



World Health
Organization



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

R E P O R T



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List of acronyms

AFR	African Region	MSMech	Member State Mechanism on substandard and falsified medical products
AFRO	African Regional Office		
AI	Artificial Intelligence	NAP	National action plan
AMA	Africa Medicines Agency	NCD	Non-communicable disease
AMR	Antimicrobial resistance	NGO	Non-governmental organisation
AMRO	Americas Regional Office	NRA	National Regulatory Authority
COPP	Certificate of Pharmaceutical Product	NSA	Non-state actors
DEG	Diethylene Glycol	OECD-	The Organisation for Economic Co-operation and Development's Development Assistance Committee
EDQM	European Directorate for the Quality of Medicines & HealthCare	DAC	
EG	Ethylene Glycol	PRP	WHO's planning department
EMR	Eastern Mediterranean Region	REG	WHO's Regulation and Safety Unit (reporting to MHP/RPQ)
EMRO	Eastern Mediterranean Regional Office		
ePQS	Electronic Prequalification System	RPQ	WHO Regulation and Prequalification Department (part of MHP Division)
EQ	Evaluation Question		
EUR	European Region	ROI	Return on investment
EURO	European Regional Office	RSS	Regulatory System Strengthening
FENSA	Framework of Engagement with Non-State Actors	SDG	Sustainable Development Goal
FP	Focal point	SEAR	South-East Asian Region
GBT	Global Benchmarking Tool	SEARO	South-East Asian Regional Office
GBS	Governing Bodies Secretariat	SF	Substandard and falsified
GSMS	Global Surveillance and Monitoring System	TA	Technical assistance
HQ	Headquarters	ToC	Theory of Change
ICMRA	International Coalition of Medicines Regulatory Authorities	TOR	Terms of Reference
IMPACT	International Medical Products Anti-Counterfeiting Taskforce	UK	United Kingdom of Great Britain and Ireland
ISF	WHO Incidents and Substandard/Falsified Medical Products team (reporting to MHP/RPQ/REG)	UN	United Nations
IT	Information Technology	UNODC	United Nations Office on Drugs and Crime
KPI	Key Performance Indicator	USA	United States of America
LDC	Least Developed Countries	USD	United States Dollars
LEG	WHO's Office of Legal Counsel	WCO	World Custom Organization
LMIC	Low- and middle-income countries	WHA	World Health Assembly
MHP	WHO Division for Access to Medicines and Health Products	WHO	World Health Organization
		WPRO	Western Pacific Regional Office

Executive summary

Background

In 2012, the Sixty-fifth World Health Assembly adopted resolution WHA65.19 in which it decided to establish the Member State mechanism on substandard and falsified medical products¹ to improve effective collaboration among Member States and WHO to prevent and control substandard and falsified medical products. This resolution was a pivotal step in facilitating the protection of public health and seeking to ensure the provision of medical products that are both cost-effective and high quality. The Member State mechanism is the primary intergovernmental mechanism for Member States to convene, make policy recommendations, exchange knowledge, support mutual efforts and coordinate actions to address the challenge of substandard and falsified medical products. Its nine objectives include those on strengthening relevant national and regional capacities; contributing to the work of other areas of WHO; and facilitating collaboration with other relevant stakeholders.

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

At the recommendation of the Member State mechanism at its eleventh meeting,³ the Seventy-sixth World Health Assembly decided to request the Director General to conduct an independent evaluation of the Member State mechanism based on the terms of reference to be developed by the Member State mechanism's Steering Committee, and to report on the evaluation to the governing bodies.⁴ The purpose of the evaluation was to assess progress made by the Member State mechanism in achieving its objectives since the 2017 Member State mechanism review⁵ to end 2023, provide relevant lessons learned and make recommendations to inform the Member State mechanism's future strategic direction and ways of working. The evaluation objectives were to document the Member State mechanism's achievements, opportunities, challenges and gaps since 2017, assess the effectiveness and added value of the Member State mechanism tools and products, and the relevance of the Member State mechanism's format and governance to ensure that it remains fit for purpose. The evaluation assessed the work of the Member State mechanism at the global, regional, and country levels.

The evaluation employed a non-experimental design with a theory-based, utilization-focused approach. It used mixed methods to collect both quantitative and qualitative data, enabling robust triangulation of

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

² See resolution WHA65.19.

³ See document A/MSM/11/6.

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

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

findings. Data collection methods included desk review of 102 key documents, secondary data analysis focusing on the WHO Global Surveillance and Monitoring System for substandard and falsified medical products incidents reporting, and 89 key informant interviews. The key informant interviews were conducted with a diverse group of stakeholders both internal (to the Member State mechanism and WHO) and external (covering the global and regional levels), and 12 focus countries⁶ diverse in their geographic and economic representation as well as additional national-level informants. There were 16 distinct categories of key informants, of which the largest was Member State mechanism government representatives (31% of the total). In addition, an online survey was administered to 400 recipients at the global, regional, and country levels with 204 responses received (51% response rate). The largest categories of survey respondents were from national/regional pharmaceutical regulatory agencies and ministries of health.

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

Findings

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

Finding 2 (Effectiveness): While an activity-based workplan exists and there has been recent progress on reporting, the Member State mechanism has lacked a results framework and a theory of change showing pathways to change. There were no baselines, indicators or processes to monitor progress towards objectives, and so it is hard to assess the full extent of achievements. Progress with planned activities is mixed, although some planned activities have been successfully implemented. Feedback suggests these have had a positive influence at the country level, although there is a lack of robust evidence on the effectiveness and impact of activities. Key factors that have hindered Member State mechanism progress and effectiveness include: suboptimal Member State participation; variable effectiveness of working groups and lack of accountability; limited engagement with other (non-State) stakeholders; and lack of funding. Country-specific factors, some of which are outside the control of the Member State mechanism, include limited leadership and commitment, weak capacity of regulatory and health systems, and poorly enforced laws. The Member State mechanism's secretariat has clear value and provides good support to ensure effective functioning of the mechanism, although there are concerns about its overstretched capacity and the efficiency of its communication.

Finding 3 (Efficiency): It is difficult to fully ascertain efficiency in the absence of systematic monitoring and evaluation (some progress has been made in 2024, with development of outcome level indicators) and budgetary detail. At the same time, there is no evidence of major visible inefficiencies in how the Member State mechanism uses its resources. Resources have increased, especially for working group activities, noting they come from a narrow, mainly external donor base and are also at times earmarked.

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

There is limited funding from most Member States, although some contribute indirectly, e.g., through meeting attendance. Activity spend is well-targeted and meeting costs in line with comparable events, although there is low participation (most Member States do not attend any meetings). There is also little collaboration with other substandard and falsified medical product stakeholders to create synergies and avoid duplication, which could potentially reduce the Member State mechanism's efficiency.

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

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

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

Conclusions

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

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

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

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

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

Conclusion 5 (Sustainability): The Member State mechanism (and its secretariat) reliance on two main external donors, who could easily change their funding priorities, risks its financial sustainability beyond the current biennium. This is compounded by the currently very small Member State contributions. Uncertainty regarding donor funding is a major threat to the future of the mechanism, and so a stronger investment case for donors is required if its long-term future is to be secured. Changes to legislation, regulation and regulatory capacity in Member States, because of Member State mechanism support, are likely to positively affect the sustainability of its results.

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

Recommendations

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

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

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

- **Option A:** Dissolving the current Member State mechanism and establishing a new format which would report to the WHO Director-General but would still have significant input from Member States. This could be an advisory group or a more bespoke hybrid format. Such revision would need to be proposed by the Member State mechanism and approved by the World Health Assembly through the Executive Board. A task force could be established to guide this process.
- **Option B:** Using the existing Member State mechanism format and to experiment with increasing the involvement of technical experts in the fields related to the mechanism's working groups, and increasing Member States' participation as well as engagement with external stakeholders, including in formal meetings (in line with relevant World Health Assembly resolutions and decisions, World Health Assembly rules of procedure and within the Framework of Engagement with Non-State Actors).

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

Recommendation 2: Develop an integrated planning and review approach to further develop the Member State mechanism's work planning, costing/budgeting, prioritization and reporting processes (in line with results-based management approaches). Actions to develop a more comprehensive integrated planning and review system should include refining the draft Member State mechanism strategy, to include a theory of change and results framework with clear output and outcome indicators to track performance, costing potential activities to help to prioritize and resource these, developing workplans with timelines and milestones, and establishing a feedback system to help to disseminate learning. Resource constraints may entail this approach being developed to a less than comprehensive extent initially (unless the mechanism's secretariat capacity is significantly expanded).

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

authorities and Member States' representation, to incentivize and support Member State meetings and working group participation (especially those from low-income countries).

