<table>
<thead>
<tr>
<th>Initiative</th>
<th>Objectives related to Pharmacovigilance initiatives</th>
<th>Scope</th>
<th>Membership</th>
<th>Frequency of meetings</th>
<th>Work Products</th>
<th>Contact Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ICH International Conference on Harmonisation</td>
<td>1. To provide standardised definitions and methodology procedures. 2. To aid in planning pharmacovigilance activities. 3. To facilitate sharing of regulatory information internationally for the production and use of harmonised regulatory guidelines and standards.</td>
<td>Medical Products for Human Use</td>
<td>Standing Regulatory Members: The Health Canada; The European Medicines Agency (EMA); The Japan Health and Labour and Welfare of Japan (MHLW); The National Institute of Health and Care Excellence (NICE); The National Health Service (NHS); The Medicines and Healthcare products Regulatory Agency (MHRA); The European Federation of Pharmaceutical Industries and Associations (EFPIA); The International Council for Harmonisation (ICH); The International Generic and Biosimilar Medicines Association (IGBA); The Pharmaceutical Research and Manufacturers of America (PhRMA); The Japan Pharmaceutical Manufacturing Association (JPMA); The World Health Organisation (WHO)</td>
<td>Meetings of Steering Committees and Expert Meeting Groups twice yearly.</td>
<td>1. Definitions and standards for expedited reporting on clinical safety data management. 2. Bioequivalence and efficacy data transfer (ICHQ6) 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 (PP). 7. Development of safety data update report. 8. The Medical Dictionary for Regulatory Activities Terminology (MedDRA). 9. Bioequivalence Standards for the Tenderer of Regulatory Information (MTRT-Gateway). 10. Regular Pharmacovigilance Trainings/Courses. 11. IDMP.</td>
<td>GVSI Secretariat: <a href="mailto:admin@gvsi.org">admin@gvsi.org</a></td>
</tr>
<tr>
<td>2. VEST The Global Vaccine Safety Initiative</td>
<td>To provide a framework for enhancing vaccine pharmacovigilance for improving the Blueprint strategy. The biennial aims to ensure that all countries have at least a minimal capacity to monitor vaccine safety. Countries in transition should establish early warning systems for vaccine safety activities. The strategic objectives focus on building and supporting a systematic approach to vaccine pharmacovigilance in all low- and middle-income countries.</td>
<td>Medical Products for Human Use</td>
<td>Standing Regulatory Members: The European Medicines Agency (EMA); The Australian Therapeutic Goods Administration (TGA); The National Institute of Health and Care Excellence (NICE); The National Health Service (NHS); The Medicines and Healthcare products Regulatory Agency (MHRA); The European Federation of Pharmaceutical Industries and Associations (EFPIA); The International Council for Harmonisation (ICH), The International Generic and Biosimilar Medicines Association (IGBA); The Pharmaceutical Research and Manufacturers of America (PhRMA); TheJapan Pharmaceutical Manufacturing Association (JPMA); The World Health Organisation (WHO)</td>
<td>GVSI Meeting is expected to meet at least once a year.</td>
<td>1. IT tools for AEFI reporting, collection, management and analysis. 2. IT bridges among existing systems to ensure regional data safety collection and analysis. 3. Harmonisation Strategies, Guidance, Guidelines, SOPs and Global manuals; Surveillance Systems. 4. Safety Studies/Analysis, Monitoring Initiatives and Collaboration programmes. 5. Design of global projects to enhance capacity of National Pharmacovigilance programs. 6. Standard IDMP Investigation forms; Public Assessments. 7. Vaccine Safety Net, Vaccine Pharmacovigilance Network. 8. Databases and Statistics. 9. Global learning resource centre Web-platform. 10. Globally harmonised mechanisms for the selection and exchange of information. 11. Global Workshops, Courses, Trainings and Symposium on Vaccine Pharmacovigilance (GP).</td>
<td><a href="mailto:gvsi@who.int">gvsi@who.int</a></td>
</tr>
<tr>
<td>3. Developing Country Vaccine Regulatory Network</td>
<td>To support and promote the strengthening of the regulatory oversight during the clinical development of vaccines, authorisation and inspection of vaccine plants, evaluation of investigational products, evaluation of regulatory decisions and post-market surveillance of developing vaccines.</td>
<td>Vaccines for Human Use</td>
<td>Standing Regulatory Members: The European Medicines Agency (EMA); The US Food and Drug Administration (FDA); The Ministry of Health, Labour and Welfare of Japan (MHLW); The National Institute of Health and Care Excellence (NICE); The National Health Service (NHS); The Medicines and Healthcare products Regulatory Agency (MHRA); The European Federation of Pharmaceutical Industries and Associations (EFPIA); The International Council for Harmonisation (ICH); The National Health and Medical Research Council (NHMRC); The National Institute for Clinical Excellence (NICE); The Australian Therapeutic Goods Administration (TGA); The National Institute of Health and Care Excellence (NICE).</td>
<td>One a year</td>
<td>1. Encourage and facilitate information exchange amongst the MAs on national laws, regulations and performance indicators. 2. Develop guidance on procedures relevant to the regulatory oversight during trial development of vaccines, authorisation and inspection of clinical trials or evaluation of registration dossier. 3. Discuss MAs practices related to advancing mutual understanding of their respective levels of expertise and identify the potential for collaboration and joint regulatory activities. 4. Identify internationally recognised standards consistent with WHO guidelines for clinical evaluation of vaccine. 5. Promote information exchange</td>
<td><a href="mailto:vacregqualification@who.int">vacregqualification@who.int</a></td>
</tr>
</tbody>
</table>
The mission of the National Drug Monitoring - WHO Collaborating Centre - is to develop and maintain a comprehensive, up-to-date, scientifically accurate and informative database of information and documentation related to the pharmacovigilance and risk management of medicinal products for human use. The Centre also provides support to National Centres and countries establishing pharmacovigilance systems and coordinates annual conferences and training courses.

