EU, USA and Japan (II) – Reports from Regulators on Exchange Assignments

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MHLW/PMDA Liaison at EMA

PMDA

Pharmaceuticals and Medical Devices Agency

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Agenda

- **Interactions between EU & Japan**
  - Footsteps of Cooperation
  - Functions of Liaison Official
  - What I try to do as Liaison
  - Interactions in areas of interest
  - Routine & Ad-hoc exchanges
  - Personnel exchanges
  - Statistics of the number of exchanges
- **Update of activities by PMDA OIP**

Interactions between MHLW/PMDA & EMA

- **Footsteps of Cooperation**
  - Long, collaborative relationship between Japan & EU in the area of human medicines (e.g. GMP MRA, ICH and bilateral meetings).
  - Confidentiality Arrangements for 5 year period concluded in 2007. Agreed its extension for 1 year on 2 Feb 2012
  - Japan has seconded a Liaison at EMA since Nov 2009

Functions of MHLW/PMDA Liaison@EMA

- **Information provision from MHLW/PMDA**
  - Update of the pharmaceutical regulations in Japan
  - Early notification of regulatory measures
  - Information on specific medicinal products
- **Information Collection from EMA**
  - Update of the pharmaceutical regulations in the EU
  - Early notification of regulatory measures
  - Information on specific medicinal product
- **Exploring specific areas & things of interest**
  - Proposal of possible areas & things
  - Information exchanges, e.g. having TCs
  - Participation in each other's WS & symposium
- **Promotion of personnel exchanges**
  - Coordination and support of the exchange
- **Other**

Interactions in Areas of Interest

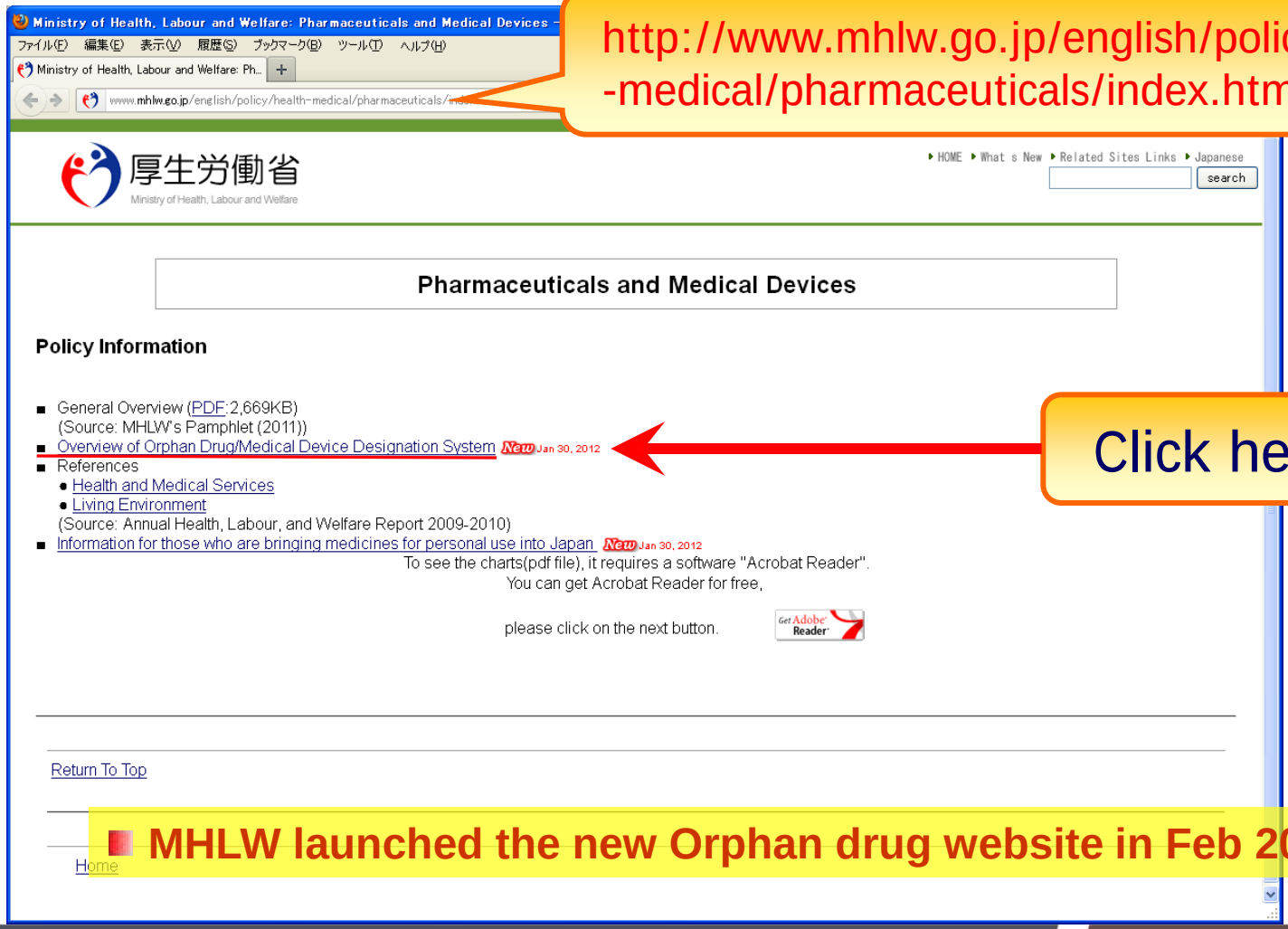
- **ATMPs**
  - PMDA staff attended CAT WS on Stem-cell based Therapies
  - EU experts presented EU regulation at the PMDA biologics symposium
- **PGx & Biomarkers**
  - PMDA has joined SAs by EMA-FDA-PMDA on certain biomarkers raised by the industry
- **Paediatrics**
  - MHLW/PMDA have participated in EMA-FDA's Paediatric Cluster as an observer

