

Pharmaceutical Intellectual Resource Services, LLC



Global Trends in Regulatory Harmonization

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Advantages of Global Regulatory Harmonization

- Improved quality, safety and efficacy of marketed products
- Faster review and approval processes that are more transparent
- Reduced costs for industry as a harmonized (CTD) format is less expensive for dossier preparation
- Improved access to medicines in all countries
- Increased public trust in approved medicines
- Facilitate entry of local industry into regional and possibly global pharmaceutical markets

Global Regulatory Harmonization

Why now?

- International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is the grandfather of all regulatory harmonization efforts
- ICH started in 1990, focused on the harmonization of standards for new drugs in the ICH regions (USA, Europe, Japan)
- ICH guidelines gradually became the reference documents for DRAs both for regions outside the ICH and the generic industry
- The globalization of industry drove the need for common standards
- Globalization aroused the interest of non-ICH countries in stimulating innovation and building local capacity
- Economic pressures – Increasing cost of healthcare

History of ICH Global Cooperation Group (GCG)

- Created in March 1999
- In November 2003, Regional Harmonization Initiatives were invited to attend the GCG
- In June 2004, RHI representatives were invited to attend ICH Expert Working Group (EWG) discussions
- In November 2007, the GCG was expanded with the creation of a Regulators Forum
- In November 2010, the ICH Steering Committee agreed in principle to include representatives from the RHIs/DRA/DoH in the EWGs

Regional Harmonization Initiatives on GCG

Regulatory Harmonization Initiatives were built around Economic Development Schemes

- Asia Pacific Economic Cooperation (APEC)
- Pan-American Network for Drug Regulatory Harmonization (PANDRH)
- Gulf Cooperation Council (GCC)
- Association of South East Asian Nations (ASEAN)
- Southern African Development Community (SADC)

DRAs and DOHs on GCG

- Drug Regulatory Authorities were invited to join GCG in 2007 based on their record of implementing ICH guidelines and/or were major producers of drug products
 - Australia
 - China
 - Chinese Taipei
 - Brazil
 - India
 - Russia
 - Republic of Korea
 - Singapore

APEC

- Asia-Pacific Economic Cooperation (APEC) created in 1989
- Currently comprised of 21 member economies
- Goals: Promote trade, sustainable economic growth and prosperity of member economies through policy alignment and economic and technical cooperation
- Unique forum, operating on basis of:
 - Non-binding commitments, open dialogue and equal respect for views of all participants
 - Decisions by consensus; commitments undertaken on voluntary basis
 - Individual and collective action

APEC region accounts for nearly 55% of world's GDP, 49% of global trade and 40% of world's population

- The GCC-DR was approved on 15th May, 1999. Its Executive Office for Health Ministers is located in Riyadh, Saudi Arabia. The GCC-DR committee consists of two members nominated by each state.
- Current Members
 - Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates (UAE). Yemen is a member in Health Council.
- Mission
 - The mission of the GCC-DR is to provide Gulf States with safe and effective medications at a reasonable price
- Scope of GCC Drug Regulatory Activities
 - GCC-DR's scope of harmonization/cooperative activities covers technical guidelines and regulatory processes, which include the registration of pharmaceutical companies and products, as well GMP inspection
 - Specific drug sectors covered include prescription, non-prescription, generics and biologics

PANDRH

- PANDRH constitutes a continental forum on drug regulatory harmonization. It was officially established in November 1999, with official recognition by the 42nd Directing Council of the Pan American Health Organization (PAHO) in September 2000.
- Members consist of drug regulatory authorities of all PAHO member states, representatives of the regional pharmaceutical industry associations (ALIFAR, FIFARMA), academia, consumer groups, professional associations and representatives from the five sub-regional trade integration groups within the Americas such as the ANDEAN COMMUNITY, CARICOM, SICA, MERCOSUR and NAFTA.
- The mission is to promote drug regulatory harmonization for all aspects of quality, safety, and efficacy of pharmaceutical products as a contribution to the quality of life and health care of the citizens of the Member Countries of the Americas.
- PANDRH's scope of harmonization/cooperative activities includes technical guidelines, regulatory processes and the strengthening of national regulatory agencies through harmonization of processes and standards to improve drug quality and quality assurance. Specific drug sectors covered include prescription, over the counter, generics, 'similar', biologics/vaccines and herbal medicines.

ASEAN

- The ASEAN Pharmaceutical Product Working Group was established in 1999 by the ACCSQ (ASEAN Consultative Committee for Standards and Quality).
- Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam are the current members
- The mission of the PPWG is to develop harmonization schemes of pharmaceutical regulations of the ASEAN Member countries to complement and facilitate the objective of AFTA (ASEAN Free Trade Area).
- The PPWG's scope of harmonization/cooperative activities include:
 - the discussion of existing technical guidelines and regulatory requirements;
 - the study of harmonized procedures and regulatory systems currently implemented in other regions relating to technical guidelines and regulatory requirements;
 - the harmonization of technical guidelines and regulatory requirements applicable to the ASEAN pharmaceutical industry;
 - the development of Common Technical Documents with a view to arriving at Mutual Recognition Arrangement (MRAs).
- The scope of pharmaceutical products covered by the PPWG includes New Chemical Entities (NCEs), biotechnological products, major and minor variation products, and generics

African Medicines Registration Harmonization Initiative (AMRH)

- Established in February 2009 by the New Partnership for Africa's Development (NEPAD) and the World Health Organization. AMRH is not a GCG member
- Current Members
 - Four regional groupings - East African Community (EAC); South African Development Community (SADC); East Africa: ECCAS/OECAC; West Africa: ECOWAS/UEMOA
- Mission
 - Assist African countries in responding to challenges of medicines registration
 - Support African Regional Economic Communities in harmonizing medicines registration requirements

Formation of APEC Regulatory Harmonization Steering Committee

Lima 2007:

- Outcomes - Series of recommendations to address issues of:
 - Support for the establishment of the APEC Harmonization Center (AHC)
 - Creation of a Regulatory Harmonization Steering Committee (RHSC)
- Separate regulatory session held to examine the value and role of LSIF
- Attended by NRAs, industry, academia and CROs from across the APEC region

Seoul 2009:

- Events attracted more than 600 participants, including officials, experts and interested parties from over 15 economies
- MRCT workshop generated a number of important recommendations
- Recommendations to be considered by RHSC, the first meeting of which was held June 18

Building a Better Harmonization Model

Development
(Standards, Guidances)

Interface

Key Enabler:
APEC Harmonization Center + RHSC



+ DRAs: Australia, Brazil, China, Chinese Taipei, India, Korea, Russia, Singapore

Regulatory Harmonization Institute

- A non-profit organization comprised of Group/Institutional members and industry and academic professionals having a deep and broad range of experience and interest in international regulatory requirements
- The only membership organization in the world whose mission is singularly focused on matters related to regulatory harmonization
- Mission is to provide an open and transparent venue for public and private stakeholders to identify divergent regulatory practices and to develop and sustain educational and work plans that will assist in harmonizing those practices
- RHI intends to be a bridge between the activities and efforts of the drug regulatory authorities and representatives of industry located all over the globe
- Intends to hold Observer status on the RHSC of APEC

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Thank You

***For Further Information,
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Questions ???

