



# IPRP

International Pharmaceutical  
Regulators Programme

## IPRP Overview

Who we are

Our history

What we want to achieve

June 2020

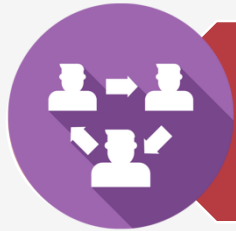
## Outline

- Concept – who we are
- History – origin of IPRP
- Mission – what we want to achieve
- Scope
- Strategic Priorities 2018 – 2020
- IPRP versus ICH – where is the difference?
- Governance
- Operating Principles
- IPRP Members and Observers
- Activities – our working groups
- Reflections on IPRP
- Looking ahead – next steps



## Concept – Who we are

**THE regulatory «hub» for regulatory authorities and organisations**



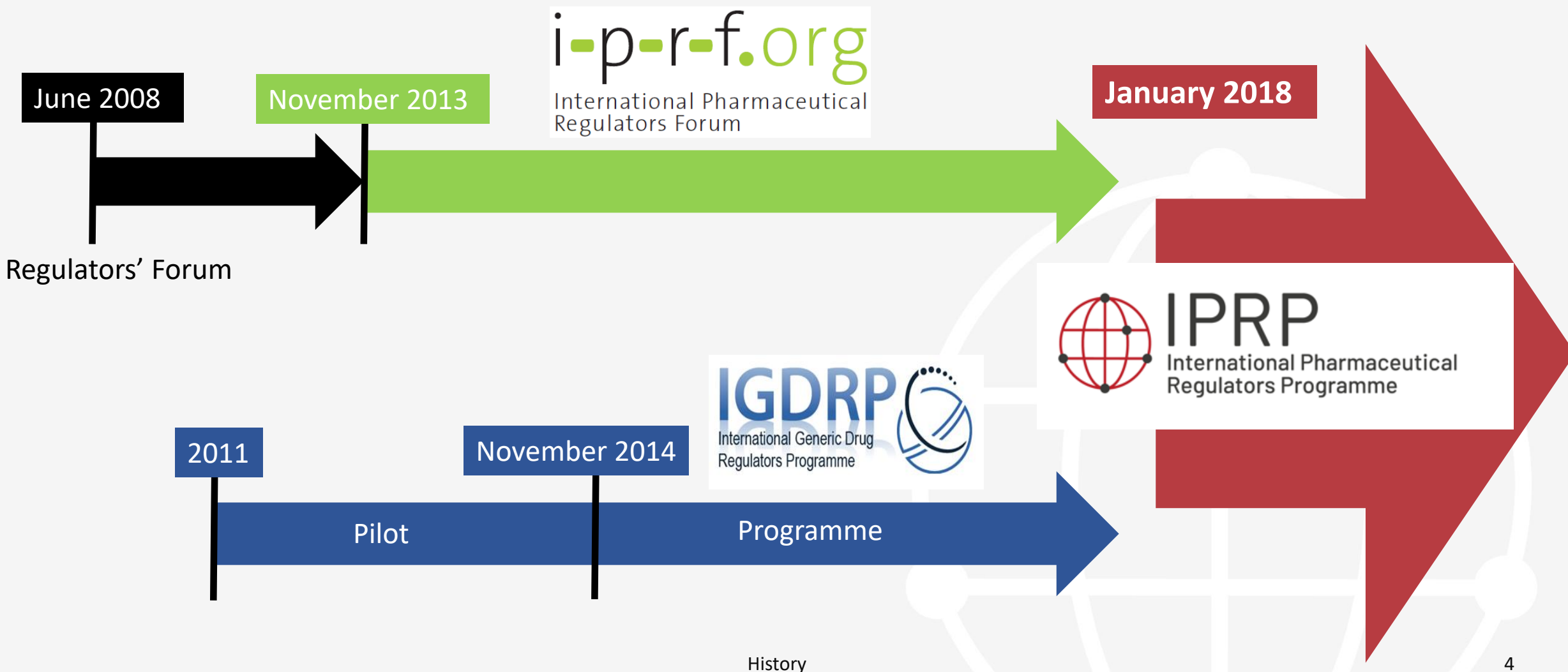
To share information



To discuss issues of common concern, especially emerging scientific areas/new technologies



To work towards regulatory convergence



## Drivers for the consolidation of IPRF and IGDRP

- A shared vision
- Creating “the” regulatory hub for pharmaceuticals
- Coherent membership and level of engagement
- Maximise synergies and avoid duplication of efforts
- Avoidance of the misperception of differences between innovative and generic medicines
- Improving governance, increasing support, saving human and financial resources of involved regulators
- Single management committee
- Permanent secretariat
- Single website, infrastructure and platform for sharing information

