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

1. The fourteenth meeting of the Member State mechanism on substandard and falsified medical products was held in Geneva, Switzerland in a hybrid format from 12 to 14 November 2025. The meeting was chaired by Professor Emile Bienvenu (Rwanda) and attended by the following Vice-Chairs: Dr Paul Huleatt (Australia), Ms Laila Mouawad (Brazil), Mrs Annam Visala (India), Dr Fatemeh Bashokouh (Islamic Republic of Iran), Dr Ronny Berkovitz (Israel), Dr Mohammed Hamdan Al Rubaie (Oman), Mr Pavle Zelic (Serbia), and Mr Mark Abdoo (United States of America). Dr Alegnta Gebreyesus Guntie participated on behalf of Ms Heran Gerba Borta (Ethiopia) and Mr Dongil Park participated on behalf of Ms Eun Hee Moon (Republic of Korea). Representatives from 64 Member States participated in the meeting and the non-Member Observer State of Palestine attended.

2. The WHO Assistant Director-General (Health Systems, Access and Data), Dr Yukiko Nakatani, opened the meeting by welcoming Member State delegates and the Steering Committee members, and by thanking Member States for their continued commitment and engagement. Dr Nakatani highlighted the mechanism's role in protecting global public health from substandard and falsified medical products, noting that WHO's Global Surveillance and Monitoring System had recorded over 10 000 suspect products since 2013. She acknowledged the significant progress achieved under the 2024–2025 workplan despite resource constraints. Looking ahead, she emphasized that the mechanism was entering a strategic phase guided by lessons from the independent evaluation, focused on ensuring sustainability, efficiency and alignment with Member States' needs. Dr Nakatani highlighted that the meeting would review progress and agree on priorities for 2026–2027 to guide implementation in the next biennium.

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

3. The Secretariat provided an update on the activities and budget to implement the mechanism's workplan, supplementing information contained in document A/MSM/14/2, which was noted. The update included an overview of the Secretariat's workplan in relation to the prioritized activities; the Secretariat noted that the financial sustainability of the workplan remained a concern. Some Member States provided comments and acknowledged the work and support provided by the Secretariat.

4. Updates were also provided on the WHO Global Surveillance and Monitoring System noting the data impact on reporting to the Global Monitoring System by the focal points. The Secretariat further provided an update on the WHO Medical Product Alerts issued in 2025 along with other related risk communications. Regarding emerging issues, the Secretariat highlighted the increasing number of reports of contaminated products containing diethylene glycol and ethylene glycol, underscoring the ongoing vulnerabilities in the sourcing and distribution of pharmaceutical excipients. The Secretariat also drew attention to recent reports of severe bacterial infections resulting in fatalities due to use of contaminated medical products. In addition, the Secretariat described a recent WHO risk communication addressed to users of malaria rapid diagnostic test kits that were linked to reported cases of false negative diagnosis, and provided an overview of the evolution of in vitro diagnostics incidents reported between 2014 and 2025. The meeting noted the updates.

Update on the list of prioritized activities for 2024–2025

5. The Secretariat and/or the respective working group Chairs provided updates regarding each of the prioritized activities. There was a focus on progress in 2025, as detailed in the report contained in document A/MSM/14/3. The meeting noted the report.

Activity A: Strengthen the capacity of national/regional regulatory authorities for the prevention and detection of, and response to, substandard and falsified medical products

6. Brazil, as Chair of the working group for Activity A, provided an update on the actions and next steps of the working group. Member States highlighted the importance of finalization and roll-out of the Epione e-tool that was used for conducting market surveillance.

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

7. The Secretariat, on behalf of Eritrea as Chair of the working group for Activity B, provided an update on the actions, indicators and activities of the working group. The Secretariat presented the revised terms of reference for the Global Focal Point Network for substandard and falsified medical products, contained in document A/MSM/14/4. The meeting approved the revised terms of reference.

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

8. Montenegro, as Chair of the working group for Activity C, provided an update on the status of actions and interim milestones on key activities and performance indicators of the working group.

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

9. South Africa, as Chair of the working group for Activity D, provided an update on the progress on implementation of actions for that prioritized activity. South Africa reported on the outcome of the pilot regarding the draft handbook on developing the national action plan against substandard and falsified medical products and highlighted the benefits and key challenges.