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

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

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

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

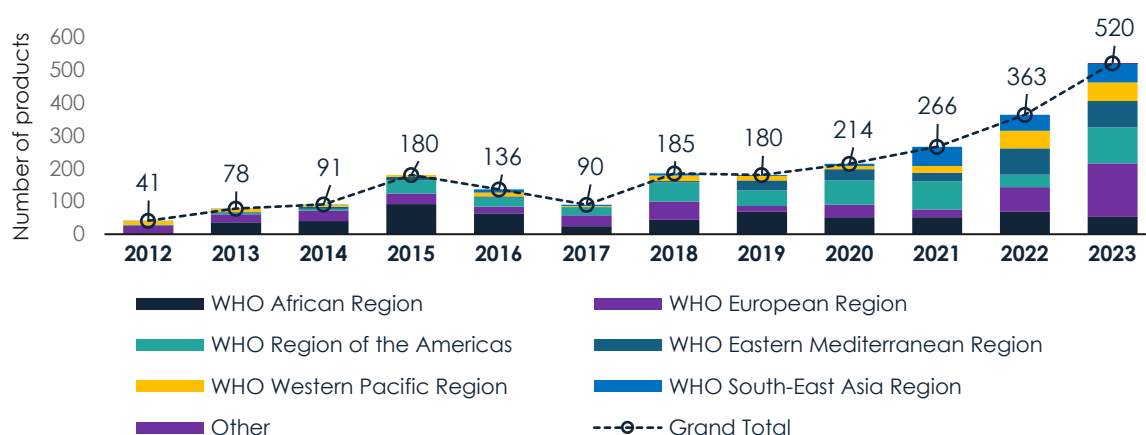
Chapter 1: Introduction

1.1 Background

Substandard and falsified (SF) medical products represent a significant global challenge, critically undermining public health and patient safety, and simultaneously undermining progress towards achieving the Sustainable Development Goals (SDGs).⁷ SF products have been identified in a wide array of product areas, including antibiotics, anti-malarial and anti-tuberculosis drugs, and medications for chronic conditions (such as diabetes, HIV/AIDS, and cancer). The prevalence of such SF products remains alarmingly high; WHO estimates by the World Health Organization (WHO) indicate that one in 10 medical products in low- and middle-income countries (LMICs) is substandard or falsified.⁸ This issue is even more pronounced in regions such as the Sahel, where, according to the United Nations Office on Drugs and Crime (UNODC), as many as 50% of the medical products available are of poor quality.⁹

The number of reports of suspected SF medical product incidents has been increasing (although it is difficult to attribute this to an actual increase versus stronger reporting): there were 520 in 2023 compared to 180 in 2019 (see Fig. 1 below), based on incidents in the Global Surveillance and Monitoring System (GSMS) reporting system. This is likely to be an underestimate, see below.

Fig. 1. Number of suspected SF medical product incidents reported by WHO region, 2012–2023



Source: GSMS incidents reported ([WHO Global Monitoring and Surveillance System](#))

Historically, SF medicines have been a major threat to health systems, especially in LMICs. Major contributing factors are weak health and pharmaceutical systems, limited regulatory capacity, and issues in the (mainly private sector) distribution and supply chain.¹⁰

⁷ WHO, 2017; Ozawa et al., 2020

⁸ WHO, 2017

⁹ UNODC, 2023

¹⁰ WHO, 2017. 6th Member State Mechanism— Secretariat Update—Substandard and Falsified Medical Products: 30 November –1 December 2017

Recent events have underscored the grave consequences of SF medical products. A particularly severe incident, observed in several countries (including Indonesia and The Gambia) involved the deaths of at least 300 children, predominantly under the age of five, from contaminated paediatric cold and cough syrups.¹¹ Initial investigations suggested poor quality control practices by manufacturers in the replacement of glycerol, which is a more costly but nontoxic solvent, with diethylene glycol (DEG) and ethylene glycol (EG).¹² Following this incident, WHO issued a medical product alert against these products (1), and samples were collected from those affected. In the case of Indonesia, laboratory analysis showed that 42.2% of drug samples and 60.3% of patient plasma samples tested positive for EG/DEG(2).¹³

In addition, the overuse or misuse of substandard antibiotics contributes significantly to the development of antimicrobial resistance (AMR).¹⁴ Subtherapeutic doses in these medicines allow bacteria to adapt, complicating disease management and treatment options in the long term.

The circulation of SF medical products also severely undermines the credibility and functionality of health care systems, particularly in LMICs.¹⁵ These countries, where a substantial portion of health care expenditure is out of pocket and directed towards medicines, are especially vulnerable to the effects of SF products.¹⁶ The global market for falsified medicines is estimated to be worth between US\$ 75 and 200 billion annually.¹⁷

Despite the enormity of the challenge, no country has effectively measured the extent of the problem, and standardized methods to estimate the prevalence of SF medicines are still lacking. This gap is partly due to the diversity and size of medicine markets, coupled with the lack of testing capacity in some countries and the high costs associated with testing medicines. To combat this issue, WHO and other agencies have stressed the need for increased public awareness regarding the dangers of falsified medical products. While many countries have implemented some form of post-marketing surveillance of medicinal products, these methods and objectives vary. One further problem is that some countries may be reluctant to report SF incidents as they perceive a stigma attached to allowing this to happen, although professionals agree that this problem can arise in any country and transparency is a key step towards reducing it.

To address the challenges, the World Health Assembly (WHA) adopted resolution WHA65.19 in 2012 creating the WHO Member State Mechanism (MSMech).¹⁸ The general goal of the MSMech is to protect public health and promote access to affordable, safe, efficacious and quality medical products, through effective collaboration among Member States and with WHO Secretariat as well as engagement with relevant stakeholders from a public health perspective.¹⁹ The Member State mechanism is the primary intergovernmental mechanism for Member States to convene, make policy recommendations, exchange knowledge, support mutual efforts and coordinate actions to address the challenge of substandard and falsified SF medical products. Its nine objectives include strengthening relevant national and regional capacities; contributing to the work of others areas of WHO; and facilitating collaboration with other relevant stakeholders. The Member State mechanism is a subsidiary body of the WHA, to which it reports every two years. The MSMech is the object of this evaluation, as discussed below.

¹¹ Tungki et al., 2023; also discussed in several Inception key informant interviews.

¹² WHO, 2023; Thiagarajan, 2022

¹³ WHO, 2023

¹⁴ Ching and Zaman, 2020

¹⁵ WHO, 2017; Orubu et al., 2020

¹⁶ Ozawa et al., 2019

¹⁷ Acri and Lybecker, 2018 ; WHO, 2017

¹⁸ WHO, 2019

¹⁹ Many multilateral organizations combat SF, including in law enforcement and customs, as do a range of NGOs, private sector participants, academics and media representatives.

Before the establishment of the MSMech, WHO's work on SF medical products was conducted through the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) between 2007 and 2009. However, Member States began to have concerns because the Taskforce included stakeholders with a wide range of interests, rather than just public health, which caused transparency and legitimacy issues. These concerns were related to the involvement of stakeholders with commercial interests (including connections to the pharmaceutical industry) (3) that might have shifted the focus away from protecting public health. As a result, the Member States decided to establish a new mechanism that would better align with public health priorities.

1.2 Object of the evaluation: WHO Member State Mechanism on Substandard and Falsified Medical Products

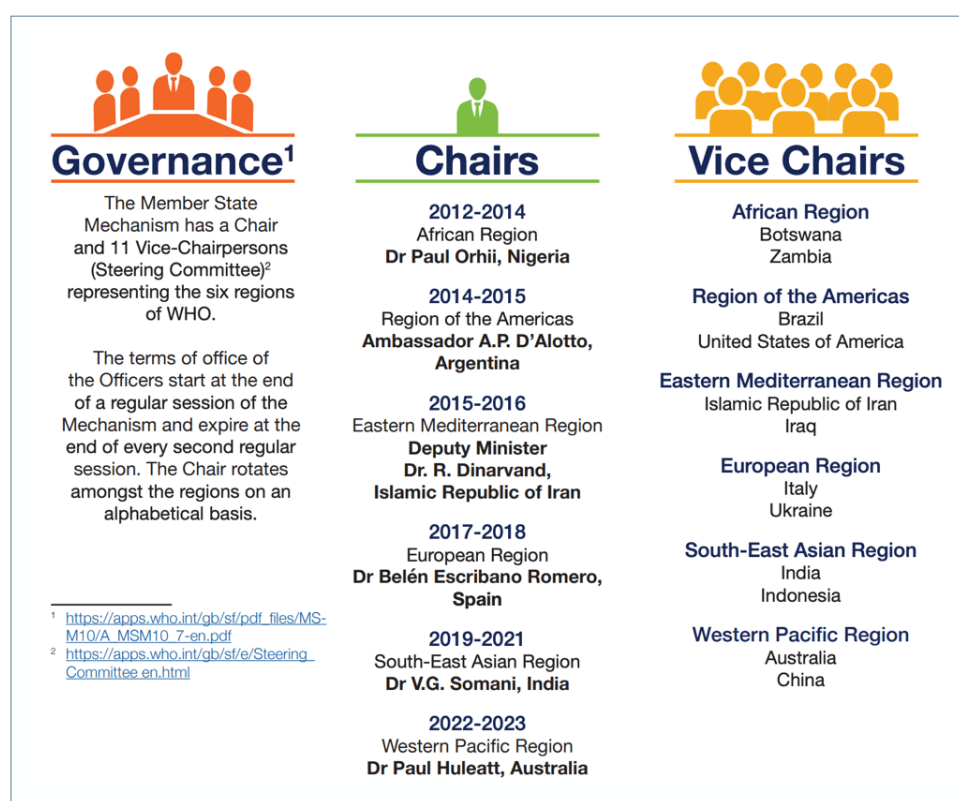
The goal and purpose of the the MSMech are noted above, including the through improved cooperation among Member States and with WHO's Secretariat and other stakeholders. Its work is to be carried out based on nine key objectives (see below) with a public health perspective, excluding trade and intellectual property considerations (4). This WHA resolution was a pivotal step in protecting public health and ensuring the provision of medical products that are both cost-effective and of high quality. The MSMech is the primary intergovernmental body for Member States to convene, make policy recommendations to the WHA, exchange knowledge, support mutual efforts and coordinate actions to address the challenge of SF medical products (5).²⁰

The MSMech Secretariat, hosted by WHO, supports the work of the mechanism, offering guidance, technical support and assistance to the Member States who hold ultimate authority and decision-making powers. Each WHO region nominates two representatives to form a steering committee with one chair and 11 vice chairs, with the chairpersonship rotating among the six WHO regions.²¹ The steering committee meets three times a year, while all Member States are invited to an annual plenary meeting that undertakes all necessary decisions; currently all of these meetings are held in Geneva (see Fig. 2 below)²²

²⁰ WHO, 2023. *MSMech Evaluation Terms of Reference*.

