate Assessment of Innovations

(Drug Price)

It is necessary to achieve a balance between the standpoints of appropriately assessing innovative new drugs and swiftly providing Japanese patients with access to the global-standard or latest therapies overseas and the sustainability of the healthcare financing. Accordingly, we will place a priority on the appropriate assessment of innovative new drugs by ensuring systems of drug pricing and pharmaceutical benefits that allow for the steady replacements of off-patent pharmaceuticals with generics. We will, therefore, deliberate on the specific form this system should take, while taking into consideration the opinions from the related industries. (To be deliberated and decided in FY2007: MHLW)

(Medical Devices)

The current system of specified insurance-covered medical materials stipulates the same price for multiple products grouped into one functional classification, and innovative medical devices have been addressed to date by simply creating new classifications. However, there have been suggestions that some existing products have not been appropriately assessed.

Based on these situations and in order to increase the incentives toward the development and clinical application of new medical devices in Japan, we will deliberate on making the necessary reviews to proceed with moderation of medical device assessments that can maintain a balance with the sustainability of healthcare financing, all the while listening to the opinions from the related industries. (To be deliberated and decided in FY2007: MHLW)

7. Development of Public-Private Promotion System

(1) Development of the R&D promotion system

In order to swiftly and strongly move forward with this 5-year strategy, we will make the effort in the health, labour and welfare administration in order to enhance the system related to the promotion of pharmaceutical/medical device R&D and practical (clinical) applications as well as improvement of international competitiveness of domestic industry. (To be decided by FY2009 and measures effectuated as is possible: MHLW)

At the same time, we will also further intensify collaborative efforts between related ministries, research institutes and industries in order to promote the strategy.

(2) Implementation of public-private discourse

We will provide venues for public-private discourse on innovative drug discovery and the medical device field once or twice a year. In addition, we will regularly review the progression of this strategy.

8. Other

We will continue with the following efforts in order to facilitate the operations and advancement of domestic corporations in overseas markets:

- We will facilitate the prior-confirmation and prior-consultation procedures associated with transfer price taxation and improve the system that enforces the taxation, while requesting related government agencies to make efforts to clarify operations of transfer price taxation. (Measures to be effectuated in FY2007: MHLW and METI)