Interactions in Areas of Interest

- **Orphan Drugs**
  - MHLW/PMDA Liaison attended “10 Years of the Orphan Regulation in Europe” Conference in EMA
  - Collaboration on Orphan drug regulation between EMA & MHLW/PMDA was driven by the visiting expert from MHLW
  - EMA & MHLW/PMDA hold periodical TCs where info on orphan designation is exchanged. Also publish info on the process of orphan drug designation in EU and Japan on each other’s website
  - Communications between EMA’s SME Office and MHLW through this channel

New MHLW webpage

‘Overview of Orphan Products Designation System’



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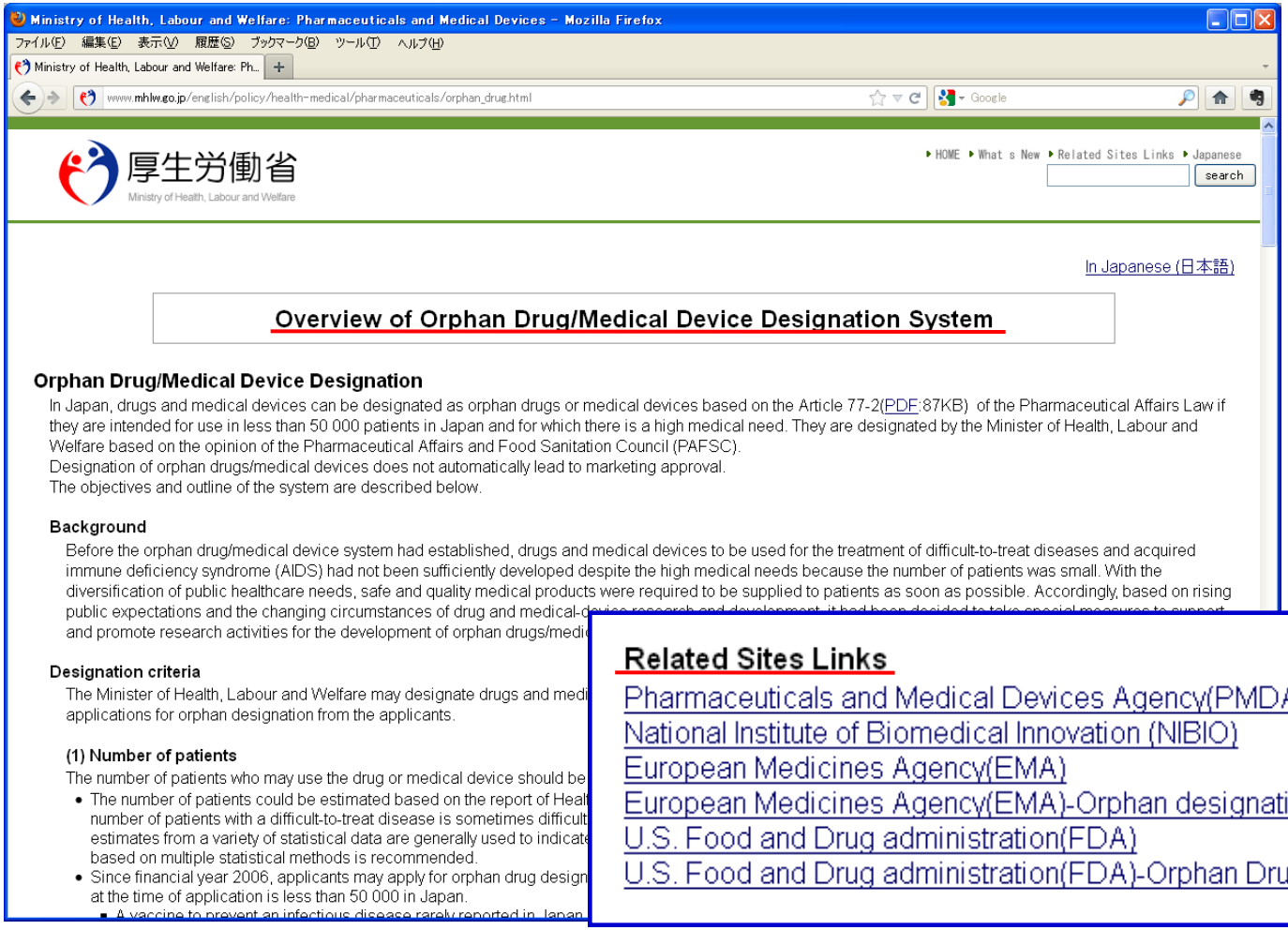


Interactions in Areas of Interest

- **Nanomedicines**
  - Japanese experts have participated in periodical TCs of the Nanomedicines International WG
  - Japanese experts attended the 1st International WS on Nanomedicines at EMA
  - Japanese expert participated in the 4th CLINAM (European Conference for Clinical Nanomedicines) in Basel
  - Developing a RP on a certain class of Nanomedicines which is being initiated by Japan in collaboration with EU experts
  - A webinar on a class of Nanomedicines by Japanese researcher was given

Interactions in Areas of Interest

- **GMP MRA**
  - EU & Japan concluded the MRA on GMP inspection of human medicines which became operational in 2004 with a restricted scope
