February 6, 2009

Pharmaceuticals and Medical Devices Agency

PMDA International Strategic Plan

—Objectives for the Second Mid-Term Plan—

Introduction

With the globalization of the development and distribution of pharmaceuticals and medical devices, Pharmaceuticals and Medical Devices Agency (PMDA) has been required to harmonize its services with the international community in order to provide people with more effective and safer pharmaceuticals and medical devices more quickly. Given this, PMDA has declared its determination, as part of its philosophy, to play an active role within the international community from a global point of view by promoting international harmonization. PMDA must implement international activities in a more organized and systematic manner in order to realize this philosophy during the coming second mid-term plan period (from FY2009 to 2013). To this end, PMDA has formulated the PMDA International Strategic Plan, which outlines the basic policies for overall international activities during this period. PMDA will appropriately meet the needs of the Japanese people for pharmaceuticals and medical devices by promoting proactive international operations in accordance with the strategic plan. In addition, PMDA will play the role expected of it within the international community by meeting the needs of people around the world for pharmaceuticals and medical devices.

Three targets to be achieved during the second mid-term plan period

1. Strengthening of cooperation and building of collaborative relations with the United States (US), the European Union (EU), Asian countries, and relevant international organizations

2. Proactive participation in international harmonization activities and further contributions to such activities

3. Improvement and strengthening of information provision to overseas countries

To achieve these targets, PMDA will steadily implement the following five strategies as its basic principles by establishing an internal office in charge of international affairs to improve and strengthen its system.

International Strategy 1

Strengthening of Cooperation with the US, the EU, Asian countries, and Relevant International Organizations

PMDA will play a full part in the review and safety of pharmaceuticals and medical devices in Japan—which together with the US and the EU is one of the main regions for new drug development—in cooperation with the US Food and Drug Administration (FDA) and the European Commission and the European Medicines Agency (EMEA). To this end, PMDA will promote continuous bilateral talks based on confidentiality agreements, information sharing, and proactive personnel exchanges as required in conducting business with relevant parties. PMDA will deploy its staff members in the FDA and EMEA, regularly invite personnel from the two organizations to its offices, and establish a system under which detailed information can be gathered and opinions can be exchanged in real time. PMDA will swiftly analyze, evaluate, and translate important overseas information and communicate it to the relevant parties.

During the second mid-term plan period, PMDA will promote the building of collaborative relations with Asian countries, with the primary focus on China and South Korea. PMDA will also examine how to promote and strengthen information sharing as required in conducting business with the other Western and Asian countries and international organizations. PMDA will also build a system to enable it to flexibly respond to training requests from other countries.

Furthermore, PMDA will strengthen cooperation with foreign countries with respect to inspections and audits conducted to ensure compliance with Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), and Quality Management System (QMS). PMDA will also develop an environment geared

toward the exchange of inspection reports and other such cooperative activities, and make continued efforts to work with relevant international organizations toward the establishment of international standards.

International Strategy 2

Strengthening of activities for international harmonization

PMDA will enhance Japan's contribution to ongoing international harmonization activities such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the Global Harmonization Task Force (GHTF), the Harmonization By Doing (HBD), and the Pharmacopoeial Discussion Group (PDG) and maintain and strengthen favorable relations with relevant countries by continuing to proactively send directors and staff members to and proactively participating in these activities. In addition, PMDA will enhance Japan's contribution to and strengthen collaborative relations with the World Health Organization (WHO), the Organization for Economic Co-operation and Development (OECD), and other relevant international organizations by proactively sending directors and staff members to international harmonization activities led by those organizations.

International Strategy 3

Promotion of personnel exchanges

PMDA will proactively and continuously send its staff members to international meetings and conferences in a variety of specialized fields and promote the building of networks with overseas regulatory agencies. PMDA will also work to increase its opportunities to send personnel to the FDA and EMEA and will promote personnel exchanges with relevant countries and international organizations.

To promote mutual understanding among Japan, China, and South Korea in particular, PMDA will promote personnel exchanges with the State Food and Drug Administration (SFDA, China) and the Korea Food and Drug Administration (KFDA) and will build a system under which information on product evaluation and safety measures can be steadily exchanged.

International Strategy 4

Fostering of internationally minded human resources with communication skills

To foster internationally minded human resources with communication skills, PMDA will promote the development of staff training programs—which will include communications with overseas parties, attendance and presentations at international conferences and meetings—and the implementation of these programs in an organized manner.

PMDA will also work to help relevant staff members improve their foreign language skills, such as English, by continuing and strengthening its foreign language training and daily educational activities for directors and staff members.

International Strategy 5

Improvement and strengthening of international publicity and information provision

To ensure that relevant overseas parties correctly understand its role and activities, PMDA will proactively implement activities such as the improvement and enhancement of its English website, which explains pharmaceutical regulations, PMDA's services, and so on. PMDA will also prepare and disclose English translations of product review reports, post-marketing safety information, legal notices, and other administrative documents. In addition, PMDA will proactively give lectures and have booth exhibits regularly at international meetings and conferences, distribute relevant information to and grant interviews to the Foreign Correspondents' Club of Japan and overseas media, and thus provide important information such as that concerning pharmaceutical regulations in Japan in an easy-to-understand and swift manner to overseas countries.