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An agency of the European

December 2016
EMA/563593/2016
International Affairs

ICMRA - Mapping of multinational project initiatives

	Initiative	Objective	Scope	Membership	Frequency of meetings	Work Products	Contact Point
1	**ICH International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (Formerly International Conference of Harmonisation)**	To make recommendations towards achieving greater harmonisation in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration, thereby reducing or obviating duplication of testing carried out during the research and development of new human medicines.	Medicinal Products for Human Use[1]	Founding Regulatory Members: The European Commission (EC); The US Food and Drug Administration (FDA); The Ministry of Health, Labour and Welfare of Japan (MHLW) also represented by the Pharmaceuticals; Medical Devices Agency (PMDA) Founding Industry Members: The European Federation of Pharmaceutical Industries and Associations (EFPIA); The Japan Pharmaceutical Manufacturers Association (JPMA); The Pharmaceutical Research and Manufacturers of America (PhRMA) Standing Regulatory Members: The Health Canada; The Swissmedic Industry Members: The International Generic and Biosimilar Medicines Association (IGBA); The World Self-Medication Industry (WSMI) Standing Observers: The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA); The World Health Organisation (WHO) Observers: Legislative or Administrative Authorities The Agência Nacional de Vigilância Sanitária (ANVISA, Brazil); The Central Drugs Standard; Control Organization (CDSCO, India); The Comisión Federal para la Protección contra Riesgos; Sanitarios (COFEPRIS, Mexico); The Health Sciences Authority (HSA, Singapore); The Ministry of Food and Drug Safety (MFDS, South Korea); The Roszdravnadzor (Russia); The Food and Drug Administration (TFDA, Chinese Taipei); The Therapeutic Goods Administration (TGA, Australia) Regional Harmonisation Initiatives (RHIs): The Asia-Pacific Economic Cooperation (APEC); The Association of Southeast Asian Nations (ASEAN); The East African Community (EAC); The Gulf Cooperation Council (GCC); The Pan American Network for Drug Regulatory Harmonization (PANDRH); The Southern African Development Community (SADC) International Pharmaceutical Industry Organisations: The Biotechnology Innovation Organisation (BIO) International Organisations with an Interest in Pharmaceuticals:; The Council for International Organizations of Medical Sciences (CIOMS); The European Directorate for the Quality of Medicines & HealthCare (EDQM); The International Pharmaceutical Excipient Council (IPEC); The United States Pharmacopeia (USP)	N/A	1. Harmonised Guidelines 2. Process of Harmonistation 3. The Medical Dictionary for Regulatory Activities Terminology (MedDRA) 4. The Common Technical Document (CTD) to assemble all the Quality, Safety and Efficacy information in a common format 5. Electronic Standards	admin@ich.org
2	**IPRF International Pharmaceutical Regulators Forum**	1. To enable members to exchange information on issues of mutual concern and regulatory cooperation. Particularly, to enable all members to identify new approaches and specific best practices, and develop smart strategies for dealing with the challenges. 2. To provide a global overview of the different regulatory developments at national and international level; to support international regulatory cooperation in areas which are not covered by existing initiatives. 3. To identify the need for regulatory harmonization or convergence, as well as for regulatory cooperation, including work-sharing, in specific areas.	Medicinal Products for Human Use[1]	Regulatory Authorities: Australia (TGA), Brazil (ANVISA), Canada (Health Canada), European Union (EC-SANTE/EMA), Japan (MHLW/PMDA), Korea (MFDS), Mexico (COFEPRIS)). Russia (Roszdravnadzor), Singapore (HSA), Switzerland (Swissmedic) and United States (FDA). Regional Harmonisation Initiatives (RHIs): APEC (Asia-Pacific Economic Cooperation); ASEAN (The Association of Southeast Asian Nations); EAC (East African Community); GCC (Cooperation Council for the Arab States of the Gulf); PANDRH (Pan American Network for Drug Regulatory Harmonization); SADC (Southern African Development Community). World Health Organization (WHO)	N/A	1. Current Working Groups are: • Gene Tharapy • Cell Therapy •Biosimilars •Nanomedicines 2. Completed Work of GCP group: • "General Principles for Training and Education of GCP inspectors" •Various Publications	https://www.i-p-r-f.org/index.php/en/