### National Drug Monitoring - WHO Collaborating Centre

**Objectives related to Medicinal Products for Human Use**

- **Scope**
  - The Centre develops, hosts and maintains a pharmacovigilance Toolkit. The Toolkit provides links to pharmacovigilance initiatives, guidelines, tools, ATC/DDD classification and DDD assignment.

- **Membership**
  - Membership is open to countries with an interest in pharmacovigilance.

- **Frequency of Meetings**
  - Annual conferences

- **Work Products**
  - Initiatives promoting Pharmacovigilance programmes
  - Pharmacovigilance Toolkit

- **Contact Point**
  - info@who-pvafrica.org

### Available Support for National Centres and Countries

- Support is provided for the development of National Centres and countries establishing pharmacovigilance systems.
- Training courses and workshops are conducted to enhance the capacity of National Centres.
- The Centre also provides support to countries conducting cohort studies.

### Scope of the Centre

- **Activities**
  - To support countries and promote communication and advocacy of pharmacovigilance including developing annual workshops, training courses on pharmacovigilance, and developing national pharmacovigilance and risk management guidelines.
  - To coordinate annual conferences and training courses.

### Membership Criteria

- Membership is open to countries with an interest in pharmacovigilance and risk management.

### Available Work Products

- **Guidelines, Guides, Best Practices and books in the pharmacovigilance and risk management area.
- Computer software for case report management designed to suit the needs of National Centres.
- Tools for management of clinical information including individual case safety reports such as WHO Vigil-iT, VigiFlow, causality assessments, and other information exchange systems.
- Tools for management of clinical information including individual case safety reports such as WHO Vigil-iT, VigiFlow, causality assessments, etc.
- Educational and training programs for National Centres.
- Annual training course on pharmacovigilance.

