World Health Organization

TENTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS
Provisional agenda item 4

A/MSM/10/5
23 September 2021

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

Status update

Prioritized activities	Status	Actions	Status update as of June 2021
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. Lead: Brazil and Secretariat	In progress	1. Develop training material for national/regional regulatory authorities, focused on promoting the technical documentation approved by the Member State mechanism. 2. Assist in the identification of the training needs, existing expertise and training materials of Member States and other institutions in order to build capacity concerning the prevention and detection of, and response to, substandard and falsified medical products. 3. Risk-based post-market surveillance: (a) Develop tools and a 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. (b) Develop guidance documents to strengthen capacities of national/regional regulatory authorities to plan, perform, and assess risk-based post-market surveillance including the effective use of the tools.	1. **Ongoing:** Brazil and Secretariat continuing to develop training materials, as needed. 2. **Ongoing:** Brazil and Secretariat continuing to identify training needs, existing expertise and training materials, as needed. 3. Risk-based post-market surveillance: (a) **In progress:** Secretariat in process of developing tools and a database to be piloted in the United Republic of Tanzania, with a finalized version to be modified based on lessons learned and used by countries. (b) **In progress:** Brazil leading a working group, with the aim of drafting a guidance document and training materials, as needed.

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B. Expand and maintain the Global Focal Point Network among national medicines regulatory authorities to facilitate cooperation and collaboration. Lead: Member State mechanism with the support of the Secretariat	In progress	1. Continue to follow up with Member States to nominate focal points. 2. Continue to train new focal points and provide refresher training for existing focal points. 3. Facilitate the exchange of information in the Global Focal Point Network.	1. **Ongoing:** Secretariat continuing to follow up with Member States to nominate and/or confirm focal points. 2. **Ongoing:** Secretariat continuing to train new focal points and provide refresher training, including via online regional training workshops. 3. **Ongoing:** Secretariat continuing to facilitate information sharing, including through quarterly technical bulletins, WHO global medical product alerts, and the upgraded online reporting portal for focal points.
C. Improve Member States' understanding of detection technologies, methodologies and "track and trace" models. Lead: Member State mechanism with the support of the Secretariat	In progress	1. Convene open-ended expert sessions to review existing field detection devices and "track and trace" models, and, as needed: (a) provide updates on existing "track and trace" and authentication technologies in use by Member States; and (b) report on existing field detection devices in use or available to Member States. 2. Working group to continue to develop the policy paper on "track and trace" and submit a finalized document to the Member State mechanism.	1. Open-ended expert sessions: (a) **Ongoing:** Secretariat continuing to facilitate expert sessions, including one planned before the tenth meeting of the Member State mechanism. (b) **Ongoing:** Secretariat continuing to facilitate expert sessions, including two sessions on detection technologies held in 2019 and 2020. 2. **Completed:** Working group developed the policy paper on traceability of medical products,[1] with ongoing efforts to update the mapping of country and regional experiences.

[1] https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products (accessed 1 September 2021).

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D. Increase Member States' knowledge of the links between substandard and falsified medical products and access to quality, safe, efficacious and affordable medical products. Lead: Member State mechanism with the support of the Secretariat	In progress	1. 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.	1. **Completed:** Secretariat prepared a report on the link between constrained access to quality, safe, efficacious and affordable medical products and substandard and falsified medical products, as contained in document A/MSM/9/6, with agreement on the recommendations outlined in paragraphs 19 and 20 of that report.
E. Develop and leverage existing activity for effective risk communication and make recommendations for awareness campaigns on substandard and falsified medical products. Lead: Member State mechanism with the support of the Secretariat	In progress	1. Conduct surveys on patient or consumer attitudes and behaviours on accessing medical products in four African countries, and (i) develop or leverage recommendations for effective risk communication and awareness campaigns; (ii) produce samples of hard and soft copy material and video and broadcast material; (iii) assess the use of social media for raising awareness; (iv) identify the full range of stakeholders and audiences; and (v) develop key and innovative advocacy material. 2. Pilot the implementation of a compulsory element in the pharmacy school curriculum in five African countries.	1. **Completed:** Secretariat completed insight studies in Ghana, Nigeria, Sierra Leone and Uganda, with evidence-based communications materials developed and rolled out in risk communication campaigns in countries. Campaigns to be concluded by the tenth meeting of the Member State mechanism, with ongoing efforts to make recommendations for strengthening awareness campaigns. 2. **Completed:** Secretariat conducting the pharmacy school curriculum pilot in Cameroon, Nigeria, Senegal, the United Republic of Tanzania and Uganda, with ongoing efforts to make recommendations for strengthening education.

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F. Enhance Member States' capacity to expand awareness, effectiveness, impact and outreach in their work on substandard and falsified medical products. Lead: Member State mechanism with the support of the Secretariat	In progress	1. Secretariat, working with Member States, to enable a proactive approach to disseminate and promote the materials and information developed by the Member State mechanism. 2. 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.	1. **Ongoing:** Secretariat continuing to proactively disseminate and promote the Member State mechanism at the national, regional and global levels. 2. **Ongoing:** Member States continuing to use documentation by the Member State mechanism to increase political awareness and general awareness within national and regional contexts.
G. Promote shared understanding among Member States from a public health perspective regarding medical products in transit. Lead: Member State mechanism with the support of the Secretariat	In progress	1. Secretariat to provide an information note on the current situation regarding medical products in transit, within the public health domain.	1. **In progress:** The information note on the current situation will be submitted for consideration by the tenth meeting of the Member State mechanism.
H. Identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet. Lead: Colombia	In progress	1. A working group was established to: (a) develop terms of reference (completed); (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 (completed); (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	1. Working Group: (a) **Completed:** Working group was established and the terms of reference completed, as contained in document A/MSM/7/INF./1. (b) **Completed:** Problem statement was completed, as contained in document A/MSM/8/3. (c) **In progress:** A survey was completed to identify experiences or regulations and the results will be shared for consideration by the tenth meeting of the Member State mechanism.

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		medical products reaching consumers; and (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.	(d) **In progress:** A guidance document will be submitted for consideration by the tenth meeting of the Member State mechanism.

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