IPRP
International Pharmaceutical Regulators Programme

IPRP Overview

Who we are
Our history
What we want to achieve

May 2025

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Outline

- Concept – who we are
- History – origin of IPRP
- Mission – what we want to achieve
- Scope
- Strategic Priorities 2018 – 2021
- 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

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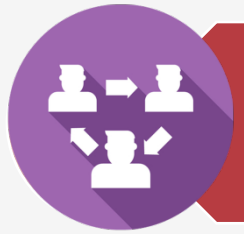
Concept – Who we are

THE regulatory «hub» for regulatory authorities and organisations

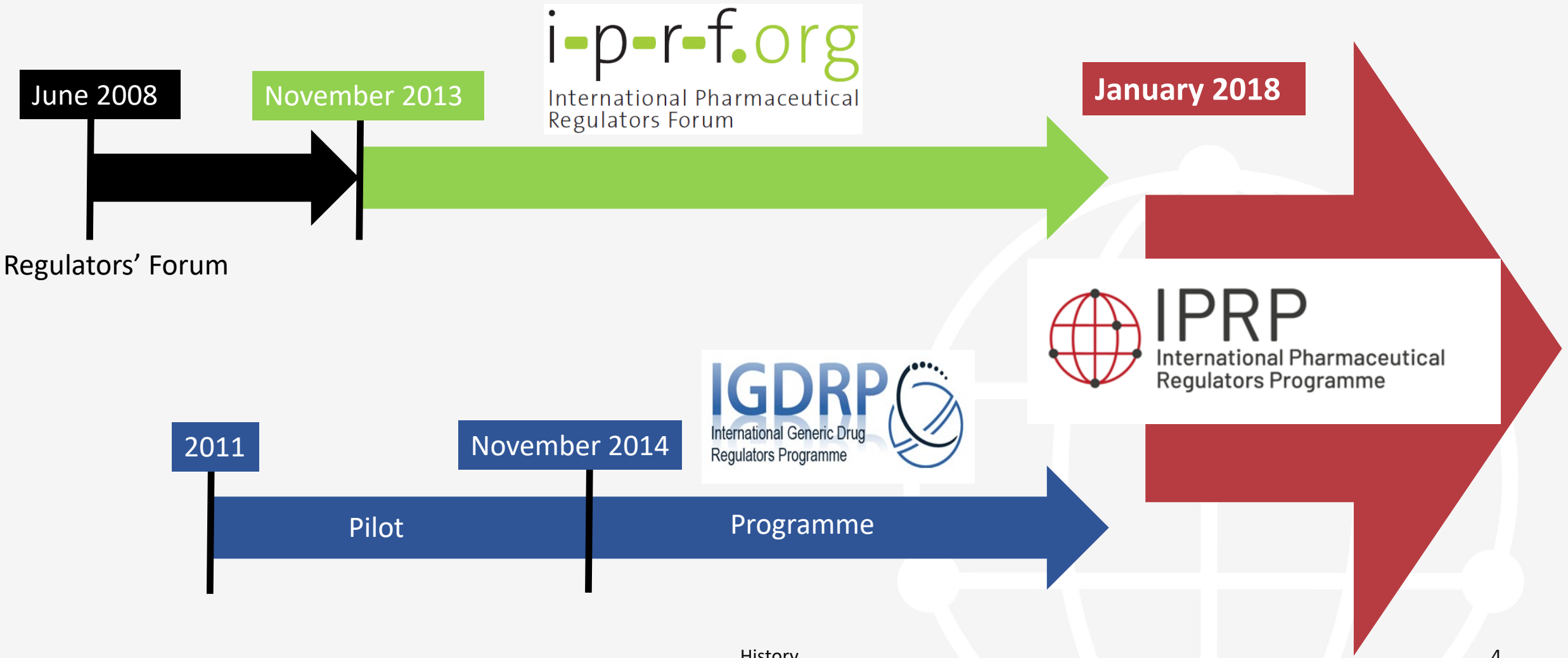


To share information

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

To work towards regulatory convergence

Where we come from



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

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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.