10. The Secretariat also reported on the status of the development of the handbook to support development and implementation of the national action plans, as well as on validation of existing plans for other Member States.

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

11. Italy, as Chair of the working group for Activity E, provided an update on the actions of the working group and an overview of next steps, including a planned online technical informal session on risk communication to be conducted in early 2026. The working group Chair reiterated the importance of Member States sharing successful risk communication and awareness models on the virtual information sharing platform. The material could then be adapted and reused by other Member States.

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

12. The United States of America, as Chair of the working group for Activity F, provided an update on the status of the working group's actions, including completed outputs for 2025. The working groups' recommendations included to: develop and conduct surveys to better understand specific concerns of key actors; draft best practice guide for investigating an incident of contaminated excipient and substandard and falsified medicine or due to contaminated excipients; develop a best practice guide for investigating an incident due to contaminated excipients with the goal of improving reaction time to prevent further exposure of patients to contaminated drugs, and collect evidence for appropriate regulatory or judicial action; and develop a list of new recommendations for inspection coverage of manufacturers, and encourage sanctions/action for specific findings.

Activity G: Identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet

13. Colombia, as Chair of the working group, provided an overview of the progress made in developing strategies to understand and address the distribution of substandard and falsified medical products via the internet. An update was provided on the MediCrawl initiative, noting that the call for expressions of interest issued on 14 August 2025 had not yet resulted in concrete commitments from Member States to host, adapt or pilot the tool. Work on exploring alternative technical partnerships would continue under a new working group in the 2026–2027 workplan.

Additionally, the working group reported the completion of the draft road map on inter-agency cooperation to counter online substandard and falsified medical products. Member States were invited to submit final comments by 28 November 2025, and the final version would be submitted to the mechanism Secretariat by 5 December 2025.

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

14. Botswana, as Interim Chair of the working group for Activity H, provided an overview on the status of implementation of its actions. The Chair described the challenges faced by the working group and made some recommendations as a next step. The working group suggested to focus on practical high impact activities that directly supported the national regulatory authority and delivered clear value to Member States. It should prioritize developing simple actionable tools, policy proposals or guidelines. That might include an informal markets on-site inspection checklist, multi-agency operational guidelines, border risk mapping templates, and public education message tools that included print and electronic media campaigns. Key updates included a planned publication of results from a recent literature review of published information on informal markets, as well as a new Member State survey to be carried forward under a new working group in the 2026–2027 workplan.

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

15. The Secretariat, on behalf of the Chair of the mechanism, who also served as Chair of the working group for Activity I, provided an update on efforts to address emerging issues of substandard and falsified medical products. The working group requested feedback from Member States mechanism members on the questions presented, including on selection criteria emerging issues. It was suggested that the Secretariat organize a technical briefing on that matter in the margins of the next plenary meeting.

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

16. The Secretariat, on behalf of Nigeria as Chair of the working group for Activity J, provided an update on the multinational survey on Member States' experiences with the traceability of medical products, and the report presenting the survey findings published in March 2025.¹ It was suggested that the Secretariat continue to work on that matter, despite the proposed sunsetting of the working group for the next biennium.

WHO's participation in relevant global and regional initiatives

17. The Secretariat provided an overview of WHO's participation in relevant global and regional initiatives in 2025, noting the ongoing initiatives as well as those that were upcoming. The importance of international collaboration and coordination was emphasized in order to address substandard and falsified medical products.

¹ [Country experiences on implementation of traceability for medical products](#). Geneva: World Health Organization; 2025 (accessed 17 November 2025).

Follow-up on the evaluation of the Member State mechanism, including a new draft theory of change and draft results framework

18. The Secretariat introduced the new theory of change and the results framework, reflecting the work done by the Steering Committee after several consultations. In reporting the status of the management response, the Secretariat described the status of the actions and activities for each recommendation and explained that actions to implement some of the recommendations had implications for structural reform and would require decisions by the governing bodies.

