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An agency of the European Union

December 2016
EMA/530778/2015
International Affairs

ICMRA - Mapping of pharmacovigilance initiatives

	Initiative	Objectives related to Pharmacovigilance initiatives	Scope	Membership	Frequency of meetings	Work Products	Contact Point
1	**ICH International Conference on Harmonisation**	1. To provide standardised definitions and methodology procedures. 2. To aid in planning pharmacovigilance activities. 3. To facilitate sharing of regulatory information internationally for medical products used by humans, by applying the MedDRA terminology on the pharmacovigilance systems (classification, retrieval, presentation, risk-benefit evaluation and assessment) and for medication error reporting (electronic exchange and communication). 4. To facilitate international electronic communication, such as on pharmacovigilance, by evaluating and recommending open and non-proprietary electronic standards.	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 and 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)	Meetings of Steering Committee and Expert Working Groups twice yearly.	1. Definitions and standards for expedited reporting on clinical safety data management 2. Electronic transmission of individual case safety reports (ICSRs) on clinical safety data management 3. Periodic safety update reports for marketed drugs 4. Periodic benefit-risk evaluation report 5. Post-approval safety data management 6. Pharmacovigilance Planning (Pvp) 7. Development of safety update report 8. The Medical Dictionary for Regulatory Activities Terminology (MedDRA) 9. Electronic Standards for the Transfer of Regulatory Information (ESTRI-Gateway) 10. Regular Pharmacovigilance Trainings/Seminars 11. IDMP	ICH Secretariat admin@ich.org
2	**GVSI The Global Vaccine Safety Initiative**	To provide a framework for enhancing vaccine pharmacovigilance implementing the Blueprint strategy. The blueprint aims to ensure that all countries have at least a minimal capacity to monitor vaccine safety. This comprises a framework of eight strategic objectives aimed at enhancing global vaccine safety activities. The strategic objectives focus on building and supporting a systemic approach to vaccine pharmacovigilance in all low- and middle-income countries.	Medicinal Products for Human Use[1] Medical Devices	Academic institutions Governmental health institutions, including immunization programmes, pharmacovigilance centres and national agencies involved in regulatory activities Individual with expertise related to the mission of the GVSI Intergovernmental organizations, including World Health Organization[2] International industry associations/umbrella organizations that have a demonstrated interest and experience in vaccine safety Non-governmental organizations Planning Group (a strategic group - SPG members - from the Brighton Collaboration Foundation in Switzerland; the University of Ghana; the JSS University of Mysore in India; the National Regulatory Authority of Chile; the Uppsala Monitoring Centre in Sweden; the Monash Children's Hospital in Australia) WHO Collaborating Centres	GVSI Meeting is expected to meet at least once a year.	1. IT tools for AEFI reporting, collection, management and analysis 2. IT bridges among existing softwares to ensure regional data safety collection and analysis 3. Harmonization Strategies, Guidance, Guidelines, SOPs and Global manuals; Surveillance Systems and performance indicators 4. Safety Studies/Analysis, Monitoring Initiatives and Collaboration programmes 5. Design of pilot projects to enhance capacity of National Pharmacovigilance programs 6. Standard AEFI Investigation form; Public Assessments 7. Vaccine Safety Net; Vaccine Pharmacovigilance Toolkit 8. Databases and Datasets 9. Global learning resource centre Web-platform 10. Globally harmonized mechanism for the collection and exchange of information. 11. Global Workshops, Courses, Trainings and Symposiums	gvsi@who.int
3	**Developing Country Vaccines Regulatory Network**	To support and promote the strengthening of the regulatory oversight during the clinical development of vaccines, authorization and inspection of clinical trials, evaluation of investigational products, evaluation of registration dossiers and post-market surveillance in developing countries.	Vaccines for human use	Brazil, Cuba, India, Indonesia, Islamic Republic of Iran, People's Republic of China, Republic of Korea, South Africa, Thailand.	Once a year	1. Encourage and facilitate information exchange among the NRAs on national laws, regulations and establish guidelines and policies relating to the regulatory control of domestic or imported vaccines 2. Develop guidelines or procedures relevant to the regulatory oversight during clinical development of vaccines, authorization and inspection of clinical trials or evaluation of registration dossier 3. Discuss NRA policies aimed at advancing mutual understanding of their respective levels of expertise and identify the potential for collaboration and joint regulatory activities 4. Identify internationally recognized standards consistent with WHO guidelines for clinical evaluation of vaccines 5. Promote information exchange	vaccprequalification@who.int

