



World Health
Organization

Evaluation of the Member State Mechanism on Substandard and Falsified Medical Products

A N N E X E S



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ANNEX 1: Terms of reference

Evaluation of the Member State Mechanism (MSM) on substandard and falsified medical products

Terms of Reference

I Background

The MSM organizational mandate

1. In 2012, the Sixty-fifth World Health Assembly adopted resolution WHA65.19, in which it decided to establish a Member State mechanism with the general goal of promoting, through effective collaboration among Member States and the Secretariat, the prevention and control of SSFFC¹ medical products and associated activities to protect public health and promote access to affordable, safe, efficacious and quality medical products.
2. Since its creation, the Member State mechanism (MSM) on Substandard and Falsified (SF) medical products has become the global forum at which Member States convene, coordinate, decide and organize activities to address SF medical products.
3. The MSM was established with the following objectives (ref. Resolution WHA65.19):
 - 1) To identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies, and control of SF medical products in order to strengthen national and regional capacities.
 - 2) To strengthen national and regional capacities in order to ensure the integrity of the supply chain.
 - 3) To exchange experiences, lessons learnt, best practices and information on ongoing activities at national, regional and global levels.
 - 4) To identify actions, activities and behaviours that result in SF medical products and make recommendations, including for improving the quality, safety and efficacy of medical products.
 - 5) To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries.
 - 6) To collaborate with and contribute to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products, including, but not limited to, the supply and use of generic medical products, which could complement measures for the prevention and control of SF medical products.
 - 7) To facilitate consultation, cooperation and collaboration with relevant stakeholders in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective.
 - 8) To promote cooperation and collaboration on surveillance and monitoring of SF medical products.
 - 9) To further develop definitions of SF medical products that focus on the protection of public health.

¹ Substandard/spurious/falsely-labelled/falsified/counterfeit.

4. The work of the MSM on SF medical products remains as relevant as ever; low- and middle-income countries spend an estimated US\$ 30.5 billion on SF medicines, accounting for 10.5% of medicines in the supply chain in these countries².
5. A review of the MSM³ was mandated by resolution WHA65.19 and covered the first five years from 2012 to 2016. The overall purpose of the review was to assess the extent to which the MSM had progressed in achieving its objectives in the period 2012-2016; to identify gaps and challenges and to make recommendations on the way forward. The review was conducted by the WHO Evaluation Office in 2017⁴.
6. At the recommendation of the MSM at its eleventh meeting, the Executive Board through decision EB152(9) (2023) recommended to the Seventy-sixth World Health Assembly to request the Director General “1) to facilitate the conduct of an independent evaluation of the MSM on substandard and falsified medical products in accordance with the terms of reference to be developed by the Steering Committee of the MSM; and 2) to report on the outcome of the evaluation to the governing bodies consistent with existing reporting requirements of the MSM on substandard and falsified medical products.”

The MSM governance, management structure and processes

7. The governance of the MSM involves both Member States and the WHO Secretariat. The mechanism is coordinated by the Secretariat, which provides guidance, technical assistance and support to Member States. The ultimate authority and decision-making reside with the Member States. The MSM has a Steering Committee led by a Chairperson who is supported by 11 Vice-chairpersons, representing the six WHO regions. The term of office for the Chair and Vice-chairs lasts two years (A/MSM/4/10 and A66/22) and the Chair rotates amongst the WHO regions on an alphabetical basis.
8. The mechanism operates under the framework of the Executive Board and the World Health Assembly resolutions, and its activities are aligned with the WHO agenda and strategy. As needed, the MSM seeks expert advice on specific topics, following standard WHO procedures for expert groups. The MSM invites other stakeholders to collaborate and consult with the group on specific topics (on a case-by-case basis).

² WHO-MHP-RPQ-REG-2022.01-eng.pdf

³ The review was carried out pursuant to resolution WHA65.19 (2012) and decision WHA68(12) (2015).

⁴ The review is available at the WHO Evaluation Office webpage: <https://cdn.who.int/media/docs/default-source/documents/evaluation>. The review's outcome was submitted to the Seventieth World Health Assembly through document A70/23 Add.1.

II Purpose, objectives and scope of the evaluation

9. The evaluation was mandated (EB152(9) (2023)) with the **purpose** to assess progress of the MSM in achieving its objectives, and to make recommendations for the future. Being both accountability and learning oriented, the evaluation will provide better understanding of the extent to which the mechanism is achieving results, including at the country level, and how to improve relevance, governance, functioning and performance for results. The evaluation will support proposals for change or improvements in the mechanism structure, way of working, collaborations and policies and it will provide lessons learned and operational recommendations to inform the way forward and a medium to long term strategy. The evaluation may also contribute to advocacy for stronger Member State participation in the MSM and resources.
10. To this end, the evaluation has the following **objectives**⁵:
- to document progress in achieving the MSM’s objectives since the 2017 review, identifying achievements, opportunities, challenges and gaps;
 - to assess the effectiveness and added value of the tools and products of the MSM against other approaches to address SF medical products; and
 - to assess the relevance of the MSM’s format and governance structures to ensure it is fit for purpose.
11. **Scope:** The evaluation encompasses the timeframe spanning from 2017 to 2023. The evaluation covers the global, regional, and country levels. It will cover progress made on all the eight strategies and action areas defined in the work plan of the MSM⁶, together with their relationship to the achievement of the objectives of the mechanism.

III Approach and methods

12. The evaluation will be conducted in line with the WHO evaluation policy⁷. The overall process and methodological approach will follow the principles set forth in the WHO Evaluation Practice Handbook⁸ and the United Nations Evaluation Group Norms and Standards for Evaluation and Ethical Guidelines for Evaluation.⁹
13. The methodology described in this section is indicative and the evaluation team that will be hired to conduct this evaluation is expected to adapt the approach and propose adjustments needed to undertake the assignment. The evaluation team will assess the options and describe in detail the suitable methods to meet the purpose, scope, and objectives of this evaluation. These include additions to the evaluation design; a stakeholder mapping and an appropriate sampling strategy for

⁵ Reference is made to the “Draft terms of reference for the evaluation of the Member State mechanism”, outlining the main elements regarding the independent evaluation of the MSM for the Steering Committee’s consideration.

⁶ Available at: https://apps.who.int/gb/sf/pdf_files/MSM10/A_MSM10_11Rev1-en.pdf

⁷ [WHO Evaluation Policy \(2018\)](#) Geneva: World Health Organization; 2018.

⁸ [WHO Evaluation Practice Handbook](#). Geneva: World Health Organization; 2013.

⁹ Norms and Standards for Evaluation. New York: United Nations Evaluation Group (<http://www.unevaluation.org/document/detail/1914>), 2016 and UNEG Ethical Guidelines for Evaluation, 2020 (<https://www.unevaluation.org/document/detail/2866>).

key informants; data collection and analysis methods; and an evaluation matrix with a description of data sources, as well as indication of methodological limitations and mitigation measures.

14. The design of the evaluation will be non-experimental and participatory, engaging with users of the evaluation process and report and focusing on utilization and use of the findings and recommendations by all key stakeholders.
15. The evaluation will seek answers to overarching and specific evaluation questions. Some specific questions, for further discussion, prioritisation (possibly for a maximum of 10 questions) and validation at the inception phase are provided below. The inception phase will provide the opportunity to the evaluation team to discuss the questions/refine these based on experience and stakeholders' needs.
16. The evaluation will apply the Organization for Economic Co-operation and Development's (OECD) Development Assistance Committee (DAC) criteria of relevance, effectiveness, efficiency and coherence¹⁰ and map questions to these criteria. Recommendations should also cover ways to improve relevance, effectiveness, efficiency, and coherence of the MSM, including at the country level, in the medium and long term.
17. At the inception phase, the evaluation team will review relevant documents (e.g. A/MSM/11/5 on Future work of the Member State mechanism) and provide a reconstructed theory of change for the MSM to clarify its expected results chain, outputs, and outcomes. The theory of change will allow framing and prioritisation of evaluation questions.

Figure 1. Evaluation questions and potential evaluation sub-questions to be discussed, prioritised and validated at inception phase.

Evaluation overarching questions	Potential evaluation specific questions
<p><i>To what extent are the MSM format and governance structures relevant and do they ensure the mechanism remains fit for purpose looking forward?</i></p> <p><i>(ref. to OECD/DAC evaluation criteria of <u>relevance</u>, and some sustainability issues)</i></p>	<ul style="list-style-type: none"> - What are the key contextual factors and evolving needs that are affecting the work of the MSM and to what extent are objectives of the MSM still relevant? - Is the governance framework clear to Member States, with well-defined roles and responsibilities, and to what extent has the MSM governance structure facilitated accountability? What strategies can enhance governance including at the national level? - To what extent has the mechanism been able to adapt to changing circumstances? Is it flexible enough to address new issues that may emerge? Have sustainability concerns been integrated?
<p><i>How effectively has the MSM achieved its objectives, are there any gaps, and which factors have either supported or hampered progress?</i></p> <p><i>(ref. to evaluation criteria of <u>effectiveness</u>)</i></p>	<ul style="list-style-type: none"> - What progress has been made in implementing activities since 2017, and what are the key results, including any unintended consequences? To what extent has the mechanism achieved its global and country-level objectives? - How to improve performance measurement for the mechanism (M&E)?

¹⁰ Organisation for Economic Co-operation and Development's Development Assistance Committee (OECD-DAC) professional evaluation criteria:

<https://www.oecd.org/dac/evaluation/daccriteriaforevaluatingdevelopmentassistance.htm>

	<ul style="list-style-type: none"> - What support is required to facilitate MSM functioning and reach? What aspects should be sustained and what challenges need to be addressed?
<p><i>How efficiently has the MSM used the resources at its disposal?</i></p> <p><i>(ref. to evaluation criteria of efficiency)</i></p>	<ul style="list-style-type: none"> - To what extent are the Secretariat and country-level activities of the MSM adequately resourced? - What improvements in efficiency of resource utilisation (financial and human) can be identified? - Has the mechanism operated within an appropriate legal framework and what measures could enhance it?
<p>Coherence: <i>How does the MSM ensure coherence and continue to bring value to address SF medical products in relation to other approaches with a similar mandate?</i></p> <p><i>(ref. to evaluation criteria of coherence)</i></p>	<p><u>External coherence</u></p> <ul style="list-style-type: none"> - How does the MSM align with approaches from other organizations with similar mandates? - To what extent have Member States cooperated at global, regional and national levels, and how has the mechanism facilitated this collaboration? How to further promote Member State participation in the mechanism (commitment, political will, adoption of supportive national legislation)? - How to enhance engagement with non-State actors in the global and country-level efforts to combat SF medical products? <p><u>Internal coherence</u></p> <ul style="list-style-type: none"> - How adequate is coordination across the MSM Secretariat, WHO HQ technical departments (e.g., HQ/HPS Health Product Policy and Standards; AMR Antimicrobial Resistance Division); regional and country offices?