19. At the request of the Steering Committee, the Secretariat developed and presented a white paper on follow up to the evaluation of the Member State mechanism on substandard and falsified medical products. The white paper outlined options for taking forward Recommendation 1a, to establish alternatives to the existing Member State mechanism intergovernmental structure, which included establishing a strategic and technical advisory group and/or a global network managed by the WHO Secretariat. The white paper also outlined options for taking forward Recommendation 1b, Revision of the Member State mechanism (while maintaining it as a subsidiary body of the World Health Assembly), which included maintaining the Member State mechanism plenary and Steering Committee only or Member State mechanism plenary only. Governance and operational considerations options were also put forward for the meeting's deliberation.

20. Following the discussions, the Member State mechanism resolved to recommend Option 1b to the 158th session of the Executive Board and that it should consider keeping the scenario of maintaining the Member State mechanism plenary plus Steering Committee with streamlined working groups by reducing the number from 10 to three. Noting resource constraints, further work would be needed to streamline ways of working, including managing meetings in a cost-effective way. Consideration should also be given to exploring innovative ways of mobilizing additional resources, as well as to identifying ways to improve participation in meetings.

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

21. The mechanism considered the draft list of prioritized activities for the period 2026–2027, submitted by the Steering Committee. Three prioritized activities were proposed by the Steering Committee in the light of the resource constraints facing the Organization.

22. Following consideration and discussion of the activities, Member States approved the draft list of prioritized activities and actions to implement the workplan of the Member State mechanism for the period 2026–2027, including the strategic plan (see Annexes 1 and 2).

23. All working groups remained open to all Member States and could be joined at any time. The Secretariat would send an overview of all working groups together with a call for enrolment in due course.

Governance matters: Steering Committee membership for the period 2026–2027

24. The Member State mechanism noted that the nominations for the Steering Committee were provided for its information and that not all nominations had been received by the end of the meeting. The mechanism recognized that the nominations were provided by the regional groups following their internal processes and suggested that consideration should be given to making the nomination process clearer and more predictable in the future, should the Steering Committee be maintained. The nominations received included:

- African Region: Mozambique, Zimbabwe
- Region of the Americas: (to be confirmed)
- South-East Asia Region: India, (second nominee to be confirmed)
- European Region: Israel, Serbia
- Eastern Mediterranean Region: Egypt, Saudi Arabia
- Western Pacific Region: Australia, (second nominee to be confirmed)

25. As recommended by the Sixty-sixth World Health Assembly in decision WHA66(10) (2013) and agreed by the Member State mechanism, the position of Chair rotated among the six WHO regions, in English alphabetical order. Accordingly, the next Chair would be identified from the Region of the Americas. It was mentioned that should the Region of the Americas not be in a position to provide a Chair, then the subsequent regions, following the rotational order, might exceptionally identify the next Chair.

26. The members present urged those regions that had still to conclude consultations to do so at the earliest opportunity.

Proposed dates of the fifteenth meeting of the Member State mechanism

27. The Member State mechanism decided that its fifteenth meeting should take place in the week of 16 to 20 November 2026. Should exigent circumstances preclude the holding of the meeting during that week, it was agreed that adjustments to the timing of the meeting would be made by the Chair, in consultation with Steering Committee members and the Secretariat.

