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

1. The thirteenth meeting of the Member State mechanism on substandard and falsified medical products was held in Geneva in a hybrid format from 20 to 22 November 2024. The meeting was chaired by Professor Emile Bienvenu, Chair (Rwanda) and the following Vice-Chairs: Dr Paul Huleatt (Australia), Ms Laila Mouawad (Brazil), Mrs Annam Visala (India), Mr Sherwin Tobing (Indonesia), 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). Representatives from 63 Member States participated in the meeting.

2. The WHO Assistant Director-General (Access to Medicines and Health Products), Dr Yukiko Nakatani, opened the meeting, welcomed participants to Geneva and acknowledged the contributions of the Steering Committee over the past year. Dr Nakatani emphasized the importance of the independent evaluation as an essential step in understanding the mechanism's impact, assessing successes and identifying areas for improvement. She noted that the evaluation findings would inform strategic planning for the mechanism as well as the implementation of actions included in the WHO management response to the evaluation report. Additionally, Dr Nakatani highlighted the 19th International Conference of Drug Regulatory Authorities meeting, held in India (October 2024), where global regulatory recommendations, including those on combating substandard and falsified medical products, were made.

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 workplan of the Member State mechanism, supplementing the information contained in document A/MSM/13/2, the contents of which were noted by the mechanism. 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.

4. Updates were also provided on the WHO Global Surveillance and Monitoring System for substandard and falsified medical products, noting that training and other network engagement events had an impact on reporting to the WHO Global Surveillance and Monitoring System. The Secretariat also provided an update on the WHO medical product alerts issued in 2024, among other risk communication activities. With regard to emerging issues, the Secretariat pointed out the increase in reports of falsified opioid and benzodiazepine medicines and the high-quality packaging of falsified medical products. The Secretariat noted that 70% of incidents related to in vitro diagnostics were primarily reported to the WHO Global Surveillance and Monitoring System by the manufacturers. The Secretariat reported on how the use of WHO's Epidemic Intelligence from Open Sources Initiative (EIOS) tool contributed to the WHO Global Surveillance and Monitoring System database by detecting and monitoring media articles on substandard and falsified medical products.

Update on the list of prioritized activities for 2022–2023

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 2024, as detailed in the report contained in document A/MSM/13/3.

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 the Chair of the working group for Activity A, provided an update on the actions and next steps of the working group. The Secretariat presented the comparative analysis of national regulatory systems based on the WHO Global Benchmarking Tool and institutional development plan data used to identify common critical gaps and needs for effective market surveillance and control – as detailed in the executive summary in document A/MSM/13/4, the contents of which were noted by the mechanism.

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

7. The Secretariat, on behalf of Eritrea as the Chair of the working group for Activity B, provided an update on the actions, indicators and future activities of the working group. In 2025, the working group intended to conduct a review of the terms of reference of the Global Focal Point Network for substandard and falsified medical products.

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

8. Montenegro, as the Chair of the working group for Activity C, provided an update on the status of actions, interim milestones on key activities and performance indicators of the working group. The Chair of the working group also presented the results of a Member State survey on the use of technologies – as detailed in the executive summary in document A/MSM/13/5, the contents of which were noted by the mechanism.

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 the Chair of working group for Activity D, provided an update on the progress on implementation of actions for that prioritized activity. The working group Chair raised concerns regarding reduced attendance and called for the addition of new members to the group, particularly from countries implementing national action plans on substandard and falsified medical products. The Secretariat also provided information on the status of the development of a handbook to support the development and implementation of national action plans and a pilot in South Africa, as well as the validation of existing plans for the Gambia and Nigeria.

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

10. The Secretariat, on behalf of Italy, the 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 survey to be conducted in 2025 to assess the current status, challenges and best practices in risk communication and awareness-raising activities by Member States. The working group Chair reiterated the importance of Member States sharing successful risk communication and awareness-raising models on the virtual information sharing platform. That 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

11. The United States of America, as the Chair of the working group for Activity F, provided an update on the status of the working group's actions, including next steps to complete outputs for 2025. A representative from UNODC presented the tentative findings from an ongoing study to establish the drivers and weaknesses in the pharmaceutical excipient supply chain that led to the proliferation of oral liquid medicines contaminated with diethylene glycol and ethylene glycol. The mechanism would further consider the matter when the UNODC report was finalized. The Secretariat provided information on existing WHO-coordinated model certification schemes on the quality of pharmaceutical products and pharmaceutical starting materials. The schemes were voluntary administrative instruments to certify core details of pharmaceutical products and pharmaceutical starting materials entering international trade and could be used by Member States to assure product quality.

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

12. Colombia, as the Chair of the working group for Activity G, provided an update on the status of the group's actions. The Chair of the working group emphasized the importance of first developing normative guidance, to be followed by training programmes. The working group would continue to support the development, delivery and implementation of training programmes in collaboration with the Secretariat.

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

13. The United States of America, as the Chair of the working group for Activity H, provided an overview of the status of the implementation of its actions. Key updates included the 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 rolled out during 2025. Two new actions were highlighted: developing a research methodology toolkit for adaptable, scalable studies, and exploring use of a tool to gather household-level data. Plans for 2025 would focus on completing initiatives to bridge knowledge gaps and strengthen responses to informal markets.