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4	**WHO Collaborating Centre for International Drug Monitoring - The Uppsala Monitoring Centre**	The aim is to support detection, as early as possible, of potential issues of importance for patients and public health in relation to the use and safety of medicines, supporting effective communication of the most focussed, up-to-date scientific information and providing tools for data entry, management, retrieval, reference and research; Education and training in setting up and running national pharmacovigilance programmes, as well as in using the UMC Tools.	Medicinal Products for Human Use[1] and Medical Devices	Official Member Countries (122) Andorra, Angola,, Argentina, Armenia, Australia, Austria, Bangladesh, Barbados, Belarus, Belgium, Benin, Bhutan, Bolivia, Botswana, Brunei Darussalam, Bulgaria, Burkina Faso, Cambodia, Cameroon, Canada, Cape Verde, Chile, China, Colombia, Dem Rep of Congo, Costa Rica, Côte d'Ivoire, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Egypt, Eritrea, Estonia, Ethiopia, Fiji, Finland, France, Germany, Ghana, Greece, Guatemala, Guinea, Hungary, Iceland, India, Indonesia, Islamic Republic of Iran, Iraq, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Republic of Korea, Kyrgyzstan, Lao People's Democratic Republic, Latvia, Liberia, Lithuania, The Former Yugoslav Republic of Macedonia, Madagascar, Malaysia, Malta, Mauritius, Mexico, Republic of Moldova, Montenegro, Morocco, Mozambique, Namibia, Nepal, Netherlands, New Zealand, Niger, Nigeria, Norway, Oman, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, Rwanda, Saudi Arabia, Senegal, Serbia, Sierra Leone, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, United Republic of Tanzania, Thailand, Togo, Tunisia, Turkey, Uganda, Ukraine, United Arab Emirates, United Kingdom, Uruguay, U.S.A., Uzbekistan, Venezuela, Vietnam, Zambia, Zimbabwe Associate Members (28) Afghanistan, Albania, Algeria, Anguilla, Antigua & Barbuda, Azerbaijan, Bahrain, Bosnia and Herzegovina, British Virgin Islands, Burundi, Dominica, Gambia, Georgia , Grenada, Guinea-Bissau, Maldives,Mongolia, Montserrat, Pakistan, Panama, Papua New Guinea, Qatar, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Syrian Arab Republic, Tajikistan, Zanzibar	Annual Meetings	1. Initiatives promoting Pharmacovigilance programmes 2. ADR reporting forms 3. Pharmacovigilance Toolkit 4. Data-mining approach (IC analysis) to support the clinical analysis; information exchange mechanisms between WHO, UMC and National Centres, mainly through 'Vigimed' - an internet based information exchange system 5. Publication of periodicals, newsletters, (WHO Pharmaceuticals Newsletter and Uppsala Reports), Guidelines, Guides, Best Practicesand books in the pharmacovigilance and risk management area 6. Tools for management of clinical information including individual case safety reports such as WHO Drug Dictionary and the WHO Adverse Reaction Terminology - WHO-ART 7. Consultancy support to National Centres and countries establishing pharmacovigilance systems 8. Computer software for case report management designed to suit the needs of National Centres (VigiFlow) 9. Database VigiBase	info@who-umc.org pals@who.int
5	**WHO Collaborating Centre for Drug Statistics and Methodology - The Norwegian Institute of Public Health**	Responsible for developing, updating and maintaining the ATC/DDD classification system for medicines.	Medicinal Products for Human Use[1]	Official Member Countries (122) Andorra, Angola,, Argentina, Armenia, Australia, Austria, Bangladesh, Barbados, Belarus, Belgium, Benin, Bhutan, Bolivia, Botswana, Brunei Darussalam, Bulgaria, Burkina Faso, Cambodia, Cameroon, Canada, Cape Verde, Chile, China, Colombia, Dem Rep of Congo, Costa Rica, Côte d'Ivoire, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Egypt, Eritrea, Estonia, Ethiopia, Fiji, Finland, France, Germany, Ghana, Greece, Guatemala, Guinea, Hungary, Iceland, India, Indonesia, Islamic Republic of Iran, Iraq, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Republic of Korea, Kyrgyzstan, Lao People's Democratic Republic, Latvia, Liberia, Lithuania, The Former Yugoslav Republic of Macedonia, Madagascar, Malaysia, Malta, Mauritius, Mexico, Republic of Moldova, Montenegro, Morocco, Mozambique, Namibia, Nepal, Netherlands, New Zealand, Niger, Nigeria, Norway, Oman, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, Rwanda, Saudi Arabia, Senegal, Serbia, Sierra Leone, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, United Republic of Tanzania, Thailand, Togo, Tunisia, Turkey, Uganda, Ukraine, United Arab Emirates, United Kingdom, Uruguay, U.S.A., Uzbekistan, Venezuela, Vietnam, Zambia, Zimbabwe Associate Members (28) Afghanistan, Albania, Algeria, Anguilla, Antigua & Barbuda, Azerbaijan, Bahrain, Bosnia and Herzegovina, British Virgin Islands, Burundi, Dominica, Gambia, Georgia , Grenada, Guinea-Bissau, Maldives,Mongolia, Montserrat, Pakistan, Panama, Papua New Guinea, Qatar, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Syrian Arab Republic, Tajikistan, Zanzibar	N/A	1. The Norwegian WHOCC also provide technical support, training courses and lectures to member countries using the ATC/DDD codes within their pharmacovigilance systems. 2. They also publish guidelines of ATC classification and DDD assignment.	whocc@fhi.no
6	**WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance - The Centre for Tropical Clinical Pharmacology and Therapeutics, University of Ghana Medical School**	Focus on providing pharmacovigilance training in African countries, building capacity, promoting advocacy and strengthening reporting.	