IGDRP

International Generic Drug Regulators Programme

Mission, Scope, How it works

Dr Mariana Gebara-Coghlan
Director, Pharmaceutical Chemistry Section
Therapeutic Goods Administration
Australia

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Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

PANDRH
Pan American Network for Drug Regulatory Harmonization
Pan American Health Organization
World Health Organization
Americas

Outline

IGDRP
International Generic Drug Regulators Programme

- Concept
- History
- Mission
- Objectives
- Participants
- Organisation
- Governance
- Operating Principles
- Activities

Concept

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- Access to affordable, quality generic drugs increasingly important in containing health care costs
- Effective coordination for multiple initiatives on a number of fronts
- Form an international collaborative effort in the area of generic drug review

Concept

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- Timing was right:
  - Common requirements in some areas and format provided by ICH (CTD) guidelines
  - Increasing prevalence of multi-national generic companies, including generic arms of brand name companies
  - Success of existing models:
    - EU's De-Centralised Procedure (DCP) and Centralised Procedure (CP)
    - WHO's Pre-Qualification Programme
  - Restricted set of scientific disciplines (as compared with new active substances)

Objectives

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- Create conditions which enable greater inter-agency collaboration
- Foster peer discussion to bring a broader set of perspectives to bear on scientific and regulatory issues
- Promote greater alignment of regulatory approaches and technical requirements based on international standards and best practices
- Enhance and better coordinate the international regulatory oversight of generic drug products

Objectives

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- Promote the adoption of modern science- and risk-based approaches to the development and regulation of generic drug products
- Promote increased efficiency, consistency and predictability in regulatory assessments and decisions
- Enhance communication, information-sharing, and scientific exchange leading to greater work-sharing and potential mutual reliance on regulatory assessments

Objectives

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- Enhance communication, information-sharing, and scientific exchange leading to greater work-sharing and potential mutual reliance on regulatory assessments
- Promote transparency and clarity of regulatory and procedural requirements
- Enhance the development of human resources and competencies
- Reduce regulatory burden without compromising the safety, efficacy, or quality of generic drug products.

International collaborative effort in the area of generic products

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Active Participants

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- ANVISA
- COFEPRIS
- EDQM
- EU
- HC
- HSA
- MCC
- MFDS
- PMDA
- SWISSMEDIC
- TFDA
- TGA
- USFDA
- WHO

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Current Organisation

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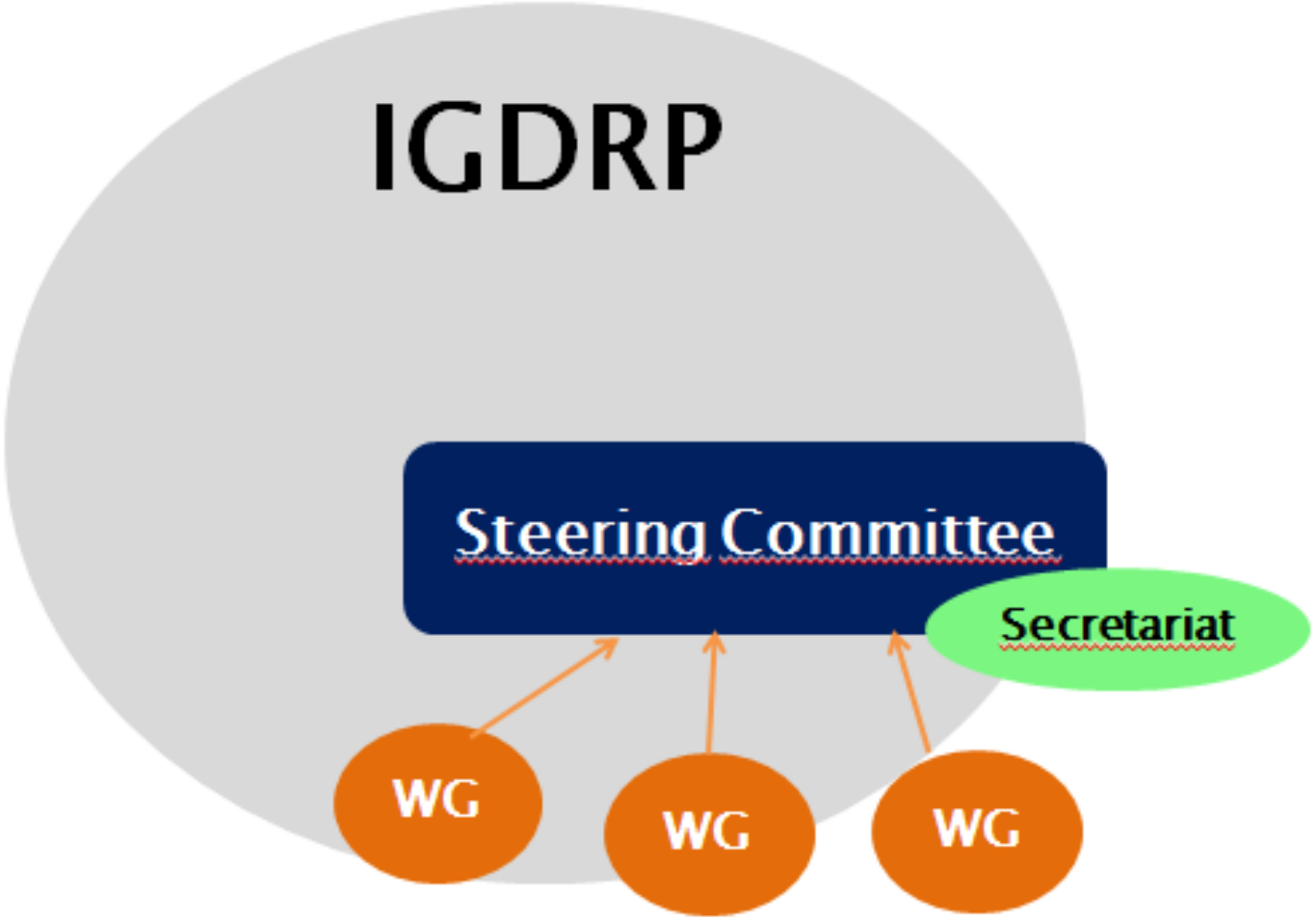