3	**ICMRA International Coalition of Medicines Regulatory Authorities**	To provide high level of leadership to address current and emerging human medicine regulatory and safety challenges. Particularly, to develop and establish an International executive coalition of Heads of Medicines regulatory authorities, allowing HoAs to exercise collective and concerted strategic leadership over existing and new international initiatives and enablers, as well as over shared regulatory issues and challenges.	Medicinal Products for Human Use[1]	The Heads of the regulatory authorities of: Australia (TGA); Brazil (ANVISA); Canada (HPFB-HC); China (CFDA) Europe (EMA and EC)France (ANSM); Germany (PEI); Ireland (HPRA); Italy (AIFA); Japan (PMDA and MHLW); Korea (MFDS); Mexico (COFEPRIS); the Netherlands (MEB); New Zealand (Medsafe); Nigeria (NAFDAC); Singapore (HSA); South Africa (MCC); Switzerland (Swissmedic); United Kingdom (MHRA); United States (FDA) Observer: World Health Organization (WHO)	N/A	1. Generic project 2. GMP project 3. Rapid sharing of information and confidentiality commitment within the ICMRA project 4. Capacity building project 5. Mapping existing International project 6. Supply-chain project 7. Pharmacovigilance project 8. Crisis management project	ICMRA.SEC@HC-SC.GC.CA

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4	**PIC/S Pharmaceutical Inspection Co-operation Scheme**	To lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products. Generally. international co-operation in the field of GMP.	Medicinal Products for Human Use [1] Medicinal Products for Veterinary Use	Participating Authorities: Argentinian (INAME); Australia (TGA); Austria (AGES); Belgium (AFMPS); Canada (HPFBI); Chinese Taipei (TFDA); Cyprus (CyPHS); Czech Republic (SUKL and ISCVBM); Denmark (DHMA); Estonia (SAM); Finland (FIMEA); France (ASNM and ANMV); Germany (BMG and ZLG); Greece (EOF); Hungary(GYEMSZI); Iceland (IMA); Indonesia (NADFC); Ireland (IMB); Israel (ISCP); Italy (AIFA), Latvia (ZVA); Liechtenstein (AG); Lithuania (SMCA); Malaysia (NPCB); Malta (MAM); the Netherlands (IGZ); New Zealand (Medsafe); Norway (NOMA); Poland (MPI); Portugal (INFARMED IP); Romania (NAMMD); Singapore (HSA); Slovakia (SIDC); Slovenia (JAZMP); South Africa (MCC); Spain (AEMPS); Sweden (MPA); Switzerland (Swissmedic); Ukraine (SAUMP); United Kingdom (MHRA and VMD); United States of America (US FDA) Partners: European Directorate for the Quality of Medicines & HealthCare (EDQM); European Medicines Agency (EMA); United Nations International Children's Emergency Fund (UNICEF); World Health Organization (WHO)	N/A	1. Harmonised GMP standards and guidance documents 2. Training activities/Seminars 3. Harmonised inspections procedure 4. Audits of inspectorates	https://www.picscheme.org/
5	**IGDRP International Generic Drug Regulator's Programme**	To promote collaboration and regulatory harmonisation in the area of generic medicines, in order to strengthen the ability of health authorities to meet their respective mandates. The project aims to reach: a greater availability of generics; mutual reliance and worksharing; international regulatory oversight; and exchange of safety and quality information on marketed products.	Medicinal Products for Human Use [1] (Generics only)	Members: Brazil (ANVISA), China (CFDA), European Union (EC/EMA), Mexico (COFEPRIS), Russia (Federal Service for Surveillance in Healthcare and Social Development), Canada (Health) Canada, Singapore (HAS), korea (MFDS), Japan (MHLW), Aouth Africa (MCC), New Zealand (Medsafe), Switzerland (Swissmedic), Taiwan (TFDA), Australia (TGA), United States of America (US FDA) Observers: European Directorate for the Quality of Medicines & HealthCare (EDQM); World Health Organization (WHO)	N/A	1. Current Working Group: • Active substance master files/ drug master file (ASMF/DMF) (establishing a framework for information-sharing and potential mutual reliance in the assessment of ASMFs/DMFs) • Biowaivers (establishing a common set of conditions for granting biowaivers as well as the possible expanded application of waivers) • IT Business needs (an IT platform for information sharing). 2. Work sharing models - Currently testing the EU's Decentralised Procedure (DCP) as a policy model for worksharing.	https://www.igdrp.com/