Medicinal Products for Human Use[1]	WHO members with focus on African countries Official Member Countries (122) Andorra, Angola,, Argentina, Armenia, Australia, Austria, Bangladesh, Barbados, Belarus, Belgium, Benin, Bhutan, Bolivia, Botswana, Brunei Darussalam, Bulgaria, Burkina Faso, Cambodia, Cameroon, Canada, Cape Verde, Chile, China, Colombia, Dem Rep of Congo, Costa Rica, Côte d'Ivoire, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Egypt, Eritrea, Estonia, Ethiopia, Fiji, Finland, France, Germany, Ghana, Greece, Guatemala, Guinea, Hungary, Iceland, India, Indonesia, Islamic Republic of Iran, Iraq, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Republic of Korea, Kyrgyzstan, Lao People's Democratic Republic, Latvia, Liberia, Lithuania, The Former Yugoslav Republic of Macedonia, Madagascar, Malaysia, Malta, Mauritius, Mexico, Republic of Moldova, Montenegro, Morocco, Mozambique, Namibia, Nepal, Netherlands, New Zealand, Niger, Nigeria, Norway, Oman, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, Rwanda, Saudi Arabia, Senegal, Serbia, Sierra Leone, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, United Republic of Tanzania, Thailand, Togo, Tunisia, Turkey, Uganda, Ukraine, United Arab Emirates, United Kingdom, Uruguay, U.S.A., Uzbekistan, Venezuela, Vietnam, Zambia, Zimbabwe. Associate Members (28) Afghanistan, Albania, Algeria, Anguilla, Antigua & Barbuda, Azerbaijan, Bahrain, Bosnia and Herzegovina, British Virgin Islands, Burundi, Dominica, Gambia, Georgia , Grenada, Guinea-Bissau, Maldives,Mongolia, Montserrat, Pakistan, Panama, Papua New Guinea, Qatar, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Syrian Arab Republic, Tajikistan, Zanzibar	Annual conferences	1. Activities to support countries and promote communication and advocacy of pharmacovigilance include: hosting annual workshops, visiting countries to assess national centres, and developing high-level training material and risk management plans. 2. The Centre develops, hosts and maintains a pharmacovigilance Toolkit. The Toolkit provides links to publications, handbooks, e-learning courses, and guidelines. There are specific tool-kits for pharmacovigilance in HIV, malaria and immunization programmes. 3. The Accra Centre works with the WHO/SAV to provide support for countries conducting cohort event monitoring (CEM) and other active surveillance studies of new medicines and vaccines.	info@who-pvafrica.org
7	**WHO Collaborating Centre for Pharmacovigilance - Centre Anti Poison et de Pharmacovigilance du Maroc**	Assistsing WHO by building capacity in the eastern Mediterranean, francophone and Arabic countries.	Medicinal Products for Human Use[1]	WHO members with focus on African countries Official Member Countries (122) Andorra, Angola,, Argentina, Armenia, Australia, Austria, Bangladesh, Barbados, Belarus, Belgium, Benin, Bhutan, Bolivia, Botswana, Brunei Darussalam, Bulgaria, Burkina Faso, Cambodia, Cameroon, Canada, Cape Verde, Chile, China, Colombia, Dem Rep of Congo, Costa Rica, Côte d'Ivoire, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Egypt, Eritrea, Estonia, Ethiopia, Fiji, Finland, France, Germany, Ghana, Greece, Guatemala, Guinea, Hungary, Iceland, India, Indonesia, Islamic Republic of Iran, Iraq, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Republic of Korea, Kyrgyzstan, Lao People's Democratic Republic, Latvia, Liberia, Lithuania, The Former Yugoslav Republic of Macedonia, Madagascar, Malaysia, Malta, Mauritius, Mexico, Republic of Moldova, Montenegro, Morocco, Mozambique, Namibia, Nepal, Netherlands, New Zealand, Niger, Nigeria, Norway, Oman, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, Rwanda, Saudi Arabia, Senegal, Serbia, Sierra Leone, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, United Republic of Tanzania, Thailand, Togo, Tunisia, Turkey, Uganda, Ukraine, United Arab Emirates, United Kingdom, Uruguay, U.S.A., Uzbekistan, Venezuela, Vietnam, Zambia, Zimbabwe Associate Members (28) Afghanistan, Albania, Algeria, Anguilla, Antigua & Barbuda, Azerbaijan, Bahrain, Bosnia and Herzegovina, British Virgin Islands, Burundi, Dominica, Gambia, Georgia , Grenada, Guinea-Bissau, Maldives,Mongolia, Montserrat, Pakistan, Panama, Papua New Guinea, Qatar, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Syrian Arab Republic, Tajikistan, Zanzibar	Annual training course	1. To facilitate regional and national training courses in this geographical area and also support normative functions to promote patient safety. 2. The annual training course covers topics such as VigiFlow, causality assessments, pharmacovigilance of herbal medicines, patient safety, vaccines, and medication errors. 3. The Rabat Centre is also involved in projects aimed at integrating patient safety reporting systems across different types of health facilities; and pharmacovigilance in public health programmes such as multi-drug resistant TB treatment programmes. 4. The Rabat Centre supports WHO in developing appropriate guidelines, tools and methods to detect and minimize medication errors through pharmacovigilance. The Centre also surveys and evaluates performance and development of pharmacovigilance systems in Africa.	N/A	

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8	**WHO Collaborating Centre for Pharmacovigilance in Education and Patient Reporting - The Netherlands Pharmacovigilance Centre Lareb**	Focus on the process and scientific evaluation of patient spontaneous reporting.	Medicinal Products for Human Use[1]	Official Member Countries (122) Andorra, Angola,, Argentina, Armenia, Australia, Austria, Bangladesh, Barbados, Belarus, Belgium, Benin, Bhutan, Bolivia, Botswana, Brunei Darussalam, Bulgaria, Burkina Faso, Cambodia, Cameroon, Canada, Cape Verde, Chile, China, Colombia, Dem Rep of Congo, Costa Rica, Côte d'Ivoire, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Egypt, Eritrea, Estonia, Ethiopia, Fiji, Finland, France, Germany, Ghana, Greece, Guatemala, Guinea, Hungary, Iceland, India, Indonesia, Islamic Republic of Iran, Iraq, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Republic of Korea, Kyrgyzstan, Lao People's Democratic Republic, Latvia, Liberia, Lithuania, The Former Yugoslav Republic of Macedonia, Madagascar, Malaysia, Malta, Mauritius, Mexico, Republic of Moldova, Montenegro, Morocco, Mozambique, Namibia, Nepal, Netherlands, New Zealand, Niger, Nigeria, Norway, Oman, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, Rwanda, Saudi