PMDA update and International Cooperation

Tatsuya Kondo

Chief Executive

Pharmaceuticals and Medical Devices Agency (PMDA)

August 2nd, 2014

1st Brazil-Japan Seminar

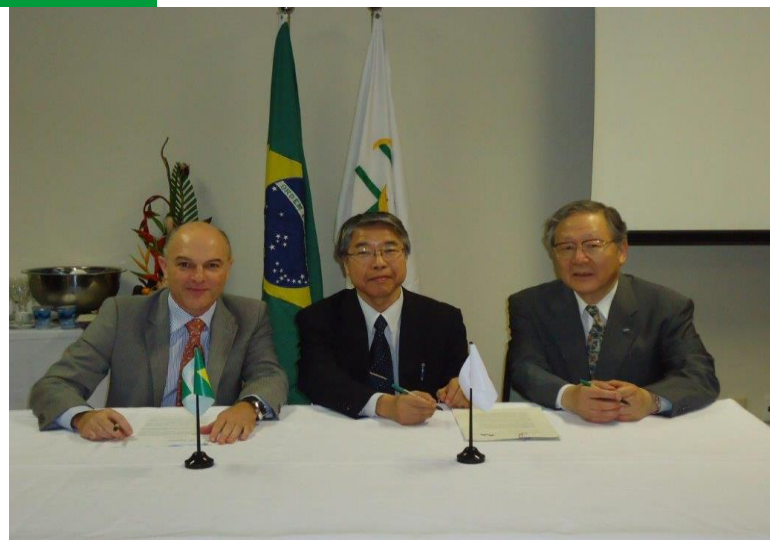
Today's Topics

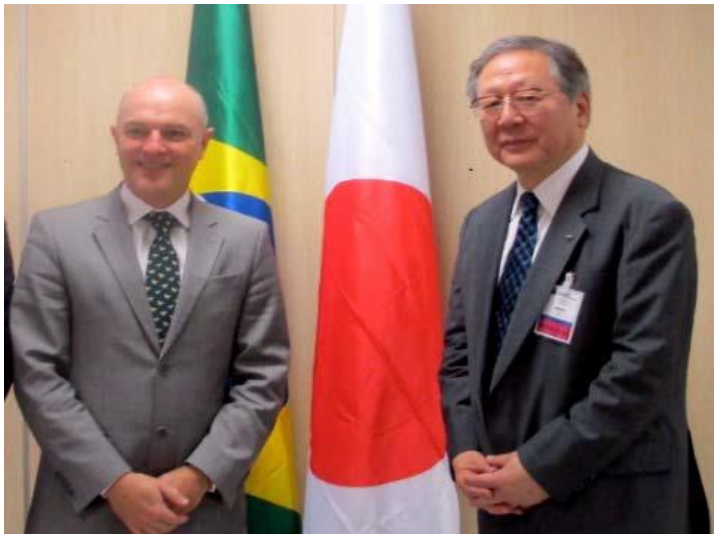
1. Introduction

2. International Cooperation

3. Conclusion

Regulatory Cooperation: Brazil and Japan





Conclusion of Confidential Arrangement
（Manaus, November 2012）

Decision of holding Joint Seminar
(Brasilia, February 2014)

Pharmaceuticals and Medical Devices Agency

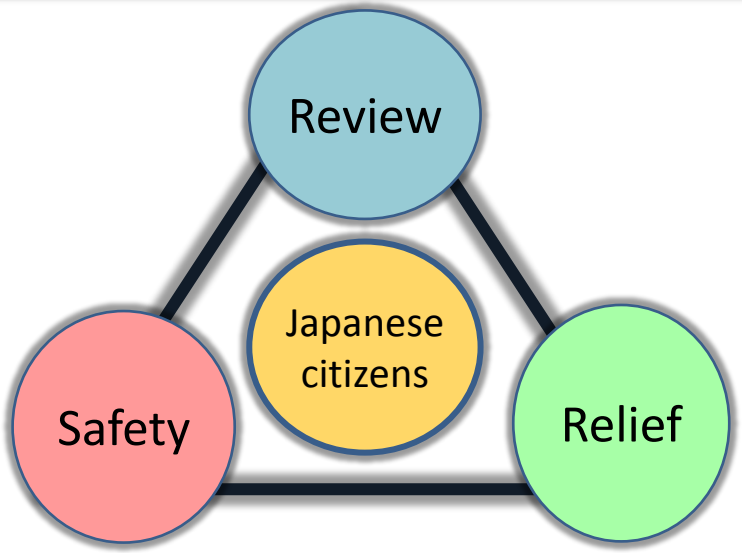
Date of Establishment : April 2004

Kansai Branch

Major Services

- Scientific Review for Drugs & Medical Devices
- GCP, GMP Inspection
- Consultation on Clinical Trials
- Safety Measures
- Relief Services

