World Health Organization

**SIXTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS**
**Provisional agenda item 5**

**A/MSM/6/2**
**23 November 2017**

# Draft list of prioritized activities to implement the workplan of the Member State mechanism for the period 2018–2019

| Prioritized activities | Status | Actions |
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| 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.<br><br>Lead: Brazil (maintain working group) | In progress | 1. Develop a guidance document on criteria for risk classification and assessment prioritization of cases of substandard and falsified medical products.<br>2. Assist in the identification of existing expertise and training material from Member States and other institutions concerning the prevention, detection and response to substandard and falsified medical products.<br>3. Assist in the identification of training needs of different national/regional regulatory authorities.<br>4. Develop recommendations regarding national registers of manufacturers, importers, distributors and medical products authorized by Member States.<br>5. Develop training material for national/regional regulatory authorities, focused on promoting the technical documentation approved by the Member State Mechanism.<br>6. 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. |
| B. Expand and maintain the global focal point network among national medicines regulatory authorities to facilitate cooperation and collaboration.<br><br>Lead: Secretariat | In progress | 1. Continue to follow up with Member States to nominate focal points.<br>2. Continue to train new focal points and provide refresher training for existing focal points.<br>3. Facilitate the exchange of information in global focal point network. |

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| C. Improve understanding of Member States on detection technologies, methodologies and "track and trace" models.<br><br>Lead: Argentina (to be confirmed, working group is suspended) and the Secretariat | In progress | 1. Convene open-ended expert sessions to review existing field detection devices and track and trace models and, as needed:<br>(a) Provide updates on existing "track and trace" technologies in use by Member States;<br>(b) Report on existing field detection devices in use or available to Member States;<br>(c) Provide updates on existing available authentication technologies. |
| D. Increase Member States' knowledge of the links between substandard and falsified medical products and access to quality, safe, efficacious and affordable medical products.<br><br>Lead: Secretariat | In progress | 1. WHO 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. |
| E. Develop and leverage existing activity for effective risk communication and make recommendations for awareness campaigns on substandard and falsified medical products.<br><br>Lead: United Kingdom of Great Britain and Northern Ireland (maintain working group) | In progress | 1. Develop or leverage recommendations for effective risk communication and awareness campaigns.<br>2. Produce samples of hard and soft copy material and video and broadcast material.<br>3. Assess the use of social media for raising awareness.<br>4. Identify full range of stakeholders and audiences.<br>5. Develop key and innovative advocacy material. |
| F. Enhance Member States' capacity to expand awareness, effectiveness, impact and outreach in their work on substandard and falsified medical products.<br><br>Lead: to be confirmed | New activity | 1. Develop a communications strategy (managed by Steering Committee and Member State Mechanism) for the work of the Member State Mechanism.<br>2. Work with selected Member States (driven by Secretariat, reported to Steering Committee, and transmitted to Member State Mechanism) to assess the current state of play in terms of challenges and risks.<br>3. Disseminate and use the study on the public health and socioeconomic impact of substandard and falsified medical products and the report on the WHO Global Surveillance and Monitoring System for substandard and falsified medical products as a tool to increase awareness and advocate at the highest policy levels nationally, regionally and globally for support and resources to prevent, detect and respond to substandard and falsified medical products. |

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| G. Promote shared understanding among Member States from a public health perspective regarding medical products in transit.<br><br>Lead: to be confirmed | New activity | 1. Establish a working group, which may seek expert advice from other stakeholders.<br>2. Develop terms of reference, including a common understanding of the term "in transit".<br>3. Develop guidance and risk indicators to identify possible justifications for an intervention by competent authorities from a public health perspective. |
| H. Identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet.<br><br>Lead: to be confirmed | New activity | 1. Establish a working group.<br>2. Develop terms of reference.<br>3. 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.<br>4. 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. |

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