

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

Report by the Director-General

Background

1. The agreed list of prioritized activities to implement the workplan of the Member State mechanism¹ 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. All the activities are led by Member States with the support of the WHO Secretariat. 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, with the Secretariat aligning its efforts to the WHO Global Benchmarking Tool to ensure training materials are accessible to national and regional regulatory authorities. Working Group A reviewed a consultant's analysis of consolidated benchmarking results, institutional development plans and proposed training needs from 35 national regulatory authorities. An updated review is available. The Secretariat continues to strengthen post-market surveillance through the deployment of Epione, a risk-based electronic tool. Enhancements are under way and several countries are expected to adopt the updated version. A new guideline on market surveillance and control activities, developed with contributions from Member States across all WHO regions, was tabled at the WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2025 for formal endorsement as a global norm and standard.

¹ The Director-General transmitted 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.

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 reinforce the Global Focal Point Network by delivering ongoing online training sessions for Member States, organizing regional training (African Region, February 2024) and systematically monitoring and validating focal point contact information. The launch of the online Global Surveillance and Monitoring System course in March 2023 has contributed to an increase in the reporting of substandard and falsified incidents. Furthermore, Working Group B has revised the terms of reference of the Global Focal Point Network and established key performance indicators³ to assess its functionality, with the objective of building a well-structured, visible and resilient global network.

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, with the support from the Secretariat, published a report presenting the findings of a multinational survey on the detection methodologies and tools used by Member States to detect substandard and falsified medical products within their jurisdictions.⁴ Additionally, the Working Group is developing user requirements for an optimal handheld device to screen such products. The Working Group organized a series of technical briefing sessions (two held in November 2024 and May 2025, respectively, and one scheduled for November 2025) aimed at enhancing Member States' understanding and adoption of relevant technologies.

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 has drafted a handbook to support Member States in developing and strengthening national action plans for the prevention, detection, and response to substandard and falsified medical products. Working Group D reviewed the draft handbook, which is currently being trialled through a pilot exercise in South Africa prior to its finalization. Additionally, the national action plans for the Gambia and Nigeria were validated using a theme-based checklist developed from the draft handbook.

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 activity is led by Italy. Working Group E has finalized the compilation of various communication and awareness-raising initiatives conducted by Member States participating in the Working Group. To complete this mapping exercise, the Working Group is planning to launch a survey targeting all Member States. The aim is to create a virtual bookshelf of existing risk communication models that Member States can use and adapt to their specific needs. In November 2024, the Working Group held an informal technical meeting focused on effective risk

³ See document A/MSM/14/4.

⁴ [Report of existing technologies used to screen and detect substandard and falsified medical products.](#) Geneva: World Health Organization; 2025.

communication and awareness strategies for addressing substandard and falsified medical products, featuring case studies from Member States. By the end of 2025, the Working Group plans to organize an online conference on risk communication and awareness campaigns, inviting not only Member States but also key stakeholders and partners.

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

7. This activity, led by the United States of America, was initiated in response to recent contamination incidents involving diethylene glycol and ethylene glycol. Working Group F is focused on developing upstream and downstream strategies to prevent, detect and respond to the use of substandard or falsified excipients in medicine manufacturing. The Working Group discussed and supported the development of self-assessment surveys targeting excipient manufacturers, finished product producers and Member States. The proposed surveys would aim to gather data on current practices and identify gaps, including insights from the joint WHO–UNODC report on *Contaminated Medicines and Integrity of the Pharmaceutical Excipients Supply Chain*. Members also recommended that future data collection be de-identified to better capture “near-miss” events and support broader risk mitigation efforts.

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 focused on strengthening Member States’ capacity to respond to the distribution of substandard and falsified medical products via the internet, including through the use of policy recommendations derived from the Member State mechanism’s internet guidance. The Working Group and the Secretariat explored a pilot study with volunteer Member States to evaluate the effectiveness of MEDICRAWL, a web tool designed to detect suspicious websites. Following changes in the tool’s development, the Working Group is now exploring options to relaunch the initiative with support from a sponsoring Member State or expert consultants.

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 and Botswana (ad interim). Working Group H aims to develop strategies for national regulatory authorities to mitigate public health risks associated with the distribution of substandard and falsified medical products through informal markets. The Working Group is currently reviewing ongoing activities and identifying appropriate strategies to gather evidence and address existing knowledge gaps. One of the key outputs for 2025 will be a peer-reviewed publication based on research conducted on behalf of the Working Group. The paper describes the different types of informal markets, the medical products sold, the drivers behind informal market medical products, their sources and the profiles of clients using them. The manuscript is currently undergoing WHO clearance in preparation for publication.

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

10. This 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 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 activity is led by Nigeria. Working Group J conducted a multinational survey on Member States' experiences with the traceability of medical products, including the mapping of national traceability systems and associated technologies. With support from the Secretariat, the Working Group published the report presenting the survey findings in March 2025.⁵ Additionally, the Working Group organized a series of technical briefing sessions (held in November 2024 and May 2025) aimed at enhancing Member States' understanding of the importance of implementing national traceability systems.

Action by the Member State mechanism

12. The mechanism is invited to note this report and provide any specific guidance or advice relating to the activities and actions outlined above.

⁵ [Country experiences on implementation of traceability for medical products](#). Geneva: World Health Organization; 2025.