## ICMRA - Mapping of Generic Initiatives

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<th>Initiative</th>
<th>Objective</th>
<th>Scope</th>
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<tr>
<td>1 IGDROP International Generic Drug Regulators’ Pilot</td>
<td>To establish faster approvals and greater availability of generic medicines to market; more efficient use of resources through mutual reliance and work-sharing; strengthen the review process and international regulatory oversight, while reducing regulatory burden; promote the adoption of modern, science and risk-based approaches; allow for the rapid exchange of safety and quality information for products already on the market; and enhance the development of human resources.</td>
<td>Activities that best meet the needs of participants in the area of generic drug regulation. Does not include biosimilars.</td>
<td>Australia, Brazil, Canada, China, China Taipei, European Union, Japan, Korea, Mexico, Singapore, Switzerland and United States</td>
<td>Twice per annum plus technical working group meetings</td>
<td>1. Establish a framework for information sharing 2. Potential mutual reliance in the assessment of ASMX/DMF and quality aspects of drug products 3. Create a repository of technical requirements and review practices/approaches on some specific areas 4. Convergence and harmonising data requirements</td>
<td>WHO provides Secretariat Support for this Initiative. <a href="https://www.igdtop.com/contact">https://www.igdtop.com/contact</a></td>
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<td>2 Heads of Agencies Quadrilateral Consortium Generic Work-sharing Project</td>
<td>To maximise international cooperation, reduce duplication, and increase each agency’s capacity to ensure consumers have timely access to high quality, safe, effective therapeutic goods.</td>
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<td>TGA: <a href="mailto:TGA.International@tga.gov.au">TGA.International@tga.gov.au</a>  Swissezmedic: <a href="mailto:Networking@swissmedic.ch">Networking@swissmedic.ch</a>  HSA (Singapore): <a href="mailto:HSA_Info@hsa.gov.sg">HSA_Info@hsa.gov.sg</a></td>
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<td>3 Regulatory Cooperative Initiative</td>
<td>1. Enhance regulatory cooperation Reduce duplication of work common to both agencies. 2. Greater reliance on work undertaken by each agency. 3. Maintain sovereign decision making powers.</td>
<td>Exchange of submission lists &amp; review reports Staff exchange</td>
<td>Australia and Canada</td>
<td>Heads of Agency meet 1-2 times per annum</td>
<td>1. Bilateral exchange of submissions lists and review reports Staff exchanges 2. Exploring development of a common evaluation template and guidance documents.</td>
<td>TGA: <a href="mailto:TGA.International@tga.gov.au">TGA.International@tga.gov.au</a>  Health Canada: <a href="mailto:Info@hc-sc.gc.ca">Info@hc-sc.gc.ca</a> /</td>
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<td>4 US FDA-EMA Generic Medicines Application Inspections Initiative</td>
<td>1. To streamline information sharing on inspections of bioequivalence studies conducted and planned for generic medicines marketing authorisation applications. 2. To share information in negative inspection outcomes, which reveal system problems of these facilities, and with potential impact on the acceptability/ reliability of the data obtained from other studies conducted in the same facility. 3. To conduct joint inspections of clinical trial sites all over the world. 4. To provide training opportunities to improve bioequivalence inspections.</td>
<td>Bioequivalence studies submitted to the EMA, the FDA, and/or regulatory authorities in some EU Member States in support of marketing authorisation applications for generic medicines.</td>
<td>The US Food and Drug Administration (US FDA) and the European Medicines Agency (EMA).</td>
<td>This initiative involves an 18 month Pilot Phase, which commenced on 2 January 2014.</td>
<td>1. Streamline information sharing on inspections of bioequivalence studies conducted and planned for generic drug applications (Inspectional information will be shared for clinical facilities, analytical facilities or both) 2. Share information about negative inspection outcomes that reveal system problems at a facility 3. Conduct joint inspections at facilities all over the world; and provide training opportunities to improve bioequivalence inspections.</td>
<td><a href="mailto:GCP@ema.europa.eu">GCP@ema.europa.eu</a></td>
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<td>5 European Mutual Recognition and Decentralised Procedures</td>
<td>1. Mutual recognition between EU competent authorities of assessments of generic medicinal products. 2. Avoid Duplication.</td>
<td>Marketing authorisations for medicinal products for human and veterinary use</td>
<td>Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Norway, Iceland, Liechtenstein</td>
<td>Monthly (CMDh)</td>
<td>1. Common assessments, Mutual recognition of assessments 2. Coordinated Inspections (GMP and BE), Public assessment reports 3. Work sharing on active substance master files</td>
<td>CMDh Secretariat: H- <a href="mailto:CMDhSecretariat@ema.europa.eu">CMDhSecretariat@ema.europa.eu</a>  CMDv: <a href="mailto:CMDv@ema.europa.eu">CMDv@ema.europa.eu</a></td>
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**ICMRA - International Conference on Medicines Regulatory Affairs**
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| **6 WHO Prequalification Programme** | In close cooperation with national regulatory agencies and partner organizations, the WHO Prequalification Programme aims to make quality priority medicines available for the benefit of those in need. | - Evaluation and inspection activities carried by WHO teams