  - Info exchange on the MRA has been leveraged since MHLW/PMDA Liaison's placement
  - PMDA colleagues have been invited to the joint MRA meeting as well as the GMP Inspectors WG
  - Dialogues at a technical level to expand the scope of the MRA on GMP inspection is ongoing with a view to Japan's accession to the PIC/S

Challenges for Japan to join in PIC/S

- **Consolidate and coordinate the QS of each GMP Inspectorates, i.e. PMDA & Prefectures**
  - GMP inspectorates carry out their inspections based on the single and identical QS
- **Ensure level of each GMP inspector's skill (Performance of the inspection should meet the international level)**
  - Set out qualifications for inspectors, education and training program
  - Maintain the standard of inspection even if a personnel change could happen
- **Ensure equivalence between GMP related legislation in Japan and PIC/S guidelines**

Interactions in Areas of Interest

- **GCP**
  - PMDA staff has continuously participated in the EMA GCP Inspectors Training WS
  - MHLW/PMDA Liaison joined the Int'l WS on the draft RP on ethical and GCP aspects of clinical trials of medicines for human use conducted in third courtiers
  - PMDA shares inspection info with EU MSs
- **Contributions to Draft GLs and other documents**
  - EMA and MHLW/PMDA regularly provide comments each other to selected draft documents under preparation