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Scope

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

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

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Strategic Priorities 2018 – 2021 (ongoing revision in 2024)

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?

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- 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 t**echnical Guideline development

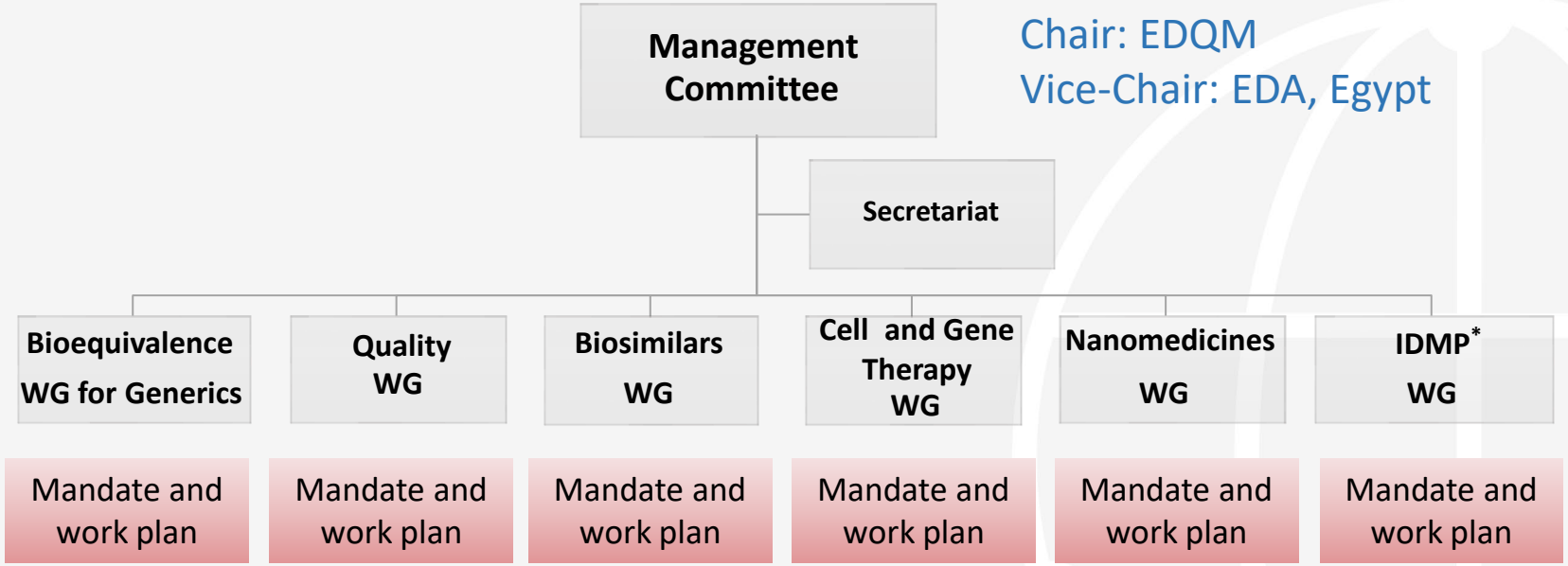
Once «mature», a topic can be handed over to ICH

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 – 2021 (ongoing revision in 2024)
- Terms of Reference (ToR)
- Standing Operating Procedure (SOP)



*IDMP: Identification of Medicinal Products

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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 6 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 May 2025)

- ANMAT, Argentina
- ANPP, Algeria
- ANVISA, Brazil
- CECMED, Cuba
- COFEPRIS, Mexico
- CPED, Israel
- CPPS, Uzbekistan
- DIGEMID, Peru
- DINAVISA, Paraguay
- EC, Europe
- EDA, Egypt
- EDQM - Observer
- FDA, United States

IPRP Members and Observers – 2 of 3 (as of May 2025)

