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Pharmaceuticals and Medical Devices Agency

## Proposal of PMDA International Strategic Plan

With the globalization of the development and distribution of pharmaceuticals and medical devices, not only domestic but also international cooperation is required to provide more effective and safer pharmaceuticals and medical devices in a speedy manner and to promote their use.

Consequently, Pharmaceuticals and Medical Devices Agency (PMDA) has discussed with the Ministry of Health, Labour and Welfare (MHLW) how to implement international activities for pharmaceuticals and medical devices in future, and has formulated a framework for international activities with the following aims:

- (1) Further strengthening of partnerships with regulatory agencies in the United States (US) and the European Union (EU)
  - Rapid exchange of a wide range of information through the promotion of executive-level talks with the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) and the dispatch of manager-level resident officers to these agencies.
  - Maintenance and development of initiatives led by Japan, the US, and the EU, including the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).
- (2) Creation of partnerships with regulatory agencies in Asian countries such as information exchanges
  - Strengthening of cooperation with China and South Korea through meetings such as director-general level meetings concerning pharmaceutical affairs.
  - Promotion of information provision and the acceptance of trainees in line with the needs of regulatory agencies in Asian countries.

Based on the above framework, PMDA has decided to establish the PMDA International Strategic Plan, which outlines the basic policies and objectives to be achieved during the coming second mid-term plan period (from FY2009 to 2013), in order to implement its international activities in a more organized and systematic manner in close cooperation with the Ministry of Health, Labour and Welfare.