Unique Three-pillar System Securing Nation's Safety



Dr. Tatsuya Kondo (Chief Executive, PMDA)

Our Philosophy

(September, 2008)

PMDA continues to 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.

We conduct our mission in accordance with the following principles:

- We pursue the development of medical science while performing our duty with greater transparency based on our mission to protect public health and the lives of our citizens.
- We will be the bridge between the patients and their wishes for faster access to safer and more effective drugs and medical devices.
- We make science-based judgments on quality, safety, and efficacy of medical products by training personnel to have the latest technical knowledge and wisdom in their field of expertise.
- We play an active role within the international community by promoting international harmonization.
- We conduct services in a way that is trusted by the public based on our experiences from the past.

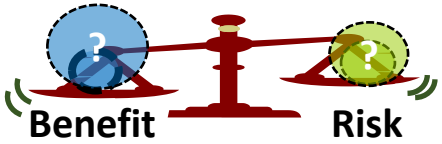
Dr. Tatsuya Kondo (Chief Executive, PMDA)

Promotion of Regulatory Science

Regulatory Science;
Ethical Science for the Society and People

RS Microscopic
Improvement of evaluation method
(quality, efficacy, safety)

RS Macroscopic
Multifactorial Evaluation of Balance



accumulation → DB

accumulation → DB

RS Engineering
Regulations on translational research

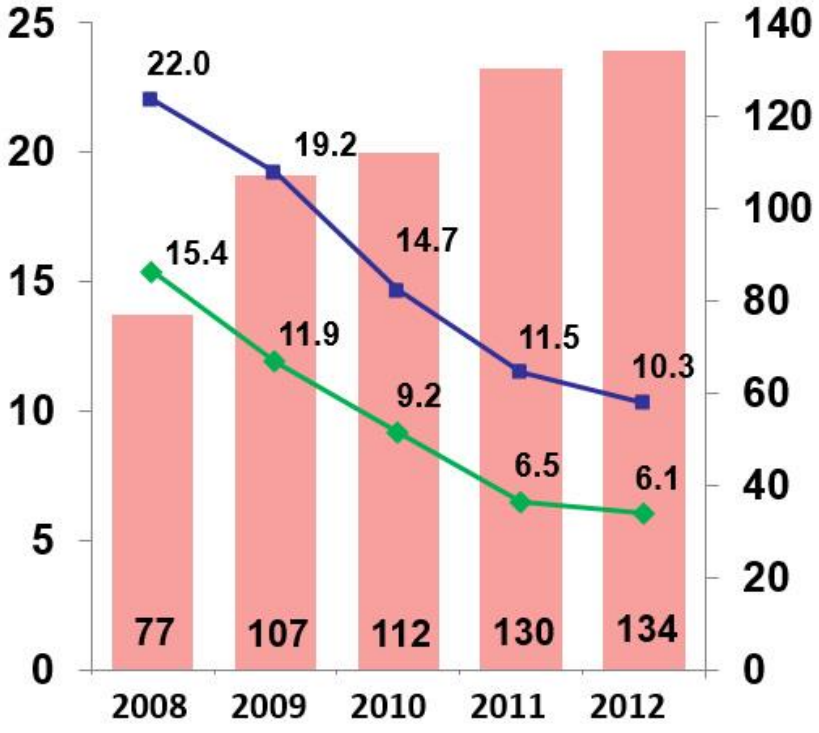
Results (e.g.)

