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International Affairs

ICMRA - Mapping of supply chain/anticounterfeiting initiatives

Strategy/policy focussed initiatives
*** Initiatives to strengthen the legitimate supply chain**
**** Initiatives focused on preventing illegal entry into the legitimate supply chain**

I - Global Initiatives

	Initiative	Objectives related to supply chain / anticounterfeiting initiatives	Scope	Membership	Work products	Contact Point
I.1	**WHO SSFFC Surveillance and Monitoring (Substandard, Spurious, Falsely labelled, Falsified and Counterfeit Medical Products)****	1. To protect public health and promote access to affordable, safe, efficacious and quality medical products, promote, through effective collaboration among Member States and the Secretariat, the prevention and control of substandard/spurious/falsely-labelled/falsified/counterfeit medical products and associated activities. 2. Facilitate operational cooperation. 3. Inform policy makers of threats. 4. Enable evidence based decision making. 5. Provide reliable evidence, not anecdote.	Medicines Vaccines Diagnostics	All WHO Member States: 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	1. Rapid alert form 2. SSFFC database 3. Focal points (80 Member States and 18 procurement agencies)	qsm@who.int Rapid alert form: rapidalert@who.int
I.2	**Interpol Operation PANGEA***	Combating the sale of illegal medicines online	Medicines and medical devices	N/A The annual operation brings together customs, health regulators, national police and the private sector from countries around the world. PANGEA VII, June 2015: 115 participating countries	1. 429 investigations 2. 156 arrests 3. Suspension of 550 online adverts for illicit pharmaceuticals 4. 2,414 websites taken offline 5. 50,000 packages seized by customs and regulatory authorities during the week of action (9 – 16 June) 6. Interventions on the ground	N/A

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I.3	**WHO Member State Mechanism***	The objective of this initiative is the cooperation, the communication and the capacity building between national and regional regulatory authorities to identify major needs and challenges and make policy recommendations on SSFFC medical products. This collaboration aims to monitor and ensure the integrity of the supply chain, but also to educate and to raise awareness.	SSFFC medical products	All WHO Member States: 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. The steering committee is composed of the Chairperson, and two vice-chairpersons for each WHO region.	1. Guidelines 2. Training 3. Online portal 4. assessment of track and trace technologies 5. Awareness Campains 6. Economic impact study	N/A
I.4	**ICMRA white paper on Unique Facility Identifier (FDA lead)***	Establishment of a common unique identifier for facilities to be used by all ICMRA members	Manufacturers of medicinal products and active substances (drug products and drug substances	N/A Current discussion at ICMRA, PIC/S and EMA FDA has published a draft guidance http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm367199.pdf	Common global Unique Facility Identifiers (Currently, the FDA proposes the Data Universal Numbering System (DUNS) number as appropriate to meet Agency needs for a data standard for drug establishment registration UFI, but this is not approved.)	N/A
I.5	**PFIPC Permanent Forum on International Pharmaceutical Crime****	The Permanent Forum on International Pharmaceutical Crime is an international enforcement forum aimed at protecting public health and safety through the exchange of information and ideas to foster mutual cooperation.	Pharmaceuticals	Republic of Korea - Criminal Investigation Office - Ministry of Food and Drug Safety South Africa - Medicines Control Council Singapore - Health Sciences Authority (HSA) UK - Northern Ireland Department of Health, Social Services and Public Safety UK - Medicines and Healthcare Products Regulatory Agency (MHRA) Belgium - Federal Agency for Medicines and Health Products France - Gendarmerie Nationale - Environnement et santé publique (OCLAESP) Germany - Bundeskriminalamt (BKA) Ireland - Health Product Regulatory Authority (HPRA) Italy - Arma dei Carabinieri (NAS) Netherlands - Inspectie voor de Gezondheidszorg Spain - Spanish Civil Guard Switzerland - Swiss Agency for Therapeutic Products (Swissmedic) Israel - Israel Ministry of Health (MOH Canada - Health Canada Canada - Royal Canadian Mounted Police USA - Food and Drug Administration-Office of Criminal Investigations (FDA-OCI) Australia - Department of Health - Therapeutic Goods Administration (TGA) New Zealand - New Zealand Medicines and Medical Device Safety Authority (MEDSAFE)	1. International Laboratory Forum on Counterfeit Medicines (ILFCM) 2. International Conference on Pharmaceutical Crime 3. PFIPC Internet day of action 4. Production of a training manual for IMPACT specifically aimed at detection and investigation of counterfeit medical products. (IMPACT is aimed at combating counterfeit medicines in countries with a high proportion of counterfeit products but with insufficient enforcement facilities of their own.)	N/A

