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

1. The eleventh meeting of the Member State mechanism on substandard and falsified medical products was held in Geneva, Switzerland in a hybrid format on 19 and 20 October 2022. The meeting was chaired by Dr Paul Huleatt, Chair (Australia) and the following Vice-Chairs: Dr Celda Molake-Tiroyakgosi (Botswana), Ms Laila Mouawad (Brazil), Mr Liu Jingqi (China), Dr Tri Asti Isnariani, on behalf of Ms Meutia Hasan (Indonesia),¹ Dr Yasmine J. Ameen Kannan (Iraq), Dr Domenico Di Giorgio (Italy), Mrs Maryna Taran (Ukraine), Mr Mark Abdo (United States of America) and Mr Lyoko Nyambe (Zambia). Representatives from 66 Member States participated in the meeting.

2. The WHO Director-General, Dr Tedros Adhanom Ghebreyesus, opened the meeting and underscored the importance of access to safe and quality medical products as a cornerstone of universal health coverage. Substandard and falsified medical products undermine health systems and put everyone in every country at risk. The Director-General highlighted recent tragic incidents where substandard contaminated medicines had potentially been linked with acute kidney injuries and dozens of deaths among children.² The Member State mechanism was established 10 years ago and the prevalence of substandard and falsified medical products remains high. Combating the issue demands effective collaboration between Member States to help ensure effective, safe and quality products. The Director-General thanked Member States for their contributions to the Member State mechanism and urged them to continue sharing their experiences and providing guidance to facilitate the future work of the mechanism.

Update by the Secretariat on the 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, including the estimated budget for 2022 and 2023 and the main funding sources. Updates were also provided on reports to the WHO Global Surveillance and Monitoring System (GSMS). For 2022, all activities are fully resourced. Resources for 2023 are yet to be finalized.

4. Reporting trends from GSMS were shared and the annual increase in reported incidents over the past four years was noted. The reporting disparity both among WHO regions and in the classification of reported products was noted, along with the ongoing challenges concerning information sharing and

¹ Following requests by the Steering Committee member from Indonesia, it was agreed that, exceptionally, another individual from this delegation could participate in the meeting in the member's absence.

² See [https://www.who.int/news/item/05-10-2022-medical-product-alert-n-6-2022-substandard-\(contaminated\)-paediatric-medicines](https://www.who.int/news/item/05-10-2022-medical-product-alert-n-6-2022-substandard-(contaminated)-paediatric-medicines), accessed 3 November 2022).

transparency, which can act as barriers to reporting. Member State focal points were encouraged to continue to enter their reports into the GSMS system for the benefit of all Member States.

5. During the discussion, transparency in sharing information reported through GSMS on substandard and falsified coronavirus disease (COVID-19) vaccines, therapeutic products and paediatric medicines was noted as being particularly useful. Member States noted the update by the Secretariat on its activities and budget to implement the workplan of the Member State mechanism, as contained in document A/MSM/11/3. The Secretariat was requested to prepare a report for the next Steering Committee meeting on barriers to creating greater transparency with regards to reporting of data in the GSMS.

Update on the list of prioritized activities for 2022–2023

6. The Secretariat and activity leads provided updates on the prioritized activities for 2022–2023, as indicated below.

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

7. Brazil, as the Chair of the working group associated with Activity A, provided an update with respect to the progress made on this prioritized activity. For the biennium 2022–2023, the working group is working on four actions. Action one relates to using global standard tools to assist in the identification of training needs, existing expertise and training materials for Member States and other institutions to prevent, detect and respond to substandard and falsified medical products. Two existing tools will be used to identify the training needs, namely a global benchmarking tool (GBT), and the global competency framework for regulators of medical products (draft). The online handbook is expected to be finalized by the next plenary meeting in 2023. The other aspects of Action one will be ongoing.