## Mission

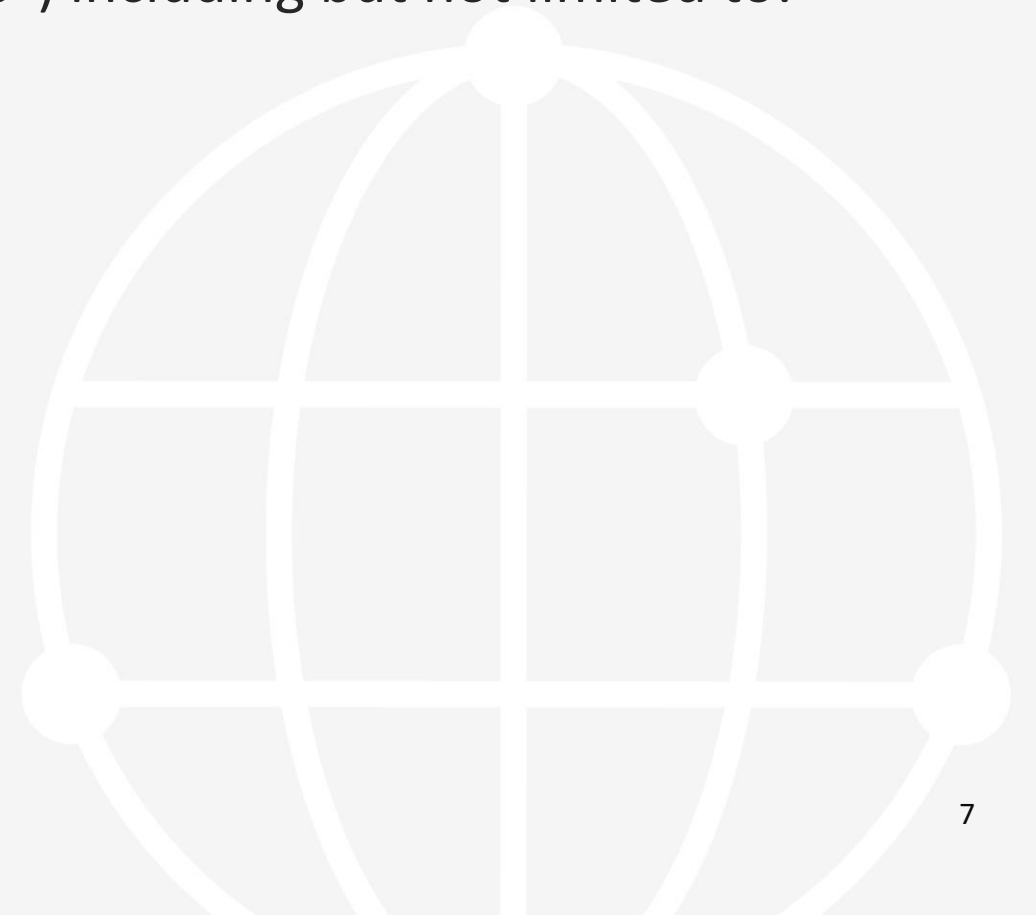
Promotion of regulatory convergence by means of practical and operational information exchange which fosters trust and a mutual understanding of the range of challenges and contexts facing each regulatory authority.

This is done in order to enhance the health of our populations by the most efficient means possible.

## Scope

Medicinal products for human use (“pharmaceuticals”) including but not limited to:

- innovator pharmaceuticals,
- cell and gene therapies,
- biologics,
- biosimilars,
- generic pharmaceuticals, and
- nanomedicines





## Strategic Priorities 2018 - 2020

- 1 Create a discussion forum for regulatory authorities and regulatory organisations to identify and address emerging issues of shared interest and discuss approaches
- 2 Establish a collaborative environment to share regulatory perspectives on ICH work, discuss challenges and promote consistent implementation of ICH guidelines
- 3 Promote greater convergence in regulatory approaches based on international standards and best practices
- 4 Create conditions to facilitate greater inter-agency collaboration, enhance communications and support capacity building (e.g. training)



## IPRP versus ICH – where is the difference?

### IPRP

- Regulators-only forum
- Identifying and addressing emerging regulatory issues of shared interest
- Discussing of potential approaches towards convergence resulting in reflection papers, common templates, articles in journals, ...
- **NO** technical Guideline development