18. To address these questions, the evaluation will follow a participatory approach designed to maximize opportunities for discussions and provision of feedback by stakeholders. The evaluation will be conducted using a combination of quantitative and qualitative methods, to be further refined during the inception phase, including:

- a desk review of available documentation, including MSM reports and data¹¹, partners' documents, including available WHO guidance and tools, strategic documents and past reviews/evaluations/audits;
- key informant (KI) interviews /focus group discussions with key stakeholders including relevant WHO staff at headquarters, regional and country level (e.g. staff working on matters related to essential medicines and health products, staff providing Secretariat (WHO Incidents and SF medical products team) support to the MSM, etc.) and a selection of Member States (i.e. health ministries and national/regional regulatory agencies). In the sampling of key informants, it will be important to respect regional representation (all six WHO regions). KIs will be identified through discussion with the MSM Secretariat, regional offices, the Steering Committee and adopting a snow-ball approach while respecting balance in country/regional representation and types (e.g. country income level).
- an online survey/questionnaire with focus on key stakeholders at the country level.

19. The methodology is expected to enable rigorous and systematic data collection and analysis and identify emerging good practices which could be replicated. Findings should be based on triangulated evidence, and conclusions and recommendations should derive from the findings. Multiple sources should be used to ensure that the findings can be generalized and are not the

¹¹ WHO Governance - Member State mechanism on substandard and falsified medical products
<https://apps.who.int/gb/sf/>

results of bias or the views of a single organisation or type of actor. Triangulation should allow evaluators to determine how much weight to put on diverse findings.

20. **Human rights, equity and gender equality.** With reference to the UNEG guidance on Integrating Human Rights and Gender Equality in Evaluation and the WHO 2023 specific guidance¹², the evaluation is expected to integrate human rights, equity and gender equality considerations in its design, data collection, analysis and reporting, including an analysis of the extent to which actions and interventions contribute to addressing inequalities.
21. **Ethical considerations.** The evaluation will be expected to follow UNEG 2020 Ethical Guidelines. The inception report will outline how the evaluation team will adhere to ethical considerations including: confidentiality and anonymity, do no-harm approaches in the administration of qualitative methods with respondents, data management and storage, and integration of appropriate cultural/language considerations.
22. **Evaluation users.** Evaluation users are the MSM Steering Committee and other Member States; the MSM WHO Secretariat and staff working on matters related to essential medicines and health products. Other users are development partners including bilateral donors and country level implementing partners such as regulatory agencies.

IV Evaluation management

23. The evaluation will be managed by the WHO Evaluation Office in collaboration with the MSM Secretariat (WHO Incidents and SF medical products team). The Evaluation Manager is responsible for supporting the evaluation team during the evaluation exercise including facilitation of the evaluation process, identification of relevant documentation and data, access to key interlocutors within and outside WHO, dissemination of evaluation deliverables for comments, organization of meetings and stakeholder workshop.
24. The Evaluation Manager will be supported by a technical Evaluation Reference Group (ERG). The ERG will provide advice to the Evaluation Manager and be kept informed throughout the evaluation process. The ERG will:
 - Review the evaluation questions;
 - Review the draft inception report, the draft and final reports and the recommendations;
 - Act as a source of knowledge for the evaluation;
 - support the dissemination phase as relevant.
25. The evaluation will be conducted by an external evaluation team (a consultancy firm), selected competitively. Evaluators must have freedom to conduct their evaluative work impartially, without undue pressure throughout the evaluation process and with access to information on the evaluation subject (independence). The evaluation team should have appropriate evaluation skills mix and

¹² UNEG Integrating Human Rights and Gender Equality in Evaluations, 2014 (<http://www.unevaluation.org/document/download/2107>) and Guidance note on Integrating Health Equity, Gender Equality, Disability Inclusion and Human Rights in WHO evaluations, 2023 (<https://www.who.int/publications/m/item/guidance-note-on-integrating-health-equity--gender-equality--disability-inclusion-and-human-rights-in-who-evaluations>)

understanding of evaluation methodologies as well as strong technical understanding of the field (public health background (medical or pharmaceutical degree), with specific technical knowledge and experience on access to safe, effective and quality medical products, and regulatory background in an international context).

It is desirable that the team has relevant experience in performing similar evaluations and understanding of WHO and the United Nations system. The evaluation team will be responsible for:

- Designing, planning and implementing the evaluation, drafting the evaluation report, using the approach to be agreed in the inception report, and for delivering in accordance with the terms of reference specifications and timeline;
- Consulting and liaising, as required, with the Evaluation Manager, to ensure satisfactory delivery of all deliverables;
- Scheduling and conducting all meetings, interviews, focus group discussions and final workshop with stakeholders.

26. The evaluation team is expected to carry out the evaluation with a high degree of autonomy and manage their own travel and other administrative arrangements as relevant.

V Evaluation deliverables

Deliverable 1: Inception report

27. The inception phase will involve active participation and inclusivity through exploratory interviews with stakeholders, working collaboratively with the ERG to refine evaluation questions, and address other methodological aspects. During the inception phase, the contracted evaluation team will develop an inception report that will detail the evaluators' understanding of what is being evaluated and why, including an agreed set of questions and showing how each evaluation question will be answered by way of: proposed methods; sources of data; and data collection procedures. The inception report should include an evaluation matrix, proposed schedule of tasks, activities and deliverables, a reconstructed theory of change for the MSM, identified key informants for the interviews (based on a stakeholder mapping), and evaluation tools such as interview guides and survey questions. The draft inception report will be submitted by the evaluation team to the Evaluation Manager and presented online to the MSM Secretariat and the ERG for review. Templates for the inception report as well as other reports are to be agreed with the Evaluation Office.

Deliverable 2: Draft evaluation report

28. The evaluation team will submit a draft evaluation report to the Evaluation Manager and present it to the MSM Secretariat and the ERG. The draft report will contain findings, conclusions, and recommendations. The approach to develop the recommendations will be based on co-creating them with stakeholders of the evaluation. The recommendations should be sufficiently detailed and actionable to enable the formulation of a management response, with clear timelines and responsibilities.

Deliverable 3: Stakeholder workshop PowerPoint presentation

29. The evaluation team will present the draft findings, conclusions and recommendations to the main stakeholders of the evaluation (in a PowerPoint presentation format) in a stakeholder workshop to be held either online or in person. The draft report will be finalized following discussion with key stakeholders and taking due consideration of comments received.

Deliverable 4: Final evaluation report and communication documents

30. The evaluation team will submit a final evaluation report, including findings, conclusions and recommendations to the Evaluation Manager. The report will include an executive summary. The report will be disseminated internally and posted on the WHO Evaluation Office website (www.who.int/about/evaluation/en/).

31. The final report will be delivered together with a two-pager policy style brief highlighting main findings/conclusions and recommendations. The evaluation team may also collaborate with the Evaluation Office communication specialist to deliver additional evaluation material with the main messages from the final evaluation report.

Note: The revisions of any of the deliverables produced by the evaluation team will be accompanied by feedback on each comment received. This feedback will succinctly summarize if and how comments were addressed, and if they were not, it will justify why.

VI Timeline

32. Key milestones envisaged for the evaluation are provided below (tentative):

- Development of specific terms of reference for the evaluation: October 2023
- Selection of the evaluation team: November 2023
- Inception report: January 2023
- Data collection: January 2023 – April 2024
- Stakeholder workshop: May 2024
- Draft evaluation report: June 2024
- Final evaluation report: June 2024

The final evaluation report will be submitted through the Steering Committee by the MSM at its Thirteenth meeting in 2024. In accordance with decision WHA76(9) of the World Health Assembly, the Director-General will report on the outcome of the evaluation to the 156th Executive Board and the Seventy-eighth Health Assembly in 2025.

ANNEX 2: Evaluation framework

OECD-DAC Criteria	Evaluation questions and sub-questions	Indicators	Sources of information	Data collection methods	Indicative alignment with ToC
Relevance	1.1 To what extent are objectives of the MSM still aligned to needs?	Perceptions of stakeholders on extent of alignment of objectives to needs	MS rep.; WHO: HQ, regional, and country level; other global and regional stakeholders Documents: including needs assessments, design, response, progress	Document review Key informant interviews Online Survey	This question is essentially aligned with the outputs and activities and will shed light on the relevance of the MSM's action
	1.2 To what extent is the governance framework clear to Member States, (how well-understood are roles and responsibilities)?	Percentage perception of MS representatives having a good understanding of the governance framework	MS rep. and NRAs WHO: HQ, regional, and country level	Document review Key informant interviews Online Survey	This question is linked to the efficiency of Inputs 1 and 2 and that of the Organization (cross-functional)
	1.3 To what extent has the mechanism been flexible, able to adapt to changing circumstances and respond to emerging issues?	Views of stakeholders on the mechanism's ability to adapt in order to respond to emerging SF regional and global issues; evidence of MSM response to emerging issues over time	MS rep. WHO: HQ, regional, and country level, other global and regional stakeholders Documents: including list of emerging issues, activities and products	Document review Key informant interviews	This question refers to Organizational aspects that influence the Pathways of change
	1.4 Overall what are the advantages and disadvantages of the current MSM format?	Expert opinion of relevant stakeholders on	MS rep. WHO: HQ, regional, and country level	Document review	This question relates to the framework established for the

		influence of legal framework on MSM	Documents: including list of emerging issues, activities and products.	Key informant interviews	MSM's activities to be carried out
Effectiveness	2.1 To what extent have the MSM activities and products been implemented?	The extent to which the activities and products have been implemented (progress report)	MS rep. WHO: HQ, regional, and country level, other global and regional stakeholders Documents: including MSM reporting	Document review Key informant interviews Online Survey	The Pathways of change activities are directly concerned by this question
	2.2 To what extent was WHO MSM Secretariat support (IT and communication and dissemination) to MSM adequate to facilitate MSM functioning and reach?	Perception of stakeholders on Secretariat ability to adequately support the Mechanism	MS rep.; WHO: HQ, regional, and country level, other global; and regional stakeholders Documents: including needs assessments, response, progress	Document review Key informant interviews Online Survey	This question refers to Organizational aspects that influence the Pathways of change
	2.3 Which aspects of MSM worked well and which less well?	List of processes (with rationale and evidence) and factors of MSM that worked well and those that worked less well	MS rep.; WHO: HQ, regional, and country level, other global; and regional stakeholders	Document review Key informant interviews Online Survey	This question focuses more on the efficiency of Inputs and, to a lesser extent, on Activities
	2.4 What strategies can enhance national engagement in the MSMs discussions and activities?	Perception of stakeholders regarding influence of alternative governance strategies	MS rep.; WHO: HQ, regional, and country level	Document review Key informant interviews	This question relates to the influence of governance over Activities and Outputs

