World Health Organization

Executive Board
156th session

Provisional agenda item 10 EB156/12

6 January 2025

Substandard and falsified medical products

Report on the evaluation of the Member State mechanism

1. In 2023, the Seventy-sixth World Health Assembly adopted decision WHA76(10), in which it requested the Director-General:

> (1) to facilitate the conduct of an independent evaluation of the Member State mechanism on substandard and falsified medical products in accordance with the terms of reference to be developed by the Steering Committee of the Member State mechanism; and
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> (2) to report on the outcome of the independent evaluation of the Member State mechanism on substandard and falsified medical products to the governing bodies consistent with existing reporting requirements of the Member State mechanism on substandard and falsified medical products.

2. That request for an independent evaluation was included in the Organization-wide evaluation workplan for 2024–2025, approved by the Executive Board at its 154th session in January 2024.[1] The evaluation itself was conducted by an external independent evaluation team, selected by the WHO Evaluation Office through a competitive process. The external evaluation team undertook its main work during the period December 2023–September 2024 and delivered the final evaluation report in October 2024.[2]

3. The evaluation report and WHO management's draft response to the report were discussed at the thirteenth meeting of the Member State mechanism, held from 20 to 22 November 2024. A report of that discussion is included in the report of the thirteenth meeting of the Member State mechanism transmitted to the Board at its 156th session.[3]

4. The Director-General has the honour to transmit to the Board at its 156th session the executive summary of the independent evaluation (Annex).

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[1] See decision EB154(2) (2024).

[2] The evaluation report and annexes are available from the WHO thematic evaluations webpage (accessed 15 December 2024).

[3] See document EB156/11.

Action by the Executive Board

5. The Board is invited to note the report and to provide comments and guidance on follow-up actions to the independent evaluation, including the question below.

- What measures can be taken to increase Member States' participation in the mechanism and its work?

Annex

Independent evaluation of the Member State mechanism on substandard and falsified medical products

Executive summary

Background

In 2012, the Sixty-fifth World Health Assembly adopted resolution WHA65.19 in which it decided to establish the Member State mechanism on substandard and falsified medical products[1] to improve effective collaboration among Member States and WHO to prevent and control substandard and falsified medical products. This resolution was a pivotal step in facilitating the protection of public health and seeking to ensure the provision of medical products that are both cost-effective and high quality. The Member State mechanism is the primary intergovernmental mechanism for Member States to convene, make policy recommendations, exchange knowledge, support mutual efforts and coordinate actions to address the challenge of substandard and falsified medical products. Its nine objectives include those on strengthening relevant national and regional capacities; contributing to the work of other areas of WHO; and facilitating collaboration with other relevant stakeholders.

The Member State mechanism is a subsidiary body of the World Health Assembly, to which it reports every two years. Each WHO region nominates two representatives to form a Steering Committee with one Chair and eleven Vice-Chairs, with the chairpersonship rotating among the regions. The Steering Committee meets three times a year, while all Member States are invited to an annual plenary meeting where it undertakes all necessary decisions; currently all of these meetings are held in Geneva. Working groups are established by the plenary to address Member State mechanism objectives, with Member States forming these groups on a voluntary basis and pursuing prioritized activities intended to contribute to achieving the objectives. The Member State mechanism is assisted by a technical secretariat (drawn from WHO's Incidents and Substandard/Falsified Medical Products team) with additional support from WHO's Office of the Legal Counsel and the Governing Bodies department. Resolution WHA65.19 urges Member States to provide sufficient financial resources to strengthen the work of the WHO Secretariat.[2]

At the recommendation of the Member State mechanism at its eleventh meeting,[3] the Seventy-sixth World Health Assembly decided to request the Director-General to conduct an independent evaluation of the Member State mechanism based on the terms of reference to be developed by the Member State mechanism's Steering Committee, and to report on the evaluation to the governing bodies.[4] The purpose of the evaluation was to assess progress made by the Member State mechanism in achieving its objectives since the 2017 Member State mechanism

[1] See the WHO Member State mechanism and the WHO governance webpages (accessed 8 October 2024).

[2] See resolution WHA65.19.

[3] See document A/MSM/11/6.

[4] See decision WHA76(10) (2023); decision EB152(9) (2023); and document EB152/7.

review[5] to end 2023, provide relevant lessons learned and make recommendations to inform the Member State mechanism's future strategic direction and ways of working. The evaluation objectives were to document the Member State mechanism's achievements, opportunities, challenges and gaps since 2017, assess the effectiveness and added value of the Member State mechanism tools and products, and the relevance of the Member State mechanism's format and governance to ensure that it remains fit for purpose. The evaluation assessed the work of the Member State mechanism at the global, regional, and country levels.