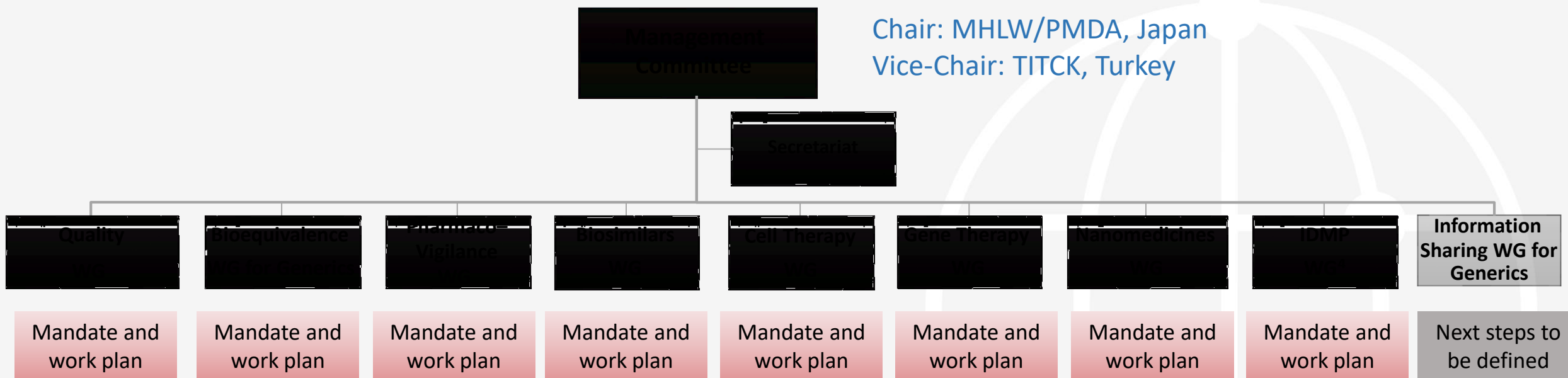
Once «mature», a topic  
can be handed over to  
ICH

### ICH

- Non-Profit Association under Swiss law between Regulators, Industry and other Organisations
- Harmonisation of technical requirements in the area of quality, safety, efficacy and multidisciplinary topics
- **Outcome:** harmonised technical Guidelines

## Governance

- IPRP Strategic Vision 2018 – 2020
- Terms of Reference (ToR)
- Standing Operating Procedure (SOP)



<sup>4</sup>IDMP: Identification of Medicinal Products

## Operating principles

- Voluntary network of members and observers with possibility to “opt-out”
- Management Committee (MC) as decision making body and laying out the strategic vision
  - ☞ decision making is consensus driven (no voting)
  - ☞ meets face-to-face twice a year within the margins of ICH
  - ☞ comprised of up to three (3) official representatives from each participating member and observer
  - ☞ Chair and Vice-Chair for the term of one year (can be renewed for up to three times)
- MC is supported by a permanent secretariat
  - ☞ IPRP Secretariat function is provided by ICH Secretariat based upon an MoU between IPRP and ICH
- Financing:  
Contributions on a voluntary basis by its members through funding mechanisms that are consistent with the laws regulating the activities of each member
- Currently 9 Working Groups (WGs) reporting to MC

## Membership / Observership

Representatives from

- Pharmaceutical regulatory authorities
- Organisations with responsibilities relating to the regulation of medicinal products for human use
- Regional Harmonisation Initiatives (RHIs)

### **Principal rules:**

- 👉 No differences in expectations and level of participation between members and observers.
- 👉 Inclusive membership

## IPRP Members and Observers – 1 of 3 (as of June 2020)

- National Administration of Drugs, Foods and Medical Devices of Argentina (ANMAT) (Argentina)
- Agência Nacional de Vigilância Sanitária (ANVISA) (Brazil)
- Indonesian Food and Drug Administration (Badan POM) (Indonesia)
- Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos (CECMED) (Cuba)
- Federal Commission for the Protection against Sanitary Risk (COFEPRIS) (Mexico)
- Center for Pharmaceutical and Enforcement Division (CPED) (Israel)
- European Commission (EC) / European Medicines Agency (EMA) (Europe)
- European Directorate for the Quality of Medicines and Healthcare (EDQM) (Observer)
- United States Food and Drug Administration (FDA) (United States)
- Health Canada (HC) (Canada)
- Health Sciences Authority (HSA) (Singapore)
- National Food and Drug Surveillance Institute (INVIMA) (Colombia)