6	**WHO/EMP World Health Organization - Essential Medicines and Pharmaceutical Policies**	To support the achievement of the health-related Millennium Devolopment Goals (MDGs) by assisting governments and organizations to ensure equitable access to efective medicines of assured quality, and their rational use by prescribers and consumers.	Medicinal Products for Human Use[1] Medical Devices	Afghanistan; Albania; Algeria; Andorra; Angola; Antigua and Barbuda; Argentina; Armenia; Australia; Australia; Azerbaijan; Bahamas; Bahrain; Bangladesh; Barbados; Belarus; Belgium; Belize; Benin; Bhutan; Bolivia (Plurinational State of); Bosnia and Herzegovina; Botswana; Brazil; Brunei Darussalam; Bulgaria; Burkina Faso; Burundi; Cabo Verde; Cambodia; Cameroon; Canada; Central African Republic; Chad; Chile; China; Colombia; Comoros; Congo; Cook Islands; Costa Rica; Côte d'Ivoire; Croatia; Cuba; Cyprus; Czech Republic; Democratic People's Republic of Korea; Democratic Republic of the Congo; Denmark; Djibouti; Dominica; Dominican Republic; Ecuador; Egypt; El Salvador; Equatorial Guinea; Eritrea; Estonia; Ethiopia; Fiji; Finland; France; Gabon; Gambia; Georgia; Germany; Ghana; Greece; Grenada; Guatemala; Guinea; Guinea-Bissau; Guyana; Haiti; Honduras; Hungary; Iceland; India; Indonesia; Iran (Islamic Republic of); Iraq; Ireland; Israel; Italy; Jamaica; Japan; Jordan; Kazakhstan; Kenya; Kiribati; Kuwait; Kyrgyzstan; Lao People's Democratic Republic; Latvia; Lebanon; Lesotho; Liberia; Libya; Lithuania; Luxembourg; Madagascar; Malawi; Malaysia; Maldives; Mali; Malta; Marshall Islands; Mauritania; Mauritius; Mexico; Micronesia (Federated States of); Monaco; Mongolia; Montenegro; Morocco; Mozambique; Myanmar; Namibia; Nauru; Nepal; Netherlands; New Zealand; Nicaragua; Niger; Nigeria; Niue; Norway; Oman; Pakistan; Palau; Panama; Papua New Guinea; Paraguay; Peru; Philippines; Poland; Portugal; Qatar; Republic of Korea; Republic of Moldova; Romania; Russian Federation; Rwanda; Saint Kitts and Nevis; Saint Lucia; Saint Vincent and the Grenadines; Samoa; San Marino; Sao Tome and Principe; Saudi Arabia; Senegal; Serbia; Seycheller; Sierra Leone; Singapore; Slovakia; Slovenia; Solomon Islands; Somalia; South Africa; South Sudan; Spain; Sri Lanka; Sudan; Suriname; Swaziland; Sweden; Switzerland; Syrian Arab Republic; Tajikistan; Thailand; The former Yugoslav Republic of Macedonia; Timor-Leste; Togo; Tonga; Trinidad and Tobago; Tunisia; Turkey; Turkmenistan; Tuvalu; Uganda; Ukraine; United Arab Emirates; United Kingdom; United Republic of Tanzania; United States of America; Uruguay; Uzbekistan; Vanuatu; Venezuela (Bolivarian Republic of); Viet Nam; Yemen; Zambia; Zimbabwe	N/A	1. Medicines Policy: • Governance and Country Collaboration • Medicines Policy • Essential Medicines and Human Rights • Monitoring and Evaluation • Technical Briefing Seminars • Country and Regional Medicines Projects • Good Governance in the Pharmaceutical sector • Pharmaceutical Country Profile • Information and Publications. 2. Quality Assurance and Safety: • Medicines International Nonproprietary Names • Quality Assurance • Blood Products and Related Biologicals • Spurious/falsely-labelled/falsified/counterfeit (SFFC) medicines • Regulatory Support • Safety and Efficacy • The International Pharmacopoeia, Prequalification of medicines; Regulation 3. Medicine Access and Rational Use: • Access to Non Communicable Diseases Medicines • Antimicrobial Resistance • Better Medicines for Children • Controlled Substances • Medicine Pricing and Financing • Medicines Supply • Rational Use • Selection. 4. Quality, Safety & Standards	empinfo@who.int

