Incorporated Administrative Agency - Pharmaceuticals and Medical Devices Agency (PMDA)

Midterm Targets (**Provisional Translation*)

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

No. 0401003 of the Minister, MHLW dated April 1, 2004
Amended: No. 0331002 of the Minister, MHLW dated March 31, 2005

In accordance with Article 29, Paragraph 1 of the Law on the General Rules of Incorporated Administrative Agency (Law No.103, 1999), the targets to be achieved by the Pharmaceuticals and Medical Devices Agency in its operations management shall be established as stated below.

April 1, 2004
Chikara Sakaguchi
Minister of Health, Labour and Welfare

No.1 Duration of the Midterm Targets

The duration of these Midterm Targets as specified under Article 29, Paragraph 2, Item 1 of the Law on the General Rules of Incorporated Administrative Agency (Law No. 103, 1999, hereinafter referred to as "the General Rules") shall be from April 2004 to March 2009, a period of five years.

No.2 Items concerning increased improvement in the overall operations of the Pharmaceutical and Medical Devices Agency (hereinafter referred to as "the Agency") and those concerning improvement in the quality of its services provided to the public, and other operations.

The targets concerning operational efficiency as specified under Article 29, Paragraph 2, Item 2 of the General Rules, and those on improvement of the quality of services and other operations provided to the public, associated with the entirety of the Agency are as follows:

(1) Efficient and flexible operations management

a. The Agency shall establish an efficient and expeditious operational system, and make improvements in such system, by evaluating a modality of the operational control and the operating method using a third party or other measures.

b. The Agency shall promote the computerization of its operations to establish an efficient system of operations

(2) Expense savings, etc., delivered by increased efficiency of operations

a. By the end of the effective period of the Midterm Targets, the Agency shall save: (a) the general administrative expenses (excluding retirement allowances) by approximately 15% from the FY 2003 level, by increasing efficiency in operations; (b) the general administrative expenses due to accrue from FY 2004 in connection with the revisions to laws and systems and other matters, by approximately 12 % from the FY 2004 level; (c) the general administrative expenses due to accrue from FY 2005 in connection with the enforcement of the revised Pharmaceutical Affairs Law in FY 2005 by approximately 9% from the FY 2005 level.

b. By the end of the effective period of the Midterm Targets, the Agency shall save: (a) the program expenses (excluding benefit-related expenses, and single-year expenses due to accrue in connection with creation of programs) by approximately 5% in comparison with the FY 2003 level, by increasing efficiency in operations; (b) the program expenses due to accrue from FY 2004 in connection with the revisions to laws and systems and other matters by approximately 4% in comparison with the FY 2004 level; (c) the program expenses due to accrue from FY 2005 in connection with the enforcement of the revised Pharmaceutical Affairs Law in FY 2005 by approximately 3% in comparison with the FY 2005 level.

c. The Agency shall promote efficiency in its operations by centrally managing data on products manufactured by each company related to Contribution Funds for adverse drug reaction (ADR), infectious disease, and safety measures.

(3) Improvement of services provided to the public

The Agency shall improve services provided to the public by strengthening the consulting system and ensuring transparency of its operations.

No.3 Items concerning improvement in operations of each section, and improvement in the quality of services provided to the public and other operations.

1 Adverse Health Effect Relief Services

With regard to Adverse Health Effect Relief Services, the Agency shall work to publicize the Adverse Drug Reaction Relief and Biological Product-derived Infectious Disease Relief System (hereinafter referred to as “the System”) to as many people as possible. While managing the system appropriately, it is important that the Agency provides appropriate and prompt relief service to those people who suffer adverse drug reactions from pharmaceuticals and adverse health effects from biological product-derived infections.

Taking such perspectives into consideration, the Agency shall achieve the following targets:

(1) Promotion and review of the dissemination of information regarding the System

a. The Agency shall enhance the services providing information regarding the System and increase transparency in managing the System.

b. The Agency shall increase efficiency in operations by reducing incomplete applications cases that cause delays in processing.

(2) Proactive public relations activities toward familiarity with the System

The Agency shall familiarize the public with information on the System.

(3) Expansion of the scale of the consultation office

The Agency shall expand the scale of its consultation office for a wider range of consultations regarding benefit procedures of the System.

(4) Unified management of information through the database

The Agency shall take measures to upgrade the database of information on relief services for further user-friendliness and thereby promote efficiency in operations.

(5) Expeditious processing of relief applications cases through fact-finding study and other measures

a. The Agency shall expeditiously process applications for relief benefits.

b. The Agency shall produce an increase in the number of cases that can be judged as either payable or not payable within the standard administrative process time (including the time required for medical and pharmaceutical judgment by the Ministry of Health, Labour and Welfare (MHLW)). (However, the period of time in which administrative processing could not be conducted with cases which require medical and pharmaceutical science-based judgment, and thus require additional/supplementary materials and surveys against requestors or medical institutions, shall be excluded from the standard administrative process time.)

(6) Promotion of appropriate communication of information through cross-functional collaboration

The Agency shall seek cross-functional collaboration to appropriately provide its postmarketing safety section with instances of benefit payments in relief services.

(7) Consideration of conducting surveys on adverse health effects, etc.

As a part of its health and welfare services, the Agency shall consider conducting a survey such as for example on the actual damage and condition of the recipients of relief benefits. The survey shall be conducted based on the result of that consideration.