²¹ African Region, Region of the Americas, Eastern Mediterranean Region, European Region, South-East Asian Region and Western Pacific Region.

²² WHO, 2023. *MSMech Evaluation Terms of Reference*.

Fig. 2. Structure and governance of the MSMech, 2022–2023²³

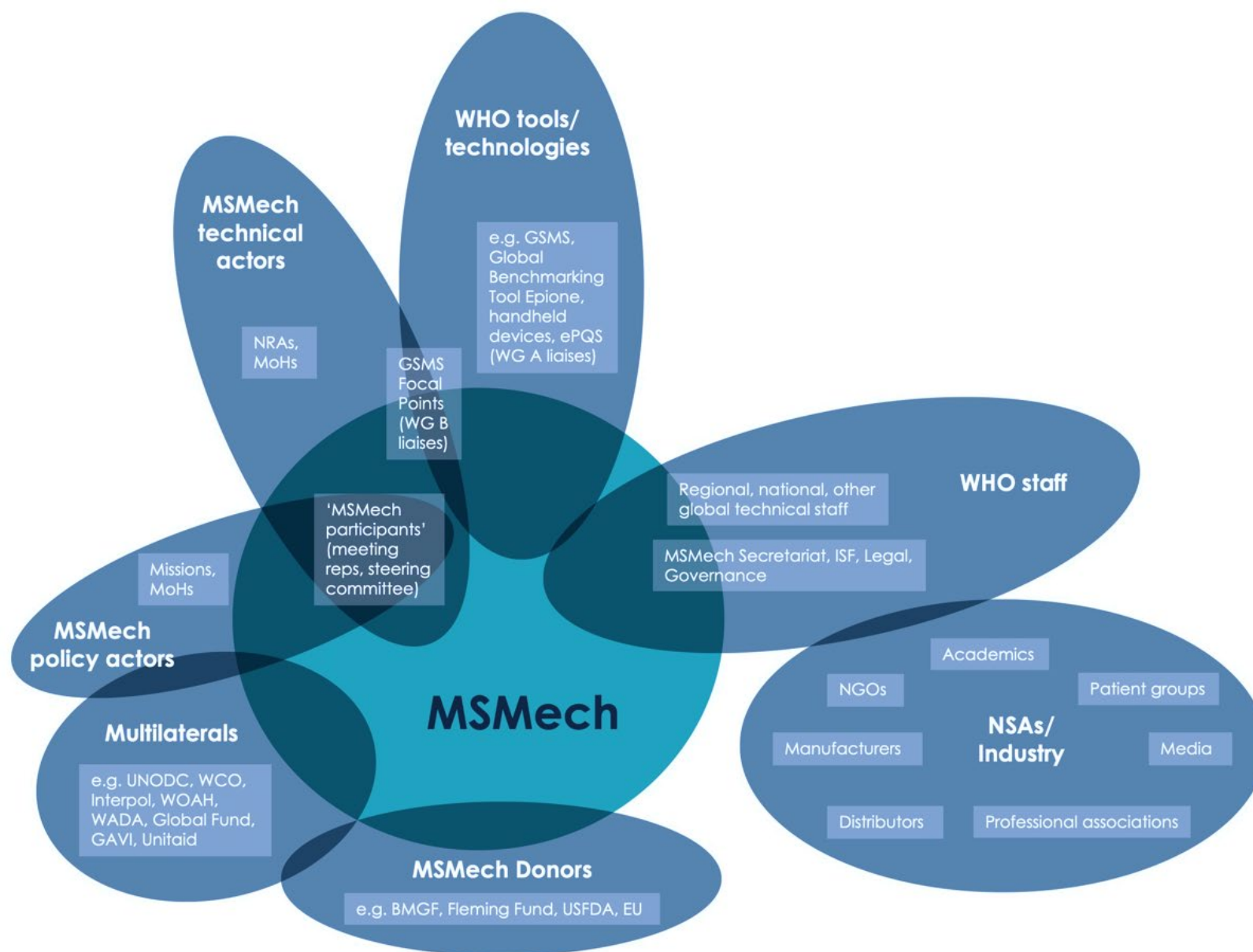
Source: World Health Organization, 2022. *The WHO Member State Mechanism on Substandard and Falsified Medical Products update 2022: How WHO Member States work together to increase access to safe, effective and quality medicines, vaccines and other medical products.*

The MSMech governance framework is defined by WHA resolutions and decisions. Every second year, the MSMech reports its progress and specific actions to the WHA through the Executive Board (6). For technical guidance, the MSMech establishes its own working groups and draws on the expertise of WHO, Member States and, in some instances, other stakeholders. The MSMech may additionally collaborate with various other stakeholders, though this is not frequent.

The landscape of the MSMech and other SF stakeholders is a complex one. The evaluation team constructed a graphic to set out each of the stakeholder groups as well as key elements of the MSMech (Fig. 3).

²³ Note: Chairs are listed for previous years but Vice-Chairs are only given for 2023.

Fig. 3. SF medical products stakeholders



The MSMech has nine key objectives:²⁴

1. **To identify major needs and challenges**, and make policy recommendations, and develop tools in the areas of prevention, detection methodologies, and control of SF medical products to strengthen national and regional capacities.
2. **To strengthen national and regional capacities** to ensure the integrity of the supply chain.
3. **To exchange experiences, lessons learned, 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 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.

The MSMech created eight working groups to:

A – strengthen the capacity of national/regional regulatory authorities for the prevention and detection of, and response to SF medical products (Name changed in 2022);

B – develop, expand and maintain global networks of stakeholders to facilitate cooperation and collaboration;

C – improve Member States’ understanding and uptake of technologies to screen and detect SF medical products and the implementation of national traceability systems;

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;

E – enhance Member States’ capacity to run effective risk communication campaigns for SF medical products;

F – enhance Member States’ capacity to expand awareness, effectiveness, impact and outreach in their work on SF medical products;

²⁴ WHO, 2023. *MSMech Evaluation Terms of Reference*.

G (2018– 2021) – promote shared understanding among Member States from a public health perspective regarding medical products in transit;

G' (2022–2023) – identify and develop appropriate strategies to understand and address the distribution or supply of SF medical products via the internet;

H (2018–2021) – identify and develop appropriate strategies to understand and address the distribution or supply of SF medical products via the internet; and

H' (2022–2023) – develop strategies for national regulatory authorities to mitigate public health risks posed by the distribution of SF medical products through informal markets.

In December 2012, during the first MSMech meeting, the MSMech established a workplan with eight different areas related to the nine objectives of the MSMech (7). In 2014, during the third MSMech meeting, prioritized activities were mentioned for the first time (8), and six prioritized activities were established; plus one for the MSMech secretariat. Since then, the prioritized activities have continued to evolve. In December 2017, Activity F was completed and three new prioritized activities were established, with a total of eight prioritized activities for 2018–2019 (9).

Leadership for each activity was assumed by a Member State. The MSMech secretariat within WHO was tasked, by the mechanism itself, with guiding a coalition of Member States to fulfil the actions associated with their designated priority area. The prioritized activities were categorized into the following groups (10):

- **Activity A:** guidance on registers, risk assessment
- **Activity B:** expanding the global FP Network²⁵
- **Activity C:** detection technologies, tracking, pilot studies
- **Activity D:** access roadmap including SF medical products
- **Activity E:** global communications framework, campaigns
- **Activity F:** advocacy across WHO regions
- **Activity G:** transit issues discussion paper
- **Activity H:** addressing online SF medical product distribution

As actions were implemented and the context continued to evolve, the MSMech workplan was updated. These changes reflected the evolution of prioritized activities and actions. In the MSMech workplan for 2022–2023, the following modifications were made to the above Activities.

- **Activity B** changed for the period 2020–2021 to become “expand and maintain the Global FP Network among national medicines regulatory authorities to facilitate cooperation and collaboration”. For 2022–2023 it became “develop, expand and maintain global networks of stakeholders to facilitate cooperation and collaboration”.
- **Activity D** shifted to enhance stakeholder abilities and promote effective governance to reduce the prevalence of SF medical products.

²⁵ The GSMS FPs are officially nominated by the countries as the technical persons to be in close contact, collaborate and report to WHO and the GSMS. They are focal points until there are new nominations due to change of position, retirement, change of jobs, etc. For mechanism meetings, the MSMech gets the nominations from the Member States (delegation) at every meeting. Member States are encouraged to include in their delegations members with expertise in national health and medical products regulatory matters.