- Health Canada, Canada
- HSA, Singapore
- Indonesian FDA, Indonesia
- INVIMA, Colombia
- JFDA, Jordan
- Medsafe, New Zealand
- MHRA, UK
- MFDS, Republic of Korea
- MHLW/PMDA, Japan
- MOH, Kuwait
- NAFDAC, Nigeria
- National Center, Kazakhstan
- NPRA, Malaysia

IPRP Members and Observers – 3 of 3 (as of May 2025)

- NRA, Iran
- Roszdravnadzor, Russia
- SAHPRA, South Africa
- SFDA, Saudi Arabia
- SRS, El Salvador
- Swissmedic, Switzerland
- TFDA, Chinese Taipei
- TGA, Australia
- TITCK, Turkey
- Thai FDA, Thailand
- WHO - Observer

Regional Harmonisation Initiatives

- APEC
- ASEAN
- EAC
- GHC
- PAHO/PANDRH
- SADC

Activities – Our Working Groups

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Bioequivalence Working Group for Generics

Co-Chairs	HSA, Singapore and Swissmedic, Switzerland
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 (available here)	▪ Bioequivalence study designs
	  ▪ Survey on the Bioequivalence Study Design Requirements for Immediate-Release Solid Oral Dosage Forms
	▪ 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
	  ▪ Asessment Report template
	  ▪ Survey of the requirements for additional strength biowaivers for immediate-release oral solid dosage forms
	▪ Alternative comparator product policies
	  ▪ A Survey of the Criteria Used for the Selection of Alternative Comparator Products by Participating Regulators and Organizations of the IPRP
	▪ Biowaivers for various dosage forms
	  ▪ Dosage Form Biowaiver Assessment Report Templates

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Biosimilars Working Group

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 (available here)	▪ Reflection Paper on Extrapolation of Indications in Authorisation of Biosimilar Products ▪ Training Manual on the Basics of Analytical Comparability of Biosimilar Monoclonal Antibodies (English, Spanish, Russian) ▪ Training Manual on the Basics of the Nonclinical Comparability Exercise of Biosimilar Monoclonal Antibody for Regulatory Reviewers (English) ▪ Public Assessment Summary Information for Biosimilars (PASIB) ▪ Primer on Biosimilar-Related Regulatory Topics for Regulatory Reviewers ▪ Workshop Summary Report on Increasing the Efficiency of Biosimilar Development Programs — Reevaluating the Need for Comparative Clinical Efficacy Studies

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Cell and Gene Therapy Working Group

Chair	FDA, United States serves as secretariat
Mandate	▪ Retain knowledge of regulatory activities in participating regions ▪ Identify Topics for regulatory convergence or harmonization ▪ When appropriate, present topics to ICH ▪ Collaborations and information sharing with other international and regional bodies

Identification of Medicinal Products (IDMP) Working Group

Chair	EC, Europe
Mandate	▪ Ensure the awareness and understanding of the IDMP standards more globally by pharmaceutical regulators ▪ Clarify how and why these standards can add value to regulator business processes to improve the quality and effectiveness of shared regulatory functions ▪ Share strategies and experiences for their successful and consistent implementation
Main Achievements (available here)	▪ IDMP Frequently Asked Questions, version 7.0

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Nanomedicines Working Group

Co-Chair	ANMAT, Argentina and FDA, United States
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 (available here)	▪ 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

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Quality Working Group

Co-Chairs	INVIMA, Colombia and SAHPRA, South Africa
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
Main Achievements (available here)	▪ Lexicon of Quality Terms ▪ Common ASMF/DMF Submission Form ▪ Quality Assessment Report (QAR) template for ASMFs/DMFs ▪ Quality Assessment Report (QAR) – Full Dossier template ▪ Gap Analysis on ASMF/DMF frameworks and procedures ▪ Criteria for when a separate ASMF/DMF should be submitted ▪ Guidance for Quality Assessors-Drug Substance ▪ Guidance for Quality Assessors-Drug Product ▪ Paper on Survey on Administrative Procedures and Terminologies for Quality Variations/Post-approval Changes ▪ Summary Report of Experiences and Lessons Learned on the ASFM/DMF Pilot Project ▪ Executive Summary on Survey Implementation of IPRP Quality Assessment Tools

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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

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Next steps

- How to approach Stakeholder Engagement?
  - ☞ Stakeholder Engagement Plan published on the website – ongoing revision in 2025
- 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 2025 in Singapore.