Efficiency	3.1 How have MSM resources and their sources evolved? How have MSM resources and their sources evolved? Are there any resource gaps and have they significantly evolved?	Evidence of budget evolution and deployment; Expert opinions of MSM processes that face major resource challenges	MS rep.; WHO: HQ, regional, and country level Documents: including needs assessments, response, progress, annual budgets, annual frameworks	Document review Key informant interviews Online Survey	This question focuses on the efficiency of Input 1
	3.2 To what extent have the resources been used appropriately? Has there been unnecessary use of resources, duplication/complementarity (i.e. synergy), timeliness of MSM responses?	The extent to which MSM's processes are inefficient (delayed)	Documents: including needs assessments, design MS rep.; WHO: HQ, regional, and country level	Document review Key informant interviews	This question refers to Inputs and to a lesser extent to the Outcomes
	3.3 Is the MSM's M&E adequate for performance measurement?	Number of MSM's M&E criteria adequate to measure MSM activities, reported use, ET expert judgement	Documents: other relevant M&E systems; design MS rep., WHO HQ	Document review Key informant interviews	This question is essentially aligned with the measurement of the Outputs
Coherence - External coherence	4.1 How does the MSM align with approaches from other organizations including multilaterals/bilaterals and also Non-State Actors (NSAs) which are also active in the field of SF products?	Cross-analysis of mandates and of other evidence from comparable organizations; Expert opinions of the complementarity of the approach with other agencies	Documents: other relevant organizations MS SCM, WHO HQ	Document review Key informant interviews	This question refers to External factors that influence the Pathways of change and to a lesser extent to Outcomes
	4.2 To what extent have Member States cooperated at global, regional and national levels, and how has the mechanism facilitated this collaboration?	Perception of the MSM's role in facilitating coordination, examples	Documents: correspondence between MSM	Document review Key informant interviews	This question focuses on Input 2 and to a lesser extent to Outcome 3

		of best practices/ challenges	Secretariat, MSM SC and countries MS SCM, WHO HQ and country	Online Survey	
Internal coherence	4.5 To what extent is the coordination adequate across the MSM Secretariat, WHO HQ technical departments (e.g., HQ/HPS Health Product Policy and Standards; AMR Antimicrobial Resistance Division); regional and country offices?	Extent to which the various relevant WHO departments are mobilized to support the work of the mechanism	Documents: correspondence MS SCM, WHO HQ, regional, country	Document review Key informant interviews Online Survey	This question focuses on Input 2 and to a lesser extent to Outcome 3
Sustainability	EQ5: To what extent are achievements of the MSM work likely to remain (in the absence of an MSM) and its work continued on SFP?	Extent of development of relevant institutional capacity that could operate independently of MSM	MS rep.; WHO: HQ, regional, and country level, other global; and regional stakeholders Documents: including plans and budgets of global, regional and national stakeholders; legislation	Document review Key informant interviews Online Survey	This question relates to Input 3, Activities and Outcomes
Equity	EQ 6: How is the MSM considering issues of gender equality, implementation equity and human rights in its functioning?	Extent of consideration of marginalized populations; gender representation; disability access. Mention in key MSM documents, awareness of respondents etc.	MS rep.; WHO: HQ, regional, and country level, other global; and regional stakeholders Documents: including staff and attendance lists; evidence of implementation	Document review Key informant interviews Online Survey Analysis of disaggregated data for considerations of marginalized populations; gender representation; disability access	This question cuts across all aspects of the MSM

ANNEX 3: MSMech 2017 evaluation recommendations

This Annex was prepared by the external independent evaluation team.

A review of the MSMech was carried out in 2017 by the WHO Evaluation Office (*Review of the Member State mechanism on substandard / spurious / falsely labelled / falsified / counterfeit medical products*), covering the period 2012 to 2016, and looked at the extent to which the mechanism had achieved its objectives, the factors behind this and how effectiveness might be strengthened in the future. The evaluation team conducted a rapid assessment of progress, summarized in the table below, and with some comments below.

Table 1. Progress against MSMech 2017 evaluation recommendations

2017 Recs.	Action points	Done
1. Members of the Steering Committee of the Member State mechanism to revisit the current workplan, ensuring outstanding activities within the workplan are completed, and consider plans and activities for the next phase.		(+)
2. Develop appropriate processes for effective coordination, communication and dissemination of information on main action areas and outputs		(-)
	Strengthen coordination and harmonize procedures between the mechanism and relevant technical teams in WHO at headquarters and regional levels, and between the mechanism and Member States.	(+)
	Establish better systems for regional communication and dissemination of information between the mechanism and Member States, including strengthening use of electronic platforms and focal points networks.	(-)
	Improve coordination and communication on SSFFC matters across the three levels of the organization.	(-)
	Encourage active engagement of more Member States in the work of the mechanism.	(-)
3. Build and expand national capacity to address SSFFC medical products		(-)
	Provide training to national focal points on the prevention, detection and response to SSFFC medical products.	(-)
	Develop tools to support implementation of the mechanism's activities.	(+)
	Expand the number of Member States that are actively engaged in the process.	(- -)
4. Secure sufficient additional resources for the mechanism to be able to achieve all of its objectives.		(- -)
	The mechanism should support secretariat efforts to secure additional resources from Member States and the international donor community.	(- -)
	WHO's senior management should consider prioritizing support and funding for the mechanism's secretariat.	(- -)
5. Encourage the engagement of additional actors in the mechanism, including academia, manufacturers, nongovernmental organisations, civil society and related technical institutions at global, regional and country levels.		(-)

Legend:

(- -) = Not at all

(-) = A little

(+) = Partially
(++) = Fully

1. Members of the Steering Committee of the Member State Mechanism to revisit the current workplan, ensuring outstanding activities within the workplan are completed, and consider plans and activities for the next phase.

Progress on implementing activities is mixed; working groups have had varied success, with some producing tangible outputs, while others have been less productive. More progress has been made in areas related to capacity building, tools and technologies and traceability systems, communications campaigns (in specific pilot countries) and strategies to address distribution via the internet and informal markets than those related to global networking of stakeholders, leveraging the competencies of relevant stakeholders, and capacity to expand awareness.

It is difficult to assess the wider impact of MSMech activities due to lack of evidence of effectiveness. There is also a need to pay more attention to follow up to see how much actual implementation of MSMech outputs is happening. Accountability for activity completion is somehow lacking.

There has been a gradual move towards improving MSMech performance measurement. For the first time, for 2024-2025, expected outcomes are stated in biennial plans, although there are not yet activity and output indicators.

2. Develop appropriate processes for effective coordination, communication and dissemination of information for main action areas and outputs

Strengthen coordination and harmonize procedures between the mechanism and relevant technical teams in WHO at headquarters and regional levels, and between the mechanism and Member States.

The MSMech model shows strong potential for fostering collaboration at global, regional, and national levels, though improvements are needed. While Member States have generally collaborated well across these levels, regional engagement varies. The African and Eastern Mediterranean regions have shown stronger support compared to the Americas and Western Pacific regions. WHO regional offices, despite their key role, are often not fully integrated into the MSMech, leading to potential confusion for countries. Working groups within the MSMech facilitate collaboration, but they operate in isolation with limited interaction between groups. Communication challenges, including cumbersome protocols and low participation levels, hinder collaboration. Despite these issues, the MSMech Secretariat has effectively coordinated with other WHO technical teams, although continuous communication is needed, particularly for the exchange of timely information on substandard and falsified (SF) medical products. Aligning MSMech's work with WHO guidelines remains crucial, with potential for greater integration in the future. (See coherence section of the report for more details and references.)

Establish better systems for regional communication and dissemination of information between the mechanism and Member States, including strengthening the use of electronic platforms and focal points networks.

Currently the GSMS and Rapid Alert are the main tools for reporting and sharing information. Internal systems between the MSMech and Member States are weak and undeveloped. There is little evidence that the focal point network is being used to its full potential (e.g., WHO regional offices have limited contact with national and regional MSMech focal points).

Improve coordination and communication of SSFFC matters across the three levels of the organization.

It is unclear whether this has been improved since 2017. The communication in WHO between the country level and headquarters on SF medical products is effective. WHO regional offices seem to be less included than they should be. In some cases, there is no interaction between the MSMech regional focal points (Member States) and the WHO regional offices, although the latter play a role in sharing SF medical product reports using the Rapid Alert mechanism. Due to the fact WHO (at all levels) does not participate in, and is sometimes unaware of the appointment process for MSMech focal points, there can be a disconnect between the MSMech regional focal point and the WHO regional office.

Encourage active engagement of more Member States in the work of the mechanism.

Engagement and participation of Member States are suboptimal. While some Member States are active participants in the MSMech, others are not. Several informants highlighted the limited participation of African countries in the Steering Committee, working groups and plenary meetings. A key challenge is the relatively small number of Member States that engage in the working groups. The evaluation found little evidence of a proactive approach, or actions taken by the MSMech to encourage the active participation of Member States.

3. Build and expand national capacity to address SSFFC medical products

Provide training to national focal points on the prevention, detection and response to SSFFC medical products.

Capacity building – Key informants highlighted the need for increased support for LMICs including capacity building, equipment and training for national regulatory authorities and quality control laboratories. Survey respondents also identified the need to enhance capacity building. Overall, the evaluation team found that the MSMech developed a training handbook but did not deliver training; WHO did.

Develop tools to support implementation of the mechanism’s activities.

Informants also said that there has been good progress on work related to Activity C (Member State understanding and uptake of technologies and national traceability systems), especially for policy and tools, but more needs to be done to enable country adoption and implementation. It was also noted that MSMech-supported tools and technologies are helpful, but adoption and implementation of these tools will be more challenging for countries with limited capacity and resources.

Expand the number of Member States actively engaged in the process.

The number of Member States’ representatives participating in MSMech meetings increased during the COVID-19 pandemic after meetings were open to online participation. Since then, however, participation has declined to pre-COVID-19 levels.

4. Secure sufficient additional resources for the mechanism to achieve all its objectives

The mechanism should support secretariat efforts to secure additional resources from Member States and the international donor community.

Lack of funding – Lack of resources (and donor earmarking of funding) was identified as a factor limiting progress. Increasing Member States’ expectations at the same time as reduced willingness to contribute resources has

resulted in growing reliance on donor funding by WHO and the secretariat. There is scope to increase donor funding for work on substandard and falsified medicines, but this could be challenging because donors are excluded from the MSMech. The team found no evidence of a resource mobilization strategy. The evaluation team found no evidence of the mechanism supporting secretariat efforts to secure additional resources

WHO's senior management should consider prioritizing support and funding for the mechanism secretariat.

In the budget there is no budget line for the Secretariat. (See Volume of the report)

5. Encourage the engagement of additional actors in the mechanism, including academia, manufacturers, nongovernmental organisations, civil society and related technical institutions at global, regional and country levels.