- Establishment of evaluation method for new technology
- Establishment of guideline
- Establishment of review standards

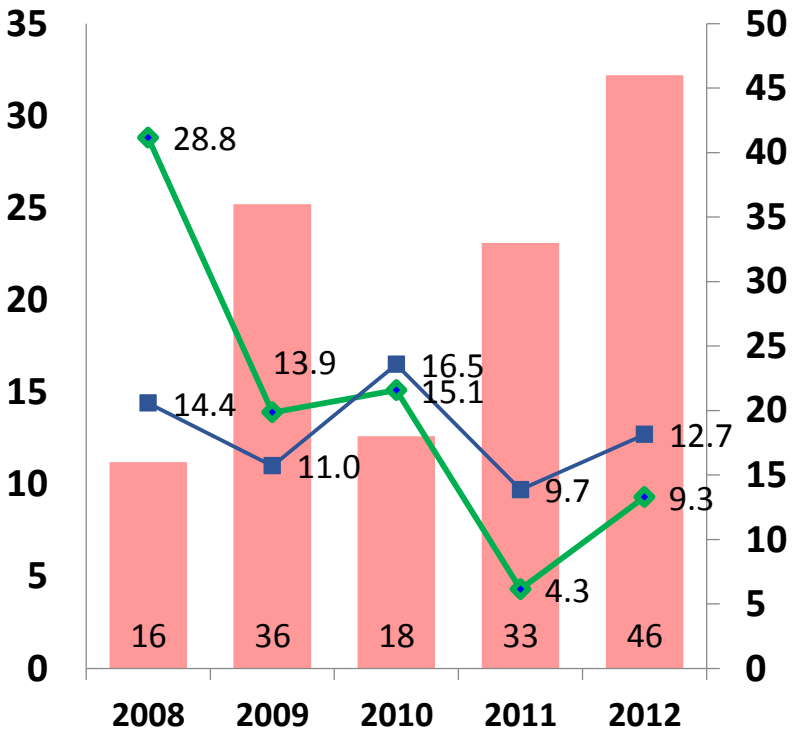
Proposed by PMDA: Oct, 2010 modified: May, 2013

Number of Approvals and Review Time

New Drugs



Medical Devices



No. of approvals

Priority review

Standard review

3rd 5-year mid-term plan of PMDA (FY2014-2018)

Major challenges

- **Shortening the time from early development to approval**
  - "Zero" review time lag Support for elimination of development time lag
- **High quality review/consultation services**
- **Enhancing safety measures**
- **Globalization**

Specific measures

- **Accelerated review process**
  (Improvement of approval predictability)
- **Improvement of prior assessment**
  (substantial acceleration of approval review process)
- **Enhanced overseas inspection system**
- **Drastic improvement of consultation service**
  Active involvement from the early development phase
  - Improvement of pharmaceutical affairs consultation service on R&D strategy
  - Improvement of clinical trial consultation service

Enhancement of regulatory science research and human resource development

- **Development of advanced review/consultation framework using innovative assessment techniques**
- **Cross-products analysis of accumulated large data sets by PMDA using innovative techniques**
- Utilization of Science Board (cooperation with the academia)

Utilization of medical information database

Readiness for introduction of risk management plan

Goal

- ●Development of Japan's original innovative drugs and medical devices
- ●Marketing of cellular and tissue-based products

Activation of the industry

Extending health and life span of Japanese people

Contribution to global medicine

Responding to social needs such as Japan Reconstruction Strategy and Health/Medical Care Strategy

Appropriately accommodate the most advanced technologies including personalized medicine and regenerative medicine

Prerequisites:
US/EU-equivalent system and human resources with excellent skills

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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.

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.

Dr. Tatsuya Kondo (Chief Executive, PMDA)

Global Activities

Summit | ICH | IMDRF | PIC/S | HBD

APEC LSIF RHSC | OECD | PDG | IDGRP |  and more…

Abbreviation	Official Name
Summit	International Summit of Heads of Medicines Regulatory Agencies
ICH	International Conference on Harmonization
IMDRF	International Medical Device Regulators Forum
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
HBD	Harmonization By Doing
APEC LSIF RHSC	APEC Life Science Innovation Forum Regulatory Harmonization Steering Committee
OECD MAD	OECD Mutual Acceptance of Data
PDG	Pharmacopoeial Discussion Group
IGDRP	International Generic Drug Regulators Pilot

ICH

MHLW/PMDA have been working as a steering committee member for ICH to harmonize guidelines across different countries and regions to built up the global standard for regulatory administration.