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Governance

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- IGDRP consists of a Steering Committee and Working Groups
- Role of the Steering Committee:
  - makes decisions on behalf of the IGDRP
  - provides strategic direction
  - identifies and prioritises challenges to be addressed and collaborative activities
  - determines the implementation process and monitors the work plan(s)

Governance

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– authorises resources in support of advancing the IGDRP's goals and objectives.

- The Steering Committee is made up of one representative from each participating member and one observer each from the World Health Organization (WHO) and the European Directorate for the Quality of Medicines (EDQM)

Operating Principles

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- Voluntary
- Consensus driven in terms of governance and administrative issues
- Participating regulators may “opt-out” from particular work plan activities
  - Provides necessary operational flexibility given diversity in systems and capacities
- Activities will complement and not duplicate work undertaken in other international activities

Overarching Activities

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- Regulatory Gap Analysis (lead: ANVISA, Brazil)
- Comparison of review process and features – legislation, key regulatory guidelines, phases of the application process, timelines, user fees (lead: HSA, Singapore)
- IT platform/central repository (lead: Swissmedic, Switzerland)
- Information and Work Sharing models:
  - Decentralised Procedure (DCP) pilot (launched July 2014)
  - Centralised Procedure (CP) pilot (launched January 2015)
  - Sharing of EU assessment reports in “real time”

Activities - WGs

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Quality Working Group

Co-Chairs: Australia and WHO

Mandate:

- Establish frameworks and mechanisms for information sharing and work sharing of Quality information for generics - current focus on ASMF/DMF

Projects:

- Development of Assessment tools (Lexicon of Quality Terms, Common Submission Form, Assessment template, Guidance for Assessors)
- ASMF/DMF Gap Analysis Survey prepared by PMDA: published in the WHO Journal
- Stakeholder engagement strategy
- Actively exploring mechanisms for a common secure ASMF/DMF database

Activities - WGs

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Bioequivalence Working Group

Co-Chairs: HC and WHO

Mandate:

- Identify issues of common interest related to assessment of bioequivalence for generics
- Establish a common set of conditions for granting biowaivers
- Focus on biowaivers

Projects:

- Survey of BCS biowaiver requirements from each jurisdiction
- Documentation to support a BCS biowaiver request
- Waivers for additional non-biostudy strengths
- Criteria for acceptability of a Foreign Comparator
- Biowaivers for Dosage Forms

The Future

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Drivers to Continue:

- New and emerging science, medicines and technologies
- Globalisation of issues and production chains
- Emerging public health threats and needs
- Sustainability and appropriateness of regulatory systems and oversight
- Need to support risk-based and science-based review functions

The Future

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Drivers to Continue:

- Interest and the need for international alignment and sharing of best practices
- Governmental initiatives for regulatory convergence and cooperation
- Need for modernised information sharing systems
- Public demand for greater openness and transparency and availability of information to make informed decisions.

The Future

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Roadmap under development that will:

- make available a strategic vision to articulate and guide the collective efforts of IGDRP in terms of where we are going and how we are going to get there
- provide overarching concepts for the strategic priorities, describes inter-dependencies, as well the key objectives that will facilitate an assessment of the success of meeting our common goals.

Thinking globally, acting locally

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icdra

ICMRA

i-p-r-f.org
International Pharmaceutical Regulators Forum

ICH
harmonisation for better health

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Thank you

Next IGDRP Meeting: May 2017, Ottawa, Canada

Contact: IGDRPSecretariat@tga.gov.au

Website: www.igdrp.com

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