Mid-term Targets of the Pharmaceuticals and Medical Devices Agency *(Provisional Translation)*

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Targets related to the management of operations to be achieved by the Pharmaceuticals and Medical Devices Agency shall be as follows, based on the provision of Article 29-1 of the Law on General Rules of Incorporated Administrative Agency (Law No. 103, 1999).

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Part 1 Effective Period for Mid-term Targets

The effective period for the Mid-term targets according to Article 29-2-1 of the Law on General Rules of Incorporated Administrative Agency (Law No. 103, 1999; hereinafter referred to as "General Rules") shall be 5 years from April 2009 to March 2014.

Part 2 Items Related to Improvement in the Overall Management of Operations and the Quality of Services and Other Operations Rendered to the Public

With regard to targets related to efficiency improvement in the management of operations in accordance with Article 29-2-2 of the General Rules and targets related to improvement in the quality of services and other operations rendered to the public in accordance with Article 29-2-3 of said law, targets related to the Agency as a whole shall be as follows.

<1>Efficient and Flexible Management of Operations

(a) The Agency shall establish an efficient and flexible system for managing operations, confirm the way of operational control and methods for implementing operations through external evaluation, and improve the management of operations based on the following points:

- Improve internal control on the way of implementation of operations and other matters by obtaining instructions from accounting auditors, and proactively disclose measures taken.
- Examine the way of internal control by making use of the professional knowledge of third parties.

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* *This translation of the original Japanese text is for information purpose only (in the event of inconsistency, the Japanese text shall prevail).*

(b) The Agency shall promote computerization in operations and increase efficiency in the system for managing operations.

(c) The Agency shall reduce systems costs, ensure transparency in systems procurement, streamline the management of operations, and reduce expenses by reviewing the overall system configuration and the procurement method, based on the results of re-examination of information systems management services that are common throughout the Agency, and review services.

To achieve this goal, the Agency shall integrate individual review systems, based on the Optimization Plan for Operations and Systems that was developed at the end of FY 2007, and promote activities to optimize operations and systems by constructing systems for advancing information sharing among review services, safety measures services, and adverse health effects relief services.

<2>Cost Control through Increased Efficiency of Operations

(a) By increasing efficiency in the management of operations, the Agency shall reduce general administrative expenses (excluding expenses for office relocation and retirement allowances) by the end of the effective period for the Mid-term targets, through the following specific measures:

(1) Approximately 15% reduction in comparison with FY 2008

(2) General administrative expenses to be incurred starting in FY 2009 shall be reduced by approximately 12% in comparison with FY 2013 and FY 2009 for the increase, due to efforts to speed up approval reviews in accordance with the report issued by the Council for Science and Technology Policy, entitled “Revision of Structures Aimed at the Promotion of Science and Technology and Return of Achievements to Society” (dated December 25, 2006; hereinafter referred to as “Report of the Council for Science and Technology Policy”).

(3) General administrative expenses shall be as follows in consideration of activities to speed up approval reviews based on the “Action Program to Accelerate Reviews of Medical Devices” (dated December 11, 2008):

- General administrative expenses to be incurred starting in FY 2009 shall be reduced by approximately 12% in comparison with FY 2013 and FY 2009 for the increase.

- General administrative expenses to be incurred starting in FY 2010 shall be reduced by approximately 9% in comparison with FY 2013 and FY 2010 for the increase.

- General administrative expenses to be incurred starting in FY 2011 shall be reduced by approximately 6% in comparison with FY 2013 and FY 2011 for the increase.

- General administrative expenses to be incurred starting in FY 2012 shall be reduced by approximately 3% in comparison with FY 2013 and FY 2012 for the increase.

(4) General administrative expenses to be incurred in FY 2009 will be reduced by approximately 12% in comparison with FY 2013 and FY 2009 for the increase due to efforts to strengthen and enhance safety measures in accordance with the Interim Report of the Committee for Verification of Drug-induced Hepatitis Cases and for Examination of Drug Administration to Prevent Similar Diseases, entitled "How Drug Administration Should Function to Prevent Similar Drug-induced Diseases" (dated July 31, 2008; hereinafter referred to as "Interim Report of the Verification Committee on Drug-induced Hepatitis").