Member Countries

EU US Japan

Observers

(Canada and Switzerland became SC members in June 2014)

ICH was established in 1990 in order to

- improve efficiency of new drug development and registration process
- promote public health
- prevent duplication of clinical trials in humans
- minimise the use of animal testing without compromising safety and effectiveness

Outcomes of ICH

ICH has developed 80 harmonized guidelines regarding technical elements about the evaluation of quality, efficacy and safety, as well as the format of application form and the post-market safety measures, including Common Technical Document (CTD) and their electrical submission system. ICH also directed the development of the Medical Dictionary for Regulatory Activities (MedDRA) Terminology.

Future of ICH

ICH reform; Membership expansion, Legal entity, New funding etc.
ICH reactivation; Proactive adaption of new topics etc.

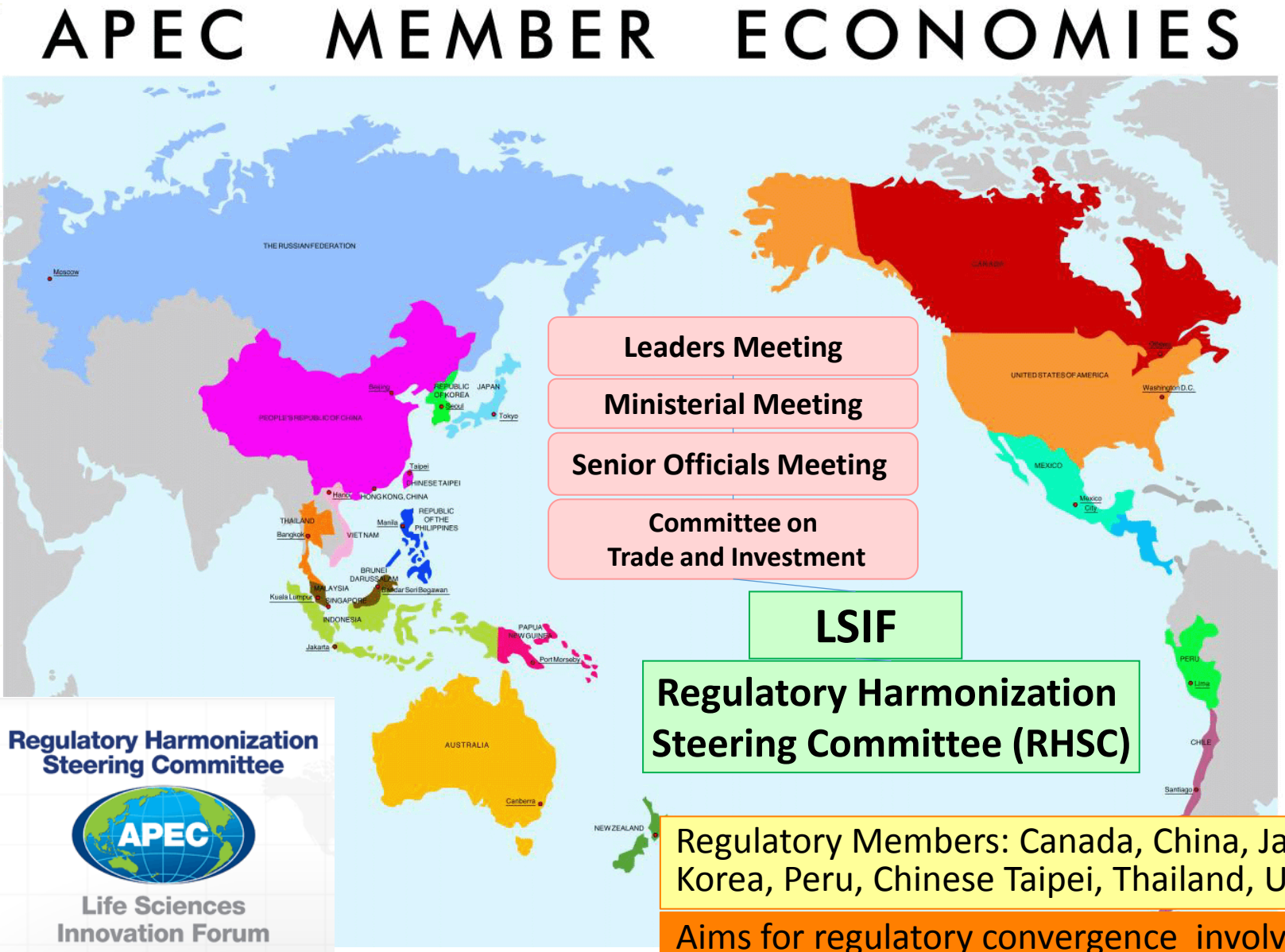
Japan Approved Member at the 38th PIC/S Committee Meeting