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7	**CIOMS** **Council for International Organizations of Medical Sciences**	To facilitate and promote international activities in the field of biomedical sciences; to maintain collaborative relations with the United Nations and its specialized agencies, in particular with WHO and UNESCO; and to serve the scientific interests of the international biomedical community in general.	Medicinal Products for Human Use[1]	International Members: World Allergy Organization; International College of Angiology International Society of Audiology; International Union of Basic and Clinical Pharmacology (IUPHAR); International Association of Bioethic; International Society of Internal Medicine; International Federation of Otorhinolaryngological Societies; World Association of Societies of Pathology and Laboratory Medicine (WASPaLM); International Society for Pharmacoepidemiology (ISPE); International Society of Pharmacovigilance (ISOP); World Psychiatric Association; International Rhinologic Society; World Federation for Ultrasound in Medicine and Biology; Medical Women's International Association; World Medical Association. National Members: Belgium - Comité des Académies Royales de Médecine; Bulgaria - Union of the Scientific Medical Societies of Bulgaria; Czech Republic - Czech Medical Association; Germany - Association of the Scientific Medical Societies in Germany; Israel -The Israel Academy of Sciences and Humanities; Republic of Korea - Korean Academy of Medical Sciences; Kuwait - Islamic Organization for Medical Sciences (IOMS); Netherlands - Royal Netherlands Academy of Arts and Sciences; Norway -The Research Council for Norway/The National Committee for Medical Research Ethics; South Africa - South African Medical Research Council; Switzerland - Swiss Academy of Medical Sciences Associate Members: Medical Sciences Society (MSS-UQ) of Queensland University, Haiti; American Society for Bioethics and Humanities; Consulta di Bioetics; American College of Chest Physicians; World Federation of Chiropractic; International Federation of Clinical Chemistry and Laboratory; Medicine; World Organization of Family Doctors (WONCA); Good Clinical Practice - Alliance International Council for Laboratory Animal; Science (ICLAS); International Society of Hepatic Encephalopathies & Nitrogen Metabolisim (ISHEN); Academy of Medical, Dental and Pharmaceutical; Sciences of Japan; The World Association for Medical Law; International Union of Microbiological Societies; Asia Pacific Academy of Ophthalmology; International Union of Physiological Sciences; Federation of Polish Medical Organizations Abroad; Federation of Polish Medical Societies; International Medical Sciences Academy; National Fund for Scientific Research (NSFR); International Federation of Medical Student Associations	N/A	1. Long-term programmes on Drug Development and Use: • Safety requirements for the use of drugs; • Assessment and monitoring of adverse drug reactions (Pharmacovigilance) and pharmacogenetics, with recommendations on: international reporting of adverse drug reactions - introduction of the standardized "CIOMS I reporting form", international reporting of periodic drug-safety updates (PSUR), core clinical safety information on drugs, evaluation of benefit/risk balance, current challenges of pharmacovigilance, management of safety information from clinical trials and development safety update report (DSUR)and signal detection in pharmacovigilance 2. Working Groups dedicated to pharmacogenetics, standardised MedDRA Queries (SMQs), reporting and terminology of adverse drug reactions, vaccine pharmacovigilance, drug development research and pharmacovigilance in resource-poor countries 3. International Workshops	info@cioms.ch
