
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 reiterates its support for the implementation of the Member State mechanism workplan. While resource mobilization efforts remain a priority, the financial sustainability of the workplan continues to pose challenges, particularly in the context of ongoing organizational restructuring and prevailing fiscal constraints. This report provides a comprehensive account of the principal achievements and challenges encountered during the 2024–2025 implementation period, thereby informing deliberations on the proposed direction for the upcoming biennium.

Ensuring global and national systems for market surveillance

2. Efforts have been initiated to support three WHO regions and 15 countries in conducting risk-based post-market quality surveillance. Collaborations with regional offices and national authorities are ongoing; initial assessments have been completed in several countries. However, challenges remain in terms of data collection and analysis, particularly in low-income countries. Of the allocated budget, 50% has been utilized, with the remaining 50% required for 2025. The funds have been efficiently used to establish surveillance mechanisms and conduct training workshops.

3. The development of electronic tools and spectral libraries for detecting substandard and falsified medical products is under way. Preliminary versions of these tools have been piloted in the African Region. A significant funding gap exists for expanding the deployment of these tools and ensuring that they are accessible to any Member State that may need them.

4. Guidance and knowledge tools were developed and implemented in five countries during 2024 to support effective market surveillance and control. However, there is a need to expand these efforts to more countries and to address specific needs in different contexts. Half of the allocated budget has been used, with additional funds required to further refine these tools and adapt them to country-specific contexts.

Implementing prevention, detection and response strategies

5. A global landscape analysis has been conducted and support provided to countries to select appropriate technologies for screening and detecting substandard and falsified medical products. However, challenges remain in terms of affordability and accessibility, particularly in vulnerable low- and middle-income countries. There is a significant funding shortfall, which may impact the completion of this activity.
6. Support has been provided to countries to establish procedures for reporting incidents related to in vitro diagnostics and to implement guidance on regulating internet sales and informal markets. However, further efforts are needed to ensure consistent compliance and enforcement. Adequate resources are available to that end.
7. Progress has been made in conducting landscape analyses and providing support to countries to implement guidance on models for national traceability systems. However, further investment is required to develop and implement robust traceability systems in all countries. Funding is still needed to advance these initiatives.

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

8. The Secretariat has supported countries in reporting incidents and field safety corrective actions related to WHO-recommended in vitro diagnostics through the Global Surveillance and Monitoring System for substandard and falsified medical products. Nevertheless, further efforts are needed to strengthen comprehensive reporting and ensure the timely management of incidents.
9. The Secretariat has undertaken efforts to manage, upgrade and maintain the WHO Global Surveillance and Monitoring System, including strengthening its integration with other relevant databases. These enhancements are expected to improve user experience and increase reporting through the portal. While progress has been made, sustained investment is essential to ensure the System's long-term effectiveness and stability. Additional funding is required in 2025 to support ongoing upgrades and maintenance and to safeguard the System's ability to respond to emerging public health needs.

Communicating risk and impact of substandard and falsified medical products

10. Risk communication efforts are ongoing, including the issuance of global medical product alerts and plans to share interactive content on substandard and falsified products via the WHO website. These initiatives aim to raise awareness and support timely action. Additional funding is however needed to expand the reach and impact of these efforts, alongside strengthened global collaboration and more transparent information sharing among stakeholders.
11. Annual and semi-annual reports based on data from the WHO Global Surveillance and Monitoring System have been produced, providing valuable insights into the scope and impact of substandard and falsified medical products. However, there is a need to further analyse and interpret the data to inform policy- and decision-making.

Supporting countries in developing and implementing strategies

12. A comprehensive review is being conducted; the preliminary findings have identified significant barriers to reporting in certain regions. Further efforts are needed to address these barriers and support countries in implementing effective reporting systems. Additional funds are required to finalize and disseminate guidance.

13. Following a benchmarking exercise, support has been provided to 10 countries to implement market surveillance, control and vigilance-related institutional development plans. However, there is a need to expand this support to more countries and to ensure the sustainability of the plans.

14. Guidance on national action plans to combat substandard and falsified medical products has been developed, piloted and successfully rolled out in five Member States, generating strong interest from several others. To ensure effective implementation and address country-specific needs, additional support remains essential. While half of the allocated budget has been utilized, the remaining funds are needed to sustain and expand this work. Continued financial investment, coupled with tailored technical assistance, will be critical to translating interest into impactful national plans.

Enhancing external support and internal capacity

15. Collaborative advocacy, training and capacity-building activities have been conducted with key strategic partners, focusing on customs and law enforcement in 10 countries. However, there is a need to expand these activities to more countries and to address the specific needs of different stakeholders.

16. Support has been provided to establish regional focal point networks for substandard and falsified medical products and to promote coordination and collaboration among those networks and with the Global Focal Point Network for substandard and falsified medical products. However, further efforts are needed to strengthen the networks and ensure their effectiveness. Funds are required for 2025 to continue these efforts.

Leveraging data for policy, legislative and programme activities

17. Measures have been taken to support and promote the prioritized activities and working groups of the Member State mechanism. Several initiatives are already producing positive outcomes. Funds are required for 2025 to continue these efforts.

Challenges

18. Significant funding gaps remain for many activities, particularly in the areas of national traceability systems, national action plans and institutional development planning. It is recommended that increased funding be secured to address these gaps and ensure the sustainability of activities.

19. There is a need for continued capacity-building at the regional and country levels to support the implementation of activities relating to substandard and falsified medical products. Ongoing training and capacity-building activities are essential for the success of the workplan but require sustained funding and resources.

20. The reach of risk communication efforts needs to be expanded to ensure that critical information about substandard and falsified medical products is disseminated widely and effectively.

21. Significant progress has been achieved in several areas, despite funding challenges and some delays. Continued monitoring and adjustments to the workplan will be essential to adapt to evolving needs and circumstances.

Action by the Member State mechanism

22. 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.

- What strategies can be implemented to prioritize the most critical components of these activities, ensuring alignment with available resources?
- How can collaboration with regional and global partners be strengthened to pool resources and expertise in order to continue and expand these activities?