Arabia, Senegal, Serbia, Sierra Leone, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, United Republic of Tanzania, Thailand, Togo, Tunisia, Turkey, Uganda, Ukraine, United Arab Emirates, United Kingdom, Uruguay, U.S.A., Uzbekistan, Venezuela, Vietnam, Zambia, Zimbabwe. Associate Members (28) Afghanistan, Albania, Algeria, Anguilla, Antigua & Barbuda, Azerbaijan, Bahrain, Bosnia and Herzegovina, British Virgin Islands, Burundi, Dominica, Gambia, Georgia , Grenada, Guinea-Bissau, Maldives,Mongolia, Montserrat, Pakistan, Panama, Papua New Guinea, Qatar, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Syrian Arab Republic, Tajikistan, Zanzibar	Conference on Patient Reporting	1. Its role is to assist WHO in training Member Countries on how to handle patient reports. It holds workshops and hosts visitors at the Centre to share their experiences of patient reporting. Support is provided to countries with patient reporting by providing information and feedback. The Lareb Collaborating Centre offers training on practical aspects of collecting information about adverse drug reactions and on patient reporting. 2. The Centre also conducts research on the contribution of patient reports to pharmacovigilance. The research is conducted in collaboration with the University of Groninge. Further to the work involving patient reports, the Centre promotes pharmacovigilance education in academia by developing and maintaining a curriculum for medical, pharmacy and paramedical students. A project collecting information on the content of pharmacovigilance core curricula is in process and the Lareb Centre will organize workshops for Member Countries within the WHO Programme for International Drug Monitoring to discuss the curriculum.	whocc@lareb.nl.
9	**ISoP International Society of Pharmacogivilance**	ISoP aims to foster science and learning in pharmacovigilance and enhance all aspects of the safe and proper use of medicines, in all countries, by providing opportunities for networking in a friendly environment, convivial support among fellow pharmacovigilance professionals, an open and impartial forum for sharing experience and knowledge, a platform for discussion and generation of new research and ideas, meetings, education and affordable training.	Medicinal Products for Human Use[1]	Argentina, Australia, Austria, Bahrain, Belgium, Bosnia and Herzegowina, Brazil, Bulgaria, Cambodia, Canada, Chile, China, Congo,, Croatia, Czech Republic, Denmark, Egypt, Finland, France, Germany, Ghana, Greece, Hong Kong, Hungary, India, Iran, Iraq, Ireland, Italy, Japan, Jordan, Kyrgyzstan, Mali, Mexico, Morocco, Nepal, Netherlands, New Zealand, Nigeria Norway, Panama, Philippines, Poland, Portugal, Romania, Saudi Arabia, Serbia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Tunisia, Turkey, UAE United Arab Emirates, United Kingdom, Uruguay, USA and Venezuela	ISoP Annual Meetings	1. An open forum for sharing experience and knowledge 2. A Platform for discussion and generation of new research and ideas 3. Publication of the Drug Safety Journal and Guidelines for Submitting Adverse Event Reports (under the joint ISoP-ISPE group) 4. Currently established SIGs (groups of ISoP members) on 'Risk communication', 'Women's medicines', and a new SIG 'Risk minimisation in Asia' 5. ISoP trainings/courses and ISoP ETP (Education Training Programme)	administration@isoponline.org
10	**ISPE International Society for Pharmacoepidemiology**	ISPE aims to advance the health of the public by providing an International forum for the open exchange of scientific information among academia, government, and industry and for the development of policy; education; and advocacy for the field of pharmacoepidemiology, including pharmacovigilance, drug utilization research, outcomes research, comparative effectiveness research, and therapeutic risk management.	Medicinal Products for Human Use[1] and Medical Devices	Government/Regulatory Agency Department of Epidemiology, Lazio Regional Health Service Pharmaceutical Industry F. Hoffmann-LaRoche AG; GlaxoSmithKline; Sanofi-Aventis Service Providers RTI Health Solutions Non-profit and for-profit private organizations Academic Institutions Center for Drug Safety & Effectiveness, Department of Epidemiology, Johns Hopkins School of Public Health; Center for Drug Safety & Pharmaceutical Health Services Research Graduate Program, University of Maryland School of Pharmacy; Center for Pharmacoepidemiology Research and Training (CPeRT), Pereleman School of Medicine at the University of Pennsylvania; Department of Pharmaceutical Outcomes & Policy, College of Pharmacy, University of Florida; Division of Pharmacoepidemiology & Pharmacoeconomics, Brigham and Women's Hospital & Harvard Medical School; Drug Safety Research Unit, Associated Department, School of Pharmacy, Portsmouth University; Harvard School of Public Health; London School of Hygiene and Tropical Medicine; McGill Pharmacoepidemiology Research Unit, McGill University Pharmacoepidemiology Program, Department of Epidemiology, Gillings School of Global Public Health, University of North Carolina at Chapel Hill; Russian National Society of Evidence-Based Pharmacotherapy; Rutgers, The State University of New Jersey	1. Annual International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE) 2. Annual mid-year meeting 3. Annual Asian Conference on Pharmacoepidemiology (ACPE)	1. Committees (organizations programs, projects and special initiatives), Councils, SIGs (Special Interest Groups whic provide global forums, trainings, Databases, webpages) and Chapters (Regional and Students Chapters) 2. Guidance, Webinars, Conferences, Meeting Courses 3. EuroDURG (EU Drug Utilisation Research Group) 4. International Pharmacoepidemiology Legislation project 5. A quarterly newsletter, and an official journal — Pharmacoepidemiology and Drug Safety	ISPE@paimgmt.com mepstein@paimgmt.com