Interactions in Areas of Interest

- **Routine Exchanges**
  - MHLW/PMDA receive communications before/after CHMP meetings
  - MHLW/PMDA provide EMA with info on safety measures and new drugs approval
  - Periodical pharmaceuticals and medical devices safety information, PMDA updates and info on relevant topics and meetings in Japan
- **Ad-hoc Exchanges**
  - A number of ad-hoc exchanges, e.g. urgent safety issues, regulatory operations and specific products

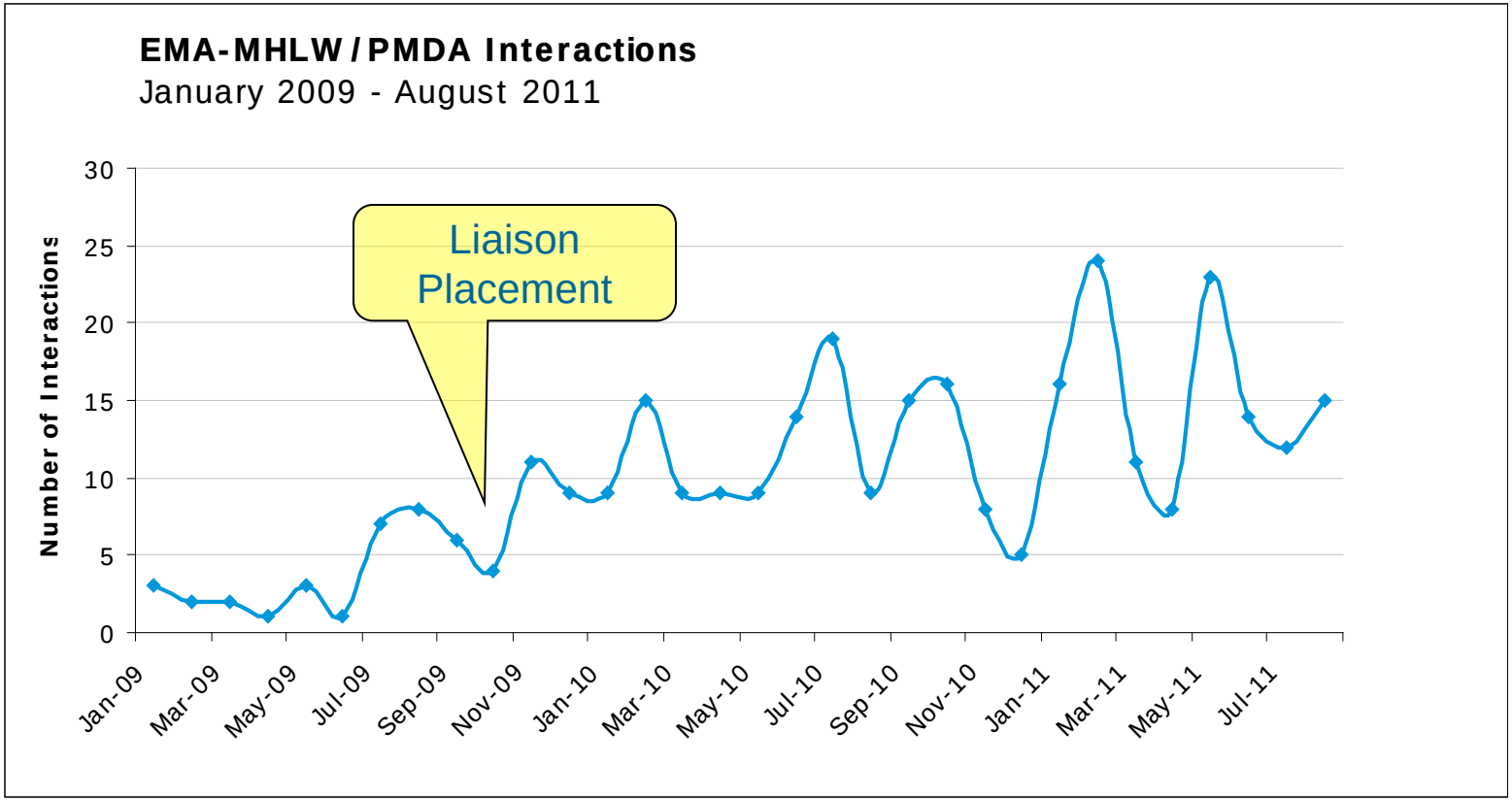
Interactions in Areas of Interest

- **Personnel Exchange, Visit and Meeting Participations**
  - MHLW/PMDA staff visited EMA to attend/observe Committees, WSs & Inspectors WGs. They also met EMA staff to discuss topics of interest and developed contacts with EMA
  - MHLW/PMDA Liaison has given an overview of Japan's regulatory system & PMDA's international activities
  - MHLW/PMDA Liaison has participated in various Committees & WSs and has conveyed info obtained there to Japan
  - Visiting expert from MHLW spent the period at EMA Orphan drug section and provided info to EMA colleagues
  - EU experts invited to present EU regulation at the PMDA symposium & academic meeting
  - Heads of EMA, FDA & MHLW/PMDA met in the Head of Medicines Regulatory Agencies Summit, etc

Interactions between MHLW/PMDA & EMA

- **Key activities since my placement:**
  - Increase in routine/ad-hoc info exchanges
  - Enhanced interactions in areas of interest
  - Enhanced cooperation on Orphan drugs & Nanomedicines
  - Participation of PMDA in the FDA-EMA interactions, e.g. Paediatric medicines, PGx & Biomarkers
  - Interactions on GMP & GCP inspections
  - Visits by Japanese officials to EMA while EU experts participated in the symposium in Japan
  - Meeting of heads of EMA, FDA & MHLW/PMDA

Table - EMA-MHLW/PMDA Interactions (Jan 2009 to Aug 2011)



What I try to do as Liaison

- **Two objectives:**
  - To build a trusting relationship with EMA
  - To boost PMDA's international stature
- **What I keep in mind for attaining these goals**
  - Communication on an equal footing
  - Reciprocal relation
  - Speedy response
  - Provide important info accurately in English AQAP
  - Feedback an outcome of the info exchange to the info provider

Challenges

- In addition to the ad-hoc interactions, the proportion of those in more sustainable form has gradually increased
- Two-way interactions have also increased