### Contacts

- **info@who-pvafrica.org**
- **info@who-umc.org**

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**Note:** The information provided is an excerpt from a larger document. For comprehensive details, please refer to the full document. The text is designed to be readable and comprehensible, with headings, subheadings, and paragraphs to guide the reader through the content.
The International Society of Pharmacovigilence (ISoP) is a non-profit organization established jointly by WHO and UNESCO. Its primary objectives are to enhance all aspects of the safe and proper use of medicines, in all countries, by providing an International forum for the open exchange of scientific information among academia, government, and industry and for the development of pharmacovigilance initiatives for the benefit of public health.

ISoP Annual Meetings
1. 1st Annual International Conference on Pharmacovigilance & Medicinal Risk Management
2. 2. Annual mid-year meeting
3. 3. Annual end-year meeting
4. 4. Annual ISoP conference on Pharmacovigilance & Medicinal Risk Management

ISoP Annual Meetings
1. 1. An open forum for sharing experience and knowledge
2. 2. A platform for discussion and generation of new research ideas
3. 3. Publication of the Drug Safety Journal and Guidelines for Submitting Adverse Event Reports (under the joint ISoP-ISPE group)
4. 4. Currently established SIGs (groups of ISoP members) on ‘Risk communication’, ‘Women’s Health’, and a new SIG on ‘Risk communication in Africa’
5. 5. ISoP Sponsors/courses and Staff KTP (Moutain Training Programme)
<table>
<thead>
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<tbody>
<tr>
<td>11</td>
<td>Strengthening Collaboration for Operating Pharmacovigilance in Europe</td>
<td>BSRB aims to help medicines regulators operate pharmacovigilance systems in the European Economic Area (EEA). During the development, and implementation of new work packages, eight work packages, each of which are 'horizontal' and each of which are 'vertical'. These work packages range from improvements in Adverse Drug Reaction (ADR) reporting to measurement of quality management systems. This project will close in Q4 2016.</td>
<td>Work Package Leaders: Portugal, Croatia, Netherlands, Spain, Hungary, Italy, UK&lt;br&gt;Work Package Leaders: Belgium, Switzerland, Norway&lt;br&gt;Active Partners: Lithuania, Czech Republic, Bulgaria, Greece&lt;br&gt;Collaborating Partners: University of Nottingham, Sapienza University, Medical Centre Dr. Arakawa, Maastricht University, and the European Pharmacovigilance Centre Lead</td>
<td>1. NP meetings four to five times a year&lt;br&gt;2. General Advisory Board (GAB) Face to face annual meeting&lt;br&gt;3. WP teams face to face biannual meeting&lt;br&gt;4. Multiple PM ad hoc teleconferences</td>
<td>1. Develop guidance, training in key aspects of pharmacovigilance, and to lead to pharmacovigilance regulatory mechanisms for adverse drug reactions; signal management across the EEA network; Risk Communications (through the creation of a standardised toolkit), for management and awareness, and measuring effectiveness of risk minimisation.&lt;br&gt;2. Provide training materials, living documents, and templates which can be reviewed and adapted periodically.&lt;br&gt;3. Development of reference support scheme.&lt;br&gt;4. Provide recommendations and to develop and establish quality management systems for pharmacovigilance (requirements for pharmacovigilance system operation).&lt;br&gt;5. Focus on the interaction among the European regulatory authorities to strengthen regulatory collaboration.</td>
<td><a href="mailto:ras@eufp.org.uk">ras@eufp.org.uk</a></td>
</tr>
<tr>
<td>12</td>
<td>EudraVigilance European Database of Adverse Drug Reactions</td>
