EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 Facsimile +44 (0)20 7418 8416
E-mail info@ema.europa.eu Website www.ema.europa.eu
An agency of the European

December 2016
EMA/275766/2014
International Affairs

ICMRA - Mapping of generic initiatives

	Initiative	Objective	Scope	Membership	Frequency of meetings	Work products	Contact Point
1	**IGDRP International Generic Drug Regulators' Pilot**	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.	Activities that best meet the needs of participants in the area of generic drug regulation. Does not include biosimilars.	Australia, Brazil, Canada, China, Chines Taipei, European Union, Japan, Korea, Mexico, Singapore, Switzerland and United States	Twice per annum plus technical working group meetings	1. Establish a framework for information sharing 2. Potential mutual reliance in the assessment of ASMF/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	WHO provides Secretariat Support for this initiative. https://www.igdrp.com/contact
2	**Heads of Agencies Quadrilateral Consortium Generics Work-sharing Project**	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.	1. Assessment of manufacturing sites 2. Communication strategies for proactive sharing of information 3. Evaluation of generic medicines assessments 4. IT architecture to develop 'cloud' technology for sharing of confidential information 5. International pharmacovigilence monitoring 6. Workload sharing in relation to ICH participation	Health regulatory agencies: Therapeutic Goods Administration (TGA) of Australia; Health Products and Food Branch (HPFB) of Health Canada; Health Sciences Authority (HSA), Singapore; Swissmedic, Swiss Agency for Therapeutic Products, Switzerland	The steering committee meets 3-4 times per annum plus technical working group meetings	1. Development of common templates and guidance documents 2. Framework for strategic communication exchange 3. Establishment of a secure portal for exchange of information	TGA: TGA.International@tga.gov.au Health Canada: Info@hc-sc.gc.ca Swissmedic: Networking@swissmedic.ch HSA (Singapore): HSA_Info@hsa.gov.sg
3	**Regulatory Cooperative Initiative**	1. Enhance regulatory cooperation Reduce duplication of work common to both agencies. 2. Greater reliance on work undertaken by each agency. 3. Maintain soveriegn decision making powers.	Exchange of submission lists & review reports Staff exchange	Australia and Canada	Heads of Agency meet 1-2 times per annum	1. Bilateral exchange of submissions lists and review reports Staff exchanges 2. Exploring development of a common evaluation template and guidance documents.	TGA: TGA.International@tga.gov.au Health Canada: Info@hc-sc.gc.ca /
4	**USFDA-EMA Generic Medicines Application Inspections Initiative**	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.	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.	The US Food and Drug Administration (FDA), European Medicines Agency (EMA), France, Germany, Italy, the Netherlands and the United Kingdom	This initiative involves an 18 month Pilot Phase, which commenced on 2 January 2014.	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.	GCP@ema.europa.eu
5	**European Mutual Recognition and Decentralised Procedures**	1. Mutual recognition between EU competent authorities of assessments of generic medicinal products. 2. Avoid Duplication.	Marketing authorisations for medicinal products for human and veterinary use	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, United Kingdom, Norway, Iceland, Liechtenstein	Monthly (CMDh)	1. Common assessments, Mutual recognition of assessments 2. Coordinated Inspections (GMP and BE), Public assessment reports 3. Work sharing on active substancce master files	CMDh Secretariat: H-CMDhSecretariat@ema.europa.eu CMDv: CMDv@ema.europa.eu

	Initiative	Objective	Scope	Membership	Frequency of meetings	Work products	Contact Point
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.	1. Evaluation and inspection activities carried by WHO teams 2. Building national capacity for sustainable manufacturing and monitoring of quality medicines.	Participating National Medicines Regulatory Authorities (NMRAs): Armenia, Botswana, Ethiopia, Georgia, Ghana, Kenya, Kyrgyztan, Madagascar, Malawi, Mozambique, Namibia, Nigeria, Tanzania, Uganda, Ukraine, Zambia, Zanzibar, Zimbabwe. Manufacturers and sites that are participating in the WHO Prequalification Programme	N/A	1. Apply unified standards of acceptable quality, safety and efficacy. 2. Comprehensively evaluate 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. Prequalify quality control laboratories of pharmaceuticals. 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	Angola, Botswana, Democratic Republic of Congo (DRC), Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, United Republic of Tanzania, Zambia and Zimbabwe	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; Bioequivalence/Bioavailability; HIV Vaccine Clinical Trials; Registration of Nutritional Supplements; Validation, Advertising and Licensing; Post-marketing Surveillance; Registration 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.	Medicinal Products for Human Use1	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; Paraguay; 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: ALIFAR FIFARMA Academia Consumer groups Professional associations Representatives from the five sub-regional trade integration groups within the Americas: ANDEAN COMMUNITY CARICOM SICA MERCOSUR NAFTA	Biennial Pan American conferences. The SC meets once a year.	1. Endorsing standards, guidelines and other recommendations, including norms/procedures in areas such as, GMPs, Bioequivalence, GCP, medical plants, 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

	Initiative	Objective	Scope	Membership	Frequency of meetings	Work products	Contact Point
9	**AMRH African Medicines Regulatory Harmonisation**	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.	1. Access: Communities get quicker, greater access to priority essential medicines of good quality. 2. Availability: The availability of affordable essential medicines can be improved through simplified, harmonized, efficient and transparent regulatory approval processes. 3. Affordability: With more generics (lower priced) on the market, patients can achieve greater savings. Governments and donors can enjoy cost savings from subsequent downward pressure on prices through enhanced competition and pooled (shared) procurement	Rregional econominic communities and institutions: East African Community (EAC) Southern African Development Community (SADC) Economic Community of Central Afrcan States (ECCAS) Community of Sahel and Saharan 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) Regional and global partners: African Development Bank (ADB) African Union Commission (AUC) Bill & Malinda Gates Foundation (BMGF) Clinton Foundation Health Access Initiative (CHAI) Pan-African Parliament (PAP) World Bank, UK Department of International Development (DfID) UNAIDS World Health Organization (WHO HQ, AFRO and EMRO).	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).	amrh@nepad.org

Abbreviations	
i.e.: API	*Active Pharmaceutical Ingredients*
CMDh	*ommittee for Mutual recognitionand Decentralised Procedures (human)*
CMDv	*mmittee for Mutual recognitionand 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 rhere are continuous changes, EMA strongly recommends to check the iformation with the relevant websites or directly with the relevant organisations.