

## **Draft list of prioritized activities to implement the workplan of the Member State mechanism for the period 2020–2021**

<b>Prioritized activities</b>	<b>Status</b>	<b>Actions</b>
<p>A. Develop and promote training material and guidance documents to strengthen the capacity of national/regional regulatory authorities for the prevention and detection of and response to substandard and falsified medical products.</p> <p>Lead: Brazil and Secretariat</p>	In progress	<ol style="list-style-type: none"> <li>1. Develop training material for national/regional regulatory authorities, focused on promoting the technical documentation approved by the Member State Mechanism.</li> <li>2. Risk-based post market surveillance – to develop a system and database to automate the conduct of medical products quality surveys and enhance the quantity and quality of data captured to inform risk-based post market surveillance programmes based on existing WHO guidance.</li> <li>3. Develop guidance documents to strengthen capacities of national/regional regulatory authorities for a better prevention, better detection and more effective response to substandard and falsified medical products and on the use of medicine quality surveys system and database.</li> <li>4. Assist in the identification of existing expertise and training material from Member States and other institutions concerning the prevention and detection of and response to substandard and falsified medical products.</li> <li>5. Assist in the identification of training needs of different national/regional regulatory authorities.</li> </ol>
<p>B. Expand and maintain the global focal point network among national medicines regulatory authorities to facilitate cooperation and collaboration.</p> <p>Lead: Secretariat</p>	In progress	<ol style="list-style-type: none"> <li>1. Continue to follow up with Member States to nominate focal points.</li> <li>2. Continue to train new focal points and provide refresher training for existing focal points.</li> <li>3. Facilitate the exchange of information in the global focal point network.</li> </ol>

Prioritized activities	Status	Actions
<p>C. Improve Member States' understanding of detection technologies, methodologies and "track and trace" models.</p> <p>Lead: Secretariat</p>	In progress	<ol style="list-style-type: none"> <li>Convene open-ended expert sessions to review existing field detection devices and "track and trace" models and, as needed:               <ol style="list-style-type: none"> <li>provide updates on existing "track and trace" technologies in use by Member States;</li> <li>report on existing field detection devices in use or available to Member States; and</li> <li>provide updates on existing available authentication technologies.</li> </ol> </li> <li>Working group to refine and present for approval a workplan for 2020–2021 through the Steering Committee as appropriate.</li> </ol>
<p>D. Increase Member States' knowledge of the links between substandard and falsified medical products and access to quality, safe, efficacious and affordable medical products.</p> <p>Lead: Secretariat</p>	In progress	<ol style="list-style-type: none"> <li>Secretariat to review and report on future WHO activities on access to quality, safe, efficacious and affordable medical products, from the angle of links with substandard and falsified medical products.</li> </ol>
<p>E. Develop and leverage existing activity for effective risk communication and make recommendations for awareness campaigns on substandard and falsified medical products.</p> <p>Lead: Secretariat</p>	In progress	<ol style="list-style-type: none"> <li>Develop or leverage recommendations for effective risk communication and awareness campaigns.</li> <li>Produce samples of hard and soft copy material and video and broadcast material.</li> <li>Assess the use of social media for raising awareness.</li> <li>Identify the full range of stakeholders and audiences.</li> <li>Develop key and innovative advocacy material.</li> </ol>
<p>F. Enhance Member States' capacity to expand awareness, effectiveness, impact and outreach in their work on substandard and falsified medical products.</p> <p>Lead: Secretariat</p>	In progress	<ol style="list-style-type: none"> <li>Secretariat, working with Member States, to develop a workplan for the Secretariat and Member States to disseminate and promote the materials and information developed by the Member State mechanism.</li> <li>Member States to use documentation developed by the Member State mechanism and WHO reports as tools to increase political awareness and advocacy at the highest policy levels about the need to support and dedicate resources to prevent, detect and respond to substandard and falsified medical products.</li> </ol>

Prioritized activities	Status	Actions
G. Promote shared understanding among Member States from a public health perspective regarding medical products in transit.	In progress	1. Secretariat to provide an information note on the current situation regarding medical products in transit, within the public health domain.
Lead: Secretariat		
H. Identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet.	In progress	1. Establish a working group to: <ul style="list-style-type: none"> <li>(a) develop terms of reference;</li> <li>(b) provide a problem statement identifying the range of issues that facilitate the sale and supply of substandard and falsified medical products through the internet both nationally and across borders;</li> <li>(c) identify experiences or regulation of the distribution or supply of medical products via the internet to prevent and reduce the risk of substandard and falsified medical products reaching consumers; and</li> <li>(d) develop guidance on strategies to enable national/regional regulatory authorities to address the distribution or supply of substandard and falsified medical products via the internet.</li> </ul>
Lead: Colombia		

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