

ICMRA - Mapping of crisis management initiatives

| | Initiative | Objectives related to Crisis Management initiatives | Scope | Membership | Frequency of meetings | Wor |
|---|--|--|---|--|--|--|
| 1 | The European Union regulatory network incident management plan for medicines for human use | To continuously monitor incidents, to review their public health impact, and to take the necessary routine measures to remedy the situation. To request further analysis under the form of the Preliminary Risk Analysis when routine measures are not considered sufficient to address the incident. To undertake in case of a confirmed crisis the initiatives necessary to manage and control the situation, whereby urgent and coordinated action within the EU Regulatory Network is necessary. | The event or the new information may be related to quality, efficacy or safety concerns The product may have been authorised through the centralised procedure, the mutual recognition procedure, the decentralised procedure and/or a national procedure | European Medicines Agency (EMA) European Commission (EC) Medicines regulatory authorities in the EU Member States: Austrian Agency for Health and Food Safety (Austria); Federal Agency for Medicines and Health Products (Belgium); Bulgarian Drug Agency (Bulgaria); Agency for medicinal products and medical devices of Croatia (Croatia); Ministry of Health - Pharmaceutical Services (Cyprus); State Institute for Drug Control (Czech Republic); Danish Medicines Agency (Denmark); State Agency of Medicines (Estonia); Finnish Medicines Agency (Finland); National Agency for the Safety of Medicine and Health Products (France); Federal Institute for Drugs and Medical Devices (Germany); Paul Ehrlich Institute (Germany); National Organization for Medicines (Greece); National Institute of Pharmacy and Nutrition (Hungary); Icelandic Medicines Agency (Iceland); Health Products Regulatory Authority (HPRA, Ireland); Italian Medicines Agency (Italy); State Agency of Medicines (Latvia); Office of Health / Department of Pharmaceuticals (Liechtenstein); State Medicines Control Agency (Lithuania); Ministry of Health (Luxemburg); Medicines Authority (Malta); Medicines Evaluation Board (Netherlands); Healthcare Inspectorate (Netherlands); Norwegian Medicines Agency (Norway); Office for Registration of Medicinal Products, Medicial Devices and Biocidal Products (Poland); Main Pharmaceutical Inspectorate (Poland); National Authority of Medicines and Health Products (Portugal); National Medicines Agency (Romania); State Institute for Drug Control (Slovakia); Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (Slovenia); Spanish Agency for Medicines and Health Products Regulatory Agency (United Kingdom) | Ad-hoc basis | 1. System for the 2. The inc 3. Exchange of information clu |
| 2 | EU-HSC European Commission Health Security Committee | To support the Member States in their efforts to prepare for health crises, to tackle health crises efficiently and to mitigate the impacts of health crisis on citizen and society. | Public health-related crisis (Pandemic influenza-biological and chemical attacks, etc) | Informal advisory group on health security at the European level: It brings together high-level representatives from the Ministries of Health of the 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), Norway, Iceland and Switzerland under the Commission chairmanship. Observers: European Centre for Disease Prevention and Control (ECDC), European Medicines Agency (EMA) and World Health Organization (WHO) | The HSC holds twice a year plenary meetings in Luxembourg. In an emergency the HSC can meet through audio conferences, if necessary on a daily basis. | 1. Commu 2. Threat 3. Prep 4. S 5. Crisis manag 6. |
| 3 | GHSI Global Health Security Initiative | To strengthen health preparedness and response globally to threats of biological, chemical, radio-nuclear terrorism (CBRN) and pandemic influenza. | The GHSI was envisaged as an informal group to fill a gap for like- minded countries to address health issues of the day, such as global health security. The Initiative was not intended to replace, overlap or duplicate existing fora or networks | Health Canada European Commission (EC) - DG SANTE France - Ministère de la Santé et des Solidarités Germany - Federal Ministry of Health Italy - Ministry of Health Japan - Ministry of Health, Labour and Welfare Mexico - Ministry of Health United Kingdom - Department of Health United States - Department of Health and Human Services Observer: World Health Organization (WHO) | Yearly meetings | 1. Risk Management an 2. Global Laborat 3. Pandemic 4. Chemical 5. Radio-Nucle |
| 4 | GLOPID-R Global Research Collaboration for Infectious Disease Preparedness | To facilitate an effective research response within 48 hours of a significant infectious diseases outbreak with pandemic potential. | Research | Canadian Institutes of Health Research (CIHR) – Canada Consejo Nacional de Ciencia y Tecnología – Mexico European Commission – DG Research & Innovation – European Union German Federal Ministry for Education and Research (BMBF) / PT-DLR – Germany Institut de microbiologie et des maladies infectieuses (INSERM/IMMI) – France Instituto Butantan and Instituto Fiocruz – Brazil Instituto de Salud Carlos III – Spain Japan Agency for Medical Research and Development – Japan Ministry of Science, Technology and Productive Innovation – Argentina National Health and Medical Research Council – Australia National Research Foundation of Korea – South Korea South African Medical Research Council – South Africa Thai National Institute of Health, Department of Medical Sciences – Thailand U.S. Department of Health and Human Services – USA | Yearly meetings | Facilitate th Address scientific, le Implement a 'One Heat between human a Establish a strateg Connect infection Actively inv |

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| ork Products | Contact Point | | | |
|--|-------------------------|--|--|--|
| e rapid exchange of information icident review network n outside of the EU - Pharmacovigilance luster with FDA | N/A | | | |
| nunication to the public at and risk assessment aparedness activities Scientific advice agement and testing of plans 6. Cooperation | N/A | | | |
| and Communications Working Group atory Network Working Group : Influenza Working Group al Events Working Group lear Threats Working Group | <u>contact@ghsi.ca.</u> | | | |
| he exchange of information egal, ethical and financial challenges ealth' approach with close cooperation and animal health researchers egic agenda for research response ious disease research networks volve developing countries | contact@glopid-r.org | | | |

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| WHO-IHR 5 WHO International Health Regulations | To prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade. | Public health-related crisis | 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; 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; Trinida and Tobago; Tunisa; Turkey; Turkmenistan; Tuvalu; Uganda; Ukraine; | There have been 6 meeting of the Emergency Committee since 2005 | National IHR Focal Points Event-based surveillance Critical information and communications platforms for decision support | ihrinfo@who.int. |

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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.