(8) Appropriate conduct of relief services for SMON (subacute myelo-optico-neuropathy) patients and those patients infected with HIV from blood preparations

The Agency shall appropriately conduct relief services for SMON patients and those patients infected with HIV from blood preparations.

2 Reviews and Related Operations / Postmarketing Safety Operations

In order that the public can feel assured in the use of pharmaceuticals and medical devices at an international level, the Agency shall ensure that: better pharmaceuticals and medical devices are provided to the medical arena faster and with greater safety; that pharmaceuticals and medical devices are used properly; and that health hazards are prevented or responded to properly and promptly in the event of such occurrences. It is of importance in its operations of premarket reviews and postmarketing safety that the Agency enables such pharmaceuticals and medical devices to play their part in enhancing the public health for the long term.

Taking such perspectives into consideration, the Agency shall strengthen its structures for consultation/review and postmarketing safety measures, promoting the organic collaboration of both operations to achieve the following targets:

(1) Faster access to leading-edge pharmaceuticals and medical devices

a. The Agency shall ensure that the public and healthcare professionals swiftly enjoy the maximum benefits of leading-edge, yet safe, pharmaceuticals and medical devices that answer their needs. Additionally, the Agency shall ensure benefits for the pharmaceutical and medical device industry that are brought forth by such swiftness.

b. To this end, the Agency shall establish a target time (the target time under normal times excluding such exceptional cases as times under significant changes in the review system or in social conditions to reduce the review process time (referred to as “the process time that reviewers consumed for products approved in the year”) for applications submitted on and after April 1st 2004. By so doing, the Agency shall increase efficiency in its operations and establish an efficient review structure.

c. The Agency shall endeavour to accelerate reviews of new pharmaceuticals so that by the end of the current Midterm Targets period, it can establish a target time for total review time (process

time of the reviewer side plus that of the applicant side for products approved in that year) for the next Midterm Targets period.

d. The Agency shall improve its pre-application consultation process, and give priority to conducting clinical trial consultations for pharmaceuticals and medical devices expected to be highly useful in order to shorten the period of time required for their approval.

e. With a view to the rapid developments in such advanced technologies as biotechnology and genomics, the Agency shall improve the level of its guidance and review techniques in such fields.

(2) Improvement in reliability of reviews and related operations/ postmarketing safety operations

Through further improvement of the reliability of its review and postmarketing safety operations, the Agency shall provide pharmaceuticals and medical devices that the public and healthcare professionals can feel confident to use.

a. In its review and postmarketing safety operations, the Agency shall work to upgrade the skills of its staff members to build a group of technical experts whose level is comparable to international counterparts.

b. By focusing on the condition of each patient, the Agency shall provide support to allow smooth implementation of clinical trials for technologies or products that could offer the most effective, yet safe, medical services to eligible patients. Furthermore, the Agency shall facilitate reviews of products to which such technologies are applied.

c. The Agency shall promote the transparency of review and postmarketing safety operations

d. Furthermore, the Agency shall take measures that will contribute to improvement in the reliability of any other reviews and postmarketing safety operations.

(3) Reinforcement of information management and emergency management systems

The Agency shall reinforce its risk management system and related staff in order to avoid risks such as adverse reactions to the use of pharmaceuticals and medical devices, and to promptly address occurrences of such adverse reactions.

a. The Agency shall study and introduce a method to find new relevance in multiple pieces of information on adverse reactions, and to uncover/analyze new safety information.

b. In order to provide focus on safety measures for pharmaceuticals postmarketing use, the Agency shall study and introduce a new system to ensure postmarketing safety where healthcare professionals are required to use pharmaceuticals with caution.

c. The Agency shall work to efficiently collect effective safety information with the use of effective measures such as information technology.

d. The Agency shall work to expand access to information, and to provide feedback, to health professionals and companies. This shall include the results of analysis of safety information collected, as well as expanding the means of providing proper use information to patients, thereby establishing a comprehensive system to provide safety information.

No.4 Items concerning improvement in the composition of finances

The objective concerning improvement in the composition of finances as specified under Article 29, Paragraph 2, Item 4 of the General Rules shall be as follows:

As for the items specified under aforementioned No.2 (1) and (2) of this Midterm Targets, the Agency shall develop a budget for the Midterm Plan which takes into account the cost reduction expected. The Agency shall manage in accordance with the budget.

No.5 Other important operational items

Other important operational items as specified under Article 29, Paragraph 2, Item 5 of the General Rules shall be as follows:

(1) Items concerning personnel matters

a. In addition to proper implementation of staff development to enhance the professionalism of staff members, the Agency shall implement in an appropriate manner a personnel evaluation system that takes into consideration the work performance of staff members. Through such measures, the Agency shall work to further motivate its staff members.

b. To ensure smooth enforcement of the revised Pharmaceutical Affairs Law in FY 2005, the Agency shall secure an appropriate number of staff members.
Recruiting shall be done with due consideration to the impartiality of the Agency.

c. In order for the Agency's operations and services to avoid any suspicion of inappropriate ties with pharmaceutical and medical device companies and others, the Agency shall take appropriate

measures in the recruitment and placement of its executives and staff members, as well as in the re-employment of those who retire.

(2) Ensuring security

To protect personal information and proprietary information of corporations, the Agency shall ensure the security of its offices, and related spaces, and, moreover, exert its utmost efforts in the secure management of information.