Current Status and Challenges of Bilateral/Multilateral Meetings

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Agenda

- Our Mission
- PMDA International Vision
  - PMDA EPOCH toward 2020
- Current Collaboration with Regulatory Agencies
- Challenges in the Collaborations

Our Mission

- Improve the public health and safety of our nation by reviewing applications for marketing approval of pharmaceuticals and medical devices, conducting safety measures, and providing relief to people who have suffered from adverse drug reactions.

http://www.pmda.go.jp/english/about/philosophy.html

Common Mission to Regulators(1)

- To promote and to protect the public health of our citizens – in a science lead manner – when it comes to the products for which we are responsible within our jurisdictions

Common Mission to Regulators(2)

- Bilateral and multilateral efforts to leverage the human, scientific, and financial resources of and the knowledge and experience of other key regulatory authorities so as to avoid duplication of effort, to make our activities more efficient, and to allow us to focus our limited resources on higher-risk areas of concern.

PMDA INTERNATIONAL VISION

PMDA EPOCH Toward 2020

- PMDA International Vision
  - Established in November 2011
  - Secure the highest level of **E**xcellence in Performance
  - Maintain a close **P**artnership with the **O**rient for the common benefit
  - Actively **C**ontribute to International **H**armonization of regulations, guidelines, and standards for the benefit of both Japan and the world

http://www.pmda.go.jp/english/international/pdf/PMDA_International_Vision/pmda_vision.pdf

Roadmap for the PMDA International Vision

Five Important Areas Where RMs are needed

1) Response to advanced science and technology

・Proactively provide information about the policies for review and scientific consultation of cutting-edge products and recommendation for relevant guideline developments.
・Introduce progressive analyzing and predictive methods.

2) Improvement of international operation basis

・Improve the organizational structure enabling wide range international activities and cultivate new internationally minded personnel* in a prompt manner.

*A personnel who has 1) good command of foreign languages, 2) an international human network, 3) abundant knowledge of his or her related area of expertise , 4) ability to make appropriate decisions under the given circumstances domestically and internationally, and 5) trustworthy international relations.

3) Dissemination of English information on regulatory review of medicinal products, especially publication of review reports in English

・Increase the number of English version of review reports (aiming to cover all the necessary review reports in English in the future).

4) Dissemination of information and international cooperation on safety measures

・Enhance exchanging information and establish a system to share evaluation reports with our overseas counterparts.
・Enrich the contents related to safely information in the English website.

5) Increase of the leverage of Japanese Pharmacopoeia (JP)

・Publish the newest JP version simultaneously in English and Japanese.
・Enhance cooperative relationship with the USP, EP, WHO and each Asian pharmacopeia.

Note) As we have been committed to emphasize the activities with ICH, IMDRF and other foreign regulatory agencies, the effort should continue for the future development.

CURRENT COLLABORATION WITH REGULATORY AGENCIES

Confidentiality Arrangements

- Australia (TGA)
- Brazil (ANVISA)
- Canada (Health Canada)
- EU (EC/EMA)
- France (ANSM)
- Ireland (IMB)
- Italy (AIFA)
- Singapore (HSA)
- Switzerland (Swissmedic)
- UK (MHRA)
- USA (FDA)

Bilateral Meetings

- Specific points of contact for public information
- Face to Face meeting (Annual basis)
- Specific cluster communications

Liaison Officers

- EMA
- Swissmedic
- USP
- Health Canada?

Role of Japan Liaison at EMA(1)

- To work within the EMA
- To help coordinate MHLW/PMDA activities in Europe regarding the regulation of medicinal products
- To serve as a resource on Japanese regulations, guidance, and practices