- **Activity G** 2022–2023 focused on the distribution or supply of SF medical products via the Internet; and **Activity H** focused on informal markets as mentioned (11).

Available donor funding for the MSMech via WHO (12),²⁶ comes from the European Commission, the United States Food and Drug Administration, the UK's Fleming Fund and the Bill and Melinda Gates Foundation (3, 11, 13, 14) (refer to Efficiency Section).

2017 review of the MSMech

A review of the MSMech was carried out in 2017 by the WHO Evaluation Office (15). It covered the initial period of 2012–2016, 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. It found that the MSMech's organizational structures worked well to generate a collaborative climate. The MSMech's steering committee, supported by WHO, was seen to have shown leadership, developed good products and convened meetings of experts as well the core committee itself.

The main areas of continued challenge were found to be an unfinished technical agenda, a limited coordination process and inadequate systems of communication and dissemination to the Member States. Strategic recommendations included a greater focus on completing outstanding activities, revised plans (including securing stronger funding) and an expansion of the MSMech stakeholder base to consolidate support to Member States. These were supplemented with a series of more specific recommendations accompanied by action points. This evaluation has assessed the extent to which the recommendations have been implemented (see Annex 3).

MSMech theory of change and its use in the evaluation

A theory of change (ToC) is a framework that outlines how and why desired changes are expected to occur in a specific context, linking inputs (e.g. funds and human resources) to outputs and outcomes (e.g. combating SF medical products), as well as identifying key assumptions that, if not met, would prevent achievement of results. It provides a roadmap for planning, implementing and evaluating interventions. ToC discussions often help organizations and programme managers improve their focus on intended achievements. The ToC developed for this evaluation provides a way of characterizing the MSMech and the logical path between inputs, outputs, outcomes and impact.

As the MSMech did not have a ToC, an initial high-level ToC was constructed during the evaluation inception phase, drawing upon elements of the recently developed MSMech monitoring and evaluation (M&E) framework (including outcomes) and information provided in MSMech documents.²⁷ This was revised based on data collected during the evaluation and then validated in a ToC workshop with the steering committee, evaluation reference group members and MSMech secretariat staff.²⁸

One of the key features tested during the ToC validation workshop was the linkage across the inputs and results areas (outputs, outcomes and impact) as well as the mapping of evaluation questions (see Annex 2). In addition, it enabled some understanding of the extent to which planned outcomes were addressed through planned outputs, based on available evidence and the strength of these causal pathways. The

²⁶ The Incidents, Substandard/Falsified Medical Products team (ISF) (part of the Regulation and Prequalification Department) serves as the MSM secretariat. Donors do not fund the MSMech directly. Rather they provide voluntary funds to WHO to support the RPQ department, the ISF team and, by extension, the MSMech.

²⁷ Given in the document EB 140/23 Annex.

²⁸ The ToC workshop was held on 11 June 2024.

revised ToC is also intended to serve as a future reference for the MSMech, with causal pathways that can be progressively refined and made more explicit, informed by evidence generated through this evaluation and beyond (Fig. 4 below).



TOC assumptions

Overarching assumptions

- There is strong political commitment among Member States, and reducing the availability and use of SF medicines and products is a priority for Member State governments.
- Countries have supportive policies, strategies and plans and resources allocated for SF-related activities.
- Internal stakeholders (other departments and teams within WHO) collaborate to deliver MSMech activities and objectives.
- A wide range of external stakeholders offers a variety of potential inputs and outputs that can also usefully address SF problems.
- The nature and scale of SF problems will continue to evolve.

MSMech-specific assumptions

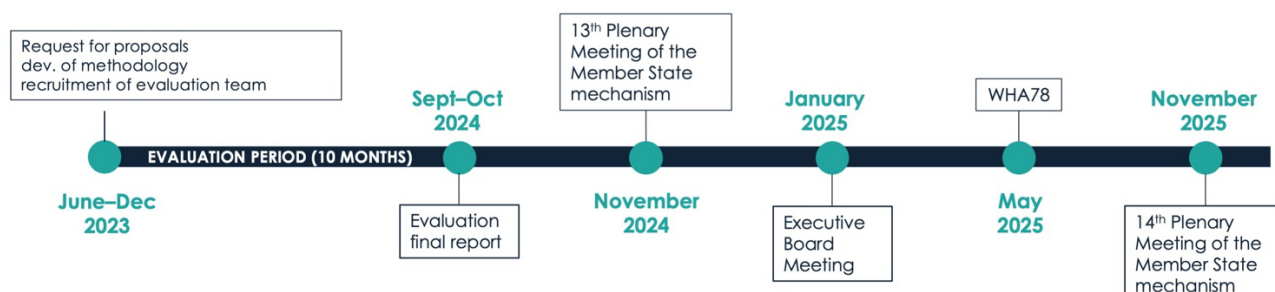
- The MSMech adds value to existing actions of Member States, WHO and other relevant stakeholders and enhances Member State engagement on SF medicines and products.
- The objectives of the MSMech reflect the diverse and evolving needs of Member States.
- The MSMech has a coherent strategy and action plan at global and country level that have clear objectives and targets and address sustainability, equity and gender issues.
- The MSMech's activities are aligned with and complement the actions of other organizations and initiatives.
- The MSMech has effective governance including strong steering committee commitment and leadership, clear roles and responsibilities, and accountability.
- The MSMech secretariat has appropriate capacity and resources to support the MSMech.

1.3 Evaluation purpose, objectives and scope

The evaluation was intended to ensure accountability and provide the opportunity for learning. It also aims to enable a better understanding of the extent to which the mechanism has achieved its results, including at the country level, and to make recommendations on how to improve relevance, governance, functioning and performance (see Annex 1 for the evaluation's terms of reference).

It has reviewed options for change or improvements in the mechanism structure, ways of working, collaborations and policies, providing lessons learned and future operational recommendations. It has also assessed the MSMech's progress against its objectives since the 2017 Review (see Annex 4) (15). The evidence generated may be used to contribute to advocacy for stronger Member State participation as well as additional resources to support its operations. The evaluation findings, conclusions and recommendations will be presented at the MSMech 13th annual meeting in November 2024, the Executive Board meeting in February 2025 and subsequently to the WHA in May 2025, ensuring its timeliness and utility (see Fig. 5).

Fig. 5. Key MSMech events informed by the evaluation



Source: WHO

The specific objectives of the evaluation were to:

- **document progress** in achieving the MSMech's objectives since the 2017 review, identifying achievements, opportunities, challenges and gaps;
- **assess the effectiveness and added value** of the tools and products of the MSMech against other approaches to address SF medical products; and
- **assess the relevance** of the MSMech's format and governance structures to ensure that it is fit for purpose.

The evaluation scope is as follows:

- Its **time scope** encompassed all MSMech activities undertaken from 2017 to the end of 2023. It should be noted that despite the requested scope being to the end of 2023, the evaluation has also given due consideration to MSMech objectives and activities since 2024. The period from the MSMech's establishment until the 2017 review has not been covered; however, an assessment of progress against the 2017 review has been provided.
- Its **geographical scope** covered global, regional and country levels.
- Its **strategies and action areas** included all those defined in the work plans of the MSMech (14).
- Its **key stakeholders** included MSMech participants, Member States, the MSMech secretariat and WHO staff. The evaluation also considered the views of relevant NSAs and other relevant external stakeholders (e.g. multilateral organizations, donors, private sector entities).
- **Progress was considered against the 2017 review recommendations**, progress being ascertained based on the extent to which recommendations have been actioned and challenges experienced.
- **Alternative structures/formats** were analysed. The evaluation assessed the advantages and disadvantages of the current MSMech structure/format and made high-level recommendations regarding its continuation, reform or change. However, a detailed blueprint for future development has not been provided as it is beyond the scope of this evaluation.

1.4 Evaluation approach, criteria and questions

Evaluation approach

To enable accountability and the opportunity for learning, the evaluation focused on utilization and participation.

- **Utilization.** The evaluation was undertaken for and with specific primary and secondary users.²⁹ It ensured that the stakeholders had a high level of involvement during throughout. The evaluation team attended and conducted various meetings and workshops (i.e. regional meeting of focal points and steering committee meeting) to engage with and consult stakeholders, reinforcing its utilization focus.
- **Participation.** The approach also emphasized participation and collaboration during the evaluation process by engaging key stakeholders in the design of the methodology, data collection tools and analysis through regular consultations and opportunities to provide feedback. This enabled the stakeholders to gain a better understanding of the objectives and findings. Increased ownership is expected to improve the likelihood of these stakeholders using the evaluation recommendations to inform their decisions.

The evaluation team frequently engaged with the MSMech steering committee and the evaluation reference group, composed of:

- members of the MSMech steering committee (delegates from two regions)
- the head of the WHO Regulation and Safety Unit
- a representative from the WHO Governing Bodies Secretariat
- a representative from the WHO Office of the Legal Counsel
- regional WHO advisors for access to medicines – six regions.

Evaluation criteria

The Evaluation questions were structured according to the OECD-DAC evaluation criteria of relevance, effectiveness, efficiency, coherence and sustainability, with the addition of equity. Below are the definitions of each criterion that guided the questions; the bold text indicates the specific focus of the evaluation (16).