With PIC/S Chair Dr. Joey Gouws

- Japan（MHLW, PMDA, 47 prefectures）
  GMP Inspectors applied for PIC/S membership on March 2012
- On-site examination on September 9-13, 2013
- Decided to become official membership on July 1st 2014 at the committee meeting on may 15-16, 2014（Rome）
- 45th member

PIC/S(Pharmaceutical Inspection Convention and Co-operation Scheme)
:Cooperative framework between GMP inspectors aimed to achieve harmonized GMP standards within the pharmaceutical area and the international development, enforcement, and conservation of the quality system. PIC/S is emerging to become the world standard in the GMP domain.

APEC LSIF (Life Science Innovation Forum)



Regulatory Harmonization Steering Committee

APEC

Life Sciences Innovation Forum

Regulatory Members: Canada, China, Japan, Korea, Peru, Chinese Taipei, Thailand, US

Aims for regulatory convergence involving the 21 member economies

PMDA and the World

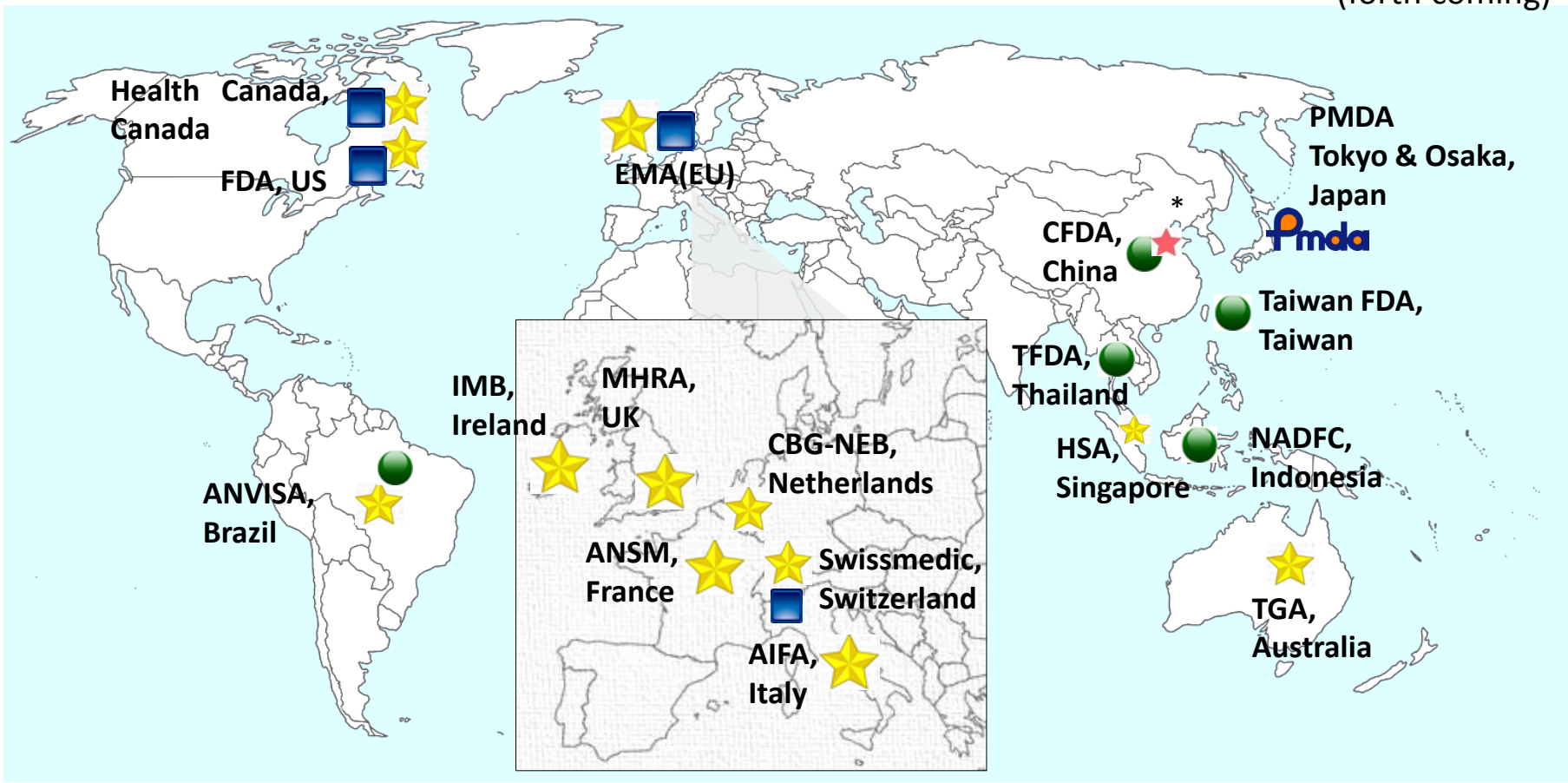
Confidentiality Arrangement

Memorandum of Understanding (MOU)

Resident Staff

Joint Symposium

(forth coming)



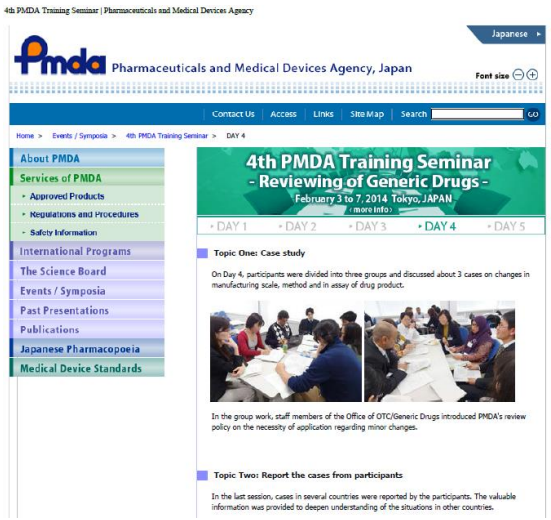
** MOU between the Chinese SFDA (present CFDA) and the Japanese MHLW, under which PMDA supports cooperative activities*

Training Opportunities: Seminars

2014 October 6-10: 5th PMDA Training Seminar (Reviewing New Drugs (including biopharmaceuticals and tissue and cellular products))

2014 February 3-7: 4th PMDA Training Seminar (Reviewing Generic Drugs)

17 participants (Korea 3, Saudi Arabia 3, Taiwan 2, Indonesia 2, Yemen 1, Russia 1, WHO 1, Vietnam 4*) *WHO Fellows



2013 January 21-25: 3rd PMDA Training Seminar

