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International Affairs

ICMRA - Mapping of GMP inspection initiatives

Initiative		Objective	Scope	Membership	Frequency of meetings	Work products	Contact Point
I. Single Unified System							
I.1	**EU Inspection System**	**A Single European GMP inspection system.**	GMP inspections of the manufacturers of active pharmaceutical ingredients and finished dosage forms	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	Multiple meetings	1. (non-exhaustive) Reliance on GMP inspections performed by any EU authority, common inspection procedures, common approach to training and qualifications of inspectors 2. Rapid alert system for quality defects 3. Joint Audit Programme	EMA: info@ema.europa.eu
II.Reliance focussed							
II.1	**MRA Mutual Recognition Agreement**	Legally binding treaty between two participating parties and exchange of GMP Certificates based on equivalent GMP Compliance Program.	May cover Human and Veterinary Products	Bilateral between individual Countries and/or regions	On-going teleconferences as far as the confidence building phase is evolving	1. On-going communication (e.g. Joint Sectoral Group meetings, exchange of annual maintenance reports, Ad Hoc MRA Partners meeting) 2. "Lead to similar and not identical approaches	N.A.
II.2	**ASEAN MRA Association of Southeast Asian Nations Mutual Recognition Arrangement**	Recognition of Good Manufacturing Practice (GMP) Inspection of manufacturers of medicinal products between 10 ASEAN Member States.	Medicinal products in finished dosage forms, and excludes products such as biopharmaceuticals, radiopharmaceuticals, traditional medicines and investigational medicinal products	10 Participating authorities: Brunei, Cambodia, Indonesia, Laos, Malaysia, Burma (Myanmar), Philippines, Singapore, Thailand, Vietnam	Not applicable	Under this MRA, all ASEAN Member States shall accept and recognize the GMP Certificates and/or inspection reports of a Listed Inspection Service.	http://www.asean.org/information/contact-us
II.3	**EMA/FDA/TGA API Programme**	To foster cooperation and mutual confidence between participating regulators through better communication and exchange of information on inspection planning.	Joint inspections of API manufacturers located outside the participating regions Reliance on API inspections by other authorities Extended inspections on behalf of other countries	EU Authorities: European Medicines Agency (EMA) European Directorate of the Quality of Medicines and Healthcare (EDQM) European National Supervisory Authorities The US Food and Drug Administration (FDA) Australian Therapeutic Goods Administration (TGA) World Health Organization (WHO)	Monthly TCs	1. Joint inspections 2. Reliance on inspections by other authorities 3. Feedback	EMA: info@ema.europa.eu TGA: TGA.International@tga.gov.au
II.4	**EMA/FDA Mutual reliance Confidence building***	Allows some inspections on each others' territories to be deferred or waived completely based on a number of considerations.	The strategy is applicable to GMP inspections related to manufacturing sites located in USA and EEA involving products for both human and veterinary use	Not applicable	Ad hoc meetings	*Ongoing*	EMA: info@ema.europa.eu
II.5	**EU API listing**	Listing of a country as having equivalent GMP inspection and supervision standards to those in the EU.	API only	Bilateral between EU and country requesting list	Not applicable	Country listed as equivalent	EMA: info@ema.europa.eu

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III. Cooperation focussed						
III.1 **PIC/S Pharmaceutical Inspection Co-operation Scheme**	1. International co-operation in the field of GMP 2. Developing and promoting harmonised GMP standards and guidance documents 3. Training GMP inspectors 4. Assessing (and reassessing) GMP inspectorates 5. Facilitating co-operation and networking and planning of inspection	Initially restricted to medicinal products for human use, now some veterinary authorities are included Initially restricted to FP, currently being extended to APIs GDP added to mandate New Expert Circle on PIC/S GCP & GPV	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) Partner to PIC/S EDQM - European Directorate for the Quality of Medicines & HealthCare, EMA - European Medicines	Twice a year for the Comiittee of Officials Once a year for seminar and experts circles	1. Training activities/Seminars/ expert circles 2. Guidance documents for inspectorates and industry 3. Harmonised inspections procedure 4. Reports on audited inspectorates	info@picscheme.org
III.2 **PAHO/WHO Latin American Initiative**	1. Establishment of cooperation mechanisms that will make possible to strengthen the steering role for other national regulatory authorities. 2. Cooperation Actions for GMP are being conducted to strengthen capacity building of Central America and Caribbean Regulatory Authorities.	Some technical cooperation on marketing authorisation and inspections International inspections Periodic audits of NRA	Steering committee: Brazil, Argentina, Mexico, Cuba, Colombia	2 meetings annually (one at PAHO/Washington and the other at one of the Steering Committee countries)	1. Audits of national regulatory capabilities 2. Cooperation mechanisms for inspections 3. Recognition of regulatory capacity in inspections	http://www.paho.org/hq/index.php?option=com_content&view=article&id=9365&Itemid=40181&lang=en
III.3 **EMA/FDA Finished Products programme***	The overall objective is to see whether greater international collaboration can help to better distribute inspection capacity, allowing more sites to be monitored and reducing unnecessary duplication.	This project is restricted to inspections of manufacturers of human medicinal (finished drug) products which come under the authority of FDA's Center for Drug Evaluation and Research and the centralised marketing authorisation process in the European Union	European Medicines Agency (EMA) The US Food and Drug Administration (FDA)	Initially Monthly meetings, then ad hoc	Joint inspections	EMA: info@ema.europa.eu

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III.4	**International Regulators Consortium Swissmedic/Singapore/HC/AU**	Promotes greater regulatory collaboration and alignment of regulatory requirements.	Exchange of information on regulatory issues and challenges	Switzerland, Canada, Australia and Singapore	Members participate in informal teleconferences on a regular basis to exchange information on regulatory issues and challenges	*Ongoing*	CH: questions@swissmedic.ch HAS: N/A HC: Info@hc-sc.gc.ca TGA: TGA.International@tga.gov.au
III.5	**Observed inspections**	Participation as an observer in a GMP inspection carried out by another regulatory authority	API/FP	Pharmaceutical Inspection Co-operation Scheme (PIC/S) Members: 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) Partner to PIC/S: EDQM - European Directorate for the Quality of Medicines & HealthCare, EMA - European Medicines Agency, UNICEF - United Nations International Children's Emergency Fund, WHO - World Health Organization Joint Visit Programme (JVP) in PIC/S EU Authorities World Health Organization (WHO) Pre-qualification MRA Partners	Not applicable	Contributes to audits of authorities	N.A.

Abbreviations	
API	Active Pharmaceutical Ingredients
FP	Finished Products

*The initiatives VI and VII are closely related. VI derived from VII.

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.