1. **Relevance.** The extent to which the intervention's objectives and design respond to beneficiaries' global, country and partner/institution needs, policies and priorities and continue to do so if circumstances change. The definition of relevance comprises four main dimensions: responding to needs, policies and priorities; being sensitive and responsive to context; quality of design; and responsiveness over time. **Focus: The relevance of MSMech's objectives, governance and legal framework.**

²⁹ The evaluation's approach will be broadly in line with Michael Quinn Patton's [UFE checklist 2013.pdf \(wmich.edu\)](#).

2. **Effectiveness.** The extent to which the intervention achieved, or is expected to achieve, its objectives and its results, as well as factors contributing to under/overachievement of results. **Focus: MSMech's activities and their results including at the national level and WHO's relevant support.**
3. **Efficiency.** The extent to which the intervention delivers, or is likely to deliver, results in an economic and timely way. This also includes assessing operational efficiency (how well the intervention was managed). **Focus: MSMech's resources, processes and M&E.**
4. **Coherence.** The compatibility of the activities with other interventions being undertaken by WHO and other organizations (internal and external coherence). This includes complementarity, harmonization and co-ordination with others. **Focus: MSMech's alignment and cooperation with external organizations and the rest of WHO, as well as Member State participation.**
5. **Sustainability.** The extent to which the benefits of the response will continue or are likely to continue. **Focus: The ways in which MSMech has helped establish institutions and capacity that will help sustainably combat SF products in the future – even in the absence of the MSMech.**
6. **Equity.** This was considered as a specific question, involving evaluation of the extent to which differences in need, vulnerability, gender, disability and human rights are taken account of in the MSMech's work, as well as respect of equity between the Member States.

Evaluation questions and evaluation framework

The evaluation questions and evaluation framework were guided by the OECD-DAC criteria presented above, and equity was a cross-cutting theme. In turn, the evaluation questions and evaluation framework guided the approach to the evaluation, including data collection and analytical methods. During the analysis and drafting process, the evaluation team was guided by the evaluation questions and subquestions agreed during the inception phase, as given in Table 1 below (see Annex 2 for the evaluation matrix).

Table 1. Evaluation criteria and questions

OECD-DAC Criteria	Evaluation questions and subquestions
Relevance	EQ1: To what extent are the MSMech format and governance structures relevant and do they ensure the mechanism remains fit for purpose looking forward? 1.1 To what extent are the objectives of the MSMech still aligned to needs? 1.2 To what extent is the governance framework clear to Member States (how well understood are roles and responsibilities)? 1.3 To what extent has the mechanism been flexible, able to adapt to changing circumstances and respond to emerging issues? 1.4 Overall what are the advantages and disadvantages of the current MSMech format?
Effectiveness	EQ2: To what extent has the MSMech achieved its objectives, and what factors have supported/hindered progress? 2.1 To what extent have the MSMech activities and products been implemented? 2.2 To what extent was WHO MSMech secretariat support (e.g. IT and communication and dissemination) to the MSMech adequate to facilitate the MSMech functioning and reach? 2.3 Which aspects of the MSMech worked well and which less well?

	2.4 What strategies can enhance national engagement in the MSMech discussions and activities?
Efficiency	EQ3: How efficiently has the MSMech used the resources at its disposal? 3.1 How have MSMech resources and their sources evolved? Are there any resource gaps and have they significantly evolved? 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 MSMech responses? 3.3 Is the MSMech's M&E adequate for performance measurement?
Coherence	EQ4: How does the MSMech ensure coherence and continue to bring value to address SF medical products in relation to other agencies and their approaches with a similar mandate? <u>External coherence</u> 4.1 How does the MSMech align with approaches from other organizations including multilateral/bilateral and also NSAs which are also active in the field of SF medical products? 4.2 To what extent have Member States cooperated at global, regional and national levels, and how has the mechanism facilitated this collaboration? <u>Internal coherence</u> 4.3 To what extent is the coordination adequate across the MSMech secretariat, WHO headquarters technical departments (e.g. HQ/Health Product Policy and Standards (HPS); Antimicrobial Resistance Division (AMR)); regional and country offices?
Sustainability	EQ5: To what extent are achievements of the MSMech work likely to remain (in the absence of an MSMech) and its work continued on SF medical products?
Equity	EQ6: How is the MSMech considering issues of gender equality, health equity, disability and 'leaving no one behind', and human rights in its functioning?

1.5 Evaluation methodology

Methodological approach and data collection methods

The evaluation employed a non-experimental design with a theory-based, utilization-focused approach, reconstructing a ToC. The evaluation's methodological approach was built on the evaluation criteria, questions and framework to produce coherent findings. It used mixed methods to collect both quantitative and qualitative data, enabling robust triangulation of findings (See Annex 6 for the KII guide and Annex 5 for the survey instrument).

Data was collected in-person, during the Regional Meeting for GSMS FPs of the WHO South-East Asian Regional Office held in Cambodia in February 2024, and remotely, from April to June 2024. Data collection methods used included a desk review, secondary data analysis, KIIs (remote and in person) and one online survey.

Further information related to each is provided below.

- **Desk Review:** The preliminary document review conducted during the inception phase served as the basis for a comprehensive and systematic review of 102 key WHO internal and external documents from 2017 to 2023. A document review matrix was used to extract and organize the relevant information according to the evaluation questions. For a list of references refer to Annex 8.

- **Secondary Data Analysis:** This was undertaken focusing on the GSMS incidents reporting data and budget/financial data. This allowed the evaluation team to assess timeliness of response and patterns of incident management.
- **KIIs:** These were conducted with a diverse group of stakeholders, both internal (to the MSMech and WHO) and external, covering global, regional and country levels. These interviews provided in-depth insights into the personal experiences and perceptions of those directly involved with or affected by the MSMech's activities or working in the area but not directly involved with the MsMech. These interviews used a semi-structured guide aligned with the evaluation questions, including tailored prompting questions to address specific issues relevant to different stakeholder categories. While the broader surveys (see below) captured a wide range of respondent insights, the KIIs were specifically designed to engage key stakeholders more deeply. Additionally, group interviews were conducted for certain topics to gather more nuanced perspectives.

The KIIs were conducted at global and regional levels and within six focus countries that are diverse in their geographical and economic representation. The selected countries were:

- **Africa:** Cameroon and Nigeria, for their emergency contexts and engagement levels;
- **Americas:** Brazil and Canada, representing both middle- and higher-income countries with varying degrees of SF medical products involvement;
- **Southeast Asia:** Sri Lanka and Indonesia, selected for their roles as affected producers and emergency contexts;
- **Europe:** Sweden and Montenegro, involved in regional SF medical products leadership and engagement;
- **Eastern Mediterranean:** Syria and Egypt, chosen for their conflict situations; and
- **Western Pacific:** Papua New Guinea and Malaysia, selected for being a low-income and a middle-income country, respectively.

A total of 85 KIIs were conducted with 43 male and 42 female informants. Disaggregation across the stakeholder groups interviewed is provided in Table 2 below.

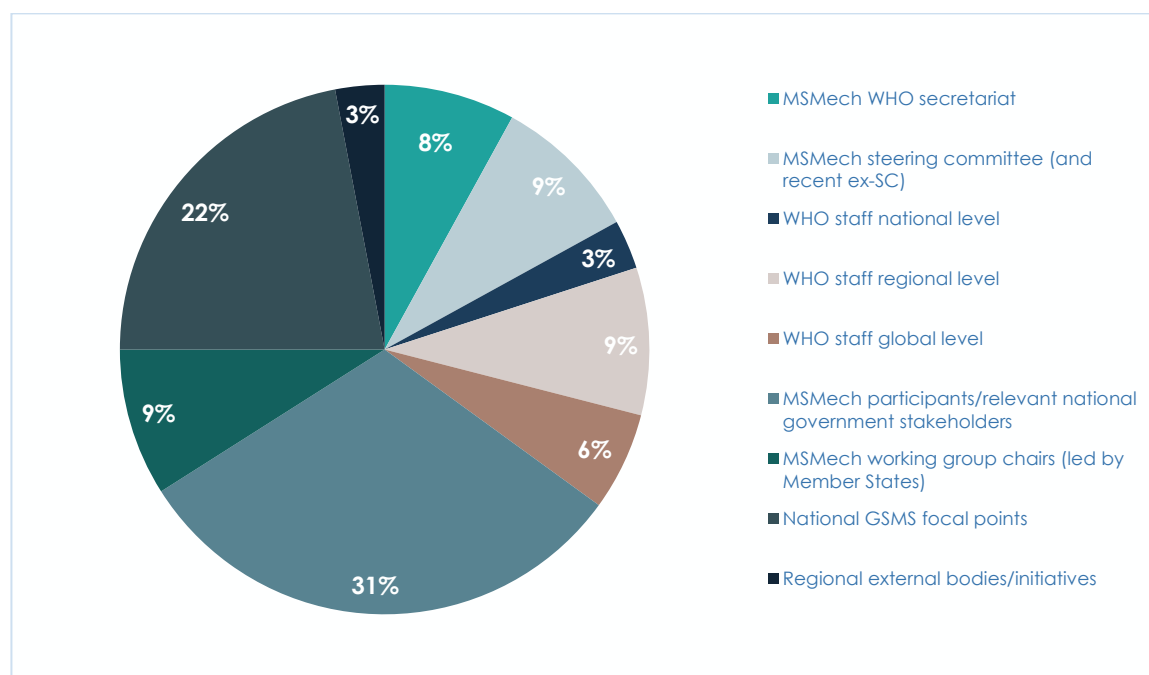
Table 2. KIIs – sample planned and achieved across category of respondents