Annex 1

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

Prioritized activities		Proposed actions	Metrics/Success indicators	Expected outcomes
A.	Detection technologies, risk communication and regulatory strengthening for the prevention, detection and response to substandard and falsified medical products.	1. Use WHO tools to assess training needs, update training materials and roster of experts.	1. Consolidated list of training needs and materials, and updated roster of experts.	1. Member States having targeted training and tools to address substandard and falsified medical products.
		2. Support and promote adoption of optimal screening technologies and ensure interoperability.	2(a) Develop WHO guidance on how to select and use technologies to screen for substandard and falsified medical products.	2. Enhanced data collection and risk-based post-market surveillance.
		3. Assist Member States in developing and implementing effective risk communication strategies.	2(b) At least 10 Member States adopting the Epione tool and maintaining risk-based surveillance data.	3. Improved practices in screening of substandard and falsified medical products in the supply chain.
		4. Improve availability, dissemination and usability of WHO knowledge base resources.	3(a) Survey and mapping of Member State risk communication activities completed.	4. Improved awareness and communication to prevent and detect substandard and falsified incidents.
		5. Conduct technical briefings and share best practices between Member States.	3(b) WHO guidelines on risk communication and awareness published and disseminated.	
Lead: tbc			4. WHO guidelines on risk-based market surveillance published and disseminated.	
			5. Technical briefings delivered (at least one per year) with participation from Member States.	
B.	Develop strategies to address unregulated distribution channels for substandard and falsified medical products through informal markets, including internet sales.	1. Develop inter-agency and multisectoral strategies to strengthen capacity to detect, monitor and respond to substandard and falsified medical products sold online and through informal markets.	1. Strategic guidance document on unregulated channels available.	1. Member States equipped with strategies, tools and guidance to counter substandard and falsified product distribution via the internet and/or through informal markets.
		2. Develop a comparative analysis of existing online surveillance tools to assist identification of substandard and falsified medical products.	2. Recommendations on the specific requirements for a surveillance tool to assist the identification of substandard and falsified medical products online.	2. Improved cooperation and information sharing among Member States.
		3. Conduct technical briefings and share best practices between Member States.	3. Technical briefings delivered (at least one per year) with participation from Member States.	
Lead: tbc				
C.	Strengthen the supply chain of high-risk excipients and related raw materials.	1. Conduct a global risk assessment to identify high-risk excipients.	1. Risk assessment report and list of high-risk excipients completed.	1. Improved identification and mitigation of risks in excipient supply chains.
		2. Map vulnerabilities in manufacturing, distribution and storage.	2. Survey and report on Member States' distributors' and manufacturers' practices and policies.	2. Increased awareness of substandard and falsified excipient risks through guidelines, training and shared data.
		3. Collaborate with Member States, regulatory authorities, industry and United Nations agencies to develop good practices, policies and guidelines.	3. Reports on data.	
Lead: tbc		4. Promote data sharing on excipient quality, control and safety.		

Annex 2

Strategic plan

Member State engagement The Member State mechanism is agile and forward-looking, serving as a public forum for discussion and the development of recommendations for policy-makers		
Proposed goals	Proposed actions	Proposed indicators
1. The Member State mechanism is a critical and valued partner for international organizations and policy forums. 2. All WHO regions engage in the work of the mechanism to provide regional data and trends on substandard and falsified medical products, as well as policy coherence. 3. All relevant sectors are integrated in a whole-of-government approach to prevent, detect and respond to substandard and falsified medical products. 4. All relevant stakeholders at the regional, national and local levels participate holistically to prevent, detect and respond to substandard and falsified medical products.	The mechanism 1. Raise the mechanism's profile and improve policy alignment, with the Chair attending relevant policy forums to advocate and communicate on behalf of the mechanism. 2. Improve engagement by Member States, especially in respect of Steering Committee roles. Regional engagement 3. Improve regional engagement by leveraging regional committee meetings for Vice-Chairs to present and report on regional substandard and falsified medical product data and communicate alerts about regional trends. 4. Establish regional pre- and post-Steering Committee meetings, led by Vice-Chairs, to solicit input on Steering Committee agenda items. Policy coherence 5. Focus on regulatory systems strengthening and multisectoral support, including legal and law enforcement sectors, to address the issue of substandard and falsified medical products adequately and comprehensively. 6. Ensure that all handbooks and guidelines emphasize the need for multisectoral collaboration and a whole-of-government approach. 7. Foster the inclusion of regional, national and local officials to prevent, detect and respond to substandard and falsified medical products.	WHO Global Benchmarking Tool indicators 1. RS01.05: Legal provisions and relevant regulations to take action. 2. RS04.03: Rapid alert and recall system. 3. MC01.02: Legal provisions and/or regulations authorize market surveillance and control activities. 4. MC01.03: Legal provisions and/or regulations address the role of national regulatory authorities. General progress indicators 5. The mechanism engages with and develops policy coherence in respect of substandard and falsified medical products with relevant organizations and stakeholders at regional and international levels. 6. The mechanism demonstrates increased collaboration, communication and cooperation with relevant organizations and stakeholders on issues related to substandard and falsified medical products.