## IPRP Members and Observers – 2 of 3 (as of June 2020)

- Medicines and Medical Devices Safety Authority (MEDSAFE) (New Zealand)
- Ministry of Food and Drug Safety (MFDS) (South Korea)
- Ministry of Health, Labour and Welfare (MHLW) / Pharmaceuticals and Medical Devices Agency (PMDA) (Japan)
- National Center for Expertise (Kazakhstan)
- National Pharmaceutical Regulatory Agency (NPRA) (Malaysia)
- National Regulatory Authority (NRA) (Iran)
- Federal Service for Surveillance in Healthcare and Social Development (Roszdravnadzor) (Russia)
- South African Health Products Regulatory Authority (SAHPRA) (South Africa)
- Saudi Arabia Food and Drug Agency (SFDA) (Saudi Arabia)
- Swissmedic, Swiss Agency for Therapeutic Products (Switzerland)
- Taiwan Food and Drug Administration (TFDA) (Chinese Taipei)

## IPRP Members and Observers – 3 of 3 (as of June 2020)

- Therapeutic Goods Administration (TGA) (Australia)
- Turkish Medicines and Medical Devices Agency (TITCK) (Turkey)
- World Health Organization (WHO) (Observer)

### Regional Harmonisation Initiatives

- [APEC](#) (Asia-Pacific Economic Cooperation)
- [ASEAN](#) (The Association of Southeast Asian Nations)
- [EAC](#) (East African Community)
- [GHC](#) (Gulf Health Council)
- [PAHO/PANDRH](#) (Pan American Network for Drug Regulatory Harmonization)
- [SADC](#) (Southern African Development Community)



## Activities – Our Working Groups



## Bioequivalence Working Group for Generics

Co-Chairs HSA (Singapore) and WHO

Mandate

- Promote collaboration and regulatory convergence relating to the assessment of bioequivalence for generic drug products
- Develop tools (e.g., assessment templates, guidance for assessors) to aid in assessment of bioequivalence

Main Achievements

- [Biopharmaceutics Classification System \(BCS\) Biowaivers:](#)
  - Assessment Report [template](#)
  - [Survey of the Regulatory Requirements for BCS-Based Biowaivers for Solid Oral Dosage Forms](#)
- [Acceptance of foreign comparator products in bioequivalence studies:](#)
  - [Survey of the Regulatory Requirements for the Acceptance of Foreign Comparator Products](#)
- [Additional Strength Biowaivers](#)
  - Assessment Report [template](#)

## Biosimilars Working Group

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Co-Chairs      FDA (United States) and SFDA (Saudi Arabia)

Mandate      

- Promote convergence of review and regulation of biosimilar products
- Contribute to provide meaningful outcome to promote public health through more affordable biosimilar products

Main Achievements      

- [Reflection Paper on Extrapolation of Indications in Authorisation of Biosimilar Products](#)
- Training Manual on the Basic of Analytical Comparability of Biosimilar Monoclonal Antibodies ([English](#), [Spanish](#), [Russian](#))
- [Public Assessment Summary Information for Biosimilars \(PASIB\)](#)

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## Cell Therapy Working Group

Chair	Rotating Chair among members; FDA (United States) serves as secretariat
Mandate	<ul style="list-style-type: none"><li>▪ Open discussion and sharing of best practices for the regulation of cell and tissue-based therapies</li><li>▪ Support harmonization initiatives such as APEC</li><li>▪ Refer topics to appropriate organizations such as ICH, PIC/S, PANDRH, WHO</li></ul>
Main Achievements	<ul style="list-style-type: none"><li>▪ Reflection paper «<a href="#"><u>General Principles to Address the Nature and Duration of Follow-up for Subjects of Clinical Trials Using Cell Therapy Products</u></a>»</li></ul>

## Gene Therapy Working Group

Chair	Rotating Chair among members; FDA (United States) serves as secretariat
Mandate	<ul style="list-style-type: none"><li>▪ Open discussion and sharing of best practices for the regulation of gene therapy products</li><li>▪ Focused discussion of topics that are potentially suitable for regulatory convergence, and producing reflection documents</li><li>▪ Support harmonization initiatives such as APEC and PANDRH</li><li>▪ Refer topics to appropriate organizations such as ICH, PIC/S, WHO</li></ul>
Main Achievements	<ul style="list-style-type: none"><li>▪ <a href="#"><u>Reflection Paper «Expectations for Biodistribution (BD) Assessments for Gene Therapy (GT) Products»</u></a></li></ul>