Category of respondents	Level	Planned interview KIIs	Remote interviews	Face to face interviews	Male	Female
MSMech WHO secretariat	Global	8	4	2	3	3
MSMech steering committee (and recent ex-steering committee)	Global	15	3	3	3	3
WHO staff national level	National	6	2		1	1
WHO staff regional level	Regional	6	6		2	4
WHO staff global level	Global	5	9		4	5
MSMech participants/ relevant national government stakeholders	National	12	10	11	11	10
MSMech working group chairs (led by Member States)	Global	N/A	6		4	2

National GSMS FPs	National	12	9	6	7	8
Regional external bodies/initiatives	Regional	2	2	0	1	1
Global external bodies/initiatives/network	Global	3+	0	0		
Donors to the MSMech/WHO	Global	2	2	0	2	
Private sector	Global	2	1	0		1
Other NSAs in official relation with WHO and with relevant mandates	Global/ National	5	4	0	2	2
Academics	Global / National	4	5	0	3	2
Health professional associations	Global / National	2	0	0		
Patient associations	Global / National	1	0	0		
Public health related agencies			0	0		
Others	Global / Regional / National	N/A	0	0		
Total		74	63	22	43	42

Further distribution of KIIs across categories is shown in Fig. 6 below; almost half of respondents consisted of MSMech government representatives and GSMS FPs (31% and 22%).

Fig. 6. Distribution of respondents across stakeholder groups

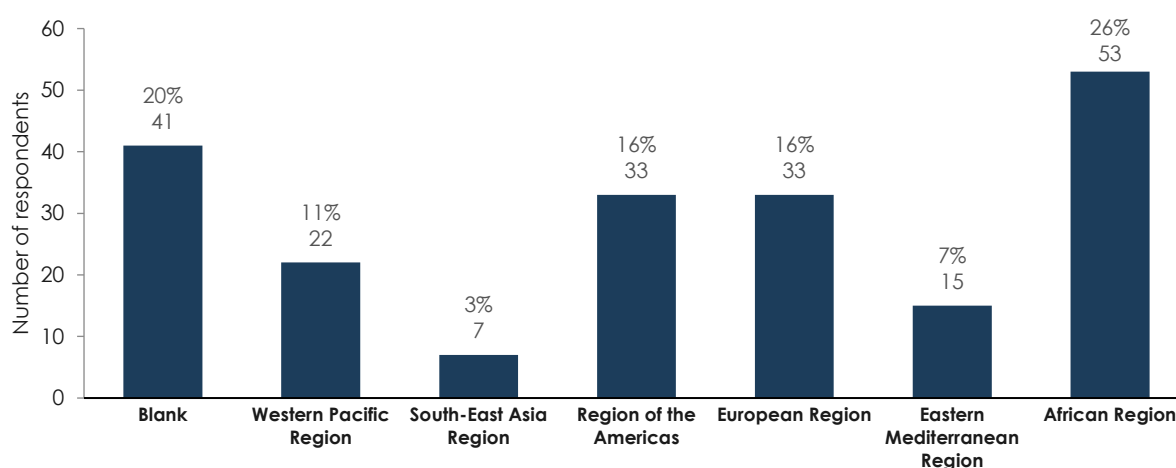


An online survey was administered at the global, regional and country levels to target a broad range of stakeholders (see Annex 5 for the survey instrument). This helped to capture a wide range of views and experiences, augmenting other data sources. The survey was administered to an estimate of 400 potential respondents with 204 responses (51% response rate). Disaggregation of responses across stakeholder categories is given in Table 3 below. The largest category of respondents was from national/regional pharmaceutical regulatory agencies (64%). Disaggregation of responses is also given across regions in Fig. 7, showing that almost one third of responses were from the Africa Region.

Table 3. Distribution of survey responses across stakeholders

Affiliation of survey respondents	No. of respondents	Percentage of respondents
National/Regional Pharmaceutical Regulatory Agency	131	64%
Ministry of Health	55	27%
Governmental institution	6	3%
Academics	4	2%
Other	5	2%
Blank	2	1%
NGO	1	0%
Total	204	100%

Fig. 7. Distribution of survey responses across regions



Source: 2024 MSMech evaluation survey

Data analysis and triangulation

Several key methods of analysis were employed.

- Thematic Analysis:** A matrix developed in Excel was used to summarize and code data from all qualitative data sources against each evaluation question and sub-question. Thematic analysis was applied to data collected from documents, KIIs and the open-ended questions from the survey. The coding framework ensured consistency across the evaluation questions, thereby providing greater reliability of results. Recurrent as well as emerging themes and patterns were identified and specifically analysed and interpreted in relation to the evaluation questions.
- Quantitative Data Analysis:** Data from the survey was analysed using Excel to identify trends. This included descriptive statistics and cross-tabulation. Analysis was presented in tables and graphs. MSMech data on SF incident reporting/response, staff, budget and other areas were also analysed using Excel to identify trends.
- Triangulation was used** to check the consistency of findings generated across different data sources, including stakeholder categories and geographical levels (regional, country and global).

Ethical considerations

The evaluation team adhered to the UN Evaluation Group ethical guidelines and WHO evaluation policies throughout the evaluation to ensure that it fulfilled its responsibility to participants. Cultural, religious and demographic differences were respected, and disruption to respondents was minimized. Pre-testing of key data collection instruments was conducted in multiple languages (English, French and Spanish). Participants were able to make informed decisions about their participation. Complaint registration mechanisms were clearly communicated (none was filed), and strict confidentiality was maintained by anonymizing information. Data was stored securely, with access provided only to the evaluation team; raw data will be deleted three months after completion of the evaluation. All intellectual property rights over the evaluation products remain with WHO. No incidents occurred during the evaluation that warranted reporting to WHO evaluation managers.

Methodological challenges and mitigation measures

The risks and mitigation measures are given in Table 4 below.

Table 4. Methodological challenges and mitigation measures

Challenges	Mitigation measures
General lack of awareness and understanding of what the MSMech was and is (MSMech is not known or understood by all SF medical products stakeholders)	The selection of people with in-depth knowledge of the MSMech, especially for KIIs, was based on geographical coverage as well as their active participation in the mechanism. In this respect the evaluation team sought support from the MSMech Secretariat. The team also directly and deliberately contacted some stakeholders who do not participate significantly with the MSMech to ascertain the reasons for this.
Limited sample size to collect diverse opinions (time and resources did not permit speaking to every Member State or SF medical products stakeholder)	The evaluation team used complementary approaches to collect data through a survey and KIIs. Within the KIIs, a focus country approach provided, to some extent, a chance to access the views of countries and represent a range of different situations. The selection of respondents across various key categories enabled triangulation and balance across different geographical and economic parameters (see Table 2).
Some degree of bias in the identification of respondents for KIIs (This is to some extent unavoidable, given that some informants were suggested by other informants)	The evaluation included a more diversified sample of external key informants that enabled it to complement those suggested by the evaluation office, MSMech secretariat and evaluation reference group.
Participants not participating in the KIIs due to unavailability	The search for alternative respondents using the same selection criteria was carried out in coordination with WHO. The WHO Evaluation Office assisted in encouraging availability and participation. Some informants were only available late on in the evaluation process but the evaluation team remained flexible in speaking to them.
Low response rate from an online survey	A larger sample size was used, and the survey was kept short as well as administered in multiple languages. In the case of WHO staff and other key stakeholders, the evaluation team gauged support from headquarters and country offices to remind and motivate staff to respond. The team allowed four weeks for a response, and multiple reminders were sent (in coordination with the WHO Evaluation Office).
Key stakeholders not aware of the evaluation, its purpose or uses	All key stakeholders were informed about the evaluation, its purpose and timings through MSMech meetings and steering committee meetings and communication channels. Additional opportunities, such as WHO regional meetings, were taken advantage of for further engagement with stakeholders and familiarizing them with the evaluation.
Data collection instruments culturally or linguistically sensitive	All data collection instruments were pretested by the evaluation team (as respondents) and revised. The survey was also translated into Spanish and French.
Relevant documents and data incomplete/lack high quality	The evaluation team considered conducting KIIs to fill these gaps.

Availability of reliable, high-quality and complete secondary data, specifically budget data	There was limited availability of reliable, high-quality and complete secondary data, specifically budget data, and it was time-consuming for the MSMech Secretariat to compile. Some approximation of relevant budget data was necessary.
Uncertainty concerning the evolution of MSMech resources and the global context	The recommendations proposed are as flexible as possible to take account of challenges in the relevant contexts. A co-creation recommendation workshop was conducted to increase ownership.
Technological problems inhibiting planned remote data collection	The evaluation team worked closely with WHO and used internal WHO mechanisms, for example for administering the survey (Dataform).
Evaluators' own bias	Detailed guidance was provided to all evaluation team members to ensure consistency of approach and minimize bias.

Chapter 2: Evaluation findings

2.1 Relevance

EQ1: To what extent are the MSMech format and governance structures relevant and do they ensure the mechanism remains fit for purpose looking forward?