<td>Reporting and evaluating suspected adverse drug reactions (ADRs) during the development, and after the marketing authorisation of medicinal products in the European Economic Area (EEA).</td>
<td>National Products for human use in the European Economic Area (EEA).</td>
<td>N/A</td>
<td>1. Electronic exchange of Individual Case Safety Reports (ICSRs), based on the E2B (Common Data Dictionary and Common Data Model) standard, of all ADRs reported at all stages of the medicinal product lifecycle to support the establishment of interoperable systems for the exchange of information on medicines used for the performance of regulatory activities and therefore reducing the operational costs due to lack of common dictionary and terminology on medicines information; 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 reaction profiles of drugs.</td>
<td><a href="mailto:eudraVigilance@ema.europa.eu">eudraVigilance@ema.europa.eu</a></td>
</tr>
<tr>
<td>13</td>
<td>PRAC Pharmacovigilance Risk Assessment Committee</td>
<td>The main responsibilities of the PRAC is to prepare recommendations on any questions relating to pharmacovigilance activities related to a medicinal product (specifically for the EEA) by providing advice to the EMA on measures required to ensure the monitoring of the effectiveness of the risk-management systems.</td>
<td>National Products for human use in the European Economic Area (EEA).</td>
<td>N/A</td>
<td>1. Assessment, summarisation, and communication relating to the role of adverse reactions, while taking the therapeutic effect of the medicine into account.&lt;br&gt;2. Design and evaluation of post-authorisation safety studies and pharmacovigilance audit.</td>
<td><a href="mailto:prac@ema.europa.eu">prac@ema.europa.eu</a></td>
</tr>
<tr>
<td>14</td>
<td>Article 57 Database</td>
<td>European database of all relevant medicinal products marketed in the EEA. The database is structured and classified by product (under the jurisdiction of the EMA) and contains all safety information (both mandatory and non-mandatory) required for regulatory purposes. The database is used to support pharmacovigilance and regulatory activities in the EEA.</td>
<td>National Products for human use in the European Economic Area (EEA).</td>
<td>N/A</td>
<td>1. Improved data analysis and signal management in Europe&lt;br&gt;2. Facilitate medicines regulation in the field of regulatory actions and regulatory obligation&lt;br&gt;3. Communicate efficiently with stakeholders&lt;br&gt;4. Reduce costs by decreasing the duplication of recording and maintenance of the same information on medicines&lt;br&gt;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 costs due to lack of common dictionary and terminology on medicines information&lt;br&gt;6. Strengthen the communication between medicines database and the EEA regulatory systems speeding up decisions and actions</td>
<td><a href="mailto:article57@ema.europa.eu">article57@ema.europa.eu</a></td>
</tr>
<tr>
<td>15</td>
<td>EPITT European Pharmacovigilance Issue Tracking Tool</td>
<td>Track and store Pharmacovigilance data for Human use.</td>
<td>National Products for human use in the European Economic Area (EEA).</td>
<td>N/A</td>
<td>1. Track the Pharmacovigilance Topics, defined as follows: Safety information related to medicinal products marketed in the European Economic Area, including non-Urgent Information (NII), Rapid Alerts (RAs), Safety signals and ACP/PRAC outcomes on specific safety information and terminology.</td>
<td><a href="mailto:epitt-users@ema.europa.eu">epitt-users@ema.europa.eu</a></td>
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</tbody>
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(Cont.)
### International Organisation for Standardisation (ISO) standards

