ICDRA Workshop I

Consideration on Global Harmonization

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Current Harmonization Activities

ICH: International Conference on Harmonisation
GHTF: Global Harmonization Task Force
IMDRF: International Medical Device Regulators Forum
PDG: Pharmacopeial Discussion Group
ICCR: International Cooperation on Cosmetics Regulation
OECD MAD OECD : Mutual Acceptance of Data
APEC LSIF RHSC : APEC Life Science Innovation Forum Regulatory Harmonization Steering Committee

And more…

Purpose and participants (1)

	Purpose	Participants
ICH	To make recommendations of technical guidelines and requirements for pharmaceutical product registration to reduce duplication of testing carried out	EC/EMA, EFPIA, MHLW/PMDA, JPMA, FDA, PhRMA
GHTF	To encourage convergence in regulatory practices, promote technological innovation and facilitate international trade	EC, EUCOMED, COCIR, EDMA, EUROM VI, Health Canada, MEDEC, FDA, NEMA, AdvaMed, MHLW/PMDA, JFMDA, TGA, MIAA,
IMDRF	To accelerate international medical device regulatory harmonization and convergence	TGA, ANVISA, Health Canada, EC, MHLW/PMDA, FDA, WHO, AHWP
PDG	To reduce manufacturers' burden of having to perform analytical procedures in different ways, using different acceptance criteria	EP, USP and JP（MHLW/PMDA）

Purpose and participants (2)

	Purpose	Participants
ICCR	To maintain the highest level of global consumer protection, while minimizing barriers to international trade	FDA, MHLW/PMDA, EU, Health Canada
OECD MAD	Data generated in a Member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP) shall be accepted in other Member countries	OECD Member countries (34 countries)
APEC LSIF RHSC	To promote a strategic and coordinated approach to regulatory harmonization and capacity building efforts within the APEC region	APEC member countries (21 economies)
China-Korea-Japan Tripartite	To promote scientific research cooperation to encourage global development and sharing clinical data	SFDA, KFDA, MHLW/PMDA

Accomplishments

ICH
- More than 70 harmonized guidelines
- Provide trainings for non-ICH regions

GHTF
- About 40 harmonized documents
- Discussions transferred to IMDRF

ICCR
- Discussion focusing on 6 topics
- Provide documents on the topics

PDG
- 28 General Chapters and 43 excipient monographs were harmonised

APEC LSIF RHSC
- Organized projects for regulatory convergence: MRCTs, Supply chain integrity, GReVP, Biosimillars, Pharmacovigilance, Advanced therapies
- Held Workshops for the implementation of projects

OECD MAD
- OECD-GLP guideline
- Mutual Acceptance of Data
- On-site evaluations of National GLP Compliance Monitoring Programmes

China-Korea-Japan
- Published the interim report on research on ethnic factors
- Project on information exchange
- Project on development of guideline for multi-regional clinical trials in the region

And more…

Common Points in Harmonization activities

Purpose

- Remove duplication
- Promote development
- Capacity building

Accomplishment

- Development of harmonized guidelines, regulatory systems, and joint documents
- Provide trainings to disseminate the harmonized attitude

Faster Access to better products

Recent trend of Global Harmonization

1. Expansion of outreach activities

   Expand harmonized regulatory systems and guidelines onto other countries (ex. ICH GCG, OECD GLP program)

2. Promotion of regional cooperative programs

   Increase cooperative activities and programs at regional level (ex. APEC RHSC, China-Korea-Japan Tripartite)

3. Increase of prospective harmonization activities

   Facilitate the trend of retrospective harmonization* to prospective harmonization** (ex. advanced technologies such as gene therapy at the ICH)

*Retrospective harmonization : the harmonization which participating countries mutually arrange their existing regulatory system in order to abolish trade barriers etc.

**Prospective harmonization: the harmonization that countries cooperate to develop common guidelines regarding product using advanced science and technologies when no country has guidelines or regulations for such products.