The evaluation employed a non-experimental design with a theory-based, utilization-focused approach. It used mixed methods to collect both quantitative and qualitative data, enabling robust triangulation of findings. Data collection methods included desk review of 102 key documents, secondary data analysis focusing on the WHO Global Surveillance and Monitoring System for substandard and falsified medical products incidents reporting, and 89 key informant interviews. The key informant interviews were conducted with a diverse group of stakeholders both internal (to the Member State mechanism and WHO) and external (covering the global and regional levels), and 12 focus countries[6] diverse in their geographic and economic representation as well as additional national-level informants. There were 16 distinct categories of key informants, of which the largest was Member State mechanism government representatives (31% of the total). In addition, an online survey was administered to 400 recipients at the global, regional, and country levels with 204 responses received (51% response rate). The largest categories of survey respondents were from national/regional pharmaceutical regulatory agencies and ministries of health.

The evaluation is framed against five criteria developed by the Development Assistance Committee of the Organisation for Economic Co-operation and Development (relevance, effectiveness, efficiency, coherence, sustainability) plus equity, and addresses six evaluation questions together with 13 additional sub-questions.

Findings

Finding 1 (Relevance): The Member State mechanism's format and governing structure initially worked well but are now less suited to its operational focus. The mechanism enjoys important strengths: potential for consensus-building; relevant objectives; a reach beyond the health sector; and visibility at the World Health Assembly. It also faces major challenges: most Member States are not active; some working groups lack both participation and expertise; working group and plenary meeting participation is limited; and very few Member States offer funding.

Finding 2 (Effectiveness): While an activity-based workplan exists and there has been recent progress on reporting, the Member State mechanism has lacked a results framework and a theory of change showing pathways to change. There were no baselines, indicators or processes to monitor progress towards objectives, and so it is hard to assess the full extent of achievements. Progress with planned activities is mixed, although some planned activities have been successfully implemented. Feedback suggests these have had a positive influence at the country level, although there is a lack of robust evidence on the effectiveness and impact of activities. Key factors that have hindered Member State mechanism progress and effectiveness include: suboptimal Member State

[5] See Review of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products – April 2017 (accessed 8 October 2024).

[6] Brazil; Cameroon; Canada; Egypt; Indonesia; Malaysia; Montenegro; Nigeria; Papua New Guinea; Sri Lanka; Sweden; and Syrian Arab Republic.

participation; variable effectiveness of working groups and lack of accountability; limited engagement with other (non-State) stakeholders; and lack of funding. Country-specific factors, some of which are outside the control of the Member State mechanism, include limited leadership and commitment, weak capacity of regulatory and health systems, and poorly enforced laws. The Member State mechanism's secretariat has clear value and provides good support to ensure effective functioning of the mechanism, although there are concerns about its overstretched capacity and the efficiency of its communication.

Finding 3 (Efficiency): It is difficult to fully ascertain efficiency in the absence of systematic monitoring and evaluation (some progress has been made in 2024, with the development of outcome level indicators) and budgetary detail. At the same time, there is no evidence of major visible inefficiencies in how the Member State mechanism uses its resources. Resources have increased, especially for working group activities, noting they come from a narrow, mainly external donor base and are also at times earmarked. There is limited funding from most Member States, although some contribute indirectly, e.g., through meeting attendance. Activity spend is well-targeted and meeting costs in line with comparable events, although there is low participation (most Member States do not attend any meetings). There is also little collaboration with other substandard and falsified medical product stakeholders to create synergies and avoid duplication, which could potentially reduce the Member State mechanism's efficiency.

Finding 4 (Coherence): The Member State mechanism has good potential for ensuring coherence via collaboration globally, regionally, nationally and between working groups, given its access to all Member States, but this has not yet been fully realized. Externally, good harmonization has been achieved on definitions across a wide range of substandard and falsified medicine stakeholders as well as ensuring alignment with WHO guidelines. However, there has also been a lack of sufficient engagement with international organizations and non-State actors. Engagement with non-State actors and other stakeholders (in line with the Framework of Engagement with Non-State Actors) is deemed important to ensure the coherence of the Member State mechanism's work. The Member State mechanism could expand consideration of greater substandard and falsified and multisectoral issues, where relevant, such as antimicrobial resistance, and animal, agricultural and environmental health (as included in the One Health agenda). The Member State mechanism's secretariat links well with WHO departments and offices, although coordination and information sharing could be further developed in some cases to support the work of the mechanism.