<table>
<thead>
<tr>
<th>Number</th>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>ISO prEN 11238</td>
<td>Substance (Core + 4 annexes): Final and stable guide</td>
</tr>
<tr>
<td>2.</td>
<td>ISO prEN 11239</td>
<td>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’</td>
</tr>
<tr>
<td>3.</td>
<td>ISO prEN 11615</td>
<td>Health Informatics, Identification of Medicinal Products (IDMP) standard ‘Data elements and structures for unique identification and exchange of regulated information on pharmaceutical products’</td>
</tr>
<tr>
<td>4.</td>
<td>ISO prEN 11616</td>
<td>Health Informatics, Identification of Medicinal Products (IDMP) standard ‘Data elements and structures for unique identification and exchange of regulated information on medicinal products’</td>
</tr>
</tbody>
</table>

**Notes:**
- Standard update of the ISO prEN 11616 planned for December 2015.

### International Organisation for Standardisation (ISO) liaison committees

<table>
<thead>
<tr>
<th>Committee</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO/TC 119 (PV)</td>
<td>Pharmacovigilance Systems and Data Exchange</td>
</tr>
<tr>
<td>ISO/TC 251 (PV)</td>
<td>Medical Devices and Healthcare Products Information Exchange (MDHPIE)</td>
</tr>
</tbody>
</table>

**Notes:**
- Liaison committee update planned for 2016.

### International Pharmaceutical Forum (IPF)

**Scope:**
- To focus on developing and promoting the implementation of modern pharmacovigilance systems.
- To support harmonization and standardization of pharmacovigilance activities.
- To improve the quality of risk management information from all sources.

**Membership:**
- IPF members: Austria, Belgium, Canada, France, Germany, Italy, Japan, Korea, Luxembourg, Norway, Singapore, Spain, United Kingdom

**Meetings:**
- IPF members meet biannually.

### APEC PV Cluster on Pharmacovigilance

**Scope:**
- To facilitate convergent evolution of pharmacovigilance (PV) standards amongst APEC economies.
- To strengthen capacity for assessing APEC pharmacovigilance regulatory standards.
- To improve the quality of risk management information from all sources.

**Membership:**
- APEC economies: Argentina, Australia, Brunei Darussalam, Canada, Chile, China, Republic of Korea, Japan, Malaysia, Mexico, New Zealand, Peru, Republic of Korea, Singapore, Thailand, United States of America, Viet Nam

**Meetings:**
- The cluster meets biannually for a 1.5-hour teleconference.

**Contact Points:**
- P. Casetti, Senior MedDRA Consultant, MedDRA, 535 West 21st Street, New York, NY 10010, USA
- Arturo Urrutia, Head of the PV Cluster, AEM surprises, Washington, D.C., USA

### APEC Roadmap to Promote Regulatory Convergence for PV

**Scope:**
- To facilitate convergent evolution of pharmacovigilance (PV) standards amongst APEC economies.
- To strengthen capacity for assessing APEC pharmacovigilance regulatory standards.
- To improve the quality of risk management information from all sources.

**Membership:**
- 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, Republic of Korea, Singapore, Thailand, United States of America, Viet Nam

**Meetings:**
- The cluster meets biannually for a 1.5-hour teleconference.

**Contact Points:**
- P. Casetti, Senior MedDRA Consultant, MedDRA, 535 West 21st Street, New York, NY 10010, USA
- Arturo Urrutia, Head of the PV Cluster, AEM surprises, Washington, D.C., USA

### Mutual Recognition for Regulatory Activities

**Scope:**
- To adopt a dedicated single standardised terminology (MedDRA) applying in multiple stages of the exclusion cycle.
- To support harmonization and standardization of pharmacovigilance activities.

**Membership:**
- Participation of EU: EU Member States, Iceland, Norway, Switzerland, EFTA: Iceland, Liechtenstein, Norway, Switzerland, US, Canada, Mexico, Japan

**Meetings:**
- The cluster meets biannually for 1.5-hour teleconference.

**Contact Points:**
- P. Casetti, Senior MedDRA Consultant, MedDRA, 535 West 21st Street, New York, NY 10010, USA
- Arturo Urrutia, Head of the PV Cluster, AEM surprises, Washington, D.C., USA

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**Notes:**
- Standard update schedule for the above standards.
- Liaison committee update planned for 2016.

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**Notes:**
- Update schedule for the above standards.
- Liaison committee update planned for 2016.

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- Update schedule for the above standards.
- Liaison committee update planned for 2016.