1. Outreach Activities

Example of outreach activity: ICH GCG*

(*The Global Cooperation Group (GCG): subgroup of the ICH Steering Committee)

- APEC
- ASEAN
- GCC
- PANDRH
- SADC
- and EAC (since 2011)

- Australia
- Brazil
- China
- Chinese Taipei
- South Korea
- India
- Russia
- Singapore

➢ GCG Mission Statement (2005)

"To promote a mutual understanding of regional harmonisation initiatives in order to facilitate the harmonisation process related to ICH Guidelines regionally and globally, and to facilitate the capacity of drug regulatory authorities and industry to utilize them."

➢ Information sharing → Proactive approach for implementation/training

GCG Training

- Recent trainings
  - China ICH Study Group workshop on ICH M Guidelines
    - October 25-26, 2012/ Beijing, China
  - DIA/ICH endorsed training on E2 Pharmacovigilance Guidelines
    - October 22-24, 2012/ Beijing, China
    - October 22-23, 2012/ Midrand, South Africa
  - APEC AHC workshop on Q8/Q9/Q10 Guidelines
    - October 4-5, 2011/ Seoul, Republic of Korea
- Number of past trainings by years

Year	Total	Quality	Safety	Efficacy	Multidisciplinary
2007	1	1	-	-	-
2008	3	1	-	2	-
2009	2	-	-	2	-
2010	3	2	-	-	1
2011	6	6	-	-	-
2012	3	-	-	2	1

OECD GLP Compliance

BETTER POLICIES FOR BETTER LIVES

Pursuant to the Council Decisions of 1981 and 1989, the data generated in the testing laboratories in an OECD Member country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of man and the environment.

At present, on-site visit evaluations are being conducted between the inspection authorities of the OECD-MAD compliant countries for the purpose of confidence-building among them.

(Reference)

- 1981 Council Decision on Mutual Acceptance of Data [C(01)30/Final])
- 1989 Council Decision/Recommendation on Compliance with Principles of Good Laboratory Practice [C(89)87(Final)])
- 1997 Council Decision on Adherence of Non-Member Countries to the Council Acts related to the Mutual Acceptance of Data [C(97)114/Final])

Outreach of OECD GLP program

OECD BETTER POLICIES FOR BETTER LIVES

OECD (All 34 Countries)
AUS, AUT, BEL, CAN, CHL, CZE, DNK, EST, FIN, FRA, DEU, GRC, HUN, ISL, IRL, ISR, ITA, JPN, KOR, LUX, MEX, NLD, NZL, NOR, POL, PRT, SVK, SVN, ESP, SWE, CHE, TUR, GBR, USA

Non-members
(5 Countries)
South Africa 2003,
Singapore 2010,
India 2011, Brazil 2011,
Argentina 2011

Slovenia and Israel (2010)

Malaysia, Thailand (Provisional)

China, Russia , Chinese Taipei, etc.

2. Promotion of regional cooperative programs

Regulatory Harmonization Steering Committee
APEC
Life Sciences Innovation Forum

APEC RHSC

Regulatory Harmonization Steering Committee

- Established under the authority of the Life Science Innovation Forum (LSIF)
- Promote a strategic and coordinated approach to regulatory harmonization & capacity building efforts within the APEC region

Membership of SC

SC were consisted with rotation of **9** member economies

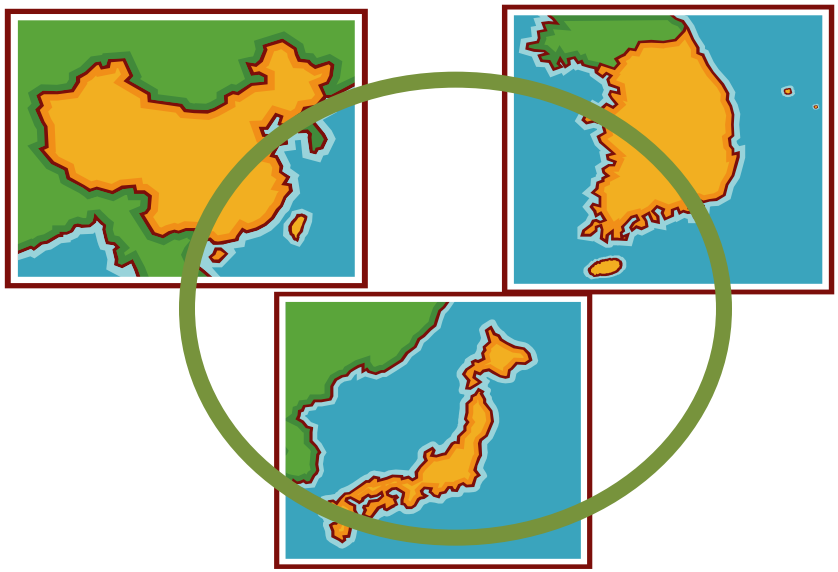
Decision to invite health regulators from all **16** economies currently contributing to this activity as members of SC and invite rest of **5** APEC economies to participate in RHSC activities (Aug. 2012)