8. The second action relates to the development of tools and a database to automate the conduct of medical product quality surveys and enhance the quantity and quality of data that is captured to inform risk-based post-market surveillance programmes based on existing WHO guidance. The Epione e-tool has been developed and is currently being piloted in the United Republic of Tanzania. The third action relates to developing a guidance document aiming to strengthen the capacities of national and regional regulatory authorities to plan, perform and assess risk-based post-market control and surveillance. The first draft is being prepared and will be circulated to the working group members in the last quarter of 2022. The document is intended to provide general guidance, highlighting the pillars for and importance of post-market surveillance. The intended deadline for completion is 2023, following the 12th meeting of the Member State mechanism. The fourth action is to support the development of training materials for national and regional regulatory authorities, focused on promoting global guidance documents and the effective use of the tools. This action is deferred until actions 1, 2 and 3 are advanced and/or have been completed.

9. The Secretariat also provided an update on country performance in accordance with GBT indicators for market control and surveillance. Gaps in the legal frameworks, regulations and related regulatory procedures were noted. For all countries assessed, an institutional development plan has been formulated to address the gaps. Implementation of recommendations is monitored by WHO through follow-up meetings for the institutional development plan. The status of sub-indicators will be reviewed and may change during the next re-benchmarking process.

10. During the discussion, the Secretariat informed Member States that the Epione e-tool will not include risk assessment in the selection of target products. Once the tool is finalized, it will be rolled out

to other Member States. Member States were encouraged to participate in the working group to inform the discussions regarding guidance on a risk matrix to determine which products to include in post-market surveillance. It was noted that the response time by national authorities to incidents of substandard and falsified medical products is critical, varies from country to country and is a function of the capacity of the national regulatory authority and the environment within which it operates.

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

11. Eritrea, as the Chair of the working group associated with Activity B, provided an update with respect to the progress made on this prioritized activity. There are four action areas that the working group is focused on. These are: (1) identify reporting barriers faced by national focal points; (2) develop strategies to improve reporting of substandard and falsified medical products; (3) facilitate the exchange of communication, information sharing and networking among the Global Focal Points Network and other mechanisms and platforms; and (4) follow up with Member States to keep focal points updated and trained. All activities are ongoing. The Chair of the working group reported that national focal points had agreed to identify reporting barriers and that a survey had been finalized for that purpose. A progress report will be ready by the end of 2022.

12. During the discussion, Member States acknowledged that the outputs of all four actions will be relevant to the Member State mechanism. With respect to the GSMS, identifying barriers to reporting will allow for the development of strategies to make the portal more user-friendly, interactive and solution-oriented. The Secretariat encouraged Member States to share suggestions to improve the quality and quantity of the reports.

Activity C: Improve Member States' understanding and uptake of technologies to screen and detect substandard and falsified medical products, and the implementation of national traceability systems

13. Montenegro, as the Chair of the working group on detection technologies associated with Activity C, provided an update with respect to the progress made on this prioritized activity. The working group is working on three actions: (1) convene technical briefing sessions (no fewer than one per year) to review existing technologies to screen and detect substandard and falsified medical products; (2) collate existing methodologies and tools used to screen and detect substandard and falsified medical products; and (3) support the process of defining the scope of WHO guidance on how to select technologies to screen and detect substandard and falsified medical products. All activities are ongoing.

14. During the discussion, the Secretariat emphasized the importance of providing guidance that is fit for purpose and useful for Member States. The guidance needs to account for different actors, such as customs officers and those outside the health sector, who may suspect that medical products are substandard or falsified. The guidance will encompass a range of products and methodologies for field and laboratory use. It will be designed to support Member States in the uptake and use of different technologies. The documentation of case studies in the guidance is not planned, but they will provide useful references for discussion in the working group. The Secretariat encouraged Member States to join the working group and contribute to the discussions.

15. Nigeria, as the Chair of the working group on traceability associated with Activity C, provided an update with respect to the progress made on this prioritized activity. The working group is working on two actions. The first action is to convene technical briefing sessions (no fewer than one per year) to review existing traceability models, including approaches and enabling technologies; it was completed for 2022 with a technical briefing session on the theme of governance and sustainability held in October.

It was acknowledged that the briefing sessions are an important means of sharing information among Member States. The next briefing session will address internationally recognized standards. The second action relates to deciding on the publication format for national traceability systems, and will be updated through a survey of Member States. This action is ongoing.

