# IGDRP Overview

## What it is / What We Are About

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## Outline

- Concept
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- Mission
- Objectives
- IGDRP Members and Observers
- Operating Principles
- Governance
  - Steering Committee, Working Groups
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- Looking Ahead / The Future

## Concept

IGDRP International Generic Drug Regulators Programme

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



## History

IGDRP International Generic Drug Regulators Programme

| | |
|---|---|
| 2011 | · **Nov.**: Ottawa, Canada *(exploratory meeting)* |
| 2012 | · **Apr.**: Washington DC, USA *(launch of 3 year pilot)*<br>· **Dec.**: Nanchang, China |
| 2013 | · **May**: Canberra, Australia<br>· **Oct.**: Geneva, Switzerland |
| 2014 | · **May**: Yilan, Taiwan<br>· **Nov.**: Singapore |
| 2015 | · **May**: Pretoria, South Africa *(transition to a "programme")*<br>· **Nov.**: Seoul, South Korea |
| 2016 | · **May**: Strasbourg, France<br>· **Oct.**: Mexico City, Mexico |
| 2017 | · **June**: Ottawa, Canada<br>· **Nov.**: Brasilia, Brazil |

## Mission and Goal

- Mission
  - Promote collaboration & convergence in generic drug regulation to strengthen the ability of health authorities to meet their respective mandates
- Goal
  - Facilitate efficient use of resources and timely authorization and availability of efficacious, safe and quality generic products



## Objectives

- 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
- Promote the adoption of modern science, and risk-based approaches to the development and regulation of generic drug products

## Objectives (continued)

- 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 the regulatory agencies assessments
- Enhance and better coordinate the international regulatory oversight of generic drug products

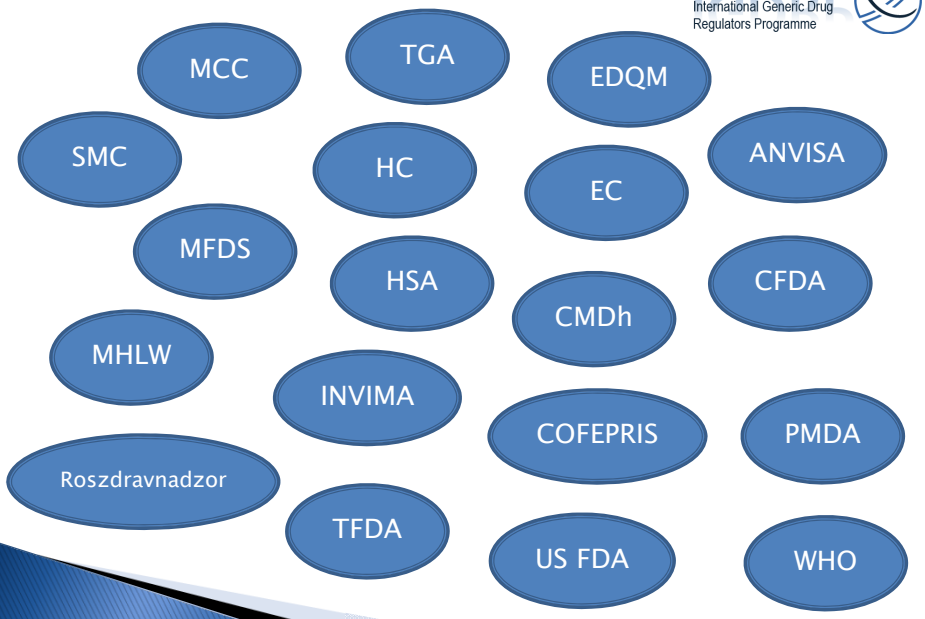


## Objectives (continued)

- Promote transparency and clarity of regulatory and procedural requirements
- Enhance the development of human eesources and competencies
- Reduce regulatory burden without compromising the safety, efficacy, and quality of generic drug products.