Aims for regulatory convergence involving the 21 member economies

Priority Work Areas

Project	Champion	Activity
Multi-regional Clinical Trials	Japan	Roadmap approved Workshop held in Seoul and Tokyo
Supply chain integrity	US	Established the expert working group
Good Review Practices	Chinese Taipei	Roadmap approved Workshop will be held in November
Good Clinical Practices	Thailand	Preparing questionnaire to compare the member economies' status of implementation
Combination Products	Chinese Taipei	Roadmap approved Workshop will be held in November
Biosimilars	Korea	Workshop held in April Discuss definition of terms
Pharmacovigilance	Korea	Roadmap approved Discussion focused on pharmaceuticals
Advanced Therapies	Singapore	Roadmap approved

China/Korea/Japan Tripartite Cooperation



Health Ministers' Joint Statement among China, Korea & Japan (April 8, 2007)

April 2008 Tokyo

Dec. 2009 Beijing

Sep. 2010 Seoul

Nov. 2011 Tokyo

China-Japan-Korea Tripartite Cooperation

Outcome of the 4ht meeting on Oct. 31, 2011

3. Increase of prospective harmonization activities

Prospective Harmonization

Rapid development of new technology & science

Emerging new regulatory issues

Early exchange of regional experiences and views among the regulators is beneficial for future potential harmonization

May take time and resources, but easier to harmonize than after each country/region has developed different regulations

Gene Therapy

- ICH Gene Therapy Discussion Group (2002-2011)
  - **Outcome: Considerations documents**
    - General Principles to Address Virus and Vector Shedding, June 2009
    - Oncolytic Viruses, September 2009
    - General Principles to Address the Risk of Inadvertent Germline Integration of Gene Therapy Vectors, October 2006
- Regulators Forum Gene Therapy Discussion Group (2012-)
  - Just launched, led by US FDA
  - Participants: **9** countries/region (Brazil, Canada, EU, India, Japan, Singapore, South Korea, Switzerland, US) + WHO
  - Continue information exchange (topics under discussion)

Cell Therapy

- No ICH guideline
- Regulators Forum Cell Therapy Discussion Group (2010-)
  - led by US FDA
  - Participants: **9** countries/region (Canada, Chinese Taipei, EU, Japan, Singapore, South Korea, Switzerland, Thailand, US) + WHO
  - Brainstorming/inventory activity for preliminary assessment of potential areas for harmonization
- APEC LSIF RHSC Cell and Tissue-based Products Roadmap (led by Singapore)

Future Challenges

1. Further outreach activities and regional cooperation should be performed to raise the level of pharmaceutical regulatory systems in countries
2. While harmonization and cooperation are important, an organic mechanism of international coalition for effective utilization of resources should be established

☞ Dual way approach should be promoted in coordinated way

3. Prospective harmonization should be promoted

☞Cooperatively respond to advanced technologies and new environment as the international community

3rd PMDA Training Seminar

Pharmaceuticals and Medical Devices Agency

(January 21 to 25, 2013)

1) Post-marketing Safety Measures
   - Collection and Analysis of ADR Information
   - Information Provision
   - Consultation Services
   - Risk Manager System
2) Relief system for adverse health effects
   - Overview of Relief Services

Detailed Information:

http://www.pmda.go.jp/english/events/3rd_pmda_training_seminar.html

All for patients longing for better product

Thank you for your attention !

Pharmaceuticals and Medical Devices Agency

http://www.pmda.go.jp/