8	**OECD** **Organisation for Economic Co-operation and Development - Health Division**	To achieve high-performing health systems and policies by measuring health outcomes and health system resource use and by analysing policies that improve access, efficiency and quality of health care. Additionally, OECD is looking into how to encourage and foster innovation which addresses health needs and priorities, maximises access to the benefits, and manages the challenges and risks in a way that is beneficial for both, innovators and health systems.	Health policies Medicinal Products for Human Use[1]	Australia, Austria, Belgium, Canada, Chile, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom, United States.	N/A	Policy analysis and statistical information on health policies (Biotechnology policies and Health policies and data), including working areas such as: 1. Improving comparative data on health policies and outcomes; 2. Enhancing the Quality of health care 3. Getting better value for money in health spending 4. The Economics of disease prevention and the Health workforce 5. Biotechnology: • Task Force on Biomedicine and Health Innovation • Biomarkers and Targeted Therapies • High-Level Forum on Medicines for Infectious Diseases • Regulatory Frameworks for Nanotechnology • Pharmacogenetics 6. Pharmaceuticals: • Requirements on the Guidelines and Principles of Good Laboratory Practice (GLP) • Recommendations on the regulatory harmonisation of Clinical Trials, Publications on Opportunities and Challenges for Health Innovation and Care, and Pharmaceutical Pricing Policies	https://www.oecd.org/contact/#
9	**International Regulators Consortium Initiative**	To promote greater regulatory harmonisation and collaboration, focused on the alignment of regulatory requirements. Its goal is to maximise international cooperation, reduce duplication, and increase each agency's capacity to ensure consumers have timely access to high quality, safe and effective therapeutic goods.	Medicinal Products for Human Use[1] Medical Devices	Therapeutic Goods Administration (TGA) of Australia Health Products and Food Branch (HPFB) of Health Canada Health Sciences Authority (HSA) of Singapore Swissmedic, Swiss Agency for Therapeutic Products, of Switzerland	N/A	Regulatory work-sharing initiatives including but not limited to: 1. Good Manufacturing Practices (GMPs) 2. Good Review Practices (GRPs) 3. Post-market medicines safety and surveillance 4. Assessment reports for pharmaceuticals including generic drugs and new chemical entities 5. Coordination of involvement of technical experts in the International Conference on Harmonisation (ICH) working groups (regulatory and guidelines harmonisation), and the collaboration on the Information Technology (IT)-architecture 6.Pilot generic medicines work-sharing program	N/A

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10	**EDQM** **Council of Europe - The European Directorate for the Quality of Medicines & HealthCare**	To contribute to the basic human right of access to good quality medicines and healthcare, achieving harmonisation of the quality of medicines throughout the European continent and beyond, and to promote and protect human and animal health.	Medicinal Products for Human Use [1] Medicinal Products for Veterinary Use Healthcare products: blood transfusion; transplantation of organs, tissues and cells; cosmetics and food packaging; pharmaceutical care	38 Members (including the EU and its Member States) : Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom, European Union 27 Observers: Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Belarus, Brazil, Canada, China, Georgia, Israel, Kazakhstan, Madagascar, Malaysia, Moldova, Morocco, Republic of Guinea, the Russian Federation, Senegal, Singapore, South Africa, Syria, Tunisia, the United States of America, the Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare, World Health Organization (WHO)	N/A	1. Establishment and provision of official standards which apply to the manufacture and quality control of medicines in all signatory States of the "Convention on the Elaboration of a European Pharmacopoeia" and beyond 2. Ensuring the application of these official standards to substances used in the production of medicines through the Certification of suitability to the monographs of the European Pharmacopoeia Scheme 3. Co-ordination of a network of Official Medicines Control Laboratories (OMCL) to collaborate and share expertise among Member States and to effectively use limited resources (surveillance of marketed medicines) 4. Proposing ethical, safety and quality standards: • For the collection, preparation, storage, distribution and appropriate use of blood components in blood transfusion; • For the transplantation of organs, tissues and cells 5. Collaboration of with national, European and international organisations in efforts to combat counterfeiting of medical products and similar crimes 6. Provision of policies and model approaches for the safe use of medicines in Europe, including guidelines on pharmaceutical care 7. Establishment of standards and co-ordination of controls for cosmetics and food packaging	N/A