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1.6	**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	International Organization for Standardization - ISO: 119 member bodies 38 Correspondent members 5 subscribers members	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 8. Maintenance arrangements under discussion (FDA/EMA)	art57@ema.europa.eu

II - Regional initiatives (Including regional economic integration

II.1	**PAHO-WG-CDC Pan American Health Organization Working Group to Combat Drugs Counterfeiting****	1. To promote, facilitate, and motivate implementation of proactive strategies for preventing and fighting medicines counterfeiting and thus contribute to the improvement of health care in our countries in the Americas. 2. Development of specific policies and strategies for implementation by countries	Counterfeit drugs	35 countries in the Americas: 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	1. Development of an action plan (road map) for the evaluation of products, in order to identify counterfeiting 2. Training 3. Workshops	N/A

	Initiative	Objectives related to supply chain / anticounterfeiting initiatives	Scope	Membership	Work products	Contact Point
II.2	**APEC Asia-Pacific Economic Cooperation Global Medical Product Integrity and Supply Chain Security***	1. Develop and implement a strategic plan for securing the supply chain of medical products throughout APEC economies. 2. Ensure the strategic plan is developed and implemented with worldwide stakeholder input.	Medical Products	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. World Health Organisation European Medicines Agency Council of Europe US Pharmacopoeia National Agency for Food and Drug Administration Control (NAFDAC, Nigeria) Other interntional organisations and private sector non-profit organisations	1. Gap assessment of relevant regulatory practices affecting supply chain integrity across APEC 2. Strategic Plan 3. Development and Dissemination of Tool Kits 4. Promotion of Public Awareness 5. Training 6. Establishment of APEC Single Points of Contact 7. International Workshops for implementing recommendations contained in Tool Kits	mark.paxton@fda.hhs.gov
II.3	**EAMI Ibero-American Medicines Competent Authorities Network****	Fighting against fraudulent and falsified medicines in Ibero American countries.	Medicines Vaccines Diagnostics	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 The secretariat of EAMI members is currently composed by Spain, Portugal, El Salvador, Argentina, Paraguay	1. Exchange of Information System of Falsified and Fraudulent Medicines in Ibero - American Countries (FALFRA System) 2. Communication of the Alerts of Falsified and Fraudulent Medicines in the portal EAMI www.portaleami.org 3. Coordination of the Network of Points of Contact in relation to the medicines falsified and fraudulent of the 21 countries that form EAMI 4. Rapid Alert system	secretariado-eami@aemps.es