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<tr>
<td>21 PIC/S Pharmaceutical Inspection Cooperating Scheme</td>
<td>The Global Advisory Committee on Vaccine Safety</td>
<td>1. To expand its activities to include training in the field of pharmacovigilance inspections</td>
<td>Autism, Advocacy, Argentina, Armenia, Australia, Austria, Bangladesh, Barbados, Belgium, Benin, Bhutan, Bolivia, Brazil, Brunei Darussalam, Bulgaria, Burkina Faso, Cambodia, Cameroon, Canada, Cape Verde, China, Chile, Colombia, Comoros, Congo, Costa Rica, Cote d’Ivoire, Croatia, Cyprus, Czech Republic, Denmark, Djibouti, Egypt, El Salvador, Eritrea, Estonia, Ethiopia, Falkland Islands, Faroe Islands, Federated States of Micronesia, Fiji, Finland, France, Georgia, Germany, Ghana, Gambia, Greece, Greenland, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, Hungary, Iceland, India, Indonesia, Irish Republic, Israel, Italy, Jamaica, Japan, Jordan, Kenya, Kiribati, Kuwait, Kyrgyzstan, Lao People’s Democratic Republic, Latvia, Lebanon, Lesotho, Liberia, Liechtenstein, Lithuania, Luxembourg, Madagascar, Malawi, Malaysia, Maldives, Mauritania, Mauritius, Mexico, Mongolia, Montenegro, Morocco, Mozambique, Namibia, Nepal, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Norway, Oman, Pakistan, Palau, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Romania, Russian Federation, Rwanda, Saint Kitts and Nevis, Saint Lucia, Samoa, San Marino, Sao Tome and Principe, Saudi Arabia, Senegal, Serbia, Sierra Leone, Singapore, Slovakia, Slovenia, Solomon Islands, South Africa, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, Syrian Arab Republic, Tajikistan, Thailand, Timor-Leste, Togo, Trinidad and Tobago, Tunisia, Turkey, Ukraine, United Arab Emirates, United Kingdom, United States of America, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Yemen, Zambia, Zimbabwe</td>
<td>B annual meetings</td>
<td>Vaccines</td>
<td><a href="mailto:info@pic-scheme.org">info@pic-scheme.org</a></td>
</tr>
<tr>
<td>22 WHO-GACVS Global Advisory Committee on Vaccine Safety</td>
<td>1. Facilitate joint visits to facilitate post visits, aimed to improve the quality of the field of pharmacovigilance inspections</td>
<td>Argentina, Australia, Austria, Belgium, Bulgaria, Chile, China, Colombia, Costa Rica, Croatia, Denmark, Egypt, France, Germany, Greece, Hungary, Iceland, India, Ireland, Italy, Japan, Jordan, Kenya, Korea (Republic of), Kyrgyzstan, Lao People’s Democratic Republic, Latvia, Lesotho, Lithuania, Luxembourg, Madagascar, Malawi, Malaysia, Maldives, Mauritania, Mauritius, Mexico, Mongolia, Montenegro, Morocco, Mozambique, Namibia, Nepal, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Norway, Oman, Pakistan, Palau, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Romania, Russian Federation, Rwanda, Saint Kitts and Nevis, Saint Lucia, Samoa, San Marino, Sao Tome and Principe, Saudi Arabia, Senegal, Serbia, Sierra Leone, Singapore, Slovakia, Slovenia, Solomon Islands, South Africa, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, Syrian Arab Republic, Tajikistan, Thailand, Timor-Leste, Togo, Trinidad and Tobago, Tunisia, Turkey, Ukraine, United Arab Emirates, United Kingdom, United States of America, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Yemen, Zambia, Zimbabwe</td>
<td>N/A</td>
<td>Medicinal products</td>
<td><a href="mailto:info@who.int">info@who.int</a></td>
<td><a href="mailto:gvsi@who.int">gvsi@who.int</a></td>
</tr>
</tbody>
</table>

**Disclaimer:**

The information on this table has been compiled by EMA according to the available data. As in certain cases, it is difficult to base accuracy or up-to-date information and there are continuous changes, EMA strongly recommends to check the information with the relevant websites or directly with the relevant organisations.