- For further development and enhancement of reciprocal relation between EU & Japan, the placement of the Liaison who totally knows and coordinates all the interactions is indispensable
- Increasing two-way interactions by TC as well as speedy info transmission in English will become even more necessary

PMDA International Strategic Plan

http://www.pmda.go.jp/english/international/pdf/pmdaisp.pdf

PMDA International Strategic Plan was formulated in Feb 2009, which outlines the basic policies for overall international activities;

Targets to be achieved during the second mid-term plan period (FY 2009-2013):

1. Strengthen cooperation with the US, the EU, Asian countries, and relevant international organizations
2. Strengthen activities for international harmonization
3. Promote personnel exchanges
4. Foster Internationally minded human resources with communication skills
5. Improve and strengthen international publicity and information provision

PMDA International Vision

- PMDA **EPOCH** toward 2020 -

As one of world's top three RAs of medical products comparable to its US & EU counterparts, PMDA aims to;

Secure the highest level ***E***xcellence in ***P***erformance in the following aspects:

- A) Quality and speed in product reviews, safety measures, and relief services (PMDA's Safety Triangle)
- B) Quality and quantity of regulatory science research
- C) Quality, quantity and speed of information transmission to the world

Maintain close ***P***artnership with the ***O***rient for common benefits through:

- A) Cooperating to improve the level of medical products regulation across Asia.
- B) Communication of information and opinions to the world as a member of the Asian community

Actively ***C***ontribute to International ***H***armonization of regulations, guidelines, and standards for the benefit of both Japan and the world

PMDA International Vision

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

- **Overview**
  - Developed, reflecting recent significant changes of the international environment
    - Changes of the int'l environment: Increase in relative importance of countries other than ICH founding members in terms of drug regulation
    - PMDA has accumulated further experience in int'l activities
  - Prepared as concrete goals to be attained in 5-10 years in line with the PMDA Int'l Strategic Plan
  - All PMDA staff is required to pursue their individual int'l activities without losing sight of the Agency's aim