Summary of key findings 1: The MSMech’s format and governance structures were well-designed to respond to the initial challenges that were faced in organizing international action against SF products.³⁰ However, they have become less suited to the mechanism’s more operational focus since then, as the working groups now focus more on actually reducing use of SF medical products.

The MSMech has demonstrated strengths, including in the ability of its governance structure to build consensus over sensitive definitions in the earlier years of its existence³¹ and in the continued relevance of its objectives. The reach of the MSMech beyond the health sector provides a potential advantage. The MSMech currently offers several possible avenues to address a sudden future emergence of SF issues since it can draw support from other government entities in addition to the health ministries. The current visibility of the MSMech at the WHA is another asset. Recognition of the limited flexibility of the MSMech, for instance restrictions on actions except when agreed in the annual plenary meeting (and the visibility of the consequences of this during the diethylene glycol and ethylene glycol incident (2022–2023) contributed to the establishment of a working group for “Identification of and response to emerging issues on substandard and falsified medical products”, for which the MSMech Chair can deploy rapidly, potentially enabling greater agility to respond.

Nevertheless, challenges in relation to the MSMech’s current governance structure are increasingly evident. Many of these relate to the current format’s expectation that Member States will play a strong proactive role. However, roles and responsibilities are not fully exercised as envisaged in the mechanism’s founding documents (4); this negatively affects performance. Working gGroups operate unevenly depending on their leadership and membership, and sometimes require the WHO MSMech secretariat to carry out meeting-related tasks that the Member States would be expected to do. Participation in MSMech meetings is also sometimes limited, as is funding from Member States.

EQ1.1 To what extent are the objectives of the MSMech still aligned to needs?

The MSMech’s nine objectives (4)³² are clear and well-aligned to needs (i.e. as identified in the background section but more specifically those reported in interviews and survey). However, they are also considered to be broad, and there is some desire by a minority of respondents to update them and create a better linkage with MSMech activities, as well as to clarify the process for their potential revision.³³

Support for the relevance of the MSMech objectives has been consistent over time. The 2012 WHA set out the MSMech objectives; these have remained unchanged ever since. Of the respondents from the 2017 review of the MSMech survey, 80% stated that the explicit goals and objectives were among the mechanism’s most

³⁰ See Background section for more information.

³¹ See Background section.

³² Refer to the section “Evaluation object” for the list of MSMech objectives.

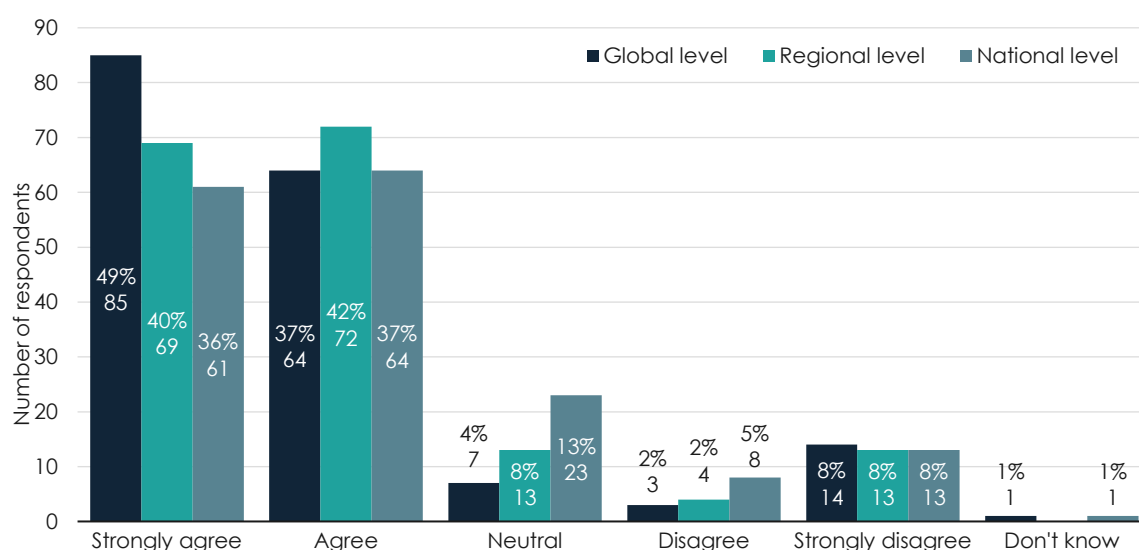
³³ KIIs.

adequate aspects. They considered that these objectives were “extremely or highly relevant from a public health perspective”, with Objectives 3, 5 and 8³⁴ receiving the highest scores, indicating their high relevance as compared to others (15).

Respondents to the 2024 MSMech evaluation survey indicate that objectives do align with needs,³⁵ with 85% agreeing or strongly agreeing at global level, 83% at regional level and 73% at national level.³⁶

More respondents strongly agreed at global (48%) and regional level (40%) than national (35%), perhaps underlining that national contexts can differ, that a globally-set agenda cannot be precisely targeted at all these levels and that there is a general lack of understanding or awareness of the MSMech beyond Geneva.³⁷ Fig. 8 below shows the extent of overall agreement on the alignment of MSMech objectives with needs.

Fig. 8. Global, regional and country level perceptions regarding the extent to which MSMech objectives are aligned with needs



Source: 2024 MSMech Survey – Evaluation

For seven of the nine MSMech objectives, over 90% respondents reported that the objectives were still relevant (see Fig. 9, below), and 85% reported that Objective 6 was still relevant. These findings show that there is still strong support regarding the alignment of MSMech objectives with needs. The fact that Objective 9 (related to definitions) was considered relevant to current needs³⁸ by fewer respondents (73%) perhaps indicates the success of MSMech’s earlier work, which was highly focused on definitions.³⁹

³⁴ Objective 3: To strengthen regulatory capacity and quality control laboratories at national and regional levels, for developing countries and least developed countries. Objective 5: 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. Objective 8: To promote cooperation and collaboration on surveillance and monitoring of SF medical products.

³⁵ See Methodology section for survey respondent information.

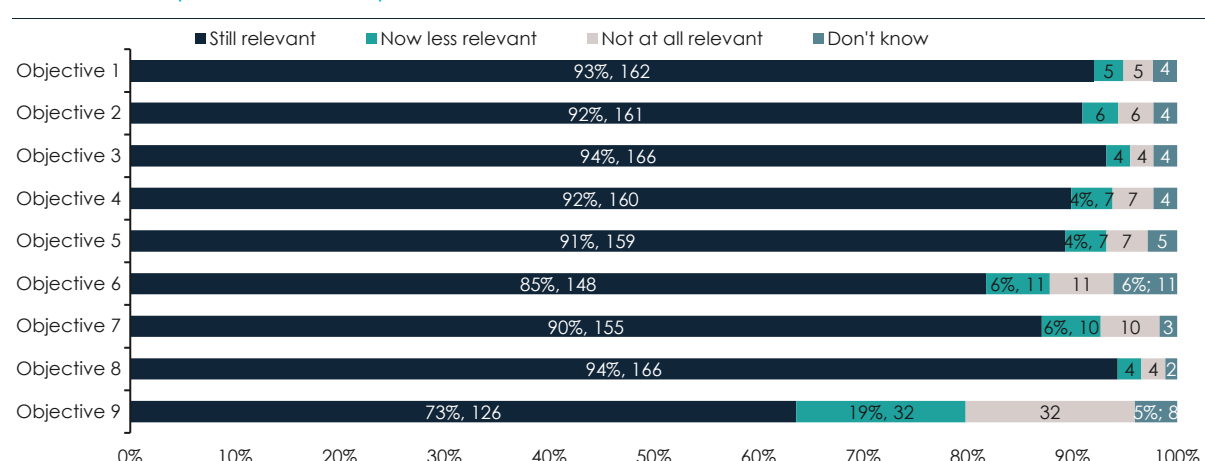
³⁶ At the global level, 48% of respondents strongly agreed and 37% agreed. At the regional level, 40% strongly agreed and 43% agreed. Nationally, 35% strongly agreed and 38% agreed.

³⁷ Evaluation team judgement.

³⁸ Evaluation team judgement.

³⁹ Evaluation team judgement.

Fig. 9. Extent to which each of the nine MSMech objectives is relevant to promoting the prevention, detection and response to SF medical products⁴⁰



Source: 2024 MSM FS Survey - Evaluation

During the MSMech's 2023 plenary,⁴¹ as in previous plenary meetings, it was confirmed that the nine objectives and related prioritized activities would constitute the workplan (a regular procedure for each biennium). A broad range of stakeholders who participated in the interviews strongly supported the relevance of the MSMech objectives,⁴² although some were not familiar with them (mainly national representatives who had not attended MSMech meetings).⁴³

However, while most stakeholders agreed that objectives do align to needs, some also suggested that they required improvements, for example using more concise language⁴⁴ and improving applicability at national level.⁴⁵ Nevertheless, the broad formulation of objectives allows for their application across diverse regions with different SF medical product threats and capacities.⁴⁶

There were also calls for the objectives to be "prioritized";⁴⁷ and "updated",⁴⁸ as well as for clearer linkage between objectives and activities.⁴⁹ Table 5 lists suggestions made by some key informants and survey respondents for possible changes to MSMech objectives (which would require a WHA decision).