(b) By increasing operational efficiency, the Agency shall reduce operating expenses (excluding expenses for office relocation and benefit payments and single-year expenses due to new project launches) by the end of the effective period for the mid-term targets, through the following specific measures:

(1) Approximately 5% reduction in comparison with FY 2008

(2) Operating expenses to be incurred starting in FY 2009 shall be reduced by approximately 4% in comparison with FY 2013 and FY 2009 for the increase due to efforts to speed up approval reviews in accordance with the Report of the Council for Science and Technology Policy.

(3) Operating expenses shall be as follows in consideration of activities to speed up approval reviews based on the "Action Program to Accelerate the Reviews of Medical Devices."

- Operating expenses to be incurred starting in FY 2009 shall be reduced by approximately 4% in comparison with FY 2013 and FY 2009 for the increase.

- Operating expenses to be incurred starting in FY 2010 shall be reduced by approximately 3% in comparison with FY 2013 and FY 2010 for the increase.

- Operating expenses to be incurred starting in FY 2011 shall be reduced by approximately 2% in comparison with FY 2013 and FY 2011 for the increase.

- Operating expenses to be incurred starting in FY 2012 shall be reduced by approximately 1% in comparison with FY 2013 and FY 2012 for the increase.

(4) Operating expenses to be incurred starting in FY 2009 shall be reduced by approximately 4% in comparison with FY 2013 and FY 2009 for the increase through efforts to strengthen

At the end of the effective period for the Mid-term targets, administrative subsidies excluding the amount for office relocation, which is scheduled during this Mid-term target period, are to be reduce by approximately 18% (or approximately 15% if subsidies are added to administrative subsidies for each year to partially cover expenses for office relocation) in comparison with FY 2013 and FY 2008 for the increase. The Agency expects to develop the next Mid-term targets on the assumption of a reduction of about 18% in comparison with FY 2008.

(c) The Agency shall promote improvement in operational efficiency by centrally managing approved item data in each company on adverse drug reaction (ADR) contributions, infection contributions and safety measures contributions.

(d) The Agency shall have reduced total personnel expenses by 5% or more in comparison with FY 2005 over a 5-year period starting from FY 2006, based on the "Law Concerning Promotion of Administrative Reforms to Realize a Streamlined and Efficient Government" (Law No. 47 dated June 2, 2006).

The Agency shall also continue to work to reform personnel expenses up to FY 2011 in accordance with the "Basic Policy 2006 for Economic and Fiscal Management and Structural Reforms" (approved in a cabinet meeting on July 7, 2006) and based on reforms in respect of national government employees.

Moreover, the Agency shall verify its remuneration standard from the following perspective, and shall publicly announce its verification results and activities.

(1) Whether or not the remuneration standard for Agency staff is higher than that for government employees, taking into account factors, such as office locations and the academic qualification of employees

(2) Whether or not it is possible to eliminate causes for the high remuneration standard for Agency staff, such as the high proportion of employees dispatched from the national government

(3) Whether or not the appropriateness of the current remuneration standard can be satisfactorily explained, taking into account the large financial expenditure of the national government, the accumulated losses, the remuneration standards of private companies that are engaged in similar services, etc.

(4) Whether or not explanation of the remuneration standard can gain full public understanding

(e) The Agency shall, in principle, conclude contracts through open competitive bidding, and shall promote appropriate optional contracts by taking the following measures:

(1) Steadily implement and disclose activities based on the Plan for the Review of Optional Contracts.

(2) Choose methods that can fully secure competitiveness and transparency, especially in planning competition and open recruitment, even where contracts are concluded through open competitive bidding.

(3) In audits by auditors and accounting auditors, the appropriateness of bidding and contracts shall be thoroughly checked.

(f) The Agency shall examine the feasibility of relocating the head office and shall take the necessary measures during the effective period for the Mid-term targets, based on the "Reorganization and Rationalization Plan for Incorporated Administrative Agency" (approved in a cabinet meeting on December 24, 2007).

<3>Improvement of Services to the Public

The Agency shall comprehensively inform the public about its services and roles, strengthen consultation systems for the public, ensure transparency in the management of operations and the contents of services, and improve the quality of services for the public.

Part 3 Items Related to Improvement in the Management of Operations in Each Division and the Quality of Services and Other Operations Rendered to the Public

1 Relief Fund Services for Adverse Health Effects

With regard to the relief fund services, it is important not only to fully inform more people of the Adverse Drug Reaction Relief System and the Relief system for Infections Derived from Biological Products (hereinafter collectively referred to as "relief system") and appropriately operate them but also adequately and promptly provide relief for those suffering from adverse drug reactions and infections derived from biological products.