This 3rd PMDA Training Seminar is a good opportunity to share our knowledge and our experiences. It is good to be here participating.
Mr. Guilherme A. Marques Buss, Brazilian Health Surveillance Agency (ANVISA)

2015 February 2-6: 2nd PMDA Medical Devices Training Seminar

2014 March 3-7: 1st PMDA Medical Devices Training Seminar

19 participants (Taiwan 4, Malaysia 4, Korea 3, Singapore 3, Saudi Arabia 2, Hong Kong 1, Switzerland 1, Uganda 1)

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Website: http://www.pmda.go.jp/english/seminar/

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Collaboration with ANVISA

1） Mutual cooperation for improvements in efficiency of the review of pharmaceuticals and medical devices. Promotion of the information exchanges for that purpose.

2） Mutual cooperation for improvements in efficiency of GMP/QMS inspections. The maintenance of the training programs such as accompanying inspections mutually.

3） Recognition of the field of expertise in pharmacopoeia for both parties and promotion of cooperation for mutual pharmacopoeial advancement. e.g. holding a symposium on pharmacopoeia.

4） Implementation of exchange of opinions on the ways and strategies for future international collaboration.

PMDA for the world

-To create society to receive the essential forefront medicines-

Swift approvals of innovative products

Review

Full measures by use and application of medical information

Safety

Japanese citizens

Swift relief for occurred health damage

Relief

Regulatory Science

Convey Japanese technology to the world

Contribute to the world's medicine

Cooperate with all agencies in the world

Thank you for your attention!

Obrigado!!

Pharmaceuticals & Medical Devices Agency