III - European Initiatives

III.1	**The EU GMP/GDP Inspectors Working Group***	1. Contribution to the implementation of the falsified medicines legislation. 2. Development and maintenance of the EU Good Distribution Practice (GDP) guide.	Medicines and Active Pharmaceutical Ingredients (API)	Senior inspectors from 31 EEA Member States: 28 EU Member States: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, UK Iceland Liechtenstein Norway	1. Rapid alert system 2. EudraGMDP database 3. GDP Certificate and statement of GDP non-compliance 4. EU GDP Guide	qdefect@ema.europa.eu
III.2	**The Working Group of Enforcement Officers (WGEO)****	1. Promote liaison and co-operation between Member States and agencies with the purpose of sharing information. 2. Identify emerging threats to the legal manufacturing and distribution chain. 3. Coordinate communications and initiatives, exchanging information with relevant working parties/groups and organisations. 4. Provide a valuable network for European counterparts to build trust, share experience, best practice and expertise relating to pharmaceutical crime. 5. Deliver a practical training platform – largely related to the four work-streams: wholesale and distribution; Internet (illegal supply of medicines); falsified medicines and training and education.	Human and Veterinary Medical products	28 EU member states: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the UK. EU Agencies	1. Internet work-stream: • Guidance document on removing websites advertising and selling unlawful medical products from the Internet • Guidance on conducting open-source Internet investigations • survey on Internet threats 2. Wholesale and distribution work-stream: • Concept paper on wholesale dealing • Report looking at the different interpretations and implementation of wholesale dealing across the EU • Questions and answers to assist suppliers together with a survey report on licences, status and inspections of bonded warehouses. 3. Falsified medicines work-stream: • Best practice paper on the handling of analytical samples • Product threat assessment template and guidance • Survey of counterfeit product recalls between 2005 and 2010 • Survey on active pharmaceutical ingredient and controls in place by medicines regulators and industry 4. Training Workgroup	WGEOSecretariat@mhra.gsi.gov.uk

	Initiative	Objectives related to supply chain / anticounterfeiting initiatives	Scope	Membership	Work products	Contact Point
III.3	**The falsified medicines directive unique identifier****	Prevention of the entry into the legal supply chain of falsified medicinal products.	Prescription medicinal products on the EU market, including imported medicinal products Medicines with high risks to be falsified	28 EU member states: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the UK.	1. A unique serial number in the form of a bar code printed or attached to every single pack of the affected products, checked-in in a database (repository system) by the manufacturer and checked-out when dispensed (pharmacy) 2. Common logo for websites of legally-operating online pharmacies/retailers 3. Awareness campaigns for Internet sales	N/A
III.4	**The Council of Europe MEDICRIME convention****	This convention aims to prevent and combat the counterfeiting of medical products and similar crimes involving threats to public health.	Medical products	Signature of the convention: Armenia, Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Guinea, Hungary, Iceland, Israel, Italy, Liechtenstein, Luxembourg, Moldova, Morocco, Portugal, Russia, Spain, Switzerland, Turkey, Ukraine Ratification of the convention: Hungary, Moldova, Spain, Ukraine Ratification in progress in: France, Belgium, Russia Beyond: Africa: Guinea, Burkina Faso, other countries expected via regional organisations (OCEAC) and consortia (TRACMed) Asia: talks via APEC	1. Single Points of Contact (SPOCs) 2. EDQM training platform for SPOCs 3. Official Medicines Control Laboratory (OMCL) Network related activities	N/A
III. 5	**FAKESHARE****	The Fakeshare project is co-funded by the "Prevention of and Fight against Crime" Programme of the EU and follows the Directive 2011/62 and Council of Europe (CoE) MEDICRIME Convention principles. Fakeshare offers cooperative web tools for strategic prevention and fights the use of the internet as a support to the distribution of counterfeit medicines and, in general, for counteracting pharmacrime through database and studies complemented and validated by enforcement experts and universities. The Fakeshare web platform was successfully used for coordinating the huge European effort that eradicated the infiltration of stolen hospital medicines in the EC distribution networks (2014-2015).	Pharmaceutical crime, web distribution of medicines	EC funded projects led by health authorities: AIFA-Italy (coordinator), AEMPS-Spain, INFARMED-Portugal, MHRA-UK, ALIMS-Serbia; EAMI MS health authorities (Mexico, Chile), enforcement agencies (Spain, Italy), Universities (Italy), International associations (IFPMA, EFPIA, ASOP, ASOP EU), private enforcement/intelligence companies (PSI, LegitScript) The FakeShare platforms are accessed by representants of all interested EU MS authorities, private stakeholders, international bodies, with different levels of priority.	1. Web platform (restricted knowledge db on pharmacrime) 2. Databases (illegal products and websites) 3. Publications and case studies 4. Training/knowledge sharing tools 5. Awareness Campains 6. Scientific studies (EG profiling of the customers of illegal e-pharmacies, model investigations, guidelines, white papers)	N/A

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.