Based on this concept, the Agency shall achieve the following targets:

<1>Expansion and Review of the Provision of Information Concerning the Relief Systems

(a) The Agency shall increase transparency in system management by improving the content of information provided concerning the relief systems.

(b) The Agency shall increase operational efficiency by minimizing factors that extend processing time, such as incomplete application documents, etc.

<2>Proactive Public Relations Activities to Broadly Inform the Public About Relief Systems

The Agency shall broadly and comprehensively publicize the relief systems.

<3>Expansion of Consultation Services

The Agency shall improve the system for accepting consultations concerning procedures for benefit payment based on the relief systems by expanding consultation services.

<4>Central Management of Information Through Databases

The Agency shall promote operational efficiency by upgrading information databases on relief fund services in order to make them easier to use.

<5>Prompt Processing of Relief Benefit Claims Through Fact-finding Investigations

(a) The Agency shall promptly process relief benefit claims.

(b) The Agency shall improve operations by setting time-reduction targets within the standard administrative processing time. (This includes the period for medical and pharmaceutical judgments by the Ministry of Health, Labour and Welfare. However, the period during which administrative processing cannot be conducted because of the need for additional or supplementary documents and investigations, which are required in respect of claimants and medical institutions for the purposes of making medical and pharmaceutical judgments, shall be excluded from administrative processing time.)

<6>Promotion of Appropriate Information Provision Through Interdivisional Cooperation

Through interdivisional cooperation, the Agency shall appropriately provide information on relief payments in particular to both review divisions and safety measures divisions.

<7>Examination of Appropriate Implementation of Health and Welfare Services

In respect of health and welfare services, the Agency shall progressively implement services based on the results of a survey on the actual states of suffering of relief beneficiaries.

<8>Appropriate Implementation of Healthcare Allowances for SMON Patients and HIV-positive Patients Affected Through Blood Products

The Agency shall appropriately pay healthcare allowances to SMON patients and HIV-positive patients who have been adversely affected as a result of use of blood products.

<9>Appropriate Implementation of Benefit Payment Services to Assist Individuals Affected by Hepatitis C Through Specified Fibrinogen Products and Specified Blood Coagulation Factor IX Products Contaminated by Hepatitis C Virus

The Agency shall appropriately implement benefit payment services to assist individuals affected by hepatitis C through specified fibrinogen products and specified blood coagulation factor IX products contaminated by hepatitis C virus.

2 Reviews and related Services and Safety Measures Services

With regard to reviews and related services and safety measures services, it is important not only to provide improved pharmaceuticals and medical devices to medical institutions more promptly and safely in order to enable the public to confidently make use of pharmaceuticals and medical devices that are of world class, but also to prevent the occurrence of health hazards, appropriately and promptly respond in the event that any such hazard occurs, and to make the pharmaceuticals and medical devices can fulfill their purposes over longer periods of time.

Based on this concept, the Agency shall reinforce systems for consultations, reviews and post-marketing safety measures, organically link such operations, and work to attain the targets listed below.

The Agency shall also accelerate approval reviews and strengthen and improve safety measures based on the Report of the Council for Science and Technology Policy, the Action Program to Accelerate Reviews of Medical Devices, and the Interim Report of the Verification Committee on Drug-induced Hepatitis.

<1>Faster Access to the Latest Pharmaceuticals and Medical Devices

The Agency shall make efforts to enable both the public and healthcare professionals to gain early and timely access, to the maximum extent possible, to the benefits of advanced and safe pharmaceuticals and medical devices that meet their needs.

(a) Based on action plans for expediting reviews in order to solve the drug lag, the Agency shall take all appropriate measures, evaluate and verify progress, and initiate additional measures where necessary.

Following completion of the target period for the action plans, in FY 2011, the Agency shall promptly verify the results.

(b) To achieve this goal, the Agency shall improve services by setting time-reduction targets (targets under ordinary conditions, excluding exceptional cases such as significant institutional changes and changes in social conditions) in relation to the review service processing time for applications on and after April 1, 2004 (“the processing time on the reviewer side for items approved for the year”). The Agency shall also establish an efficient review system.

(c) In cooperation with the United States, the European Union and Asian countries, the Agency shall proactively promote international activities aimed at improving medical services, and thereby establish its international status.

(d) The Agency shall improve pre-application consultations, and give priority to conducting consultations on clinical trials for pharmaceuticals and medical devices that are expected to be highly effective, in order to shorten approval times.