Finding 5 (Sustainability): From 2024, the Member State mechanism is starting to apply longer term planning via use of basic outcome indicators, which may contribute to more sustainable achievements. Many of its activities are already inherently sustainable in their likely effects (e.g., assisting in the revision of national regulations). However, financial security for the mechanism itself only exists for the short term (approximately the current biennium) and the narrowness of the donor base brings risk, which combined with a lack of well-developed long-term planning (see Findings 2 and 3) undermines future sustainability.

Finding 6 (Equity): The Member State mechanism's governance structure is inclusive and open to all Member States, but some (mainly high or middle income) Member States participate more than others. There is a reasonable gender balance within the mechanism's Steering Committee, among national focal points and within the mechanism's secretariat. There is limited evidence that the Member State mechanism has proactively considered gender, equity and human rights in planning and implementing its activities.

Conclusions

Based on the information gathered as described above and its analysis by the evaluation team, the following conclusions were drawn.

Conclusion 1 (Relevance): The Member State mechanism's present format has structural advantages worth retaining. However, it also presents problems, ones moreover that are likely to be increasingly challenging as the mechanism seeks to increase its efforts to prevent and control substandard and falsified medical products. There is a need for more reliable funding streams; better engagement with external substandard and falsified medical products stakeholders; demonstrated agility in substandard and falsified medical product emergencies; and active and technically proficient working groups. Structural reform should be considered yet not rushed into (in order to retain as far as possible the advantages related to Member State inclusion).

Conclusion 2 (Effectiveness): The current focus of reporting on activities (and difficulty in some cases in differentiating Member State mechanism activities from WHO activities) makes it difficult to assess progress towards its objectives. Although there is a lack of Member State mechanism capacity to demonstrate results, there has been more progress towards some objectives and some working groups have been effective in taking activities forward. Many factors have affected progress, including lack of Member State participation and engagement, limited effectiveness of some working groups, lack of accountability, lack of engagement with other stakeholders and fragmentation of efforts, and lack of funding. Some other factors, often outside of the mechanism's control, have also affected progress, including weak capacity of regulatory and health systems.

Conclusion 3 (Efficiency): Efficiency cannot be fully measured due to the lack of a systematic approach to resource allocation and of monitoring and evaluation of resource use; however, there is no evidence of any serious inefficiency in the Member State mechanism's use of its resources. The mechanism's monitoring and evaluation is rudimentary, although it has recently improved with the addition of expected outcomes in 2024. Some elements of the mechanism, such as its secretariat and the few Member States that participate significantly – seem, on balance, efficient and important to retain/expand. Meetings are also an important element to the mechanism though some aspects of them could be reviewed, such as their location exclusively in Geneva, which deters some potential attendees from attending.

Conclusion 4 (Coherence): The alignment between the Member State mechanism and external substandard and falsified medical products stakeholders on definitions of substandard and falsified products has led to useful consensus. However, the mechanism's limited interaction with other (especially non-Member State) stakeholders reduces coordination and potentially fragments global action. There is generally strong support for increased engagement and involvement of external stakeholders, both from those working in the mechanism (Member States and the secretariat) and from donors and other stakeholders. However, caution is urged with respect to both dissemination of country-specific information (e.g., in relation to substandard and falsified incidents) and to engaging non-State actors, including the private sector in accordance with the Framework of Engagement with Non-State Actors.

Conclusion 5 (Sustainability): The Member State mechanism (and its secretariat) reliance on two main external donors, who could easily change their funding priorities, risks its financial sustainability beyond the current biennium. This is compounded by the currently very small Member State contributions. Uncertainty regarding donor funding is a major threat to the future of the mechanism, and so a stronger investment case for donors is required if its long-term future is

to be secured. Changes to legislation, regulation and regulatory capacity in Member States, because of Member State mechanism support, are likely to positively affect the sustainability of its results.

Conclusion 6 (Equity): The Member State mechanism's objectives and activities tend to be inherently equity-focused, given that the risks associated with substandard and falsified products are inequitably distributed, with countries with limited resources and the poorest populations most likely to be affected. The mechanism may wish to consider giving more explicit priority to the needs of the most vulnerable population groups. More needs to be done to promote the active participation of lower income Member States in the mechanism.