There is little evidence of the MSMech encouraging the engagement of other actors in the mechanism and there are few if any opportunities for other stakeholders to be involved in the MSMech. It appears to be a rather closed mechanism, in the sense that it doesn't have a wide range of partnerships with other international organisations, and its attempts to integrate Non-State Actors (NSAs) have been limited, mostly as a choice from Member States to ensure public health remains the focus of the mechanism. However, many respondents to this evaluation believe there is significant untapped potential in external partnerships whether with international organisations, or NSAs. To note that broadening engagement to non-Member State stakeholders would need to follow various WHA and WHO rules of procedure, as well as requirements of the Framework of Engagement with Non-state Actors, and that changes may well require WHA decisions.

ANNEX 4: Progress with regards to implementation of MSMech activities (2020–2021 and 2022–2023)

This Annex was prepared by the external independent evaluation team.

Area of activity	Planned actions (2022–2023 and 2020–2021)	Implementation status	Extent of progress made
<p>A. Strengthen the capacity of national and regional authorities for the prevention and detection of and response to SF medical products</p>	<p>2022–2023:</p> <ul style="list-style-type: none"> Using global standard tools, assist in the identification of training needs, existing expertise and training materials for Member States and other institutions to prevent, detect and respond to SF medical products. Develop tools and a database to automate the conduct of medical products quality surveys and enhance the quantity and quality of data captured to inform risk-based post-market surveillance programs based on existing WHO guidance. Develop a guidance document aiming to strengthen the capacities of national/regional regulatory authorities to plan, perform and assess risk-based post-market surveillance. Support the development of training materials for national/regional regulatory authorities focused on promoting global guidance documents and the effective use of the tools <p>2020–2021:</p> <ul style="list-style-type: none"> Develop training material for national/regional regulatory authorities, focused on promoting the technical documentation approved by the MSMech Assist in the identification of the training needs, existing expertise and training materials of MSMech and other institutions to build capacity concerning the prevention and detection of, and response to, substandard and falsified medical products. 	<p>Report to Steering Committee (March 2024) states:</p> <ul style="list-style-type: none"> Consultant to be engaged Q2 2024 to review NRA benchmarking conducted and institutional development plans Competency assessment tools to be developed by Q4 2024 Updating list of available training materials ongoing Roll out Epione e-tool delayed Pilot risk-based post-market surveillance data on electronic Prequalification System (ePQS) planned in 1 country in Q2 2024 Consultant engaged to develop technical guidance on risk-based market surveillance and control Action to improve availability and usability of WHO knowledge based on SF medical products for Member States still to be addressed <p>Secretariat has developed draft handbook to support Member States to develop NAPs (see Area of activity D).</p> <p>Secretariat reported to have mapped existing training materials and plans to update the online handbook of existing training resources</p>	<p>Reporting at Steering Committee (March 2024) notes Working Group A membership and TOR reviewed together with prioritised activities for 2024-2025; reporting and planned activities show clearer set of actions and success indicators than previously.</p> <p>Reporting for 2020 and 2021 focuses on: improvements to the GSMS and reporting; field surveys on antimicrobial quality; WHO guidance on post-market and market surveillance of medical devices; WHO assessment of training needs; and training on regulatory functions. None of these relate to Working Group A planned actions.</p> <p>Reporting for 2022 and 2023 includes regional meetings and training, but it is not clear what role the MSMech, or Working Group A have played in these.</p> <p>Unclear to what extent the MSMech and Working Group A have contributed to strengthening the capacity of regional and national authorities (including identifying training needs, supporting development of training materials, and developing tools to enhance data) vs. the extent to which this has been done by WHO.</p>

	<ul style="list-style-type: none"> Risk-based post-market surveillance: (a) develop tools and a database to automate the conduct of medical products quality surveys and enhance the quantity and quality of data captured to inform risk-based post-market surveillance programmes based on existing WHO guidance and (b) develop guidance document to strengthen capacities of national/regional regulatory authorities to plan, perform and assess risk-based post-market surveillance including the effective use of the tools. 	<p>available on MedNet. by the MSMech plenary meeting in 2023</p> <p>Planned activities related to risk-based post-market surveillance implemented (tools, return on investment study, pilot post-market survey in Tanzania, online training material to build laboratory capacity to use Epione e-tool).</p>	
<p>B. Develop, expand and maintain global networks of stakeholders to facilitate cooperation and collaboration</p>	<p>2022–2023:</p> <ul style="list-style-type: none"> Identify reporting barriers faced by national FPs Develop strategies to improve reporting of SF medical products Facilitate exchange of communication, information sharing and networking among the Global FPs Network and other mechanisms/platforms Follow-up with Member States to keep FPs updated and trained <p>2020–2021:</p> <ul style="list-style-type: none"> Continue follow up with Member States to nominate FPs Continue to train new FPs and provide refresher training for existing FPs Facilitate the exchange of information in the Global Focal Point Network 	<p>Two areas of work implemented to identify barriers to reporting SF medical products to the GSMS: cross-sectional study using a quantitative approach to identify barriers and possible solutions, and qualitative study to further explore possible solutions.¹</p> <p>The technical team trains new FPs through individual online training on the use of the GSMS. All FPs have also been invited to complete the online course on SF medical products (introduction, responding to incidents and use of the GSMS portal) that has been available since April 2023 on the WHO i-Learn platform.</p> <p>The list of FPs is updated every year by the Secretariat. No progress yet with facilitating or establishing a platform for communication, information sharing and networking among Global FP Network. This is identified as an action for the 2024-2025 biennium.</p>	<p>Activities have focused on identifying and addressing barriers to reporting to GSMS by national FPs.</p> <p>Some work done on handheld devices/smartphone reporting for health care professionals (through Working Group C) to improve reporting of SF medical products.</p> <p>Limited attention given to date to facilitating exchange of information/networking among the Global FP Network. Updated TOR for the Global FP Network and KPIs for monitoring functionality is an action for the 2024-2025 biennium.</p>
<p>C. Improve Member State understanding and uptake of technologies to screen and detect SF medical products and implementation of</p>	<p>2022–2023:</p> <ul style="list-style-type: none"> Support development of the table of contents for proposed WHO guidance on how to select detection technologies Develop agenda for technical briefing session, and secure speakers 	<p>Support provided to develop scope of WHO guidance on selection of detection technologies and table of contents completed.²</p>	<p>Good progress with planned activities completed.</p> <p>2024-2025 prioritised actions include development of user requirements for handheld devices (plans for collaboration</p>

¹ Steering Committee meeting, March 2023.

² WHO, 2022. 11th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

<p>national traceability systems</p>	<ul style="list-style-type: none"> Develop questionnaire to request Member States to provide details on existing methodologies/tools used, in public and private sectors Analyse the data obtained through the questionnaire <p>2020–2021:</p> <ul style="list-style-type: none"> Convene open-ended expert sessions to review existing field detection devices and ‘track and trace’ models, and, as needed: (a) provide updates on existing ‘track and trace’ and authentication technologies in use by Member States and (b) report on existing field detection devices in use or available to MS Continue to develop the policy paper on ‘track and trace’ and submit a finalised document to the MSMech. 	<p>Technical briefings, collation of existing tools/methodologies on detection technologies completed.³</p> <p>Questionnaire on existing tools/methodologies used to screen and detect SF medical products sent to Member States – only 27 completed.⁴</p> <p>Survey on experience of implementing traceability systems – 193 invited, only 20 completed as of November 2023.⁵</p> <p>Technical and expert sessions convened; ‘track and trace’ policy paper (involving coordination with ICMRA and EDQM, including developing harmonised definitions) published.⁶</p>	<p>with Oxford University on the dashboard of technologies).</p> <p>New Working Group J on supporting country implementation of traceability systems established.</p>
<p>D. Leverage the competencies of relevant stakeholders, including policy-makers, procurers, distributors, practitioners, patients and consumers, and good governance to reduce the burden of SF medical products</p>	<p>2022–2023:</p> <ul style="list-style-type: none"> NAP handbooks roll out strategy and plan Target Maturity level 3 Monitoring and evaluation 	<p>Secretariat drafted handbook for Member States on developing/strengthening NAPs, including practical approach to implement/accelerate regulatory system strengthening in line with WHO Global Benchmarking Tools, with pilots in Burkina Faso, Gambia, Guinea, Nigeria and South Africa.⁷</p> <p>Member States requested to support piloting, roll out, implementation and M&E of uptake of the WHO NAP handbook during 2024-2025.⁸</p>	<p>March 2024 report to Steering Committee: ongoing support being provided to Burkina Faso, Gambia, Guinea, Nigeria; pilot in South Africa in the initial phase; targets for Member States with established NAPs by end 2025; ROI studies on market surveillance activities planned 2024-2025; research to inform evidence-based recommendations for policy yet to be initiated.</p>
<p>E. Enhance Member State capacity to run effective risk communication campaigns for SF medical products</p>	<p>2022–2023:</p> <ul style="list-style-type: none"> Develop an advocacy case (e.g. publication) to support Member States for investment and integration of risk communication, education and training on SF medical products 	<p>Targeted national campaigns (Risk Communication Campaign on Substandard and Falsified Medicines), based on research with the public in these countries, planned and implemented in Ghana, Nigeria, Sierra Leone, and Uganda⁹ with technical assistance from</p>	<p>Role of MSMech and Working Group E; support to national campaigns provided by WHO</p>

³ WHO, 2022. 11th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

⁴ WHO, 2023. 12th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

⁵ WHO, 2023. 12th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

⁶ WHO, 2021. 10th Plenary meeting of the WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

⁷ WHO, 2023. 12th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products

⁸ WHO, 2023. 12th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

⁹ WHO, 2021. 10th Plenary meeting of the WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