(e) In light of the rapid development of new technologies, such as biotechnology, genomics, and regenerative medicine, the Agency shall improve the level of guidance and review technologies in these areas, and shall take necessary measures for consultations and reviews in response to the development of new drugs and new medical devices based on the latest technologies.

(f) The Agency shall take measures to accelerate reviews on over-the-counter drugs and generic drugs, as in the case of new drugs.

(g) With regard to medical devices, as in the case of new drugs, the Agency shall take all appropriate measures to accelerate reviews based on the Action Program to Accelerate Reviews of Medical Devices, in order to solve the device lag.

(h) The Agency shall appropriately and efficiently conduct conformity audits.

(i) The Agency shall construct a system for appropriately conducting on-site GMP/QMS audits by the end of the effective period for the Mid-term targets.

<2>Improvement of Reliability of Review Services and Safety Measures Services

The Agency shall provide pharmaceuticals and medical devices that the public and healthcare professionals can use with a sense of security, by further improving the reliability of review services and safety measures services.

(a) In respect of review services and safety measures services, the Agency shall work to improve staff skills in order to foster a group of technical experts who are in no way inferior to their overseas counterparts. The Agency shall also further strengthen cooperation with regulatory agencies in the United States, the European Union and Asian countries, as well as domestic and overseas research institutes and researchers.

(b) The Agency shall provide support for efficient implementation of clinical trials on pharmaceuticals and medical devices that can provide patients with the most effective and safest medical care, by focusing on the individual characteristics of patients.

(c) The Agency shall further promote transparency in review services and safety measures services such as by disclosing review reports.

(d) The Agency shall develop information system infrastructures to ensure reliability and further increase efficiency in review services and safety measures services.

<3>Strengthening and Improvement of Safety Measures Services

Based on the Interim Report of the Verification Committee on Drug-induced Hepatitis, the Agency shall work to prevent risks of adverse drug reactions in the use of pharmaceuticals and medical devices, and shall further strengthen the risk management system among relevant parties in order to foster rapid response to occurrences of adverse drug reactions and malfunctions.

(a) In order to precisely respond to the sophisticated and specialized evaluation of adverse drug reaction information, the Agency shall significantly improve and strengthen the system for organizing, evaluating and analyzing such information, and shall comprehensive evaluate adverse drug reaction information systematically and regularly. The Agency shall also identify new correlations between adverse drug data by utilizing IT technologies, construct a system to efficiently and effectively evaluate safety information by studying and making use of methods to locate and analyze new safety information, and make improvements on an as-needed basis.

(b) The Agency shall expand both the use of information feedback to healthcare professionals and companies, such as analysis results on collected safety information, and the means to provide information on proper use to patients, and shall strengthen the system for providing detailed safety information, which contributes to improvement of safety measures at medical institutions. At the same time, from the perspective of making it easier for the public to understand the achievements of safety measures services, the Agency shall set indices to enable more precise ascertainment of achievements.

(c) The Agency shall appropriately evaluate safety through linkage with relief services and review services.

(d) With regard to the safety measures that have been taken, the Agency shall construct a system for confirming the states of implementation and effectiveness within companies and medical institutions.

Part 4 Matters Related to Financial Improvement

The target in relation to financial improvement as provided for in Article 29-2-4 of the General Rules shall be as follows.

With regard to matters determined in <1> and <2> of Part 2 of the Mid-term targets, the Agency shall develop the Mid-term budget plan in anticipation of cost reductions and conduct management based on this budget.

Part 5　Other Important Matters Related to the Management of Operations

Important targets related to the management of other operations provided in Article 29-2-5 of the General Rules shall be as follows.

<1>Personnel Matters

(a) To improve the expertise of staff members, the Agency shall appropriately develop their abilities through exchanges with external organizations and conduct personnel evaluation in consideration of their achievements. The Agency shall also aim to enhance staff motivation through these measures.

(b) Based on the Report of the Council for Science and Technology Policy, the Action Program to Accelerate Reviews of Medical Devices, and the Interim Report of the Verification Committee on Drug-induced Hepatitis, the Agency shall secure the workforce required for necessary reviews and safety measures.

In employing human resources, the Agency shall be fully cognizant of its neutral status.

(c) The Agency shall take appropriate measures for the employment, allocation, and post-retirement reemployment of executives and employees in order to avoid any suspicion of inappropriate operational ties with pharmaceutical companies.

<2>Ensuring Security

To thoroughly protect personal and corporate information, the Agency shall ensure security for each office and take all possible measures to securely manage information.