World Health Organization

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

A/MSM/13/3
14 October 2024

Updates on the prioritized activities for 2024–2025, including the strategic plan

Report by the Secretariat

BACKGROUND

1. The agreed list of prioritized activities to implement the workplan of the Member State mechanism[1] on substandard and falsified medical products for the period 2024–2025 contains 10 prioritized activities,[2] all led by Member States, with the support of the WHO Secretariat. The addition of two new columns to the list of prioritized activities, namely (a) "Metrics/Success indicators" and (b) "Expected outcomes", will help to better reflect the performance, impact and results of the proposed actions relating to the prioritized activities. The present 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. The Secretariat has aligned its efforts with the WHO Global Benchmarking Tool for the evaluation of national regulatory systems for medical products, to ensure that training materials are accessible and readily available to national/regional regulatory authorities. Working Group A has reviewed assessment reports for 35 benchmarked national regulatory authorities and related institutional development plans, from which training and capacity needs were extracted. An update of the review analysis is available.[3] The Secretariat has continued to focus on building a modernized, risk-based, post-market surveillance process through the deployment of its e-tool, Epione. Work is currently underway to implement the necessary enhancements and updates to Epione, and a number of countries are expected to start using the updated version of the tool. Several members of Working Group A are also working with a consultant and external experts to develop a new guideline for national regulatory authorities market surveillance and control activities.

[1] The Director-General will transmit to the Executive Board at its 156th session the reports of the twelfth and thirteenth meetings of the Member State mechanism on substandard and falsified medical products, held from 15 to 17 November 2023 and from 20 to 22 November 2024, respectively.

[2] See document A/MSM/12/9.

[3] See document A/MSM/13/4.

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

3. This activity is led by Eritrea. The Secretariat continues to strengthen the Global Focal Point Network by conducting regional training in the South-East Asia and Western Pacific regions (February 2024) and by regularly monitoring and validating focal point contacts. Working Group B is drafting the terms of reference for developing a communication platform to address incidents involving substandard and falsified medical products, which will facilitate information sharing and networking among focal points and other stakeholders. Additionally, the Working Group has begun to develop key performance indicators to monitor the functionality of the Global Focal Point Network and update its terms of reference.[1]

Activity C: Improve Member States' understanding and uptake of technologies to screen and detect substandard and falsified medical products.

4. This activity is led by Montenegro. Working Group C conducted a multinational survey on the detection methodologies and tools used by Member States within their jurisdictions. The questionnaire was distributed and the survey findings were presented at the Steering Committee meeting in March 2024.[2] Additionally, Working Group C is developing user requirements for an optimal handheld device for screening substandard and falsified medicines. The Working Group plans to organize a technical briefing session (in November 2024) on improving Member States' understanding and uptake of technologies to screen and detect substandard and falsified medical products.

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. This activity is led by South Africa. The Secretariat drafted a handbook for Member States on developing and strengthening national action plans for the prevention and detection of, and response to, substandard and falsified medical products. Working Group D reviewed the draft handbook, the contents of which are now being trialled as part of a pilot exercise in South Africa, prior to the handbook being finalized. Additionally, the Gambia and Nigeria are already using the draft handbook in their work on validating their national action plans.

Activity E: Enhance Member States' capacities to develop and utilize effective risk communication strategies, with the aim of expanding awareness of substandard and falsified medical products.

6. This new activity, led by Italy, is the result of the decision to merge, for the period 2024–2025, prioritized activities E and F.[3] Working Group E plans to collate and classify communication and awareness-raising exercises conducted by Member States. After completing this mapping exercise, the Working Group aims to create a virtual bookshelf of existing risk communication models that Member States can use and adapt to their needs. Working Group E plans to hold an informal technical meeting (in November 2024) on effective risk communication and awareness strategies for tackling substandard and falsified medical products: case studies from Member States.

[1] See document A/MSM/4/2.

[2] See document A/MSM/13/5.

[3] See document A/MSM/10/11 Rev.1 (Annex 2).

Activity F: Strengthening the supply chain of high-risk excipients and related raw materials.

7. This new activity, led by the United States of America, was initiated based on lessons learned from recent cases of medical product contamination with diethylene glycol and ethylene glycol. The purpose of Working Group F is to develop upstream and downstream strategies and interventions to prevent, detect and respond to the prevalence of substandard or falsified excipients used in the manufacture of medicines. Strengthening efforts to address excipient quality and safety in the pharmaceutical supply chain is crucial owing to: (a) the significant public health impact; (b) the need to ensure supply chain integrity; and (c) the need for global collaboration and harmonization.

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. Working Group G is working to improve capacity-building among Member States to respond to the distribution of substandard and falsified medical products via the internet, including the use of policy recommendations from the Member State mechanism internet guidance. The Working Group and the Secretariat are developing the terms of reference for the development of the internet training programme. Working Group G also plans to hold an informal technical meeting (in November 2024) on detecting and assessing websites suspected of advertising/supplying substandard and falsified medical products, with a demonstration of tools to automate and triage websites for review by regulators.

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,[1] Working Group H was established to develop strategies for national regulatory authorities to mitigate public health risks posed by the distribution of substandard and falsified medical products through informal markets. The Working Group is currently focused on refining and streamlining a pilot survey to assess Member State experiences, challenges, and responses relating to informal markets. Working Group H plans to organize an informal technical meeting (in November 2024) on how Member States respond to substandard and falsified medical products in informal markets. The Working Group also intends to finalize the output from the expert meeting held in December 2023 in Utrecht, the Kingdom of the Netherlands, which will involve developing technical activities to gather information to address identified knowledge gaps.

Activity I: Identification of and response to emerging issues on substandard and falsified medical products.

10. This new activity is led by the Chair of the Member State mechanism. It was created in response to the need to address emerging issues, based on lessons learned from the response to the latest cases involving the contamination of medical products with diethylene glycol and ethylene glycol. The purpose of Working Group I is to identify and address emerging issues of relevance to substandard and falsified medical products. The activity aims to strengthen the agility of the Member State mechanism to respond swiftly and effectively to acute and emerging trends, incidents, events and issues associated

[1] See document A/MSM/10/11 Rev.1.

with the detection and prevention of, and response to, substandard and falsified medical products, in order to safeguard public health.

Activity J: Improve Member States' implementation of national traceability systems.

11. This new activity, led by Nigeria, is the result of the decision to separate, for the period 2024–2025, the two working groups for prioritized activity C.[1] Working Group J conducted a multinational survey of Member States' experiences relating to the traceability of medical products and the mapping of national traceability systems and associated technologies.[2] The final report, containing the survey findings, will be available to all Member States.

ACTION BY THE MEMBER STATE MECHANISM

12. The Member State mechanism is invited to note the report. In its discussions, it is further invited to provide comments and guidance in respect of the following question.

- Reflecting on the low participation of Member States in the meetings and activities of the workplan for the period 2022–2023, in what ways could Member State engagement be increased to ensure that, for the remainder of the period 2024–2025 and in the future, all prioritized activities are successfully led and completed?

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[1] See document A/MSM/10/11 Rev.1 (Annex 2).

[2] See document A/MSM/13/6.