11	**CIOMS Council for International Organizations of Medical Sciences (non-profit organization established jointly by WHO and UNESCO)**	To facilitate and promote international biomedical scientific activities, for instance in pharmacovigilance practice, whilst maintaining a relationship with the United Nations organisation (particularly WHO and UNESCO).	Medicinal Products for Human Use1	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	Regular meetings	1. Long-term programmes on Drug Development and Use: Safety requirements for the use of drugs; Assessment and monitoring of adverse drug reactions (Pharmacovigilance), with recommendations on: international reporting of adverse drug reactions - "CIOMS I reporting form", international reporting of periodic drug-safety updates (PSUR), core clinical safety information on drugs, evaluation of benefit/risk balance, management of safety information from clinical trials and development safety update report (DSUR) and signal detection in pharmacovigilance. 2. Working Groups dedicated to pharmacovigilance, published CIOMS guidelines including: Definition and Application of Terms for Vaccine Pharmacovigilance Safety; Current Challenges in Pharmacovigilance: Pragmatic Approaches (CIOMS V); Development and Rational Use of Standardised MedDRA Queries (SMQs); Management of Safety Information from Clinical Trials (CIOMS VI); Development Safety Update Reports (CIOMS VII); Practical Aspects of Signal Detection in Pharmacovigilance (CIOMS VIII); Benefit-risk balance for marketed drugs (CIOMS IV); International Reporting of Periodic Drug Safety Update Summaries (CIOMS II); Guideline for Preparing Core Clinical Safety Information on Drugs (CIOMS III). 3. International Workshops	info@cioms.ch Secretary-General sjolinforsbergg@cioms.ch

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12	**SCOPE Strengthening Collaboration for Operating Pharmacovigilance in Europe**	SCOPE aims to help medicines regulators operate pharmacovigilance systems to the EU Legislative Requirements. Regulators collaborate to improve skills and capacity in the network which help safeguard public health in both national territories and the EU as a whole. The European Commission Joint Action is made up of eight work packages, three of which are 'horizontal', and the other five work packages are 'vertical'. These aim to deliver specific and measurable objectives, ranging from improvements in Adverse Drug Reaction reporting to assessment of quality management systems. 'This project will close in Q4 2016.	Medicinal Products for Human Use[1]	Work Package Leaders: Portugal, Croatia, Netherlands, Spain, Hungary, Italy, UK Topic Leaders: Sweden, Denmark, Ireland, Norway Active Partners: Lithuania, Czech Republic, Bulgaria, Greece Other Partners: Belgium, Finland, France, Estonia, Iceland, Latvia, Malta, Romania, Slovakia, Slovenia, Poland Collaborating Partners: University of Nottingham, Uppsala Monitoring Centre, University Medical Centre Groningen, Maastricht University, Netherlands Pharmacovigilance Centre Lareb	1. WP Leaders face to face annual meeting 2. General Advisory Board Face to face annual meeting 3. WP teams face to face biannual meetings 4. Multiple WP ad hoc teleconferences	1. Develop guidance, training in key aspects of pharmacovigilance, and best practices in reporting mechanisms for adverse drug reactions; signal management across the EU network; Risk Communications (through the creation of a standardised toolkit); for management and assessment, and measuring effectiveness of risk minimisation. 2. Provide training materials, living documents and templates which can be reviewed and adapted periodically. 3. Development of national reporting schemes. 4. Provide recommendations & tools and develop quality management systems for pharmacovigilance (requirements for pharmacovigilance system operation). 5. Forum for interaction amongst European National Competent Authorities to strengthen regulatory collaboration.	scope@mhra.gsi.gov.uk
13	**EudraVigilance European Union Drug Regulating Authorities Pharmacovigilance**	'Reporting and evaluating suspected adverse drug reactions (ADRs) during the development, and following the marketing authorisation of medicinal products in the European Economic Area (EEA).	Medicinal Products for Human Use1 in the European Economic Area (EEA)	EEA countries Active members: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom Provisional member: Croatia	N/A	1. Electronic exchange of Individual Case Safety Reports (ICSR, based on the ICH E2BM specifications): EudraVigilance Clinical Trial Module (EVCTM) for reporting Suspected Unexpected Serious Adverse Reactions (SUSARs); EudraVigilance Post-Authorisation Module (EVPM) for post-authorisation ICSRs. 2. Early detection of possible safety signals from marketed drugs for human use. 3. Continuous monitoring and evaluation of potential safety issues in relation to reported adverse reactions. 4. Decision making process, based on a broader knowledge of the adverse reaction profile of drugs.	EudraVigilance@ema.europa.eu