	<p>2020–2021:</p> <ul style="list-style-type: none"> • Conduct surveys on patient or consumer attitudes and behaviours on accessing medical products in 4 African countries, and develop or leverage recommendations for effective risk communication and awareness campaigns; produce samples of hard and soft copy material and video and broadcast material; assess the use of social media for raising awareness; identify the full range of stakeholders and audiences; and develop key and innovative advocacy material • Pilot the implementation of a compulsory element in the pharmacy school curriculum in 5 African countries 	<p>WHO; updates on progress with these campaigns including sharing of lessons learned provided by the four countries in May 2022 plenary meeting; next steps planned included an evaluation of the communication campaigns and development of practical guidance for Member States.¹⁰</p> <p>Limited progress reported on developing an advocacy case for Member State investment in risk communication, education and training, or media campaign materials, related to accessing antibiotics from unregulated sources.¹¹</p> <p>Low Member State participation in Working Group E noted (and proposal to merge Working Groups E and F during 2024-2025 biennium).¹²</p> <p>As of May 2022, compulsory pharmacy school modules implemented in four African countries (Cameroon, Senegal, Tanzania, Uganda) with plans to do likewise in Nigeria.</p>	<p>WHO external publication to be published June-July 2024. A risk communication handbook to be published by Q2 2025.</p> <p>Not clear if planned evaluation of risk communication campaigns has been conducted.</p> <p>Report to Steering Committee March 2024 notes plans to conduct a survey of Member State communication activities in 2024, and to map and review effective communication activities by end 2025, as well as to organise technical briefing sessions.</p> <p>Planned pilots of implementation of compulsory pharmacy school modules on track; outcome/next steps (and MSMech role) unclear and not included in 2024-2025 activities for Working Group E.</p>
<p>F. Enhance Member State capacity to expand awareness, effectiveness, impact and outreach in their work on SF medical products</p>	<p>2022–2023 and 2020–2021:</p> <ul style="list-style-type: none"> • Secretariat, working with Member States, to enable a proactive approach to disseminate and promote the materials and information developed by the MSMech • Member States to use documentation developed by the MSMech and WHO reports to increase political awareness and for advocacy at the highest levels about the need to support and dedicate resources to prevent, detect and respond to SF medical products. 	<p>Assessment of current MSMech information dissemination and outreach efforts proposed.¹³</p> <p>Two Working Group meetings in 2022; action reported to be ongoing in planned areas of activity, including prioritising materials for dissemination, promoting awareness among policy-makers, mapping relevant global and regional initiatives, and developing a strategy to promote and disseminate MSMech materials.¹⁴</p>	<p>Progress reports in 2020 and 2021 suggest that action to promote awareness, including advocacy and engagement with Member States, has largely been undertaken by WHO; slow Working Group progress and no evidence of a strategy to promote and disseminate MSMech materials.</p> <p>Note that this Working Group has been replaced by a new Working Group F (strengthening the supply chain of high-risk excipients and related raw materials); unclear where responsibility for proactive</p>

¹⁰ WHO, 2022. 11th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

¹¹ WHO, 2023. 12th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

¹² WHO, 2022. 11th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

¹³ WHO, 2021. 10th Plenary meeting of the WHO Member State mechanism on Substandard and Falsified (SF) Medical Products; WHO, 2020. 9th Plenary meeting of the WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

¹⁴ WHO, 2022. 11th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

		As of 2023, materials prioritized and mapping completed; leveraging networks and strategy for dissemination still to be achieved. ¹⁵	approach to promoting and disseminating MSMech materials and other outputs now rests.
G. identify and develop appropriate strategies to understand and address the distribution or supply of SF medical products via the internet	<p>2022–2023 and 2020–2021:</p> <ul style="list-style-type: none"> Develop terms of reference Provide a problem statement identifying the range of issues that facilitate the sale and supply of SF medical products through the internet both nationally and across borders. Identify experiences or regulation of the distribution or supply of medical products via the internet to prevent and reduce the risk of SF medical products reaching consumers. Develop guidance on strategies to enable national/regional regulatory authorities to address the distribution or supply of SF medical products via the internet 	<p>All planned activities (except development of guidance) completed as of October 2021, and internet ‘good practices’ virtual bookshelves in development.¹⁶</p> <p>Guidance developed;¹⁷ advocacy for capacity building for Member States to respond to online distribution, roadmap for interagency cooperation and collaboration with relevant stakeholders in progress in late 2022; awareness-raising and policy visibility of online distribution was planned for 2023.¹⁸</p>	<p>Good progress with planned activities completed.</p> <p>Report to Steering Committee March 2024: plans to develop/pilot internet training programme by end 2024; deliver training in each WHO region by end 2025; deliver technical briefing session by end 2024; produce strategic guidance to promote interagency cooperation and collaboration with relevant stakeholders, to respond to the distribution of SF medical products via the internet by end 2025.</p>
H. Develop strategies for national regulatory authorities to mitigate public health risks posed by the distribution of SF medical products through informal markets	<p>2022–2023:</p> <ul style="list-style-type: none"> Define informal markets as relate to medical products Understand current knowledge base and knowledge gaps Gather evidence to address knowledge gaps and to help develop long-term strategies Develop strategies and policy recommendations 	<p>Questionnaire circulated to Global FP network in 2019 with <50% response rate; findings to be used to inform notes on the current situation.¹⁹</p> <p>Definition developed and adopted July 2022.</p> <p>Literature review completed end of December 2023; survey piloted among 18 Member States in the Working Group and five Member State Steering Committee members, and received eight responses;²⁰ in 2024, Working Group is considering a survey of all Member States.</p>	<p>Progress made with definition and understanding the issues.</p> <p>Report to Steering Committee March 2024 notes: framework for technical activities to generate evidence to address knowledge gaps developed following an expert workshop in 2023; plans for technical briefing sessions in 2024 and 2025; and finalising workplan of activities to address knowledge gaps by end 2024.</p> <p>Unclear if there has been any progress with developing policy recommendations and strategies, or if there are plans to take this forward.</p>

¹⁵ WHO, 2023. 12th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products

¹⁶ WHO, 2021. 10th Plenary meeting of the WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

¹⁷ WHO, 2021. Develop guidance on strategies to enable national/regional regulatory authorities to address the distribution or supply of substandard and falsified medical products via the internet (No. A/MSM/10/10).

¹⁸ WHO, 2022. 11th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products

¹⁹ WHO, 2019. 9th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

²⁰ WHO, 2023. 12th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

ANNEX 5: Survey

Survey questionnaire

Welcome to the survey assessing the Member State mechanism (MSM) for substandard and falsified (SF) medical products.

The MSM was established by the Sixty-fifth World Health Assembly in 2012 to address public health issues related to SF medical products (<https://apps.who.int/gb/sf/>).

HealthGen Limited, a consultancy company, has been commissioned by WHO to conduct the independent evaluation of the MSM. The objectives of the evaluation are to assess the achievements of the MSM since 2017, identify challenges, extract lessons learned, and provide recommendations for the future. This survey is one of the tools of the independent evaluation.

By sharing your opinions, you are helping to shape the future of the MSM and to promote safe, efficacious, and quality medical products worldwide.

The survey is estimated to take approximately 30 minutes to complete. Rest assured that your responses will remain anonymous, and you can decide not to continue at any time.

A. Affiliation of the respondent

1. *Where are you based (please indicate which region or country as relevant)?*

- Global level
- Regional level
- Country level.

2. *What type of institution do you work for?*

- Ministry of Health
- National/Regional Pharmaceutical Regulatory Agency
- Governmental Institution other than those listed above
- WHO
- Other UN Agency
- Donor
- Private sector
- Academics
- NGO
- Patients organization
- Other: (Please specify)

3. How would you describe your knowledge about the WHO Member State Mechanism (MSM) for substandard and falsified medical products?

- I am in general very familiar with it.
- I have moderate knowledge about it.
- I don't know much about the process, but I know (some) elements of it.
- I hardly know anything about it. (skip to Mini Survey from question 21)
- I have never heard of it before receiving this questionnaire. (skip to Mini survey from question 21)

4. Do you have any official relationship with the Member State Mechanism (MSM) for substandard and falsified medical products? If yes, what is your official relationship with the MSM? Please click all that apply.

- No, I have no official relationship with the MSM
- I am or have been member of the Steering Committee
- I am or have been member of a working group of the MSM
- I am a national GSMS Focal Point
- I have used some of the outputs of the Mechanism in my country or work environment
- Other (Please specify)

B. Relevance

5. The MSM was established by the World Health Assembly (WHA) for collaboration among Member States to address global issues of relevance from a public health perspective. This is related to Substandard and Falsified (SF) medical products. Please indicate your level of agreement with the following statements.

	(1) Strongly disagree	(2) Disagree	(3) Neutral	(4) Agree	(5) Strongly agree	(-) Don't know
A Member State Mechanism is an adequate platform to foster international collaboration. This is to promote the prevention, detection and response to SF <u>at global level</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A Member State mechanism is an adequate platform to foster international collaboration. This to promote the prevention, detection and response to SF <u>at regional level</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A Member State mechanism is an adequate platform to foster international collaboration. This is to promote the prevention, detection and response to SF <u>at national level</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. To what extent do you consider the following MSM objectives relevant to promote the prevention, detection and response to substandard and falsified medical products and associated activities from a public health perspective?

	(1) Not at all relevant	(2) Now less relevant	(3) Still relevant	(-) Don't know
Objective 1. To identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies and control of SF medical products in order to strengthen national and regional capacities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 2. To strengthen national and regional capacities in order to ensure the integrity of the supply chain.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 3. To exchange experiences, lessons learnt, best practices, and information on ongoing activities at national, regional and global levels.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 4. To identify actions, activities and behaviours that result in SF medical products and make recommendations, including for improving the quality, safety and efficacy of medical products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 5. To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 6. To collaborate with and contribute to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products, including, but not limited to, the supply and use of generic medical products, which should complement measures for the prevention and control of SF medical products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 7. To facilitate consultation, cooperation and collaboration with relevant stakeholders in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 8. To promote cooperation and collaboration on surveillance and monitoring of SF medical products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 9. To further develop definitions of SF medical products that focus on the protection of public health.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. Is there any objective (s) that you would add?

Yes

Please specify: _____

No

8. Do you think that any of the following MSM aspects need change to more effectively support activities to address substandard and falsified medical products? Please rate your opinion.

Aspects of MSM	(1) No need for change	(2) Some need for change	(3) Substantial need for change	(-) Don't know
The governance structure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The work procedures of the mechanism	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The resources of the MSM	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The inclusiveness of relevant stakeholders	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. Please provide further detail, as relevant:

10. The MSM implements various activities to achieve its objectives. The activities/products from 2018 to 2023 are listed below. How would you rate their relevance to promote the prevention, detection and response to substandard and falsified medical products?