Manufacturers and sites that are participating in the WHO Prequalification Programme. | N/A | 1. Apply unified standards of acceptable quality, safety and efficacy.
2. Comprehensive evaluation of the quality, safety and efficacy of medicinal products, based on information submitted by the manufacturers, and inspection of the corresponding manufacturing and clinical sites.
3. Prequalify sources of active pharmaceutical ingredients by comprehensively evaluating the quality of the API based on information submitted by the manufacturers, and inspection of the corresponding manufacturing sites.
4. Prequality control laboratories of pharmacists.
5. Build the capacity of staff from national regulatory authorities, quality control laboratories, and from manufacturers or other private companies, to ensure medicines quality. | prequalreg@who.int |
| **7 SADC Southern African Development Community - Pharmaceutical Harmonisation Initiative** | To provide access to treatment for all citizens in need in the southern region, with the objectives of the Harmonisation Initiative being the improved quality of medicines, optimising utilization of resources and the standardization of regulatory requirements. | The initiative aims to improve the quality, safety and efficacy of medicines circulating within the SADC region, and to establish and maintain a regional shared network system for regulatory authorities. | SADC Medicines Regulatory Authority (MRA) Forum meets twice yearly. | 1. The development of technical guidelines and policies, relating to the registration and control of medicines across the SADC Member States: Application Form for Registration of Medicinal Products; Registration of Medicinal Products; Stability Study; Good Manufacturing Practices; Bioavailability/Bioequivalence; HIV Vaccine Clinical Trials; Registration of Nutritional Supplements; Validation, Advertising and Licensing; Post-marketing Surveillance; Regulation of Vaccines; Regulation of Traditional Medicines; 2. To support their implementation, regional training programmes will be developed. | registry@sadc.int |
| **8 PANDRH Pan-American Network for Drug Regulatory Harmonization** | To promote drug regulatory harmonisation for all aspects of quality, safety, and efficacy of pharmaceutical products as a contribution to the quality of life and health care of the citizens of the Member Countries of the Americas. | Drug regulatory authorities:
PAHO member states:
Antigua and Barbuda; Argentina; Bahamas; Barbados; Belize; Bolivia; Brazil; Canada; Chile; Colombia; Costa Rica; Cuba; Dominica; Dominican Republic; Ecuador; El Salvador; Grenada; Guatemala; Guyana; Haiti; Honduras; Jamaica; Mexico; Nicaragua; Panama; Peru; Saint Lucia; St. Vincent and the Grenadines; St. Kitts and Nevis; Suriname; Trinidad and Tobago; United States of America; Uruguay; Venezuela
Representatives of the regional pharmaceutical industry associations:
ALPIM,
LATAM,
Academia
Consumer groups
Professional associations
Representatives from the five sub-regional trade integration groups within the Americas:
ANDINA COMMUNITY
CARICOM
SICA
MERCOSSUR
NAFTA | Biennial Pan American conferences.
The SC meets once a year. | 1. Endorsing standards, guidelines and other recommendations, including normative procedures in areas such as, GMPs, Bioequivalence, GCP, medical plant, Pharmacopeia, Drug Counterfeiting, Drug Registration and Classification, Pharmacovigilance, Good Laboratory Practices.
2. Training courses as well (on GMP inspection, GCP, GLP, Bioequivalence and the basic functions of a regulatory authority). | fitzgerj@paho.org |
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<td>AMRH</td>
<td>To improve public health by increasing access to good quality, safe and effective medicines through the harmonization of medicines regulations, including the reduction of the time taken to register essential medicines for the treatment of diseases.</td>
<td>Regional economic communities and institutions: East African Community (EAC), Southern African Development Community (SADC), Economic Community of Central African States (ECCAS), Community of Sahel and Sahara States (CEN-SAD), Economic Community of West African States (ECOWAS), Arab Maghreb Union (AMU), Common Market for Eastern and Southern Africa (COMESA), Intergovernmental Authority on Development (IGAD), Economic and Monetary Community of Central Africa (CEMAC).</td>
<td>N/A 1. Harmonized registration dossier format and technical requirements for quality, safety and efficacy of generic medicines. 2. Progress in harmonizing technical requirements for other product groups is under way. 3. Increased technical capacity and efficient use of resources. Increased requests for registration from manufacturers. 4. Attainment of Millennium Development Goals (MDGs).</td>
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<td><a href="mailto:amrh@nepad.org">amrh@nepad.org</a></td>
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**Abbreviations**
- i.e.: API (Active Pharmaceutical Ingredients)
- CMDh: Committee for Mutual Recognition and Decentralised Procedures (human)
- ODRv: Committee for Mutual Recognition and Decentralised Procedures (veterinary)
- BE: Bioequivalence

**Notes**
1. Unless otherwise specified, Medicinal Product for Human Use includes: drugs, vaccines, biologicals, prescription, non-prescription, generics, traditional medicines, herbal medicines, etc.

**Disclaimer**
The information on this table has been compiled by EMA according to the available information. As in certain cases it is difficult to have accurate or up-to-date information and there are continuous changes, EMA strongly recommends to check the information with the relevant websites or directly with the relevant organisations.