11	**EMRN** **European medicines regulatory network**	To protect and promote public and animal health in Europe, working to foster an effective and efficient European medicines regulatory system.	Medicinal Products for Human Use [1] Medicinal Products for Veterinary Use	28 EU Member States: 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 European Medicines Agency (EMA) European Commission (DG SANTE)	N/A	(Non-Exhaustive list) 1. Single Assessment + Inspection 2. Common Assessments 3. Harmonised scientific + Regulatory Guidelines 4. Benchmarking 5. Mutual Audits 6.Trainings 7. Information Sharing 8. Common Communication 9. Policies 10. Common Standards and Procedures 11. Scientific Networks	EMA: info@ema.europa.eu
12	**EAC - MRH** **East African Community Medicines Registration Harmonization Project**	To achieve medicines regulatory harmonisation and to improve public health by increasing rapid access to good quality, safe and effective medicines by harmonising regulation systems and procedures in accordance with national and international policies and standards, and consequently by reducing the time taken to register essential medicines for the treatment of priority diseases. This project is part of the African Medicines Registration Harmonisation (AMRH) Programme created to assist African countries and regions to respond to the challenges posed by medicines registration.	Medicinal Products for Human Use[1] Medicinal Products for Veterinary Use	Republics of Kenya ; Uganda; United Republic of Tanzania; Republic of Rwanda; Republic of Burundi	N/A	1. Common technical document for registration of medicines 2. Common information management system (IMS) for medicines registration 3. Quality management system in each EAC Partner States National Medicines Regulatory Authorities (NMRA's) 4. Platform for information sharing on the harmonized registration system to key stakeholders 5. Framework for mutual recognition of regulatory decisions	health@eachq.org

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13	**SADC Southern African Development Community - Pharmaceutical Harmonisation Initiative**	To improve the quality, safety and efficacy of medicines circulating within the region, and to establish and maintain a regional shared network system for regulatory authorities	Medicinal Products for Human Use[1]	Angola, Botswana, Democratic Republic of Congo (DRC), Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, United Republic of Tanzania, Zambia, Zimbabwe	N/A	Development of technical guidelines and policies, relating to the registration and control of medicines across the SADC Member States: 1. Application Form for Registration of Medicinal Products; 2. Registration of Medicinal Products; 3. Stability Study; 4. Good Manufacturing Practices; 5. Bioequivalence/Bioavailability; 6. HIV Vaccine Clinical Trials; 7.Registration of Nutritional Supplements; 8. Validation, Advertising and Licensing; 9. Post-marketing Surveillance; 10. Registration of Vaccines; 11. Regulation of Traditional Medicines; To support their implementation, regional training programmes will be developed.	registry@sadc.int
14	**ZiZaBoNa Zimbabwe, Zambia, Botswana, Namibia, Transmission project**	1. Interconnect the four countries; Create an alternative wheeling path between north and sout 2. Decongest the central transmission corridor	Medicinal Products for Human Use 1 Medicinal Products for Veterinary Use	Zimbawe, Zambia, Botswana and Namibia	N/A	1. Collaboration among regulators 2. Innovative pathway to expedited Regulatory Approval 3. Work-sharing	musaba@sapp.co.zw