Recommendations

Recommendations 1–5 are for the Member State mechanism to consider. Recommendations 6 and 7 are for the WHO Secretariat to consider.

Recommendation 1 is the most fundamental and an early decision to pursue either option A or B within it will be helpful in setting the context and scope for implementation of recommendations 2–7. Note that recommendations do not correspond only to single conclusions.

Recommendation 1: Member States should consider revising the format of the Member State mechanism to benefit from more relevant technical expertise; better collaboration with external stakeholders; and potentially increased funding and Member State participation. Two options are possible as ways to make progress in these areas.

- Option A: Dissolving the current Member State mechanism and establishing a new format which would report to the WHO Director-General but would still have significant input from Member States. This could be an advisory group or a more bespoke hybrid format.[7] Such revision would need to be proposed by the Member State mechanism and approved by the World Health Assembly through the Executive Board. A task force could be established to guide this process.

- Option B: Using the existing Member State mechanism format but experimenting with increasing the involvement of technical experts in the fields related to the mechanism's working groups, and increasing Member States' participation as well as engagement with external stakeholders, including in formal meetings (in line with relevant World Health Assembly resolutions and decisions, World Health Assembly rules of procedure and within the Framework of Engagement with Non-State Actors).

Option A would have the best chance of success over the long term. Option B would be less challenging to achieve. In choosing between these two options, Member States could first consider exploring option B.

Recommendation 2: Develop an integrated planning and review approach to further develop the Member State mechanism's work planning, costing/budgeting, prioritization and reporting processes (in line with results-based management approaches). Actions to develop a more comprehensive integrated planning and review system should include refining the draft Member State mechanism strategy, to include a theory of change and results framework with clear output and outcome indicators to track performance, costing potential activities to help to prioritize and

[7] The WHO global coordination mechanism on the prevention and control of noncommunicable diseases is an example of a hybrid body, with a format other than an advisory group.

resource these, developing workplans with timelines and milestones, and establishing a feedback system to help to disseminate learning. Resource constraints may entail this approach being developed to a less than comprehensive extent initially (unless the mechanism's secretariat capacity is significantly expanded).

Recommendation 3: Clarify and communicate roles and responsibilities with a strong focus on strengthening Member State engagement and accountability. This would include making a clear distinction between Member State responsibilities and working group participation, and those of the WHO Secretariat. With this clarity the Member State mechanism should ensure processes are in place to strengthen accountability for the fulfilment of these responsibilities. The mechanism should also consider approaches, including the role of its secretariat in facilitating the link between national regulatory authorities and Member States' representation, to incentivize and support Member State meetings and working group participation (especially those from low-income countries).

Recommendation 4: Strengthen the Member State mechanism's visibility via stronger external communication (including benefits due to, and performance of, the mechanism) to Member States, potential donors and other stakeholders. This should communicate clearly the benefits to Member States of Member State mechanism participation, and the objectives, achievements and what can be offered by the mechanism and its secretariat in the substandard and falsified products field to external stakeholders.

Recommendation 5: Improve external engagement by developing differentiated engagement strategies (in line with the Framework of Engagement with Non-State Actors). This will include ways to engage with donors, strategic and operational partners. As a basis for developing a stakeholder engagement strategy that targets strategic and operational partners, a full mapping of stakeholders should be conducted. The Member State mechanism, in consultation with the Due Diligence and Non-State Actors unit of the Office of Compliance, Risk Management and Ethics, should specifically develop guidance for engagement with external stakeholders, such as the pharmaceutical industry that has much to offer in the fight against substandard and falsified products, but caution is required due to potential or perceived conflict of interest. At the regional level, efforts should be made to seek increased collaboration, such as by increasing regional involvement in some Member State mechanism working groups and with national focal points.

Recommendation 6: Further enhance WHO technical support for the work of the Member State mechanism. This should include increasing coordinated communication, information sharing and technical support by WHO at the headquarters and regional levels for the Member State mechanism, including for issues of product shortages and local production (pursuant to resolution WHA65.19).

Recommendation 7: Explore ways to further increase the capacity of the Member State mechanism's secretariat. Support for additional human resources should be discussed with donors and senior managers within the WHO Secretariat. Better definition and recognition of Member State (and potential additional technical expertise) responsibilities versus those of the Member State mechanism's secretariat may reduce the burden on the secretariat and capacity requirements.