Technical capacity Member States have the tools and resources to prevent, detect and respond to substandard and falsified medical products		
Proposed goals	Proposed actions	Proposed indicators
1. The legitimate medical product supply chain is secured by robust good manufacturing, distribution and pharmacy practices. 2. Import and export regulations protect the supply chain from substandard and falsified medical products. 3. Accredited laboratories support Member States' efforts to prevent and detect substandard and falsified medical products. 4. Track and trace systems and end-to-end product security and supply chain solutions are implemented to help to ensure that medical products are legitimate and enhance the detection of substandard and falsified medical products. 5. Detection technologies are deployed to survey, monitor and identify substandard and falsified medical products. 6. Member States track and respond to substandard and falsified medical products that are sold via the internet and/or through informal markets.	Supply chain security and regulatory system strengthening 1. Work with relevant organizations and key Member State focal points on regulatory systems strengthening and capacity-building. Laboratory testing 2. Prioritize building national and regional capacity for testing by, for example, including laboratory qualifications as part of meeting WHO Global Benchmarking Tool milestones and/or relevant international standards (for example, ISO/IEC 17025:2017). Track and trace systems and detection technologies 3. Support the implementation of WHO handbooks and guidelines on track and trace systems and detection technologies. 4. Ensure that handbooks and guidelines include a compendium of available track and trace systems and detection technologies, as well as advisory guidelines for health ministries and national regulatory agencies to work with other sectors to implement/deploy them. 5. Consider options for Member States to pool financial and technical resources, among others, in order to access and implement technologies on the ground. Internet sales and informal markets 6. Ensure a multisectoral approach to and raise awareness about the sale of substandard and falsified medical products via the internet and/or through informal markets.	WHO Global Benchmarking Tool indicators 1. MC01.05: Legal provisions and/or regulations exist for placement of a product's unique identification number. 2. MC01.07: Guidelines exist on the recall, storage and disposal of substandard and falsified medical products. 3. MC04.07: Documented and implemented procedures and mechanisms exist to prevent, detect and respond to substandard and falsified medical products. 4. MC04.08: Documented and implemented procedures and mechanisms to ensure safe storage and disposal of substandard and falsified medical products. General progress indicators 5. Capacity is developed to test, track and trace substandard and falsified medical products. 6. Member States demonstrate laboratory capacity, as reflected in reaching relevant national regulatory authority maturity levels.

Access to safe, effective, affordable and good quality medical products Member States provide and use good quality, comprehensive data to mitigate the harm posed by substandard and falsified medical products, thereby improving access to safe, effective, affordable and good quality medical products		
Proposed goals	Proposed actions	Proposed indicators
1. Member States contribute to and utilize databases with good quality and up-to-date data and fit-for-purpose reporting on substandard and falsified medical products. 2. Data, experiences and best practices are shared via WHO regional entities or other relevant forums.	Reporting and data In order to focus on improving the quality and consistency of data reported to the WHO Global Surveillance and Monitoring System for substandard and falsified medical products and ensure data access and transparency, the Member State mechanism should take the following actions. 1. Focus on reaching a consensus on data quality, access and transparency standards. 2. Reach a consensus on the purpose of Global Surveillance and Monitoring System reporting – for example, whether it is for event management or knowledge generation. 3. Work with the Secretariat to ensure that the Global Surveillance and Monitoring System pulls data from existing reporting systems for substandard and falsified medical products to reduce the duplication of reporting and improve the breadth of data collection. 4. Consider regional working groups to support and underpin improvements in data reporting and information sharing. 5. Train Member State focal points in the importance of reporting consistent and fit-for-purpose data. 6. Establish reporting mechanisms that both share and collect data on incidents of substandard and falsified medical products as reported by the public, health workers and/or relevant stakeholders. Sharing data and best experiences 7. Consider the impacts of regulation and surveillance on access to substandard and falsified medical products.	WHO Global Benchmarking Tool indicators 1. MC04.05: Documented and implemented procedures exist to enable the public to report substandard and falsified medical products. 2. MC06.02: Findings and regulatory decisions are communicated to all national stakeholders, including the public. 3. MC06.03: Findings and regulatory decisions are communicated and shared with other countries and regional and international organizations. General progress indicators¹ 4. Increased number of national regulatory authorities reporting substandard and falsified medical products to the Global Surveillance and Monitoring System. 5. Post-marketing surveillance indicators developed.

¹ Working Group B plans to develop performance indicators for the functionality of Member State focal points.