16. During the discussion, the Secretariat acknowledged that implementation of traceability can be resource-intensive and invited Member States to adapt and adopt WHO guidance on this topic.¹ Member States that are interested in exchanging information on national traceability systems are invited to join the working group. The Secretariat also encouraged Member States to join the briefing sessions.

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

17. In the absence of a designated lead for Activity D, the Secretariat provided an update with respect to the progress made on this prioritized activity. Progress is being made on the development of a handbook for Member States on developing and strengthening national action plans for prevention, detection and response strategies on substandard and falsified medical products. This work is being carried out in line with the GBT for evaluation of national regulatory systems of medical products and other stakeholder guidance (such as that published by the World Customs Organization and the United Nations Office on Drugs and Crime). The target audience will be national and subnational stakeholders working on combating substandard and falsified medical products. Member States interested in piloting the handbook before finalization were invited to volunteer by contacting the Secretariat.

18. During the discussion, it was clarified that feedback from the pilot phase would be used to finalize the handbook. Details on metrics to measure impact were also discussed, and the Secretariat noted that such metrics are currently under development. The Secretariat reported that the first draft of the handbook would be finished by December 2022, followed by a pilot in some countries, leading to a final draft by mid-2023 for general comments from Member States.

Activity E: Enhance Member States' capacity to run effective risk communication campaigns for substandard and falsified medical products

19. The Secretariat provided an update on the progress made on this prioritized activity by the associated working group, which is chaired by Zambia. Working group members agreed to undertake a desk review of existing draft documents and risk communication tools from Member States. The working group has met three times, but with limited participation.

20. During the discussion, the importance of risk communication was emphasized, particularly in the context of ongoing, serious incidents related to substandard and falsified products. The appointment of a working group Vice-Chair to support the working group Chair and facilitate the conduct of the group's meetings was also suggested. It was suggested that members of the Steering Committee could provide input that would help to support the working group. The Secretariat encouraged more active participation by Member States in the working group, welcomed Nepal's interest in joining the group, and encouraged others to join this or any other working group by emailing the Secretariat.

¹ See <https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products>, accessed 3 November 2022).

Activity F: Enhance Member States' capacity to expand awareness, effectiveness, impact and outreach in their work on substandard and falsified medical products

21. Australia, as the Chair of the working group associated with Activity F, provided an update with respect to the progress made on this prioritized activity. The working group has met twice in the past year, but with limited participation. The first action relates to the dissemination and promotion of the materials developed by the Member State mechanism; this action is ongoing, with materials currently being prioritized for dissemination. The second action is related to promoting awareness at the highest policy levels about the need to support and dedicate resources; this action is also ongoing. The third action is related to mapping relevant regional and global initiatives and networks to raise the profile of the Member State mechanism, and developing a strategy to disseminate and promote the materials developed by the mechanism. This work is ongoing, with Member States contributing initiatives and networks from their respective regions.

22. During the discussion, the importance of this prioritized activity was emphasized. It was also suggested that the working group may wish to consider the relevance of developing specific guidance for national and regional regulatory authorities on communicating about the actions taken on substandard and falsified products on the market, since this is a challenging area of work for many Member States.

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

23. Colombia, as the Chair of the working group associated with Activity G, provided an update with respect to the progress made on this prioritized activity. It was noted that progress is being made with respect to the first action on advocacy for capacity-building for Member States to respond to the online distribution of substandard and falsified medical products, including by utilizing the policy recommendations from the Member State mechanism's internet guidance. The second action, related to the development of a strategic roadmap promoting inter-agency cooperation and collaboration with relevant stakeholders to respond to the online distribution of substandard and falsified medical products, is expected to commence shortly. The third action, on promoting awareness raising and policy visibility of the online distribution of substandard and falsified medical products, is to be developed in 2023. A training and capacity programme for national regulatory authority officers is under development.

24. During the discussion, several Member States shared their experiences with respect to the challenges faced in addressing the distribution or supply of substandard and falsified medical products via the internet and other online environments, such as mobile applications. It was clarified that the training programme is envisaged to be developed with both online and in-person components. It was suggested that the organization of a technical briefing on internet sales could contribute to the work of this working group. During the discussion, Member States were also encouraged to link workstreams together and ensure complementarity across working groups.