## Identification of Medicinal Products (IDMP) Working Group

Chair	FDA (United States)
Mandate	<ul style="list-style-type: none"><li>▪ Ensure the awareness and understanding of the IDMP standards more globally by pharmaceutical regulators</li><li>▪ Clarify how and why these standards can add value to regulator business processes to improve the quality and effectiveness of shared regulatory functions</li><li>▪ Share strategies and experiences for their successful and consistent implementation</li></ul>
Main Achievements	<ul style="list-style-type: none"><li>▪ <a href="#"><u>IDMP Frequently Asked Questions</u></a></li></ul>

## Nanomedicines Working Group

Co-Chair Health Canada (Canada), TGA (Australia)

Mandate

- Non-confidential information sharing, regulatory harmonization or convergence focused on nanomedicines / nanomaterial in drug products and borderline and combination products
- Regulatory cooperation, including work-sharing, in specific areas of nanomedicines / nanomaterial in drug products with other related international bodies
- Collaboration of training organization between international regulators
- Promotion of potential consensus finding on standards

Main Achievements

- [Joint Research Centre \(JRC\) Technical Report: Mapping Nanomedicine Terminology in the Regulatory Landscape](#)
- [Joint Research Centre \(JRC\) Technical Reports: Identification of regulatory needs for nanomedicines](#)
- [Summary of liposomal survey and terminology poster](#)
- [Information sharing and mapping](#)



## Quality Working Group

Co-Chairs	EDQM and Health Canada (Canada)
Mandate	<ul style="list-style-type: none"><li>▪ Establish a framework and mechanisms for information sharing and work sharing of Quality information</li><li>▪ This is with a view to greater collaboration and potentially regulatory convergence in the assessment of ASMFs/DMFs and applications for generic drug products</li></ul>
Main Achievements	<ul style="list-style-type: none"><li>▪ <a href="#"><u>ASMF/DMF Database</u></a></li><li>▪ <a href="#"><u>Lexicon of Quality Terms</u></a></li><li>▪ <a href="#"><u>Common ASMF/DMF Submission Form</u></a></li><li>▪ <a href="#"><u>Quality Assessment Report (QAR) template for ASMFs/DMFs</u></a></li><li>▪ <a href="#"><u>Gap Analysis on ASMF/DMF frameworks and procedures</u></a></li><li>▪ <a href="#"><u>Criteria for when a separate ASMF/DMF should be submitted</u></a></li><li>▪ <a href="#"><u>Guidance for Quality Assessors-Drug Substance</u></a></li></ul>

## Pharmacovigilance (PV) Working Group

Chair	SFDA (Saudi Arabia)
Mandate	<ul style="list-style-type: none"><li>▪ Leverage knowledge-sharing and opportunities to advance collaboration in the area of pharmacovigilance between IPRP members</li></ul>
Main Achievements	<ul style="list-style-type: none"><li>▪ To come</li></ul>

## Information Sharing Working Group for Generics – *next steps to be defined*

Chair	EC/EMA (Europe)
Mandate	<ul style="list-style-type: none"><li>▪ Sharing assessment reports in real-time with non-EU regulatory agencies</li><li>▪ Participating IPRP Members: Health Canada (Canada); Swissmedic (Switzerland); TFDA (Chinese Taipei); TGA (Australia)</li></ul>
Main Achievements	<ul style="list-style-type: none"><li>▪ <a href="#">EU Decentralised Procedure (DCP) pilot (launched July 2014)</a></li><li>▪ <a href="#">EU Centralised Procedure (CP) pilot (launched January 2015)</a></li></ul>

## Reflections on IPRP

- Clear Mission & Vision is key to ensure there is no overlap with other international initiatives
- Close linkages and communication with other international initiatives are important
  - ☞ updates at each MC meeting
- Transition phase/implementation of the consolidation:
  - No impact on WGs activities
    - ☞ All WGs maintained the activities proposed in their workplans
    - ☞ Momentum was not lost
- Transparent communication through dedicated website is essential to raise awareness of what IPRP is and what its objectives are
  - ☞ Press Release after each MC face-to-face meeting
  - ☞ Publication of working group results/achievements

## Next steps

- How to approach Stakeholder Engagement?
  - ☞ Stakeholder Engagement Plan published on the [website](#)
- Reflection on mature topics that might be proposed to ICH for consideration by the Assembly
  - ☞ Upon proposal by respective Working Group when reporting back to MC
- Reflection on new topics to be addressed under IPRP
  - ☞ Standing item on MC meeting agenda

Next IPRP MC meeting: 19-20 November 2020 in Athens, Greece

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