PMDA International Vision (Annotation)

- **Introduction**
  - Current status – Is the Japanese regulatory authority comparable to its counterparts in the EU and the US?
  - Nature of the Vision – an image of PMDA over the next 5-10 years in the international arena of regulation
  - Relationship between domestic and international activities
- **Discussion on items of the Vision**
  - To Secure Excellence in Performance
  - To Maintain a Partnership with the Orient
  - Contribution to International Regulatory Harmonisation
- **Preconditions for the Vision**

Bilateral Meetings

EC/EMA

- Face to face top-level meeting (once a year)
- Information exchange through Liaison Officer

FDA

- Face to face top-level meeting (once a year)
- Information exchange through Liaison Officer

China

- Face to face top-level meeting (once a year)
- Working Group Studies
- Annual China-Japan Symposium

China-Korea-Japan Tripartite Meeting

Working Group Meeting – October 31, 2011

- Interim study reports were delivered from each country and discussion was made on the three projects:
  - Research on ethnic Factors in Drug Clinical Trial Data
  - Information Exchange Project on Clinical Data, etc. of Three Countries
  - Guidelines on Regional Clinical Trials in China, Japan and Korea

Director's General Meeting – October 31, 2011

- Outcomes from the Working Group Meeting was reported
- It was agreed to have next trilateral meeting in China in 2012

2011 APEC Multi Regional Clinical Trail Tokyo Workshop November 1, 2011

- Taking the outcomes of China-Korea –Japan Director-General Meeting into account, presentations were made by each regulatory authority.

International Harmonization Activities

ICH

- Face to face meetings and Tele-conferences
- Next meeting will be held in Fukuoka, Japan

GHTF (Global Harmonisation Task force) Steering Committee

- Chair country since 2011
  - Task force secretariat
  - Manage progress of Study Groups
  - Leads discussions among participating nations
- Two face to face meetings are planned in Japan in 2012

IMDRF

- GHTF will evolve into IMDRF
- Bi-annual meeting – inaugural meeting took place in Singapore in February 2012

Other International Meetings

Head of Medicines Regulatory Agencies Summit

- Face to face top-level meeting (once a year)

DIA

- Meetings in Europe, US and Japan

Confidentiality Arrangements

For information exchange / further cooperation

Concluded in 2011

- IMB (Ireland)
- TGA (Australia)

Existing Arrangements

- Swissmedic (Switzerland)
- MHRA (U.K.)
- HAS (Singapore)
- EC*
- Health Canada
- EC/EMA**
- USFDA

* EC: Oct 2009 (Madical Devices & Cosmetics)

**EC/EMA: Feb 2007 (Pharmaceuticals) extended until 2013

Visitors from around the world

PMDA welcomes more than 100 visitors/year from foreign regulatory authorities, industry and academia

TGA
Dr. Rohan Hammett
National Manager
Sep 2011

FDA Deputy Commissioner
Dr. Stephan Spielberg
Nov 2011

And more…

Trainings

PMDA gives training to officials of Asian RAs

2nd PMDA Training Seminar on Pharmaceutical GMP Inspection – Dec 2011

- 27 trainees participated from Korea, Indonesia, India….

Med and long term training

- Three weeks' training for three KFDA officials on general issues - Dec 2011
- One month training for TFDA (Taiwan FDA) officials on Medical Devices – Feb 2012

Training visit (one day training)

- Chinese officials on vaccines in JICA project – Aug 2011
- Vietnamese officials on regulating traditional medicine - Sep 2011
- Indonesian officials on pharmaceutical affairs – Nov 2011
- Russian government delegation in Russian officials training program – Mar 2012

Interactive Cooperation

- **Conclusion**
  - Activities increased since Japanese Liaison was assigned
  - A number of staff visits and exchanges with routine involvement in the scientific work of both agencies has been increased
  - The placement of Liaison is beneficial in view of the awareness of interactions as well as timely communications
  - Consolidation of communication and collaboration mechanisms between EU & Japan continues to be an important tool

Thank you for your attention!

Ministry of Health, Labour & Welfare

Pharmaceuticals and Medical Devices Agency

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