World Health Organization

Fifteenth meeting of the Member State mechanism on substandard and falsified medical products

Provisional agenda item 4 A/MSM/15/3

17 November 2026

Updates on the prioritized activities for 2026–2027, 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 mechanism[1] on substandard and falsified medical products for the period 2026–2027 comprises three prioritized activities.[2] Activities A and B are currently led by Member States with the support of the WHO Secretariat, while activity C is awaiting identification of a Member State lead. This document provides an update on progress made in implementing these activities.

Activity A: Detection technologies, risk communication and regulatory strengthening for the prevention, detection and response to substandard and falsified medical products

2. This activity is led by Jordan and co-led by Mozambique, with the support of the WHO Secretariat. Under this activity, Working Group A will consolidate a list of tools to assess training needs and update training materials; support the Secretariat in promoting the adoption of optimal screening technologies and ensuring their interoperability; assist Member States in developing and implementing effective risk communication strategies; and improve the availability, dissemination and usability of WHO knowledge base resources. The Working Group is currently developing the list of training needs and materials, drawing on the draft report on identifying common gaps in the market surveillance and control of medical products (a cross-sectional analysis of benchmarking data from 34 national regulatory authorities benchmarked between 2016 and 2024); the list will be finalized in the first quarter of 2027. A completed survey and mapping of Member State risk communication activities is planned for the first quarter of 2027. The WHO handbook and key considerations on risk communication campaigns on substandard and falsified medical products for healthcare practitioners and the public have been finalized and are undergoing the WHO publishing clearance process, with publication expected before the end of 2026. Also related to risk communication, the WHO *Risk communication and community engagement readiness and*

[1] The Director-General transmitted to the Executive Board at its 158th session the report of the fourteenth meeting of the Member State mechanism on substandard and falsified medical products, held from 12 to 14 November 2025.

[2] See document A/MSM/14/5.

response toolkit: substandard and falsified medicines was published in May 2026.[3] This toolkit presents a set of tools and methodologies to support the collection and analysis of social and behavioural data, risk assessment, stakeholder mapping, and the planning and implementation of risk communication strategies across the readiness, response and recovery phases. The WHO guidance for national action plans against substandard and falsified medical products is also in its final stages and is planned for publication by the end of 2026.

Activity B: Develop strategies to address unregulated distribution channels for substandard and falsified medical products through informal markets, including internet sales

3. This activity is led by Botswana and co-led by Rwanda, with the support of the WHO Secretariat. Under this activity, Working Group B will develop inter-agency and multisectoral strategies to strengthen the capacity to detect, monitor and respond to substandard and falsified medical products sold online and through informal markets; develop a comparative analysis of existing online surveillance tools to assist in the identification of such products; and conduct technical briefings and share best practices among Member States. The Working Group is still discussing its plans for the 2026–2027 workplan and has planned a technical briefing session on "Closing the gaps: strategies to address unregulated distribution of substandard and falsified medical products" on 26 November 2026, on the margins of the fifteenth meeting of the Member State mechanism, with the participation of Member States sharing the growing risks and strategies associated with online sales and the emerging threats of unregulated products. These actions are expected to equip Member States with strategies, tools and guidance to counter the distribution of substandard and falsified medical products through the internet and informal markets, and to improve cooperation and information sharing among Member States.

Activity C: Strengthen the supply chain of high-risk excipients and related raw materials

4. A Member State to lead this activity is yet to be identified. In line with the request of the Steering Committee, the Secretariat is seeking expressions of interest from Member States for the chairing and co-chairing arrangements of this activity. Under this activity, Working Group C will provide a forum for Member States and stakeholders to discuss approaches for strengthening oversight of high-risk excipients and related raw materials. Initial discussions included consideration of a working definition of high-risk excipients; methodologies for conducting global risk assessments; approaches to identifying vulnerabilities across manufacturing, distribution and storage pathways; and mechanisms for improving information and data sharing on excipient quality, control and safety. The Working Group also discussed exploration of lessons learned from incidents involving contaminated excipients such as diethylene glycol and ethylene glycol, and considered the potential value of tools such as a global database of high-risk excipients.

Action by the Member State mechanism

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

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[3] Risk communication and community engagement readiness and response toolkit: substandard and falsified medicines. Geneva: World Health Organization; 2026.