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International Affairs

ICMRA - Mapping of the bilateral arrangements between the ICMRA Members

Bilateral Arrangements on or Including Pharmaceuticals Between International Coalition of Medicine Regulatory Authorities (ICMRA) Members	Agreements on Exchange of Confidential Information (e.g. Confidentiality Arrangements, Memorandum of Understanding, Exchange of Letters for Information Sharing etc.) Mutual Recognition Agreements on GMP Other Agreements
Australia (AU) - Therapeutic Goods Administration (TGA)	BR CA CH CN EU[1] IE JP SG UK US / CA EU[1] SG / NZ[8] SG[9] US[10]
Brazil (BR) - Brazilian Health Surveillance Agency (ANVISA)	AU CA CH CN IE IT JP KR[3] UK US ZA[4] / US[12]
Canada (CA) - Health Products and Food Branch, Health Canada (HPFB-HC)	AU BR CH EU[1] IE JP NL SG UK US / AU EU / CN[12]
China (CN) - China Food and Drug Administration (CFDA)	AU BR DE[4] EU[1] IE JP KR NL SG UK US ZA[6] / EU[13] SG[14] CH[15]
European Union (EU) - European Commission (EC) DG SANTE and European Medicines Agency (EMA)	AU CA CH JP US / AU CH CA JP NZ / CN[13]
France (FR) - The National Agency of Medicines and Health Products Safety of the French Republic (ANSM)	EU Arrangements[1]
Germany (DE) - The Paul-Ehrlich-Institute of the Federal Republic of Germany (PEI)	EU Arrangements[1] CH CN[4] SG / KR[16]
Ireland (IE) - Health Products Regulatory Authority (HPRA)	EU Arrangements[1] BR CH KR[5] SG
Italy (IT) - Agenzia Italiana del Farmaco (AIFA)	EU Arrangements[1] BR KR[2]
Japan (JP) - Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA)	AU BR CA CH CN EU[1] KR[2] MX SG US / EU[1]
Mexico (MX) - Ministry of Health of the United Mexican states through the federal commission for the protection against sanitary risks (COFEPRIS)	JP KR US
Netherlands (NL) - Medicines Evaluation Board (MEB) and The Health Care Inspectorate (IGZ)	EU Arrangements[1] SG
New Zealand (NZ) - New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE)	GB US / EU[1] / AU[8]
Nigeria (NI) - National Agency for Food and Drug Administration and Control (NAFDAC)	
Singapore (SG) - Health Sciences Authority (HSA)	AU CA CH CN DE IE JP KR NL GB UK US / AU / AU[9] CN[14] EU[1,17]
Republic of Korea (KR) - Ministry of Food and Drug Safety (MFDS)	BR[2] CH CN IE[5] IT[2] JP[2] MX SG UK / DE[16]
South Africa (ZA) - Medicines Control Council (MCC), Department of Health	BR[3] CH CN[5] UK[2] US / EU[1,18]
Switzerland (CH) - the Federal Department of Home Affairs of the Swiss Confederation (Swissmedic)	AU BR CA DE EU[1] IE JP KR SG ZA US / EU[1] / CN[15]
United Kingdom (UK) - Medicines and Healthcare Products Regulatory Agency (MHRA)	EU Arrangements[1] BR CN KR NZ SG ZA[2]
United States (US) - Food and Drug Administration (FDA)	AU BR CA CH CN[7] EU[1] JP MX NZ SG ZA / AU[10] BR[11]
DISCLAIMER The table above provides a general overview of the existing bilateral arrangements on pharmaceuticals worldwide and reflects the information available to the European Medicines Agency after consultation with all the authorities involved, at the time of preparation of the document (February 2015). As the information in this table may be in certain cases not completely accurate and/or incomplete, due to the difficulties in obtaining it and to continuous changes, EMA strongly advises that the information in the table is confirmed with the authorities involved.	Notes 1 The European Union (EU) is formed by 28 Member States including 6 ICMRA members: France, Ireland, Italy, Germany, the Netherlands and the United Kingdom. EU bilateral arrangements are valid for all the 28 EU Member States. As all the EU Member States are part of a single EU system for pharmaceuticals, confidential information are exchanged between the EU Member States and results of inspections carried out by any of the EU Member States are automatically recognised by all the others. EU Member States can sign individual bilateral arrangements. 2 In progress 3 General MoU of BRICS 4 Memorandum of Understanding (MoU) With the Chinese National Institute for Food and Drug Control, NIFDC 5 To strengthen political and economic relations 6 On information exchange on biological products, medical devides, drug use, cosmetics 7 On safety of drugs and medical devices 8 Trans-Tasman early warning system 9 Memorandum of Intention of Cooperation (MoI) 10 Cooperative arrangements on GMP and Orphan Drugs 11 Statement of Cooperation Regarding Cooperation to Enhance Activities of Mutual Interest 12 Plan of Action on Cooperation
	13 Consultation and cooperation mechanism 14 China Singapore Free Trade Agreement (CSFTA), ASEAN-China (ACFTA) 15 Agreement on Cooperation in the Areas of Foodstuffs, Medicinal Products, Medical Devices and Cosmetics 16 Joint declaration on vaccines and biomedicines 17 Implementation Plan on the Sharing of Confidential Info between the EC's Health and Consumer Protection Directorate General and the FDA 18 Free Trade Agreement