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

25. The United States of America, as the Chair of the working group associated with Activity H, provided an update with respect to the progress made on this prioritized activity. The first action to define informal markets as they relate to medical products has been completed. The working group is

now focused on the second action, which is to understand the current knowledge base and knowledge gaps. In this regard, work is ongoing to conduct a literature review and a survey among Member States. The third action is to gather evidence to address knowledge gaps and help develop long-term strategies, and the fourth action is to develop strategies and policy recommendations.

26. During the discussion, it was clarified that the definition relates to informal markets and not to the status of the products. It was also clarified that once the literature review was conducted, a draft would be shared with the working group and any interested Member States would be invited to provide feedback at that time. Opportunities to discuss the literature review would also be available during the upcoming meetings of the working group.

WHO's participation in relevant global and regional initiatives

27. The Secretariat provided an overview of WHO's participation in relevant global and regional initiatives, noting the ongoing collaboration and participation in various global, subregional and regional initiatives. Further, the Secretariat described the ongoing work in the regions, such as providing guidance on the oversight of substandard and falsified medical products and supporting countries to have better market control and surveillance. The Secretariat noted examples of work in various regional cooperation efforts to support better supply chain integrity. WHO's role in these activities is varied and covers technical support, acting as Secretariat and participating in various meetings.

28. During the discussion, the Secretariat noted that it will provide a more comprehensive overview of its participation in relevant global and regional initiatives such as antimicrobial resistance, COVID-19 and the GBT at the next plenary meeting in 2023. Member States noted that, to maximize coordination and collaboration, feedback on their engagement in global and regional initiatives is needed. Such feedback will also enhance advocacy efforts to address the response to substandard and falsified medical products.

Future work of the Member State mechanism

29. Member States were invited to consider several aspects related to the future work of the Member State mechanism and reflect on the ideas discussed by the Steering Committee at its recent meeting (document A/MSM/11/5).

30. The Chair introduced this item and emphasized the need to demonstrate the value of the mechanism for Member States that are currently engaged, as well as for those that are not yet actively involved. Steering Committee members were first invited to further reflect on the ideas presented in document A/MSM/11/5. The need to develop metrics in order to measure what success of the Member State mechanism looks like was emphasized. This would also be an important component of any future evaluation of the mechanism. Related to this, it was suggested that strategic and longer-term planning would be beneficial and could include important pillars such as capacity-building, cooperation and reporting. Further, there were suggestions for improving accessibility to the documentation, including guidance and training materials, by making these readily available to all Member States in a user-friendly way. In addition, there were some suggestions for improving the interoperability of different systems used to report on substandard and falsified medical products at regional and global levels.

31. The Member State mechanism agreed on the following:

- (a) the Steering Committee will develop a strategic plan which can be included as an annex to the next iteration of the list of prioritized activities, which will be considered by the Member State mechanism in 2023; and

(b) the Member State mechanism will recommend to the Seventy-sixth World Health Assembly, through the Executive Board at its 152nd session, that an independent evaluation of the mechanism take place, the outcome of which will be reported back to the governing bodies in line with the current reporting requirements of the mechanism. The mechanism also tasked the Steering Committee with the development of the terms of reference for the evaluation.

32. The following draft decision will be transmitted to the Seventy-sixth World Health Assembly, through the Executive Board at its 152nd session:

The Executive Board, having considered the report on substandard and falsified medical products,

Decided to recommend to the Seventy-sixth World Health Assembly the adoption of the following decision:

The Seventy-sixth World Health Assembly, having considered the report on substandard and falsified medical products,

Decided to request the Director-General:

(a) to facilitate the conduct of an independent evaluation of the Member State mechanism in accordance with the terms of reference to be developed by the Steering Committee; and

(b) to report on the outcome of the evaluation to the governing bodies consistent with existing reporting requirements of the mechanism.

Proposed dates of the twelfth meeting of the Member State mechanism

33. The Member State mechanism decided that its twelfth meeting would take place in the week beginning 30 October 2023.

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