IGDRP
International Generic Drug Regulators Programme

IGDRP – Mission, Scope, How it works

IGDRP-EDQM Workshop
Strasbourg, France
13 May 2016

Dr. Craig Simon
Associate Director,
Bureau of Pharmaceutical Sciences
Therapeutic Products Directorate
Health Canada

Outline

IGDRP
International Generic Drug Regulators Programme

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

Concept

IGDRP
International Generic Drug Regulators Programme

- 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
- Followed a step-wise approach:
  - started by assessing feasibility and interest in such a concept through discussions with regulatory authorities and multinational generic companies

Concept (cont'd)

IGDRP
International Generic Drug Regulators Programme

- 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
    - OECD (new pesticides)
  - Restricted set of scientific disciplines (as compared with new active substances)

History

IGDRP
International Generic Drug Regulators Programme

2011	Exploratory meeting: Ottawa, November	
2012	**Launch of 3 year Pilot:** Washington, April	Nanchang, December
2013	Canberra, May	Geneva, October
2014	Yilan, May	Singapore, November
2015	**Transition to Programme:** Pretoria, May	Seoul, November
2016	Strasbourg, May	

Mission and Goal

IGDRP
International Generic Drug Regulators Programme

- 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

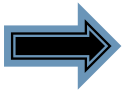
IGDRP
International Generic Drug Regulators Programme

- 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.
- 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.

Objectives (cont'd)

IGDRP
International Generic Drug Regulators Programme

- 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

Active Participants

IGDRP
International Generic Drug Regulators Programme

- TGA
- ANVISA
- Health Canada
- TFDA
- CMDh (EU)
- EDQM
- MHLW/PMDA
- MFDS
- COFEPRIS
- HSA
- MCC
- Swissmedic
- USFDA
- WHO

Organisation

IGDRP
International Generic Drug Regulators Programme

Governance

IGDRP
International Generic Drug Regulators Programme

- 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); and
  - 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

IGDRP
International Generic Drug Regulators Programme

- 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

IGDRP
International Generic Drug Regulators Programme

- Two face-to-face meetings/year, chair of Steering Committee and host rotate with each meeting (chair becomes the co-chair of subsequent meeting)

- Work continued via teleconference between meetings

Overarching Activities

IGDRP
International Generic Drug Regulators Programme

- 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 Jan. 2015)
  - Sharing of EU assessment reports in “real time”

Activities – Working Groups

IGDRP
International Generic Drug Regulators Programme

- Quality Working Group
  - Establish frameworks and mechanisms for information sharing and work sharing
  - Focus on ASMF/DMF
- Bioequivalence Working Group
  - Survey and collate and publish information from each jurisdiction
  - develop tools (e.g. assessment templates, guidance for assessors) to aid in assessment
  - Focus on biowaivers

The Future

IGDRP
International Generic Drug Regulators Programme

- 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;
  - 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 (cont'd)

IGDRP
International Generic Drug Regulators Programme

- 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;
  - provides 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.

The Future (cont'd)

IGDRP
International Generic Drug Regulators Programme

- Ongoing projects of Quality WG and Bioequivalence WG
- Ongoing Worksharing projects – DCP and CP Worksharing Pilot

- Next IGDRP Meeting: 17-20 October 2016, Mexico City, Mexico

- Contact: IGDRPSecretariat@tga.gov.au
- Website: www.igdrp.com

Thinking globally, acting locally

IGDRP
International Generic Drug Regulators Programme

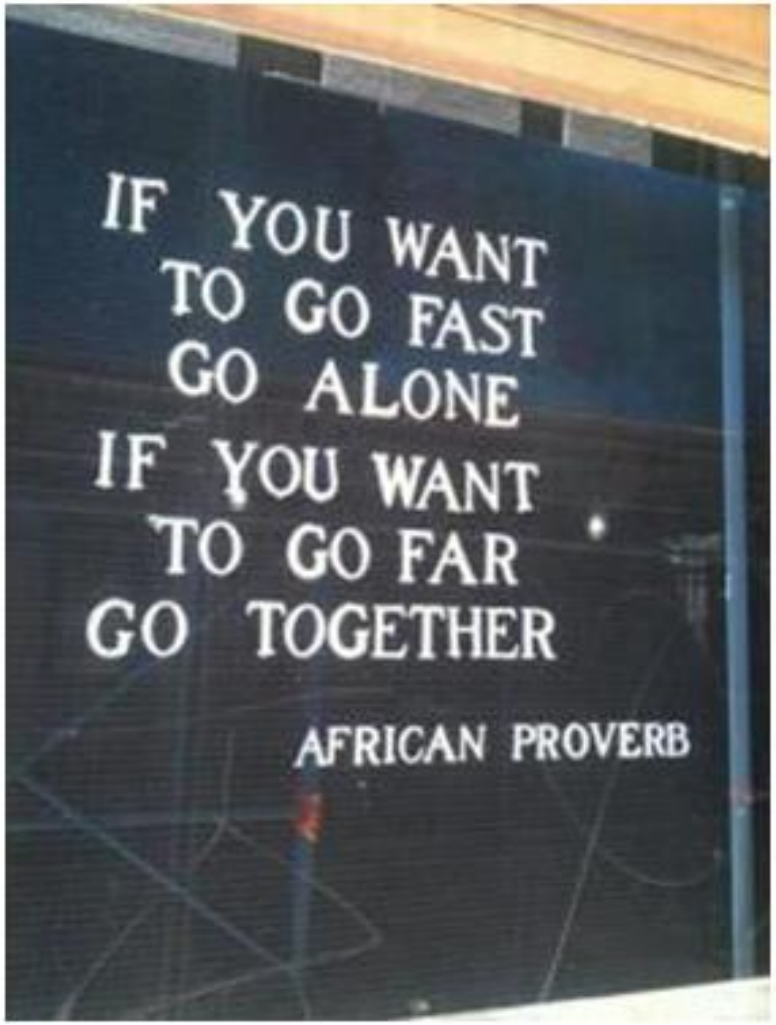
icdra

ICMRA
International Coalition of Medicines Regulatory Authorities

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

ICH
harmonisation for better health

IGDRP
International Generic Drug Regulators Programme



Thank you