	(1) Not at all relevant	(2) Now less relevant	(3) Still relevant	(-) Don't know
Document on actions, activities and behaviours that result in SF medical products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recommendations for Health authorities responsible for detecting SF medical products and training material and guidance documents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Document exchanged and information shared through the Global Focal Point Network on SF medical products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Document on existing technologies and “track and trace” models in use and with a potential to be developed by Member States	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recommendations for health authorities on developing and strengthening national action plans for prevention, detection and response strategies for substandard and falsified medical products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recommendations for effective risk communication and for awareness campaigns on SF medical products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recommendations for a strategic approach promoting inter-agency cooperation and collaboration with relevant stakeholders to respond to the online distribution of substandard and falsified medical products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Definitions related to SF medical products and environment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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11. *Is there any additional activity (ies) /product (s) that you consider important to add for the MSM to implement going forward?*

Yes

Please specify: _____

No

12. *To what extent have the activities influenced, or products been used for policy and practice in your country or work environment?*

	(1) Not at all	(2) To an extent	(3) Very much	(-) Don't know
Document on actions, activities and behaviours that result in SF medical products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recommendations for health authorities responsible for detecting SF medical products and training material and guidance documents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Document exchanged and information shared through the Global Focal Point Network on SF medical products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Document on existing technologies and “track and trace” models in use and with a potential to be developed by Member States	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recommendations for health authorities on developing and strengthening national action plans for prevention, detection and response strategies for substandard and falsified medical products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recommendations for effective risk communication and for awareness campaigns on SF medical products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recommendations for a strategic approach promoting inter-agency cooperation and collaboration with relevant stakeholders to respond to the online distribution of substandard and falsified medical products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Definitions related to SF medical products and environment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. *If possible, please provide examples of activities that have influenced or products that you have used for policy and practice in your country or work environment:*

14. *To what extent would you consider that some of the recommendations of the 2017 review for effective communication, and dissemination of information on main MSM actions have been implemented?*

Recommendations from 2017 MSM review	(1) Not at all implemented	(2) Implemented to some extent	(3) Fully implemented	(-) Don't know
Improve coordination within 3-level of WHO (global, regional and country) to disseminate information about SF medical products issues	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Establish or enhance virtual fora and communication tools to disseminate information between the mechanism and the Member States.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Strengthen the capacity of focal points at regional and national level to disseminate information between the mechanism and the Member States.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

C. EFFECTIVENESS

15. *In your opinion, what are the main areas of the MSM where things worked well and why?*
16. *In your opinion, what are the main areas of the MSM where things did not work so well and why?*
17. *To what extent do you consider that reasonable progress has been made towards achieving the MSM's objectives?*

	(1) No progress	(2) Some progress	(3) Substantial progress	(-) Don't know
Objective 1. To identify major needs and challenges and make policy recommendations, and develop tools in the area of prevention, detection methodologies and control of SF medical products in order to strengthen national and regional capacities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 2. To strengthen national and regional capacities in order to ensure the integrity of the supply chain.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 3. To exchange experiences, lessons learnt, best practices, and information on ongoing activities at national, regional and global levels.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 4. To identify actions, activities and behaviours that result in SF medical products and make recommendations, including g for improving the quality, safety and efficacy of medical products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Objective 5. To strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 6. To collaborate with and contribute to the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products, including, but not limited to, the supply and use of generic medical products, which should complement measures for the prevention and control of SF medical products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 7. To facilitate consultation, cooperation and collaboration with relevant stakeholders in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 8. To promote cooperation and collaboration on surveillance and monitoring of SF medical products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 9. To further develop definitions of SF medical products that focus on the protection of public health.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

18. *In your opinion, could the MSM work differently in the future to further reduce the presence and use of SF products?*

D. Overall Appraisal

19. *What is your overall level of satisfaction with the MSM since its establishment?*

(1) Very dissatisfied (2) Dissatisfied (3) Neutral (4) Satisfied (5) Very satisfied (-) Don't know

20. *Please elaborate on reasons for your response:*

E. Mini Survey (only if minimal knowledge about the MSM)

21. *Have you ever received information about the Member State Mechanism on SF medical products?*

Yes, from WHO headquarters

Yes, from WHO regional offices

Yes, from WHO country offices

Yes, from other sources (please specify in the comment box)

No, I have not received information

22. *In your opinion, is there still a priority need for global action against substandard and falsified medical products?*
23. *In your opinion, which of these MSM activities/products are likely to have been most helpful to reduce the presence and use of SF medical products?*

	(1) Not at all helpful	(2) Helpful to an extent	(3) Very helpful	(-) Don't know
Document on actions, activities and behaviours that result in SF medical products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recommendations for health authorities responsible for detecting SF medical products and training material and guidance documents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Document exchanged and information shared through the Global Focal Point Network on SF medical products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Document on existing technologies and “track and trace” models in use and with a potential to be developed by Member States	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recommendations for health authorities on developing and strengthening national action plans for prevention, detection and response strategies for substandard and falsified medical products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recommendations for effective risk communication and for awareness campaigns on SF medical products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recommendations for a strategic approach promoting inter-agency cooperation and collaboration with relevant stakeholders to respond to the online distribution of substandard and falsified medical products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Definitions related to SF medical products and environment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

24. *In your opinion, are there other activities that could help in the future to further reduce the presence and use of SF products (if yes please list these activities)?*
25. *In your opinion, how could the Member State's Mechanism make itself better known to other stakeholders in order to raise awareness and promote the use of its products?*

Thank you for taking the time to participate in this important evaluation. The Evaluation Report will be made available on the MSM website later this year!

ANNEX 6: Key Informant Interview Guide

Introduction of the context: These questions come from the independent evaluation team, which is currently gathering data for a forthcoming evaluation report on the MSM.

Preliminary questions

1. Can you tell us about your role and the organization/institution(s) you work with?
2. What are the ways in which you interact with the MSM, and since when?

KII Thematic questions

The following questions are to be asked if interviewees are familiar with the MSM (if they are unfamiliar with a topic, they can skip the questions).

EQS	KII questions	Comments (for the Interviewers)
	Relevance	Please ask for examples throughout the interview
<p>EQ1: To what extent are the MSM format and governance structures relevant and do they ensure the mechanism remains fit for purpose looking forward?</p> <p>1.1 To what extent are the objectives of the MSM still aligned to needs?</p> <p>1.2 To what extent is the governance framework clear to Member States, (how well-understood are roles and responsibilities)?</p> <p>1.3 To what extent has the Mechanism been flexible, able to adapt to changing circumstances and respond to emerging issues?</p> <p>1.4 Overall what are the advantages and disadvantages of the current MSM format?</p>	<ol style="list-style-type: none"> 1. Are you familiar with the MSM format/legal, governance structure, roles and responsibilities? And if so, what do you see as the main strengths and weaknesses of the MSM format, legal and governance structure, roles and responsibilities? 2. If you are familiar with the MSM's stated objectives, are they well aligned with needs on SF products? 3. Has the MSM been able to adapt quickly to changing circumstances? 4. What do you think are any alternative ways to address the issue of SF products? 	<p>To make clear to interviewees: <i>we are interested not so much in the (clear) importance of the work of the MSM, as in <u>if the MSM work is organized in the best way to achieve its objectives/activities</u></i></p> <p>In case asked: MSM is a format (governance structure) driven by Member States. There are alternative possible formats including WHO-managed global technical networks which are more driven by technical experts. Some critics of the MSM format say the second format would e.g. be able to move more quickly in response to developments. But MSs may prefer to retain greater control.</p> <p>Roles and responsibilities of MSM include participating actively in MSM meetings, setting the Objectives and Activities, provide some resources)</p>
	Effectiveness	
<p>EQ2: To what extent has the MSM achieved its objectives, and what factors have supported/hindered progress?</p>	<ol style="list-style-type: none"> 5. In your opinion, which MSM activities have been most successively implemented since 2017? Any that have been particularly useful? Please explain. 	<p>Remind interviewee: We understand effectiveness to be about achieving objectives/affecting outcomes)</p>

<p>2.1 To what extent have the MSM activities and products been implemented?</p> <p>2.2 To what extent was WHO MSM Secretariat support (e.g. IT and communication and dissemination) to the MSM adequate to facilitate the MSM functioning and reach?</p> <p>2.3 Which aspects of the MSM worked well and which less well?</p> <p>2.4 what strategies can enhance national engagement in the MSMs discussions and activities?</p>	<p>6. Which activities have been most challenging to implement Please explain.</p> <p>7. What factors have contributed to progress and what factors have hindered it, (including any MSM-supported tools and technologies)?</p> <p>8. Anything else you can tell us about how well the MSM seems to function (i.e. what works well/less well)?</p> <p>9. Any views on whether there are areas of support by the MSM Secretariat which work well or not so well?</p>	<p>See annexes re. MSM activities and products; MSM objectives; and MSM tools and technologies</p>
Efficiency		
<p>EQ3: How efficiently has the MSM used the resources at its disposal?</p> <p>3.1 How have MSM resources and their sources evolved? Are there any resource gaps and have they significantly evolved? Keep</p> <p>3.2 To what extent have the resources been used appropriately? Have there been unnecessary use of resources, duplication/complementarity (i.e. synergy), timeliness of MSM responses?</p> <p>3.3 Is the MSM’s M&E adequate for performance measurement?</p>	<p>10. How well does the MSM use its resources (i.e. to respond in a timely manner achieve complementarity/ avoid duplications? Any examples of where resources could have been put to better use?</p> <p>11. What seem to be key drivers of and obstacles to this?</p> <p>12. How well does the MSM monitor its progress? What are the challenges, including reporting to the MSM?</p> <p>13. How do you/does your country/organization report to the MSM and how do you /others use this information Please explain.</p> <p>14. How do you contribute to MSM meetings, working groups, review of official documents? Any examples.</p>	<p>Remind interviewee: We understand efficiency to be about the use of resources, timeliness of responding, complementarity with others, avoiding duplication.</p>
Coherence		
<p>EQ4: How does the MSM ensure coherence and continue to bring value to address SF medical products in relation to other agencies and their approaches with a similar mandate?</p> <p>External coherence</p> <p>4.1. How does the MSM align with approaches from other organizations including multilaterals/bilateral and also non-state actors (NSAs) which are also active in the field of SF medical products?</p> <p>4.2. To what extent have Member States cooperated at global, regional and national levels, and how has the</p>	<p><u>External coherence</u></p> <p>15. Are there other organizations you see as operating with similar mandates to the MSM (against SF products) and how much alignment and collaboration is there with the MSM?</p> <p>16. How well do member States seem to work together within the MSM, and how could this be further improved? How has the MSM helped Members States to improve collaboration between themselves? (i.e. work better together)</p> <p>17. How can engagement with non-State actors in the global, regional and country-level efforts to combat SF medical products be enhanced? What non-state actors would be useful to engage? Why? At what level?</p> <p><u>Internal coherence:</u></p> <p>18. What are some of the ways in which coordination between the MSM Secretariat and other parts of WHO have</p>	<p>Remind interviewee: We understand Coherence to be about the MSM working well with other (non-MS) entities, either outside of the WHO or inside it</p>

<p>mechanism facilitated this collaboration?</p> <p>Internal coherence</p> <p>4.3 To what extent is the coordination adequate across the MSM Secretariat, WHO HQ technical departments (e.g., HQ/Health Product Policy and Standards (HPS); Antimicrobial Resistance Division (AMR)); regional and country offices?</p>	<p>worked well/ not well, and how has this coordination evolved since 2017? How could it be further improved?</p>	
Sustainability		
<p>EQ5: To what extent are achievements of the MSM work likely to remain (in the absence of an MSM) and its work continued on SFP?</p>	<p>19. How does the MSM try to build sustainability at national, regional, and global levels (i.e., to ensure that achievements will remain and continue into the future)?</p>	<p>Remind interviewee: We understand the Sustainability of the MSM to be about how institutions and improvements can be strengthened so that they will continue into the future (possibly even in the absence of the MSM). This could include strategic planning, prioritized activities and funding. We are not asking about how the MSM might promote e.g. environmental sustainability.</p>
Equity		
<p>EQ6: How is the MSM considering issues of gender equality, health equity, disability and ‘leaving no one behind’, and human rights in its functioning²¹?</p>	<p>20. How has the MSM included gender, equity, and inclusion considerations, including any examples or gaps you are aware of?</p>	
Other		
	<p>21. Do you have any (other) recommendations for how the MSM can be strengthened or helped to work better, or how other SF stakeholders can work better to achieve the same objectives?</p> <p>22. Any other stakeholders or documents that you suggest we consult?</p>	<p>We are looking for ideas about how e.g.:</p> <ol style="list-style-type: none"> 1. Other parts of WHO could work better with MSM 2. How MSs could work better (MoHs, NRAs, etc) 3. How drug companies and distributors could work better with MSM 4. How donors could play a more helpful role with MSM

²¹ Specific additional question as requested in the ToR to [evaluate the extent to which differences in need, vulnerability, gender equality, disability and human rights are taken account of in the MSM’s work, as well as differences in interactions between the MSM and various member states.](#)

		<p>5. How the MSM could better harness the media, academia, etc</p> <p>6. How MSM coordination with other UN agencies, NSAs could work better</p> <p>Remind the interviewee that they can email us at any time with further points</p>
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ANNEX 7: Further information on way forward

Additional information is provided in relation two recommendations included in Volume 1 – Recommendation 1 and 5.

