Promotion of Asian Pharmaceutical and Medical Device Regulatory Harmonization

Basic Principles of the Asia Health and Wellbeing Initiative (AHWIN, established by the Headquarters for Healthcare Policy of Japan in July 2016; revised July 2018)

- In order to contribute to resolving the 'drug lag' between Japan and Asia, Japan will **promote harmonization efforts to make pharmaceutical approval systems and safety regulations more effective and rational** by ensuring interoperability in Asian countries/regions of data used for approval of pharmaceuticals.

Situation surrounding Asia

Economic growth

Population increase

Aging

→ Increasing public interest in high-quality pharmaceuticals and medical devices
Expansion of pharmaceutical/medical device market

Issues of access to pharmaceuticals and medical devices

- Access to innovative pharmaceuticals and medical devices is insufficient in Asian countries/regions.
- Access to pharmaceuticals and medical devices is a complex issue related to research and development, regulation, securing of intellectual property, etc.
- Globalization and diversification of products mean increasing regulations and heightened importance of international cooperation

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Work together to harmonize regulations and handle related matters by having the competent ministries and agencies through concrete measures to the AHWIN

Goals

Develop a borderless Asian market for pharmaceuticals and medical devices
Contribute to healthy and active aging in Asia as a new Japanese initiative

Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization

Four Basic Approaches

- Shared principles and values (Regulatory science)
- Respect the position of Asian countries/regions (Equal partnership)
- Coordination and cooperation with the business community's activities
- Infrastructure development with both a "hard" approach and a "soft" approach

Grand Design Measures Package

Problems that require intensive efforts in Asian countries/regions

Action 1: Establishing a system and framework

Platform Formation

- Operation of an Asian Network Meeting comprised of responsible persons from regulatory authorities

Promotion and coordination with the business community's activities

- Promotion of activities of business community-led international conferences (APAC, etc.)
- Collaboration between public and private sector in infrastructure development, including Asian countries/regions

Understanding needs and establishing a utilization scheme

- Surveying and understanding needs in Asian countries/regions (cooperation with the overseas diplomatic establishments and JETRO)
- Establishing a scheme for utilizing information on needs, chiefly in the business community

Strengthening the system

- Assigning a dedicated person-in-charge for each country within the PMDA
- Considering overseas dispatch of personnel and exchange of human resources for a certain period of time (Utilize JICA framework as appropriate)
- Transparency and dissemination to civil society

Various actions based on the system and framework

Action 2: Enhancement of clinical trial system

- It is often the case that use of highly innovative pharmaceuticals is spread from clinical trial sites to other sites.
- Thus, establishing clinical trial sites can improve access to pharmaceuticals and medical devices.

Support for establishment and maintenance of clinical trial sites

* Support site expansion according to needs of other countries ("hard" approach)
- Support by ERIA
- Consider the use of loans by ADB, etc.

- Training for clinical trial personnel (healthcare professionals, CRAs, CRCs) in cooperation with academia, etc. ("soft" approach)

Action 3: Promotion of regulatory harmonization

International standardization, promotion of Reliance*

- Support for incorporation of international standards, encouragement of participation in international conferences
- Permeation of Reliance concept in cooperation with WHO
- Promoting the use of Japanese approval review results and inspection results by fostering trust in the Japanese regulatory system

* Reliance in this context means that, when a regulatory authority of one country/region conducts approval reviews or inspections, they consider, attach importance to, and utilize in their regulatory activities, the outcomes of assessments made by their counterparts in other countries/regions. (Proposed by WHO)

Human resource development

- Strengthening of the PMDA's Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs
- Provision of GMP mock inspection training by academia
- Collaboration with WHO human resource development programs

Action 4: Handling individual areas

Pharmaceuticals

- Promotion of Asian joint clinical trials
- International standardization of generic drug regulations and permeation of those standards throughout Asia
- Improvement of health awareness and access to OTC drugs
- Harmonization of specifications and standards for herbal medicines, etc. with the Japanese Pharmacopoeia

Medical devices and in vitro diagnostics

- Systematic action based on local needs
- Technical support tied to establishment of clinical trial site

Regenerative medicine products

- Promoting establishment of regulations according to product characteristics
- Permeation of safety evaluation tests

Even fellow Asian countries/regions can differ from each other with respect to the maturity of the medical standards and systems and the decision-making process. Accordingly, it would be helpful to adjust to the actual situation in the other country by adopting a "vehicular" model where

[1] **collaboration among business community, academia, and government within Japan serves as the engine,**
[2] **the "vehicle" is steered and guided by dialog and partnership between the governments of Japan and the partner countries, which together serve as the front wheels**, and
[3] **the business communities of both countries cooperate to push from behind as the rear wheels,**

achieving **a "four-wheel drive" approach that can promote regulatory harmonization in Asian countries/regions** in an effective and organic manner.