World Health Organization

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

Provisional agenda item 2 A/MSM/15/2

17 November 2026

Update by the Secretariat on the activities and budget to implement the workplan of the Member State mechanism

Report by the Director-General

1. The Secretariat continues to support implementation of the workplan of the Member State mechanism on substandard and falsified products.[1] Following endorsement by the fourteenth plenary meeting of a streamlined set of three priority activities for 2026–2027, implementation is focused on strengthening prevention, detection and response to substandard and falsified medical products. Wider support continues through technical assistance, development of guidance and tools, evidence generation, and collaboration with Member States and partners. This approach will increasingly use global surveillance data and regional contextual intelligence to target support, identify recurring vulnerabilities, and translate reported signals into proportionate prevention, detection and response measures. Sustainable financing remains essential to accelerate country and regional implementation and maintain core global functions.

Ensuring global and national systems for market surveillance

2. The Secretariat supported implementation of institutional development plans for market surveillance and control, national action plans and risk-based post-market surveillance. The Epione risk-based surveillance e-tool was piloted in additional countries, while work continued on guidance for screening technologies, regulatory and laboratory capacity strengthening, and practical implementation support. The WHO guideline on good regulatory practices for market surveillance and control of medical products[2] and the *Digital transformation handbook for reporting substandard and falsified medical products*[3] were published.

[1] Draft list of prioritized activities to implement the workplan of the Member State mechanism for the period 2026–2027.

[2] WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-ninth report. Annex 9. Good regulatory practices for market surveillance and control of medical products. Geneva: World Health Organization; 2026.

[3] Digital transformation handbook for reporting substandard and falsified medical products. Geneva: World Health Organization; 2026.

3. Country support is being progressively aligned with regional delivery arrangements so that routine implementation, training and follow-up can be provided closer to Member States, while the Secretariat at headquarters retains responsibility for global standards, technical quality assurance and strategic oversight.

Implementing prevention, detection and response strategies

4. Work continued to strengthen countries' prevention, detection and response capacities through updated training materials, technical briefings, peer-to-peer learning and risk communication tools. The *Risk communication and community engagement readiness and response toolkit: substandard and falsified medicines*[4] was published, and three WHO medical product alerts and one information notice for users of in vitro diagnostic products were issued to support timely national action.

Applying the WHO Global Surveillance and Monitoring System for substandard and falsified medical products

5. The upgraded, multilingual WHO Global Surveillance and Monitoring System (GSMS) was launched in November 2025. The new platform supported increased submission of incidents by national regulatory authorities and focal points. Work also continued on evidence generation, including analysis of the impact of substandard and falsified medical products on vulnerable populations, links with antimicrobial resistance, and exploration of artificial intelligence and machine-learning approaches to support incident triage and surveillance.

6. Priorities for 2027 include improving GSMS data quality, focal point participation and regional analytical use. Regional offices will progressively support country reporting and contextual follow-up, while headquarters retains platform stewardship, global data governance and cross-regional analysis.

Addressing unregulated distribution channels

7. The Secretariat continued work on regulatory approaches to the online sale of medical products and informal markets. This included renewed collaboration with the national supervisory authority for medicines and medical devices in Switzerland on online monitoring approaches, consideration of open-source and cloud-hosted solutions, and development of practical guidance, inspection and risk-mapping tools. Research on informal medicine markets was completed and published, with country experiences informing future implementation guidance.

Strengthening supply chains of high-risk excipients and related raw materials

8. Collaboration continued with international and industry partners to strengthen detection and prevention of contamination involving high-risk excipients and related raw materials. Activities included evidence generation on incidents and supply-chain vulnerabilities, training on diethylene glycol and ethylene glycol testing methods, and engagement with regulators, manufacturers and suppliers on good practices and policy recommendations.

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

Supporting countries in developing and implementing strategies

9. Technical assistance continued for national action plans, institutional development plans, reporting systems and country-level application of WHO tools and guidance. Member States also requested practical support on surveillance, laboratory systems, detection technologies, digital solutions and risk communication.

10. In 2027, greater emphasis will be placed on supporting regional offices to coordinate routine country engagement, adapt global tools to regional contexts and languages, and facilitate peer learning, while complex incidents, normative work and global coordination remain led by headquarters.

Enhancing collaboration, evidence and innovation

11. The Secretariat continued collaboration with regional offices, national authorities, academic institutions and technical partners. Cross-cutting work included a return-on-investment study on market surveillance, joint WHO–World Organisation for Animal Health work on substandard and falsified antimicrobial agents and antimicrobial resistance, and exploration of digital and artificial intelligence-enabled approaches to surveillance.

12. The 2022–2025 GSMS trends and activities report will provide an evidence base for future prioritization by highlighting reported patterns of harm, surveillance and response capacity, emerging product and supply-chain risks, and areas where further research is required.

Challenges

13. The mechanism agreed to reduce prioritized activities from 10 to three to concentrate limited resources. However, continuing Member State requests to WHO for support in deprioritized areas further strain available resources. These requests explain the report's coverage of those areas and highlight ongoing needs to consider when setting priorities for the next cycle.

14. In the ongoing environment of constrained resources and prioritization, including the focus on the three priority activities in the current mechanism's workplan, the Secretariat will continue to work closely with Member States to sustain essential global functions, while promoting collaboration between mechanism Vice-Chairs and regional offices to support effective implementation of the prioritized activities at the regional and country levels.

Strategic outlook for 2027

15. In 2027, implementation will focus on the three prioritized activities, with stronger use of GSMS intelligence. Regional offices will progressively take on routine country engagement, training and implementation follow-up, adaptation of global tools to regional contexts and languages, peer learning, and support for GSMS country reporting and contextual follow-up. A review in 2027 will assess results, clarify responsibilities and determine which arrangements to sustain or adjust.

Action by the Member State Mechanism

16. The mechanism is invited to note the report. In its discussions, it is further invited to provide comments and guidance in respect of the following questions:

- How should the Secretariat respond to requests from Member States, made outside the mechanism workplan, for support on deprioritized activities?
- What opportunities are there to strengthen communication between mechanism Vice-Chairs and regional offices, so that Vice-Chairs can draw on regional- and country-level implementation of the prioritized activities?