15	**EAMI Network The Ibero-American Medicines Authorities Network**	Forum to discuss and technical information exchange, organisational information, experiences and best regulatory practices between the member countries/Competent Authorities, in order to ensure the quality, safety and efficacy of medicinal products.	Medicinal Products for Human Use[1]	22 National Competent Authorities: Central and South America: Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Dominican Republic, Uruguay and Venezuela Europe: Spain, Portugal, Andorra	N/A	1. Fight against fraudulent and falsified medicines in Ibero American countries - ONLINE Rapid Alert and Exchange of Information System of Falsified and Fraudulent Medicines in Ibero - American Countries (FALFRA System). 2. Reinforcing pharmacovigilance in Ibero American countries - Regional Pharmacovigilance System for Central America and Dominican Republic; training courses. 3. Reinforcing bioequivalence in Ibero American countries. 4. Ibero American Formulary for medicinal products prepared in pharmacies. 5. Protection of subjects involved in clinical research	https://www.redeami.net/web/contenedor_general/eami_conten_contacto.htm
16	**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 Use[1]	Drug regulatory authorities of all 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 and representatives from the five sub-regional trade integration groups within the Americas such as the ANDEAN COMMUNITY, CARICOM, SICA, MERCOSUR, NAFTA	N/A	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).	N/A
17	**ASEAN PPWG Association of Southeast Asian Nations Pharmaceutical Product Working Group**	To develop pharmaceutical regulatory harmonisation schemes of the ASEAN Member countries in order to complement and facilitate the objective of AFTA (ASEAN Free Trade Area), particularly, the elimination of technical barriers to trade posed by regulations, without compromising on drug quality, efficacy, and safety. The scope of its work integrates the discussion of existing technical guidelines and regulatory requirements; the study of harmonised procedures and regulatory systems currently implemented; and the development of CTDs with a view to arriving at Mutual Recognition Arrangement (MRAs).	Medicinal Products for Human Use[1]	Brunei Darussalam; Cambodia; Indonesia; Laos; Malaysia; Myanmar; Phillipines; Singapore; Thailand; Vietman	N/A	1. ASEAN Common Technical Requirement (ACTR), guidelines, seminars, tranings 2. ASEAN Common Technical Dossier (ACTD), seminars, trainings 3. ASEAN Glossary of Terms 4. Process and Analytical Validation, and Bioavailability/Bioequivalence, Stability, Safety and Efficacy Studies 5. Harmonising Regulation of Traditional Medicines and Health Supplements Ahead of ASEAN Integration 6. ASEAN Good Manufacturing Practice (GMP) guidelines 7. Post-market allert system 8. Establish working groups, and product working groups 9. ASEAN-MRA (Mutual Recognition Arrangement) for GMP Inspections	public@asean.org

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18	**APEC LSIF RHSC Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum - Regulatory Harmonization Steering Committee**	To achieve regulatory harmonisation for medical products, promoting a more strategic, effective and sustainable approach of harmonisation within the APEC region.	Medicinal Products for Human Use[1] Medical Devices	Regulatory bodies members: Canada, United States, China, Japan, Republic of Korea, Chinese Taipei, Thailand, Singapore, Peru Industry members from the APEC member economies Director of the APEC Harmonization Center(AHC)	N/A	Adoption and implementation of harmonised international guidances and regulatory best practices (regulatory harmonisation initiatives, trainings, actions plans and roadmaps)	info@apec.org
19	**GCC-DR Gulf Central Committee for Drug Registration Harmonisation Initiative**	To promote Regulatory Harmonisation, developing harmonised technical guidelinesand regulatory processes in order to provide to Gulf States a safe and effective medication with reasonable price	Medicinal Products for Human Use[1]	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates (UAE). Yemen is a member in the Health Council.	N/A	1. The development of technical guidelines and regulatory processes, which include the registration of pharmaceutical companies and products, as well GMP inspection. 2. Training in the areas of GMP and post-market surveillance, and other areas where training for Member States is required.	N/A

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