
Update on the list of prioritized activities for 2022–2023

Report by the Secretariat

BACKGROUND

1. The agreed list of prioritized activities to implement the workplan of the Member State mechanism¹ for the period 2022–2023² contains eight prioritized activities, of which seven are led by Member States and one is currently supported by the WHO Secretariat. This document provides a progress update on these activities.

Activity A: Strengthen the capacity of national/regional regulatory authorities for the prevention and detection of, and response to, substandard and falsified medical products

2. This activity is led by Brazil. To ensure that training materials for national/regional regulatory authorities are accessible and readily available, the Secretariat has aligned its efforts with the WHO Global Benchmarking Tool for evaluation of national regulatory systems. The prevention and detection of, and response to, substandard and falsified medical products are critical for strong regulatory systems. The Secretariat has therefore continued to focus on building a modernized risk-based post-market surveillance process through the deployment of the Epione e-tool and the conducting of a return-on-investment study in the United Republic of Tanzania. Brazil, the lead of the working group, intends to circulate the draft risk-based post-market surveillance guidance soon.

Activity B: Develop, expand and maintain global networks of stakeholders to facilitate cooperation and collaboration

3. This activity is led by Eritrea. The Secretariat has worked to strengthen the Global Focal Point Network, including by conducting regional training and through regular monitoring and validation of focal point contacts. As agreed at the ninth meeting of the Member State mechanism,³ the working group aims to: identify solutions to reporting barriers, develop strategies to improve reporting of substandard and falsified medical products, and facilitate the exchange of communication. A multinational study will be performed, the results of which will provide indications of where, and at what level, training is

¹ The Director-General will transmit to the Executive Board at its 152nd session the reports of the tenth and eleventh meetings of the Member State mechanism on substandard and falsified medical products, which met virtually from 27 to 28 October 2021 and in Geneva from 19 to 21 October 2022, respectively.

² Document A/MSM/10/11 Rev.1, Annex 2.

³ Document A/MSM/9/7.

required as well as the challenges Member States are facing when reporting substandard and falsified medical products.

Activity C: Improve Member States' understanding and uptake of technologies to screen and detect substandard and falsified medical products, and the implementation of national traceability systems

4. The working group on traceability is led by Nigeria. Member States are requested to update, every two years, information on their respective country experiences of implementing national traceability systems so as to provide guidance to other Member States looking to implement similar systems. As agreed at the ninth meeting of the Member State mechanism, a new working group on detection technologies was established and tasked with supporting the Secretariat who will develop technical guidance on this topic.¹ The working group on detection technologies is led by Montenegro. This working group aims to develop a questionnaire that will ask Member States to provide details on existing methodologies and/or tools used within their jurisdiction. It is expected that the questionnaires will be completed and the corresponding data made available by mid-2023. By the end of 2022, the working group also aims to develop a table of contents for proposed WHO guidance on the selection of detection technologies for Member State information.

Activity D: Leverage the competencies of relevant stakeholders, including policy-makers, procurers, distributors, practitioners, patients and consumers, and good governance to reduce the burden of substandard and falsified medical products

5. Pending identification of a Member State lead, this activity is being supported by the Secretariat. The Secretariat aims to develop a handbook for Member States on developing/strengthening national action plans for prevention, detection and response strategies on substandard and falsified medical products. This work is being carried out in line with the Global Benchmarking Tool for evaluation of national regulatory systems and other stakeholder guidance (such as that published by the World Customs Organization (WCO) and the United Nations Office on Drugs and Crime (UNODC)).

Activity E: Enhance Member States' capacity to run effective risk communication campaigns for substandard and falsified medical products

6. This activity is led by Zambia. Risk communication campaigns and pharmacy school curriculum pilot projects have been rolled out, the results of which will be shared with the Member State mechanism upon completion of the pilots. The new working group was established to identify ways in which Member States and other relevant stakeholders could build on the lessons learned from such projects.²

¹ Ibid.

² Ibid., paragraph 16.

Activity F: Enhance Member States' capacity to expand awareness, effectiveness, impact and outreach in their work on substandard and falsified medical products

7. This activity is led by Australia. The working group focuses on linking national, regional and global awareness-raising efforts. The Secretariat continues to proactively disseminate and promote the work of the Member State mechanism and encourages Member States to participate in this activity.

Activity G: Identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet

8. This activity is led by Colombia. As agreed at the tenth meeting of the Member State mechanism,¹ the working group aims to: develop a strategic road map promoting inter-agency cooperation and collaboration with relevant stakeholders to respond to the online distribution of substandard and falsified medical products, and promote awareness-raising and policy visibility of the online distribution of substandard and falsified medical products. Regarding next steps, the working group plans to advocate for Member State capacity-building so that all Member States can respond effectively to the online distribution of substandard and falsified medical products, including by utilizing the relevant policy recommendations available on the Member State mechanism web page.²

Activity H: Develop strategies for national regulatory authorities to mitigate public health risks posed by the distribution of substandard and falsified medical products through informal markets

9. This activity is led by the United States of America. As agreed at the tenth meeting of the Member State mechanism,³ the working group has devised a proposed definition of the term “informal markets of medical products” (see Annex). The working group tasked the Secretariat with conducting a literature review of informal markets of substandard and falsified medical products and performing a landscape analysis of existing gaps of informal markets for medical products, including known prevalence of substandard and falsified medical product sale and/or distribution, as well as regulatory interventions to control and limit the sale and/or distribution of substandard and falsified medical products. The working group identified a definition of the term “informal markets of medical products”, as contained in the Annex to this document, which will serve as a basis for conducting its work.

ACTION BY THE MEMBER STATE MECHANISM

10. The mechanism is invited to note this report and provide any specific guidance or advice relating to the activities and actions outlined above. The chairs of the various activity working groups also seek Member State participation in the discussions of those working groups, including the sharing of experiences and lessons learned related to any guidance or handbooks proposed for development.

¹ Document A/MSM/10/11 Rev.1.

² https://www.who.int/health-topics/substandard-and-falsified-medical-products#tab=tab_1 (accessed 21 September 2022).

³ Document A/MSM/10/11 Rev 1.

ANNEX

**PROPOSED DEFINITION OF THE TERM “INFORMAL
MARKET OF MEDICAL PRODUCTS”**

A sector of national or local economy where:

- the manufacture, import or export, distribution, sale, supply, or purchase of medical products takes place outside of the legal, regulatory or administrative oversight of relevant public health or regulatory authorities;
- the medical products have or have not been assessed for safety, efficacy or quality by public health and regulatory authorities;* and
- the aforementioned activities may be conducted by persons or entities with or without appropriate qualifications and may take place in a physical, virtual or hybrid environment.

*Authorized products found on the informal market are not considered substandard and falsified products per se.

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