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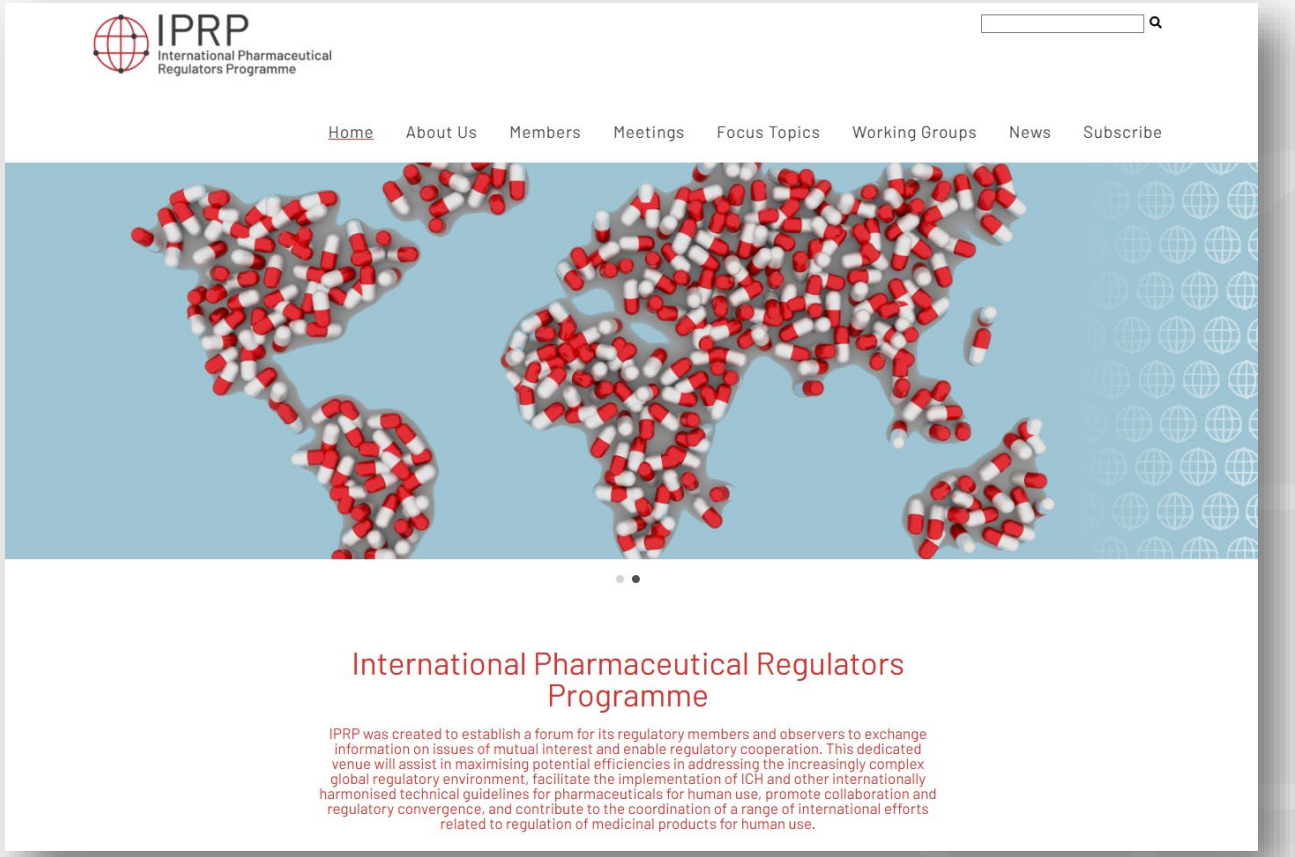
Visit us at www.iprp.global



IPRP website

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Think globally, act locally!

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