⇒ International collaborative effort in the area of generic products

# IGDRP Members and Observers






# IGDRP Members and Observers

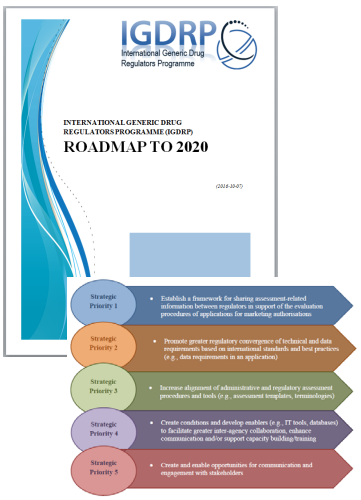
- Agência Nacional de Vigilância Sanitária (ANVISA) (Brazil)
- China Food and Drug Administration (CFDA)
- European Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) / European Commission (EC) / European Medicines Agency (EMA)
- European Directorate for the Quality of Medicines and Healthcare (EDQM) (Observer)
- Federal Commission for the Protection against Sanitary Risk (COFEPRIS) (Mexico)
- Federal Service for Surveillance in Healthcare and Social Development (Roszdravnadzor) (Russia)
- Health Canada (HC)
- Health Sciences Authority (HSA) (Singapore)
- Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) (Colombia)
- Medicines Control Council (MCC) (South Africa)
- Ministry of Food and Drug Safety (MFDS) (South Korea)
- Ministry of Health, Labour and Welfare (MHLW) / Pharmaceuticals and Medical Devices Agency (PMDA) (Japan)
- Swissmedic (SMC) (Switzerland)
- Taiwan Food and Drug Administration (TFDA)
- Therapeutic Goods Administration (TGA) (Australia)
- United States Food and Drug Administration (US FDA) (Observer)
- World Health Organization (WHO) (Observer)

## Operating Principles

- 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 complement and do not duplicate work undertaken in other international activities



## IGDRP Roadmap to 2020




- **IGDRP Task Group:**
  - Lead: HC
  - Members: EC, EDQM, WHO, TGA, COFEPRIS
- **Purpose:**
  - To 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
  - Provides overarching strategic priorities as well the key objectives for each
- **Status:**
  - Endorsed by the IGDRP Steering Committee as a final document (Oct. 2016) and is available on the IGDRP website (www.igdrp.com)

## Governance

- IGDRP consists of a *Steering Committee* and *Working Groups* and is supported by the *IGDRP Secretariat*

- The Steering Committee:
  - is made up of representatives from each participating Member and Observers presently from the World Health Organization (WHO), the European Directorate for the Quality of Medicines (EDQM) and the U.S. Food and Drug Administration (US FDA)



## Governance

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

## Overarching Activities

- Regulatory Gap Analyses
  - Comparison of review process and features legislation, key regulatory guidelines, phases of the application process, timelines, user fees etc
- Information Sharing models
  - EU Decentralised Procedure (DCP) pilot (launched July 2014)
  - EU Centralised Procedure (CP) pilot (launched January 2015)
    - *Sharing of EU assessment reports in "real time"*
- IT platform/central repository



## Working Groups

- Bioequivalence (BE) Working Group
  - Co-Chairs: Health Canada and WHO
    - Originally named the Biowaivers Working Group
  - Mandate:
    - Identify issues of common interest related to assessment of bioequivalence for generic drug products
    - Develop tools (e.g., assessment templates, guidance for assessors) to aid in assessment of bioequivalence
  - Priority work areas:
    - BCS Biowaiver Assessment Report template
    - Surveys (and plans for publications):
      - BCS-based biowaiver requirements
      - Use of a foreign-sourced comparator product
      - Biowaivers for product strengths not tested in vivo

## Working Groups

- Quality Working Group:
  - Co-Chairs: WHO and EDQM
    - Originally named the ASMF/DMF Working Group
  - Mandate:
    - Establish a framework and mechanisms for information sharing and work sharing of Quality information
    - This is with a view to greater collaboration and potentially regulatory convergence in the assessment of ASMFs/DMFs and applications for generic drug products
  - Priority work areas:
    - Lexicon of Quality Terms
    - Gap Analysis on ASMF/DMF frameworks and procedures
    - Regulatory tools, notably, Common Application Form for ASMFs/DMFs, Common Quality Assessment Report template
    - Criteria for when a separate ASMF/DMF should be provided
    - Actively developing a pilot project to facilitate information sharing (e.g., administrative information) associated with selected ASMFs/DMFs



## The Future

- 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
  - Need for modernised information sharing systems

## Looking Ahead

- Interest and need for international alignment, sharing of best practices, and regulatory convergence and cooperation
- Following in-depth discussions on the future direction for the regulatory collaboration initiatives, the *IPRF Management Committee* and the *IGDRP Steering Committee* supported the consolidation of the IPRF and IGDRP initiatives.



## Looking Ahead

- Consolidation of these two initiatives is expected to realise several opportunities including, e.g.,
  - enabling a shared vision for information exchange and regulatory cooperation;
  - maximising synergies and avoiding duplication of effort;
  - creating a regulatory hub for pharmaceuticals that covers all medicinal products, enabling closer linkages with initiatives to simplify the numerous forms of international regulatory collaboration;
  - improving governance for the management committees and the technical working groups.
- The joint initiative will be operational in Jan. 2018 with the aim to have the first face-to-face meeting of the consolidated management committee in June 2018.

# Thinking globally, acting locally


ICMRA
International Coalition of Medicines Regulatory Authorities

icdra

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

IGDRP
International Generic Drug Regulators Programme

ICH
harmonisation for better health




- Next IGDRP SC Meeting: Nov. 1-2, 2017
- Contact: IGDRPSecretariat@tga.gov.au
- Website: www.igdrp.com