Recommendation 1 – Options for possible revision of the MSMech format.

Option A would require MSMech and World Health Assembly decisions to dissolve the MSMech and to establish a new format that would report to the Director-General but still have significant input from Member States. Such a change would in turn allow a full revision of the MSMech’s operational engagement. This might potentially allow for the following:²²

- Working groups could be constituted as considered appropriate for their task in hand (e.g., with technical experts, representatives of non-health sectors participating, even if not as full members²³) and their members held accountable for measurable progress.
- Collaboration with external stakeholders could similarly be structured to maximize effectiveness and resource mobilization, provided strict policies on conflict of interest and data confidentiality are upheld.
- Meetings could be restructured to ensure dynamic discussion, higher attendance and (purposefully engaging) inputs from relevant external stakeholders, again with appropriate restrictions as per WHO policies.
- However, attempts would also be made to retain Member State inclusivity, using increased resources to facilitate all Member States to engage with plenary meetings and have input into strategic decisions.
- WHO regions would also be offered an increased role, assisting with regional meetings, plenary inputs and implementation of some activities.²⁴
- Revising the structure would require a consultation process and proposal refinement, achievable through various approaches, provided WHA approval is obtained.

The latter option would require significant change and a WHA decision and many members of the current Steering Committee and the MSMech Secretariat already recognize that more can be achieved within the rules of the current format with regards to engaging external stakeholders.²⁵ This was previously recommended by the 2017 evaluation.²⁶

Table 4 summarizes 12 key features of the MSMech and indicates, for each feature, whether it would be beneficial or useful to change or retain it.

²² This assumes a bespoke hybrid body was created, as opposed to an advisory group.

²³ Working groups can generally only be composed of members of the parent body. However, external stakeholders could be called to contribute without membership, or individuals might be coopted by a member of the parent body.

²⁴ The evaluation notes that WHO is involved in a longer-term review of governance, and this may have implications for MSMech when it is concluded.

²⁵ See, for example, ‘Governance matters: Possible engagement with non-State actors in the work of the Member State Mechanism. Report by the Secretariat’ A/MSM/12/8, 26 October 2023.

²⁶ The 2017 evaluation stated ‘strategically, the mechanism should place greater emphasis on expanding its stakeholder base, involving Member States more actively as well as regulatory agencies and non-state actors’ and recommended ‘Encourage the engagement of additional actors in the mechanism, including academia, manufacturers, NGOs, civil society and related technical institutions at global, regional and country levels.’ – WHO document A70/23 Add.1.

Key features of MSMech which may be changed or retained

Key feature (in order of priority where possible)	Current MSMech	Suggested change / retention
Technical proficiency	Incomplete – e.g., Working Group members (and sometimes plenary) do not always have relevant expertise	Increase this, e.g. technical experts to engage more with Working Groups, speak at meetings ²⁷
Participation	Incomplete – many Member States do not attend or do not participate fully in meetings	Mitigate variability, e.g. technical experts more likely to attend/participate, address Member State attendance obligations ²⁸ and encourage participation in these
Access to funding	Incomplete – Member States contribute little, few donors engaged	Increase this, e.g., demonstrate greater effectiveness to encourage additional donors ²⁹
Cross-sector (beyond health)	Good, in theory – Member States can send representatives from outside of health sector (in fact, few from law enforcement, customs, trade, etc.)	Seek to retain this, e.g., allow non-health representatives in relevant working groups, allow Member State non-health representatives at plenaries
Consensus-building	Good (potentially, when needed)	Seek to retain this, with Member State involvement in plenaries
Reporting mechanisms, accountability	Incomplete – improving but may be limits on how much Member States can be held accountable	Increase this, with stronger planning and accountability (see recommendation 2 in Volume 1)
Flexibility, agility	Incomplete – improving but may be limits on how much plenary-based decision-making can respond to crises	Increase this with greater autonomy for Working Groups, Secretariat for those issues that are rapidly evolving ³⁰
Member States relationships	Good, in theory – Member States can all attend/participate (though many do not)	Seek to retain this, with Member State involvement in plenaries and in Working Groups (if have appropriate experience)
Regional relationships	Incomplete – regional involvement in Steering Committee selection, but further collaboration possible	Increase this as possible
Global relationships	Incomplete – some contact with multilaterals but less than they would like	Increase this as possible
Other external stakeholder relationships	Incomplete – little engagement with some categories (e.g. media, private sector)	Increase this as possible

Recommendation 5 – improving internal and external engagement

There are several suggestions for supporting the development of differentiated engagement strategies for strategic and operational partners, the MSMech. As a basis for developing these, a full mapping of existing or potential stakeholders active in the SF field should be conducted. The mapping and strategy could include information related to what the stakeholder could offer the MSMech or the SF field via collaboration, or what the stakeholder might want from MSMech, both of which could include information sharing or joint action.

²⁷ This is permitted but rarely happens.

²⁸ Many Member State Working Group members do not attend Working Group meetings, so membership might be better focused on those who will attend and participate, with accountability to do so.

²⁹ This should also be discussed with the WHO department with responsibility over external contributions.

³⁰ Under the current format, there will still be limits to the extent to which the MSM plenary can relinquish control

In addition, the engagement strategy could also include how external stakeholders, where possible, be afforded the opportunity to observe or present at some MSMech meetings. This would help build a relationship and identify opportunities for collaboration. Stakeholders could be invited to MSMech Working Group, Steering Committee or plenary meetings, either as observers or, on occasion, to present relevant information from other SF-related initiatives in which they are involved. Discussions could also be held with them regarding how the MSMech's M&E results might align with donors' own M&E frameworks for SF-related efforts.

ANNEX 8: List of references

- ANVISA (2018) Update on prioritised Activity A: Develop and Promote Training Material and Guidance Documents to Strengthen the Capacity of NRRAs for the Prevention and Detection of and Response to SF Medical Products, Meeting of the Steering Committee October 2018 [PowerPoint presentation]. (Accessed 20 May 2024).
- ANVISA (2019) Update on Prioritised Activity A: Develop and Promote Training Material and Guidance Documents to Strengthen the Capacity of National/Regional Regulatory Authorities for the Prevention and Detection of and Response to SF Medical Products [PowerPoint presentation]. (Accessed: 20 May 2024).
- Brower, V., 2017. Falsified and substandard malaria drugs in Africa. *The Lancet Infection* 17, 1026–1027.
- Butt, E., Australian Government., WHO, TGA (2022) Working Group F: Impact and Awareness Virtual Meeting 16 February 2022 [PowerPoint presentation]. (Accessed: 20 May 2024).
- CPRD., NIBSC., MHRA., Medicines and Healthcare Products Regulatory Agency (2018) WHO SF Activity 'E': Global Communications Program Update, WHO MSMech Steering Committee Geneva October 2018 [PowerPoint presentation]. (Accessed: 20 May 2024).
- Draft - Not published
- El-Dahiyat, F., Fehelbom, K.M.S., Jairoun, A.A., Al-Hemyari, S.S., 2021. Combatting Substandard and Falsified Medicines: Public Awareness and Identification of Counterfeit Medications. *Front. Public Health* 9, 754279. <https://doi.org/10.3389/fpubh.2021.754279>
- Gobierno De Colombia, Minslaud, Invima (2018) WHO Member State Mechanism on Substandard and Falsified (SF) Medical Products, Plenary Session [PowerPoint presentation]. (Accessed: 20 May 2024).
- Gobierno De Colombia., Minslaud., Invima (2018) E-Commerce Good Practices: National Observatory of Illegality, Working Group H PowerPoint [PowerPoint presentation]. (Accessed: 20 May 2024).
- Gray, N.J., Barr, R.D., Karekezi, C., Chanoine, J.-P., 2023. Substandard and falsified medicines for children: UHC has a preventive role. *The Lancet Child & Adolescent Health* 7, 821–823. [https://doi.org/10.1016/S2352-4642\(23\)00227-4](https://doi.org/10.1016/S2352-4642(23)00227-4)
- INVIMA. (n.d) Mechanism of the Member States on SF Medical Products Activity H [PowerPoint presentation]. (Accessed 20 May 2024)
- Legiscript, 2019. Presentation on Internet Platforms.
- Newton, P. 2020. Presentation of Globalized monitoring “the Globe.”

Qaiser, M., Hilton, T., Saeed Bukhari, S.K., Zloh, M., Phanouvong, S., 2024. How a tragedy became a catalyst for sustainable improvement in medicine safety. *The Lancet Global Health* 12, 376–377.

Unknown author and date

Wada, Y.H., Abdulrahman, A., Ibrahim Muhammad, M., Owanta, V.C., Chimelumeze, P.U., Khalid, G.M., 2022. Falsified and substandard medicines trafficking: A wakeup call for the African continent. *Public Health in Practice* 3, 100240. <https://doi.org/10.1016/j.puhip.2022.100240>

WHO (2018). Member State Mechanism Substandard and Falsified Medical Products. 28 November 2018. [PowerPoint Presentation]

WHO (2018). Steering Committee – Secretariat Update Substandard and Falsified Medical Products. 28 November 2018. [PowerPoint Presentation].

WHO (2021). Report: open-ended expert briefing session on detection technologies, methodologies and tools.

WHO, 2017. 6th Member State Mechanism– Secretariat Update - Substandard and Falsified Medical Products: 30 November - 1 December 2017.