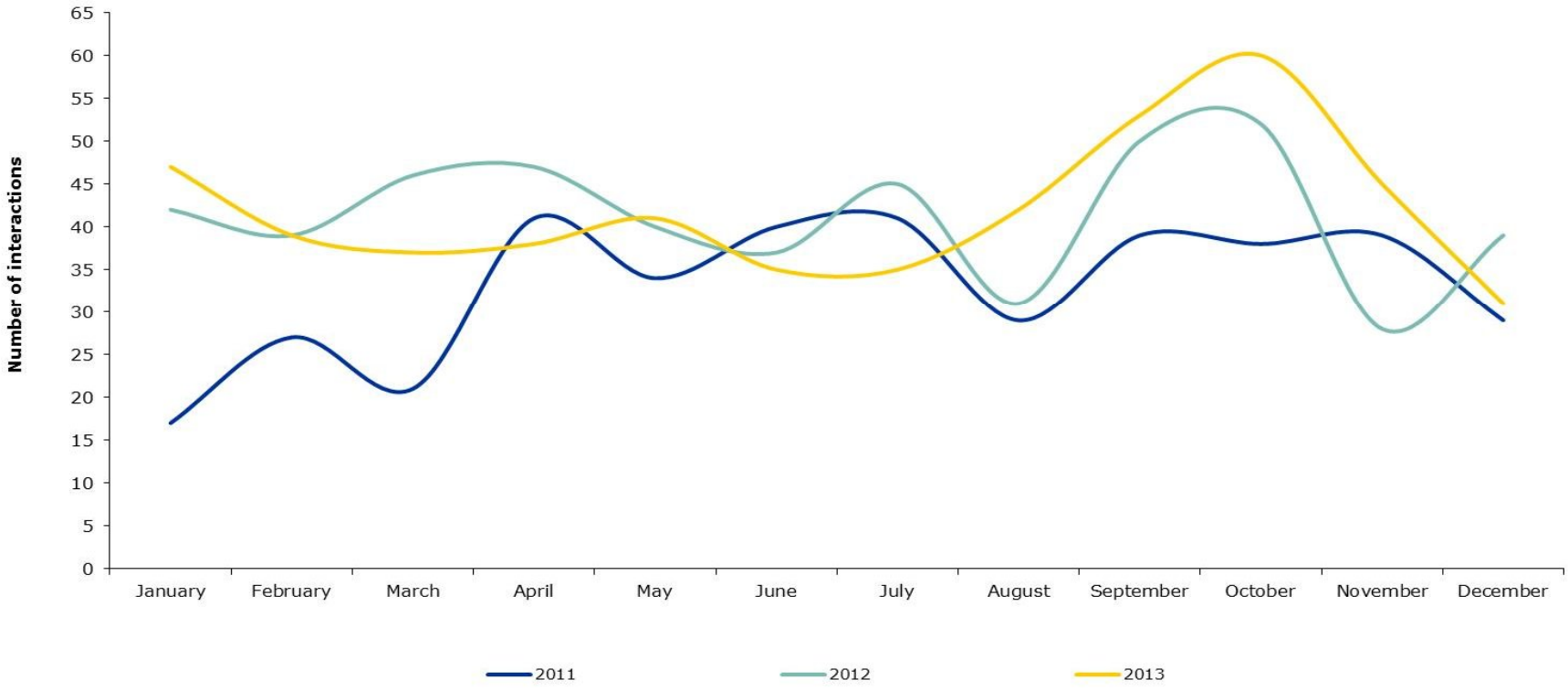
Role of Japan Liaison at EMA(2)

- All with a view to encourage scientific dialogue, clarify the regulatory context, facilitate harmonisation, and reduce regulatory burden in the best interest of the public we serve

Role of Japan Liaison Official(3)

- To enhance collaboration between EMA/EC and MHLW/PMDA for patients.
- Major Role;
  - Provide information from MHLW/PMDA to EMA
  - Provide information from EMA to MHLW/PMDA
  - Promote personnel exchange
  - Explore specific areas & things of interest with setting priority
  - Development of new collaboration area

MHLW/PMDA-EMA Interaction



MHLW/PMDA-EMA Activities

- Clusters and routine exchanges
- Inspection collaboration: GMP, GCP
- Ad hoc meetings
- Participation to workshop
- Staff visits

Clusters

- Advance Therapy Medicinal Products (ATMPs)
- Nanomedicines
- Oncology
- Orphans
- Pediatrics
- Pharmacogenomics
- Pharmacovigilance

Routine Exchanges

- Early Notification System
  - From EU
    - CHMP/CDMh
    - PRAC
  - From Japan
    - Safety Measures

Ad hoc Exchanges

•New legislation
•Opinion on individual products under review of Medicinal Authorisation Applications (MAA) or under Scientific Advice process
•The details of safety information of post-approved products

Inspection Collaboration

- GMP
  - Mutual Recognition Agreement on GMP
  - Participation to GMP Inspectors Working Group
- GCP
  - Participation to GMP Inspectors Working Group and GCP Inspectors Training Course
  - Participation to GCP inspection as Observers

Ad hoc Meetings

- Discussion on a Concept Paper/Draft Guideline etc.
- Information Sharing on the Safety Measure of a Product
- Enhancement of each Cluster

Participation to Workshop

- The EMA-FDA-MHLW/PMDA Joint Workshop on Orphan Products
- Invitation to Own Workshops Each Other
  - PMDA Forum
  - International Symposium of Biologics
  - Workshop on Inflammatory Bowl Disease

Communication with Other Regulatory Agencies

- PMDA Training Seminar
- Thailand – Japan Symposium
- Indonesia – Japan Symposium
- China – Japan Symposium
- APEC

etc.

CHALLENGES IN THE COLLABORATIONS

Go Forward for Patients

- Increase of the numbers of countries/regions hold the confidentiality agreement with JP
- More timely
- Enhance reliable relationships

Points to Keep in Mind

- Speedy response
- Telling Japanese situation, consideration and timeline
- Feedback into information providers
  - How the information was utilised in JP/EU, etc.

Summary(1)

- PMDA's Mission includes international component: … participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements…

Summary(2)

- Confidentiality arrangements allow for non-public information exchanges
- Human resources globally facilitate international cooperation
- Liaison plays the key roles in enhancing our agencies' collaborations in the best interest of the public we serve

PMDA and the World

Confidentiality Arrangement

Memorandum of Understanding (MOU)

Resident Staff (Forth Coming)

Joint Symposium (Forth Coming)

** MOU between the Chinese SFDA (present CFDA) and the Japanese MHLW, under which PMDA supports cooperative activities*

Thank you very much !

PMDA Website
http://www.pmda.go.jp/english/index.html

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