PMDA’s International regulatory activities based on PMDA International Strategic Plan 2015

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Regulatory Authorities in JAPAN

MHLW
Pharmaceuticals and Food Safety Bureau, MHLW
- Final Authorization of applications
- Publishing Guidelines
- Advisory committee
- Supervising PMDA Activities

PMDA
Pharmaceuticals and Medical Devices Agency
- Scientific Review for Drugs & Medical Devices
- GCP, GMP Inspection
- Consultation on Clinical Trials etc.
PMDA’s Three Major Services

Safety Triangle
- Comprehensive risk management undertaken by three operations -

As the only regulatory authority in the world which plays three roles in an integrated manner, PMDA contributes to improve the standard of medical care by delivering safer and higher quality products faster to medical practice based on regulatory science.

3rd 5-year plan for PMDA’s activities (FY2014 - 2018)

[Goals]
1. Extending health and life span of Japanese people
2. Contribution to global medicine
3. Activation of industries

[Major Challenges]
1. Shortening the time from early development to approval
2. High quality review/consultation services
3. Enhancing safety measures
4. Globalization
Announcement of PMDA’s International Strategic Plan 2015 on 26 June 2015

Structure - PMDA’s International Strategic Plan 2015

VISION

STRATEGY

ROADMAPS
Vision - PMDA’s International Strategic Plan 2015

1. To contribute to the world through regulatory innovation
PMDA will, based on regulatory science, promote public health globally by communicating the outcomes of its first-in-the-world product reviews, safety measures, and relief services

2. To maximize the common health benefits to other countries/regions
PMDA will, in order to realize quicker access to more effective and safer medical products for patients around the globe, communicate more closely with countries around the world to promote regulatory harmonization and collaboration

3. To share the wisdom with other countries/regions
PMDA will, by fully utilizing the accumulated knowledge and experience, contribute to the public health of partner countries/regions through provision of information and training that are essential for building regulatory capacity in those countries

Highlights of Strategy - PMDA’s International Strategic Plan 2015 (1/2)

1. Taking the lead, and disseminating the information around the globe
   a. Establish the “Regulatory Science Center” to provide consultations, conduct product review, and implement safety measures based on the latest science (by end of FY 2018)
   b. Proactively publicize globally the knowledge and experience of PMDA

2. Promoting international regulatory harmonization and global cooperation
   a. Expand the range of collaborative activities between regulatory authorities in Japan and EU, US etc.
   b. Further expedite harmonization of the Japanese Pharmacopeia, EP and USP through the activities of the Pharmacopoeial Discussion Group (PDG)
Highlights of Strategy - PMDA’s International Strategic Plan 2015 (2/2)

3. Increase efficiency of inspections that may lead to future international work-sharing
   a. Streamline international collaboration in GMP/GCP inspections

4. Contribution to international regulatory harmonization activities
   a. ICH, IGDRP, ICMRA etc.

5. Provision of information and training programs that are essential for building regulatory capacity in partner countries
   a. Establish the "Asian Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs"
   b. Deepen mutual understanding and trust of key ASEAN countries, China/Korea, BRICs, and other countries through bilateral meetings and symposia.

Asia Training Center – Example of achievements (1/3)

PDMA has set up Asia Training Center for Pharmaceuticals and Medical Devices Affairs since April 2016, and provides training opportunities including on-site training.
Based on close collaborative activities between GMP experts in Japan and EU, the Agreement on the Mutual Recognition (MRA) of GMP for pharmaceuticals between Japan and EC was amended to include the following competent authorities:

Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia, Bulgaria, Romania and Croatia

Bilateral collaboration – Example of achievements (3/3)

1. Symposium with regulatory authority
   a. Brazil (September 2015)
   b. Chinese Taipei (November 2015)
   c. Thailand (March 2016)
   d. India (May 2016)

2. Continuous assignment of MHLW/PMDA liaison official in EMA
Thank you

MHLW

PMDA