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

14. The Secretariat, on behalf of the Chair of the mechanism, who was also serving as the Chair of the working group for Activity I, provided an update on efforts to address emerging issues on substandard and falsified medical products. A stepwise approach was agreed upon, including identifying criteria to define “emerging issues”, determining when such issues fell within the mechanism’s scope, to be followed by testing those definitions using case studies. The group noted the need for a more balanced membership from across the six WHO regions. Guidance was requested on refining the approach, criteria and strategies for addressing identified issues. Next steps to focus on were expanding membership and operationalizing the agreed framework.

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

15. Nigeria, as the Chair of the working group for Activity J, provided an update on the results of a survey to better understand country experiences regarding traceability systems – as detailed in the executive summary in document A/MSM/13/6, the contents of which were noted by the mechanism. The report of country experiences implementing traceability for medical products would be made available on the WHO website.

WHO’s participation in relevant global and regional initiatives

16. The Secretariat provided an overview of WHO’s participation in relevant global and regional initiatives, noting both ongoing and upcoming initiatives. The importance of international collaboration and coordination was emphasized, in order to address substandard and falsified medical products. The Secretariat presented the recommendations made during the 19th International Conference of Drug Regulatory Authorities held in New Delhi in October 2024. The mechanism noted the report.

Evaluation of the Member State mechanism

17. The Secretariat introduced the independent evaluation of the Member State mechanism and outlined the objective, purpose and methodology employed, as detailed in the executive summary of the report contained in document A/MSM/13/7. The evaluation team described the key relevance, effectiveness, coherence, sustainability and equity findings and recommendations. In presenting the management response, the Access to Medicines and Health Products Division welcomed the evaluation, noted that the management response was a management tool and explained that actions to implement some of the recommendations had implications for structural reforms and would require decisions by the governing bodies. The Division explained that recommendations that were more operational in nature could be taken forward without delay.

18. The Chair reported on the Steering Committee’s discussion of the report on the evaluation. He explained that the Steering Committee considered that most of the recommendations were straightforward and operational in nature. With respect to recommendation 1 on a possible revision to the format of the mechanism and recommendation 5 on improving external engagement, the Steering Committee was of the opinion that it would be useful to take more time for their consideration. In that regard, the Steering Committee recommended that the Member State mechanism: (1) propose that the governing bodies refrain from taking any decisions on the evaluation at their forthcoming meetings in 2025; (2) request that the Steering Committee take such additional time as needed, for example through one or more extended meetings next year, to engage with the Secretariat to develop and consider a new theory of change and results framework, along with other follow-up actions, and only then

formulate any recommendations for the consideration of the Member State mechanism at its fourteenth meeting; (3) request that the report of the fourteenth meeting of the Member State mechanism be submitted to the Executive Board at its 158th session and to the Seventy-ninth World Health Assembly, so that the governing bodies may consider the outcomes of the Member State mechanism's deliberations on those matters and take any action that might be required.

19. The Member State mechanism expressed appreciation for the evaluation, agreed that further time was needed to consider the recommendations, and endorsed the proposal by the Steering Committee.

Governance matters

20. At the invitation of the Chair, the Secretariat explained that, in accordance with resolution WHA65.19 (2012), the report of the Member State mechanism was submitted to the governing bodies on a biennial basis. In that regard, the next report of the Member State mechanism would be submitted to the Executive Board at its 156th session and Seventy-eighth World Health Assembly, and would contain the reports of the twelfth and thirteenth meetings of the Member State mechanism, held in November 2023 and November 2024, respectively. In addition, further to the proposal in paragraph 18 above, and if agreed by the governing bodies, the report of the fourteenth meeting of the Member State mechanism will be submitted to the Executive Board, at its 158th session, and the Seventy-ninth World Health Assembly.

21. The Chair of the mechanism explained a proposal considered by the Steering Committee to invite a stakeholder to make a presentation at an upcoming Steering Committee meeting. He noted that paragraph 2 of the section on relations with other stakeholders and experts in the annex to resolution WHA65.19, which contained the goals, objectives and terms of reference of the Member State mechanism, provided that "as needed, the Member State mechanism will invite other stakeholders to collaborate and consult with the group on specific topics".

22. In that regard, there had been a proposal to invite the Bill & Melinda Gates Foundation to give a briefing at a future meeting of the Steering Committee on the Foundation's activities that were relevant to prioritized activity D, relating to reducing the burden of substandard and falsified medical products, and the Steering Committee had agreed to proceed in that manner.

23. The Chair further noted that as the Steering Committee continued its work in support of the mechanism, including oversight of the implementation of the mechanism workplan, it could be expected that the Steering Committee may identify additional matters on which consultations with other stakeholders may be desirable, and might take place. Such consultations would take place consistent with the WHO Rules of Procedure and the Framework for Engagement with Non-State Actors. The Steering Committee reports on such consultations would be a valuable addition to mechanism discussions. The mechanism expressed support for the Steering Committee proceeding in that manner.

Proposed dates of the fourteenth meeting of the Member State mechanism

24. The Member State mechanism decided that its fourteenth meeting should take place in the week of 10 November 2025. 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.

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