14	**PRAC Pharmacovigilance Risk Assessment Committee**	The main responsibility of the PRAC is to prepare recommendations on any questions relating to pharmacovigilance activities related to a medicine for human use and on risk-management systems, including the monitoring of the effectiveness of those risk-management systems.	Medicinal Products for Human Use[1]	A chair and a vice chair, elected by serving PRAC members 1 member and 1 alternate for the following EEA countries (30 active members - Liechtenstein has delegated its task to Austria): Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom 6 Independent scientific experts nominated by the European Commission 1 member and 1 alternate for representative of healthcare professionals nominated by the European Commission 1 member and 1 alternate for representatives of patients organisations nominated by the European Commission	11 times a year (Monthly except in August)	1. Assessment, minimisation and communication relating to the risk of adverse reactions, while taking the therapeutic effect of the medicine into account. 2. Design and evaluation of post-authorisation safety studies and pharmacovigilance audit.	PRACsecretariat@ema.europa.eu
15	**Article 57 Database**	European database of all authorised medicinal products in the EEA. The purpose of the database is to deliver structured and quality-assured information on medicinal products authorised in the EU that can support, EU terminologies of products, substances and organisations used to power pharmacovigilance and regulatory systems in the EU.	Medicinal Products for Human Use1 in the European Economic Area (EEA)	EEA countries (30 active members): Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom (1 provisional member): Croatia	N/A	1. Improve data analysis and signal management in Europe 2. Facilitate medicines regulation to fulfil regulatory actions and legal obligation 3. Communicate efficiently with stakeholders 4. Reduce costs by decreasing the duplication of encoding and maintenance of the same information on medicines 5. Contribute to the establishment of interoperable systems for the exchange of information on medicines used for the performance of regulatory activities and therefore reducing the operational risks due to lack of common dictionary and terminology on medicine's information 6. Strengthen the communication between medicines database and the EU regulatory systems speeding up decisions and actions	art57@ema.europa.eu
16	**EPITT European Pharmacovigilance Issues Tracking Tool**	Track and share Pharmacovigilance data for Member States.	Medicinal Products for Human Use1 in the European Economic Area (EEA)	Currently 650 users including NCAs and EMA (as of August 2015) Access to: PhVWP/PRAC members, CMD(h), CHMP members, all EMA staff via Eudranet	N/A EPITT is accessible to all the NCAs via Eudranet: all the National Competent Authorities are connected	1. Track the Pharmacovigilance Topics, defined as follow: • Safety information related to medicinal products marketed in the European Economic Area, including Non Urgent Information (NUI), Rapid Alerts (RAs), Safety signals andPhVWP/PRAC outcomes on specific PhV (Pharmacovigilance) Topics • Organisational-related topics which are not necessarily safety-related but which impact on the procedures established within the EU Regulatory Network 2. Provide a scientific memory database for PhV Topics 3. Allow the Member States and EMA to have easy access to relevant meeting documents 4. 1860 PhV Topics from which 510 safety signals (as of August 2015)	epitt@ema.europa.eu

	Initiative	Objectives related to Pharmacovigilance initiatives	Scope	Membership	Frequency of meetings	Work Products	Contact Point
17	**International Organization for Standardization (ISO) identification of medicinal products (IDMP) standards**	This initiative aims to use common standards, formats and terminologies internationallyto identify and exchange pharmacovigilance and medicinal product information amongst regulatory authorities.	Medicinal products	119 member bodies: Afghanistan; Algeria; Argentina; Armenia; Australia; Austria; Azerbaijan; Bahrain; Bangladesh; Barbados; Belarus; Belgium; Benin; Bosnia and Herzegovina; Botswana; Brazil; Bulgaria;; Burkina Faso; Cameroon; Canada; Chile; China; Colombia; Congo, The Democratic Republic of the; Costa Rica; Côte d'Ivoire; Croatia; Cuba; Cyprus; Czech Republic; Denmark; Ecuador; Egypt; El Salvador; Estonia; Ethiopia; Fiji; Finland; France; Gabon; Germany; Ghana; Greece; Hungary; Iceland; India; Indonesia; Iran, Islamic Republic of; Iraq; Ireland; Israel; Italy; Jamaica; Japan; Jordan; Kazakhstan; Kenya; Korea, Democratic People's Republic of; Korea, Republic of; Kuwait; Latvia; Lebanon; Libya; Lithuania; Luxembourg; Malawi; Malaysia; Mali; Malta; Mauritius; Mexico; Mongolia; Morocco; Namibia; Nepal; Netherlands; New Zealand; Nigeria; Norway; Oman;; Pakistan; Panama; Peru; Philippines; Poland; Portugal; Qatar; Romania; Russian Federation; Rwanda; Saint Lucia; Saudi Arabia; Senegal; Serbia; Singapore; Slovakia; Slovenia; South Africa; Spain; Sri Lanka; Sudan; Sweden; Switzerland; Tanzania, United Republic of; Thailand; The Former Yugoslav Republic of Macedonia; Trinidad and Tobago; Tunisia; Turkey; Uganda; Ukraine; United; Arab Emirates; United Kingdom; United States; Uruguay; Uzbekistan; Viet Nam; Yemen; Zimbabwe 40 Correspondent members: Albania; Angola; Bahamas; Bhutan; Bolivia, Plurinational State of; Brunei Darussalam; Burundi; Cambodia; Dominica; Dominican Republic; Eritrea; Gambia; Georgia; Guatemala; Guyana; Haiti; Honduras; Hong Kong; Kyrgyzstan; Lesotho; Macao; Madagascar; Mauritania; Moldova, Republic of; Montenegro; Mozambique; Myanmar; Nicaragua; Niger; Palestine, State of; Papua; New Guinea; Paraguay; Saint Kitts and Nevis; Seychelles; Sierra Leone; Suriname; Swaziland; Tajikistan; Turkmenistan; Zambia 4 subscribers members: Antigua and Barbuda; Belize; Lao People's Democratic Republic; Saint Vincent and the Grenadines	N/A	1. ISO prEN 11238, Health Informatics, Identification of Medicinal Products (IDMP) standard 'Data elements and structures for unique identification and exchange of regulated information on substances' Draft update of the standard planned for December 2015 Publication planned for July 2016 2. ISO prEN 11239, Health Informatics, Identification of Medicinal Products (IDMP) standard 'Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging' Final and stable standard sa of October 2015 3. ISO prEN 11240, Health Informatics, Identification of Medicinal Products (IDMP) standard 'Data elements and structures for unique identification and exchange of units of measurement' Final and stable standard sa of October 2015 4. ISO prEN 11615, Health Informatics, Identification of Medicinal Products (IDMP) standard 'Data elements and structures for unique identification and exchange of regulated medicinal product information' Draft update of the standard planned for December 2015 Publication planned for July 2016 5. ISO prEN 11616, Health Informatics, Identification of Medicinal Products (IDMP) standard 'Data elements and structures for unique identification and exchange of regulated pharmaceutical product information' Draft update of the standard planned for December 2015 Publication planned for July 2016 6. Regional implementation guides: • ISO prEN 11238 Substance (Core + 4 annexes): Final and stable guide • ISO prEN 11238 Substance (Remaining 6 annexes): Draft update planned in November 2015 and publication in July 2016 • ISO prEN 11239 Dose, pres. units, routes, packaging: Draft update planned in November 2015 and publication in July 2016 • ISO prEN 11615 Medicinal Product: Draft update planned in November 2015 and publication in July 2016 • ISO prEN 11616 Pharmaceutical Product: Draft update planned in November 2015 and publication in July 2016 7. HL7 Messaging Formats • Substance: Publication in October 2015 • Product: Publication in October 2015	art57@ema.europa.eu
18	**EMA-FDA Pharmacovigilance Cluster**	1. Exchanging information on risk assessments (with special focus on emerging safety concerns, including those assessed in EU referral procedures) and informing the participating parties of anticipated regulatory action, including public information and communication, prior to decision-making and publication 2. Exchanging information on policies, guidance documents and regulations 3. Exchanging information on concerns over marketing authorisation holder's pharmacovigilance systems and inspection findings 4. Exchanging views on impacts, priorities and goals for pharmacovigilance activities, especially in areas of emerging science of mutual interest 5. Identifying specific activities of mutual benefit (e.g. jointly sponsored scientific symposia) to support the improvement of pharmacovigilance activities.	Medicinal products within the scope of EMA and US FDA activities. For the EMA, in the pharmacovigilance area this includes the full range of items covered by the PRAC agenda.	European Medicines Agency (EMA) Obersevers: The US Food and Drug Administration (FDA); European Commission (EC); Medical Devices Agency (PMDA)	The cluster meets monthly for a 1.5 hours teleconference.	Product-related risk assessments with a special focus on emerging safety concerns, policies, guidance documents and regulations are typically exchanged during the cluster meetings.	N/A
19	**APEC's Roadmap to Promote Regulatory Convergence for PV**	1. To facilitate convergent evolution of pharmacovigilance (PV) activities among APEC economies that will support harmonized and pragmatic regulatory requirements in pharmacovigilance by 2020; 2. To identify opportunities for strengthening PV standards to better protect public health in the APEC economies; 3. To promote public health protection by coordinating evolution of PV standards that support sustainable risk-benefit assessment and management for medical products in the context of capacity-building constraints across the APEC economies; and 4. To accelerate mutual recognition through enhancing trust among and between APEC member economies.	To be defined	APEC members Australia, Brunei Darussalam, Canada, Chile, China, Hong Kong-China, Indonesia, Japan, Republic of Korea, Malaysia, Mexico, New Zealand, Papua New Guinea, Peru, Philippines, Russia, Singapore, Chinese Taipei, Thailand, United States, and Vietnam Council of Europe European Medicines Agency (EMA) National Agency for Food and Drug Administration Control (NAFDAC, Nigeria) US Pharmacopoeia World Health Organisation (WHO) Other interntional organisations and private sector non-profit organisations	N/A	1. Scope of covered products 2. Regulatory frameworks 3. Data management 4. ICH E2B is a big challenge 5. WHO-ART vs MEDDRA 6. Data analysis 7. Training 8. Communications	N/A
20	**MedDRA Medical Dictionary for Regulatory Activities**	To adopt a dedicated single standardised terminology offering a number of clear advantages for regulators, industry and other stakeholders including healthcare professionals, patients and research organisations.	registration, documentation and safety monitoring of medicinal products through all phases of the development cycle	Founding members: European Union (EU); European Federation of Pharmaceutical Industries and Associations (EFPIA); Labour and Welfare (MHLW); Japan Pharmaceutical Manufacturers Association (JPMA); Food and Drug Administration (FDA); Pharmaceutical Research and Manufacturers of America (PhRMA) Observers: European Free Trade Association (EFTA); Health Canada; World Health Organization (WHO)	N/A	1. Removal of the need to convert data from one terminology to another preventing the loss and/or distortion of data and allowing savings in resources 2. Facilitation of the electronic exchange of data relating to medicinal products 3. Improvements in the ease, quality and timeliness of data available for effective analysis, exchange and decision making 4. Consistency of the terminology throughout the different stages of the development of a medicinal product allowing effective cross-references and analysis of data	mssohelp@meddra.org