WHO, 2018. 7th Meeting Member State Mechanism Substandard and falsified medical products.

WHO, 2020. 9th Meeting of the WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

WHO, 2021. 10th Meeting of the WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

WHO, 2022. 11th Meeting of the WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

WHO, 2023. 12th Plenary meeting WHO Member State mechanism on Substandard and Falsified (SF) Medical Products.

WHO. (2018). Recommendations for health authorities on criteria for risk assessment and prioritization of cases of unregistered/unlicensed, substandard and falsified medical products. Seventh meeting of the Member State mechanism on substandard and falsified medical products. Provisional agenda item 4A A/MSM/7/3. Available at: <https://apps.who.int/gb/sf/pdf_files/MSM7/A_MS7_3-en.pdf>. [Accessed 20 May 2024].

WHO. (2018). Regulatory System Strengthening Update Steering Committee, Member State Mechanism on SF Medical Products. [PowerPoint Presentation].

WHO. (2018). Summary on WHO Regulatory Systems Strengthening Updates. 9-30 November 2018. [PowerPoint Presentation].

- WHO. (2019). Access to medicines and vaccines Report by the Director. SEVENTY-SECOND WORLD HEALTH ASSEMBLY, Provisional agenda item 11.7 A72/17. Available at: <https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_17-en.pdf>. [Accessed 20 May 2024].
- WHO. (2019). Member State mechanism on substandard and falsified medical products Report by the Director. SEVENTY-SECOND WORLD HEALTH ASSEMBLY, Provisional agenda item 12.2 A72/22. Available at: <https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_22-en.pdf>. [Accessed 20 May 2024].
- WHO. (2019). Steering Committee Meeting of the Member State Mechanism on Substandard Falsified Medical Products. 23 October 2019. [PowerPoint Presentation].
- WHO. (2020). Substandard and falsified medical products Report by the Director - General. EXECUTIVE BOARD, 148th session, EB148/12. Available at: <https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_12-en.pdf>. [Accessed 20 May 2024].
- WHO. (2020). The WHO Member State Mechanism on Substandard and Falsified Medical Products. WHO/MVP/EMP/SAV/2019.04. Available at: <<https://www.who.int/publications/i/item/WHO-MVP-EMP-SAV-2019.04>>. [Accessed 20 May 2024].
- WHO. (2020). The WHO Member State Mechanism on Substandard and Falsified Medical Products. WHO/MVP/EMP/SAV/2019.04. Available at: <<https://www.who.int/publications/i/item/WHO-MVP-EMP-SAV-2019.04>>. [Accessed 20 May 2024].
- WHO. (2022). Secretariat activities and budget to implement the work plan of the Member State mechanism Update by the Secretariat. Eleventh meeting of the Member State mechanism on substandard and falsified medical products. Provisional agenda item 3, A/MSM/11/3. Available at: <https://apps.who.int/gb/sf/pdf_files/MSM11/A_MSM11_3-en.pdf>. [Accessed 20 May 2024].
- WHO. (s.f). IDENTIFYING SUSPECT SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS
- WHO (2015) Create a focal point network for the exchange of information and consultation at large among Member States and establish an ongoing virtual exchange forum, Fourth meeting of the member state mechanism on standard/spurious/falsely labelled falsified/counterfeit medical product.
- WHO (2018) "IDEAS": A Global Communications Framework to Help Combat the Threat from Substandard and Falsified Medical Products, Seventh Meeting of the Member State Mechanism on Substandard and Falsified Medical Products: Provision Agenda Item 4E, pp. 1-8.
- WHO (2018) Activity E: Communication, Education and Awareness Raising, Slides for Plenary Meeting.
- WHO (2018) Working Group to Identify and Develop Appropriate Strategies to Understand and Address the Distribution or Supply of Substandard and Falsified Medical Products via the Internet, Seventh meeting of the Member State Mechanism on Substandard and Falsified Medical Products: Provisional Agenda Item 4H.
- WHO (2019) 'WHO Member State Mechanism on Substandard and Falsified (SF) Medical Products, Steering Committee Virtual Meeting, 24-25 June, Geneva, Switzerland' [PowerPoint presentation]. (Accessed 20 May 2024).

- WHO (2019) WHO Informal Technical Experts Working Group- Risk Based Post Market Surveillance, Draft Note for the Record, pp. 1-4.
- WHO (2020) The Link Between Constrained Access to Quality, Safe, Efficacious and Affordable Medical Products and Substandard and Falsified Medical Products, Ninth meeting of the Member State Mechanism on Substandard and Falsified Medical Products: Provisional Agenda Item 4D, pp. 1-6.
- WHO (2021) 'WHO Member State Mechanism on Substandard and Falsified (SF) Medical Products, Steering Committee Virtual Meeting' [PowerPoint presentation]. (Accessed: 20 May 2024).
- WHO (2022) Minutes of the Fifth Meeting of the Member State Mechanism Activity B: Expand and Maintain the Global Focal Point Network Among National. [Microsoft Word document]. (Accessed: 20 May 2024).
- WHO (2022) Note for the Record, Meeting of the Steering Committee of the Member State Mechanism on Substandard and Falsified Medical Products, Geneva, 5-6 July 2022
- WHO (2022) Note for the Record, Meeting of the Steering Committee of the Member State Mechanism on Substandard and Falsified Medical Products, Geneva, 21-22 March 2022.
- WHO (2022) WHO Member State Mechanism on Substandard and Falsified Medical Products: Information Note on Working Groups, pp. 1-2.
- WHO (2022) WHO Member State Mechanism on Substandard and Falsified (SF) Medical Products, Virtual Meeting, Risk Communications [PowerPoint presentation]. (Accessed: 20 May 2024).
- WHO (2023) Member State Mechanism Prioritised Activity Tracker, 2022-2025 [Spreadsheet]. (Accessed: 20 May 2024).
- WHO (n.d.) Working Group- Activity H, WHO Member State Mechanism (MSM) on Substandard and Falsified (SF) Medical Products, Deliverable II.
- WHO Secretariat (2021) Develop Guidance on Strategies to Enable National/Regional Regulatory Authorities to Address the Distribution or Supply of Substandard and Falsified Medical Products via the Internet, Report by the Secretariat on Activity H, pp. 1-40.
- WHO Steering (n.d.) Member State Mechanism on Substandard and Falsified (SF) Medical Products: Prioritised Activity A, Risk-Based Post Market Surveillance.
- WHO, 2017. Member State Mechanism on SF Medical Products - Meeting of the Steering Committee 27-28 September 2017: Draft Note for the Record.
- WHO, 2017. Member State Mechanism on SF Medical Products - Meeting of the Steering Committee 29 November 2017: Draft Note for the Record.
- WHO, 2017. Member State Mechanism on SSFFC - Meeting of the Steering Committee 29-30 March 2017: Note for the Record.

- WHO, 2017. Review of the Member State mechanism on substandard/spurious/false-labelled/falsified/counterfeit medical products - Executive Summary (No. A70/23Add.1).
- WHO, 2018. Discussion paper - medicines in transit (No. A/MSM/7/5).
- WHO, 2018. Guidance for registers of manufacturers, importers, distributors and medical products authorized by Member States (No. A/MSM/7/2).
- WHO, 2018. Member State Mechanism on SF Medical Products - Meeting of the Steering Committee 3-4 April 2018: Draft Note for the Record.
- WHO, 2018. Member State Mechanism on Substandard and Falsified (SF) Medical Products - Meeting of the Steering Committee 3-4 October 2018: Draft Note for the Record.
- WHO, 2019. Member State Mechanism on Substandard and Falsified (SF) Medical Products - Meeting of the Steering Committee 2-3 April 2019: Draft Note for the Record.
- WHO, 2019. Member State Mechanism on Substandard and Falsified (SF) Medical Products - Meeting of the Steering Committee 26-27 June 2019: Draft Note for the Record.
- WHO, 2019. Thirteenth general programme of work 2019–2023 (No. WHO/PRP/18.1).
- WHO, 2019. WHO Informal Experts Advisory Group on risk-based post market surveillance (rb-PMS). Annex 2: Agreed terms of reference. Geneva.
- WHO, 2020. Member State Mechanism Governance - Information Session.
- WHO, 2020. Note for the record - Meeting of the Steering Committee of the Member State Mechanism on Substandard and Falsified medical products.
- WHO, 2020. Note for the record - Meeting of the Steering Committee of the Member State Mechanism on Substandard and Falsified medical products.
- WHO, 2021. Notes for the record - Meeting of the Steering committee of the Member State Mechanism on substandard and falsified medical products. (June)
- WHO, 2021. Notes for the record - Meeting of the Steering committee of the Member State Mechanism on substandard and falsified medical products. (October)
- WHO, 2021. Notes for the record - Meeting of the Steering committee of the Member State Mechanism on substandard and falsified medical products. (March)
- WHO, 2022. Future work of the Member State mechanism (No. A/MSM/11/5).
- WHO, 2022. Notes for the record - Meeting of the Steering committee of the Member State Mechanism on substandard and falsified medical products. (October)

- WHO, 2022. Report of the tenth meeting of the Member State mechanism on substandard and falsified medical products (No. A/MSM/10/11 Rev.1). Geneva.
- WHO, 2022. The WHO Member State Mechanism on Substandard and Falsified Medical Products Update 2022: How WHO Member States work together to increase access to safe, effective and quality medicines, vaccines and other medical products.
- WHO, 2022. The WHO Member State Mechanism on Substandard and Falsified Medical Products - Update 2022.
- WHO, 2023. Encouraging active engagement of Steering Committee (SC) members of the Member State mechanism on substandard and falsified medical products: Practical considerations on Vice-Chairmanship from current Steering Committee members.
- WHO, 2023. Note for the record - Meeting of the Steering Committee of the Member State Mechanism on Substandard and Falsified medical products. Geneva.
- WHO, 2023. Note for the record - Meeting of the Steering Committee of the Member State Mechanism on Substandard and Falsified medical products. Geneva.
- WHO, 2023. WHO Member State mechanism on Substandard and Falsified (SF) Medical Products - Steering Committee.
- WHO, 2024. WHO Member State mechanism on Substandard and Falsified (SF) Medical Products - Steering Committee.
- WHO, 2027. Review of the Member State mechanism on substandard/spurious/falselylabelled/falsified/counterfeit medical products.
- WHO. (2017). WHO global surveillance and monitoring system for substandard and falsified medical products. WHO. <https://iris.who.int/handle/10665/326708>. License: CC BY-NC-SA 3.0 IGO
- Ziavrou, K.S., Noguera, S., Boumba, V.A., 2022. Trends in counterfeit drugs and pharmaceuticals before and during COVID-19 pandemic. *Forensic Science International* 338, 111382. <https://doi.org/10.1016/j.forsciint.2022.111382>

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