	Initiative	Objectives related to Pharmacovigilance initiatives	Scope	Membership	Frequency of meetings	Work Products	Contact Point
21	**WHO-GACVS Global Advisory Committee on Vaccine Safety**	The Global Advisory Committee on Vaccine Safety (GACVS) was established in 1999 to respond promptly, efficiently, and with scientific rigour to vaccine safety issues of potential global importance.	Vaccines	Official Member Countries (122) Andorra, Angola,, Argentina, Armenia, Australia, Austria, Bangladesh, Barbados, Belarus, Belgium, Benin, Bhutan, Bolivia, Botswana, Brunei Darussalam, Bulgaria, Burkina Faso, Cambodia, Cameroon, Canada, Cape Verde, Chile, China, Colombia, Dem Rep of Congo, Costa Rica, Côte d'Ivoire, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Egypt, Eritrea, Estonia, Ethiopia, Fiji, Finland, France, Germany, Ghana, Greece, Guatemala, Guinea, Hungary, Iceland, India, Indonesia, Islamic Republic of Iran, Iraq, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Republic of Korea, Kyrgyzstan, Lao People's Democratic Republic, Latvia, Liberia, Lithuania, The Former Yugoslav Republic of Macedonia, Madagascar, Malaysia, Malta, Mauritius, Mexico, Republic of Moldova, Montenegro, Morocco, Mozambique, Namibia, Nepal, Netherlands, New Zealand, Niger, Nigeria, Norway, Oman, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, Rwanda, Saudi Arabia, Senegal, Serbia, Sierra Leone, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, United Republic of Tanzania, Thailand, Togo, Tunisia, Turkey, Uganda, Ukraine, United Arab Emirates, United Kingdom, Uruguay, U.S.A., Uzbekistan, Venezuela, Vietnam, Zambia, Zimbabwe Associate Members (28) Afghanistan, Albania, Algeria, Anguilla, Antigua & Barbuda, Azerbaijan, Bahrain, Bosnia and Herzegovina, British Virgin Islands, Burundi, Dominica, Gambia, Georgia , Grenada, Guinea-Bissau, Maldives,Mongolia, Montserrat, Pakistan, Panama, Papua New Guinea, Qatar, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Syrian Arab Republic, Tajikistan, Zanzibar	Bi annual meetings	1. Committee reports 2. Strategic plan for strengthening vaccine safety activities 3. Building national capacity for vaccine safety in the world's poorest countries	gvsi@who.int
22	**PIC/S Pharmaceutical Inspection Co-operation Scheme**	1. To expand its activities to include training in the field of PhV inspections. 2. Initially the aim will be to facilitate joint visits, develop guidance and promote harmonisation in the field of pharmacovigilance inspections.	Medicinal products	Participating authorities Argentinian National Institute of Drugs (INAME) , Australian Therapeutic Goods Administration (TGA) , Austrian Medicines and Medical Devices Agency (AGES), Belgian Federal Agency for Medicines and Health Products (AFMPS- FAGG), Canadian Health Products and Food Branch Inspectorate (HPFBI) - Health Canada, Taiwan Food and Drug Administration (TFDA), Cypriot Pharmaceutical Services (CyPHS), Czech State Institute for Drug Control (SÚKL), Czech Institute for State Control of Veterinary Biologicals and Medicines (ISCVBM), Danish Health and Medicines Authority (DHMA), Estonian State Agency of Medicines (SAM), Finnish Medicines Agency (FIMEA), French National Agency for Medicines and Health Products Safety (ANSM), French Agency for Food, Environmental & Occupational Health Safety (ANSES), German Federal Ministry of Health (BMG), Central Authority of the Laender for Health Protection regarding Medicinal Products and Medical Devices (ZLG) (BMG and ZLG count as one PIC/S Participating Authority), Greek National Organisation for Medicines (EOF) , Hungarian National Institute of Pharmacy and Nutrition (NIPN), Icelandic Medicines Agency (IMA), Indonesian National Agency for Drug and Food Control(NADFC), Health Products Regulatory Authority (HPRA), Israeli Institute for Standardization and Control of Pharmaceuticals (ISCP), Italian Medicines Agency (AIFA), Japanese Ministry of Health, Labour and Welfare (MHLW), Japanese Pharmaceuticals and Medical Devices Agency (PMDA) (MHLW and PMDA count as one PIC/S Participating Authority). Korea (Republic of) Ministry of Food and Drug Safety (MFDS), Latvian State Agency of Medicine (ZVA), Liechtenstein's Office of Healthcare (AG), Lithuanian State Medicines Control Agency (SMCA), Malaysian National Pharmaceutical Control Bureau (NPCB), Maltese Medicines Authority (MAM) Dutch Health Care Inspectorate (IGZ), New Zealand's Medicines and Medical Devices Safety Authority (Medsafe), Norwegian Medicines Agency (NOMA), Polish Main Pharmaceutical Inspectorate (MPI) Portuguese National Authority of Medicines and Health Products, IP (INFARMED IP), Romanian National Agency for Medicines and Medical Devices (NAMMD), Singapore's Health Sciences Authority (HSA), Slovak State Institute for Drug Control (SIDC), Slovenian Agency for Medicinal Products and Medical Devices (JAZMP), South African Medicines Control Council (MCC), Spanish Agency of Medicines and Medical Devices (AEMPS) (The competence for GMP/GDP inspections in Spain is shared between the central authority, Spanish Agency for Medicines and Medical Devices (AEMPS), and the Spanish regional authorities, which count as one PIC/S Participating Authority. All Spanish Medicinal Authorities, which are listed on the AEMPS web site, are considered as PIC/S Participating Authorities and are represented in PIC/S by the AEMPS.), Swedish Medical Products Agency (MPA), Swiss Agency for Therapeutic Products (Swissmedic), Ukrainian State Administration on Medicinal Products (SAUMP), United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom's Veterinary Medicine Directorate (VMD), U.S. Food and Drug Administration (US FDA) Partners	N/A	1. Facilitate joint visits 2. Develop Guidance 3. Training in the field of PhV inspections.	info@picscheme.org

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.