⁴⁰ "Objective1: Identify needs, challenges; recommend policies; develop prevention, detection and control tools for SF medical products. 2: Strengthen national and regional supply chain integrity. 3: Exchange experiences, lessons, best practices and information at all levels. 4: Identify detrimental actions and behaviours; make recommendations to improve medical product quality, safety and efficacy. 5: Enhance regulatory capacity and quality control labs, especially in developing and least developed countries. 6: Collaborate on WHO efforts to access quality, safe, affordable medical products, including generics. 7: Facilitate transparent, coordinated consultation and collaboration with stakeholders. 8: Promote cooperation on surveillance and monitoring of SF medical products. 9: Develop public health-focused definitions of SF medical products."

⁴¹ Observed on video recording by evaluation team.

⁴² KIIs.

⁴³ KIIs.

⁴⁴ Evaluation team judgement.

⁴⁵ KIIs.

⁴⁶ Evaluation team judgement.

⁴⁷ KIIs.

⁴⁸ KIIs.

⁴⁹ KIIs.

Table 5. Suggestions for revision of MSMech objectives, from some key informants and 2024 survey respondents^{50,51}

Suggestions from key informants	Suggestions from survey respondents
General comments	General comments
Could be streamlined, fine-tuned, updated. ⁵²	There is no need for a new objective, but there is a need to prioritize among the existing ones and refine them.
Specific additions proposed by key informants	Specific additions proposed by survey respondents
A centralized monitoring system to address falsified Certificates of Pharmaceutical Product ^{53 54}	Raise awareness of the SF issue among all stakeholders, including the public.
Holding countries where SF medical products are manufactured to account ⁵⁵	Approve the basic safety controls that medicines and other health supplies must have in their wrappings and/or packaging.
Better cross-border systems. ⁵⁶	Facilitate consultation, cooperation and collaboration between the region's regulatory authorities and the population under their care regarding the surveillance and control of medical devices.
Better engagement with funders/better resource mobilization. ⁵⁷	Promote increased access to training for national FPs to prevent use of SF medical products.
	Promote and assist National Competent Authorities in developing artificial-intelligence-based, software-assisted traceability mechanisms for supply chain integrity and monitoring the recall and removal of diethylene glycol products from the market.
	Ensure that issues related to SF medical products are adequately captured in the legal instruments governing pharmaceutical products; include in the legislation strict penalties on issues related to HF medical products.

EQ1.2 To what extent is the MSMech's governance framework clear to Member States (how well understood are roles and responsibilities)?

Familiarity with the MSMech's governance framework varies significantly among the Member States, which contributes to uneven fulfilment of roles and responsibilities.⁵⁸ While past and present MSMech steering committee members and the MSMech secretariat are very familiar with the framework, only 57% of Member State National Regulatory Authority representatives considered themselves 'generally familiar' with it. Furthermore, only 22%⁵⁹ of the Member State ministry of health representatives reported being familiar (this group is the least likely to interact with the MSMech, which may explain their lack of familiarity).

As the Member States control the mechanism, it is reasonable to expect them to ensure that stakeholders within the mechanism (including themselves as principal participants) carry out their given roles and

⁵⁰ KIIs and 2024 survey.

⁵¹ Note that analysis of the relevance of MSMech activities and products in the pursuit of these objectives is covered in the following chapter, on Effectiveness.

⁵² KIIs.

⁵³ Certificates of pharmaceutical product are relied on by importing countries for registration decisions to allow distribution in that country.

⁵⁴ KIIs.

⁵⁵ KIIs.

⁵⁶ KIIs

⁵⁷ KIIs

⁵⁸ See the Background section, which sets out MSMech's history and governance format.

⁵⁹ MsMech Evaluation Survey, 2024.

responsibilities. There is, however, no detailed description of the roles and responsibilities of Member States or of how the mechanism should interact with other stakeholders.

There are some clear general statements concerning the roles and responsibilities in the foundational document for the MSMech (WHA Resolution 65.19 of 2012) as well as in the report of the initial MSMech meeting in 2012 (7). These documents are available on the MSMech website, although not well signposted for those unfamiliar with the MSMech.⁶⁰

The key roles and responsibilities as understood by the evaluation team are set out in Table 6.

Table 6. WHA resolution provisions relating to MSMech roles and responsibilities

Stakeholder	Relevant statements included in Resolution 65.19
WHO	1. WHO has “fundamental role”, should support Member State NRAs, especially in LMICs 2. Should “support Member States in strengthening national and regional regulatory infrastructure and capacity” 3. Provide “use of existing WHO structures” 4. Share information and create awareness; provide norms, standards and technical support on country situation assessment; support national policy development; capacity-building; product development and domestic production
Member States	1. Urged to “participate and collaborate” 2. Urged to “provide sufficient financial resources to strengthen the work of the Secretariat in this area”
Regional entities	1. MSMech should strengthen regional capacity and quality control laboratories, especially in LMICs 2. Regional groups will provide input “as appropriate”
Other SF medical products-related stakeholders	1. MSMech should “facilitate consultation, cooperation and collaboration of relevant stakeholders” in a transparent and coordinated manner, including regional and other global efforts, from a public health perspective
MSMech overall	1. Existence of MSMech to be reviewed after three years 2. Identify needs and challenges; make policy recommendations; develop tools for prevention, detection and control of SF products 3. Strengthen national and regional capacities 4. Promote cooperation and collaboration on surveillance and monitoring of SF products 5. Develop definitions of SF products 6. Collaborate with and contribute to other areas of WHO, e.g. that address access to quality, safe, efficacious and affordable medical products; that promote generics 7. Establish working groups and make recommendations on specific issues 8. MSMech should report to WHA through Executive Board every two years

Source: WHA Resolution 65.19 (main text and annex) (4)

⁶⁰ Evaluation team judgement.

In 2022, the MSMech secretariat discussed the need to provide additional, informal guidance to new Member State steering committee members on fulfilling the key MSMech functions to prompt more active engagement from them.

As a result of these discussions, a new document was produced, drawing on the experiences of the current steering committee members.⁶¹ This guide, for example, urges steering committee members to attend meetings in person and to “respond thoughtfully to agenda items”; it is considered useful and may have contributed to improved interactions during meetings. However, the fact that it was considered necessary to have this document suggests either a possible lack of understanding of steering committee responsibilities or that these were not met,⁶² especially before 2022.

Some Member States, from across all WHO regions, are very active and clearly do contribute significantly to the work of the MSMech. This includes the current steering committee members and several working group chairs. Contribution is through participating in meetings and collaborating via working groups and in other fora (which they usually report back on to the MSMech). The steering committee members generally participate more fully and are assisted in doing so by the MSMech secretariat as well as the more active Member States.⁶³ However, although MSMech meetings are open to all Member States, a large number do not attend or do not contribute to those that they do attend.⁶⁴ Interviewees familiar with the MSMech meetings reported that, while active participation to discussions is still often lacking, it has recently improved.⁶⁵ Similarly, many Member States representatives do not participate in the working groups that they have joined.⁶⁶ One interviewee, for example, recounted that of the 30 official members of one working group, barely five typically attend its meetings. This makes it difficult to progress on key agenda points within each meeting session.^{67,68} The MSMech’s secretariat also often steps in to carry out preparatory meeting responsibilities of the MSMech that Member States would be expected to do, and the work of working groups where Member State participation is weak.

Overall it was unclear to Member States what the division of responsibilities is between the MSMech secretariat and WHO.⁶⁹ The MSMech and several WHO units or departments involved in SF medical products issues closely work together, including the ISF Team⁷⁰ within the Regulation and Prequalification Department of WHO’s Access to Medicines and Health Products division. Other parts of WHO also play a role in MSMech. For example, the 2021 plenary report (14) confirmed that the WHO’s Regulatory System Strengthening programme assists Member States on SF medical products matters, in part addressing potentially all four of the WHO responsibilities (see Table 6).⁷¹ The same report also states that the MSMech serves as an important platform for advocacy for strong regulatory systems (see Table 6). However, despite seven references to “affordable

⁶¹ *Encouraging active engagement of steering committee members of the Member State mechanism on substandard and falsified medical products: Practical considerations on vice-chairmanship from current steering committee members*, June 2023. This document was prepared by the then-steering committee members and was circulated to regional coordinators as informal guidance and practical considerations that Member States may find helpful when they are considering joining the SC and preparing for active engagement.

⁶² KIIs.

⁶³ For example, induction documents such as: *Encouraging active engagement of steering committee members of the Member State mechanism on substandard and falsified medical products: Practical considerations on vice-chairmanship from current steering committee members*, June 2023.

⁶⁴ KIIs.

⁶⁵ KIIs.

⁶⁶ KIIs.

⁶⁷ Reasons for lack of Member State participation and collaboration are discussed in the Effectiveness section.

⁶⁸ KIIs.

⁶⁹ KIIs.

⁷⁰ The Incidents, Substandard/Falsified Medical Products team (ISF) (part of the Regulation and Prequalification Department) serves as the MSMech secretariat.

⁷¹ *Ibid.* 1. WHO has a “fundamental role”, should support Member State NRAs, especially in LMICs. 2. It should “support Member States in strengthening national and regional regulatory infrastructure and capacity”. 3. It provides “use of existing WHO structures”. 4. It shares information and creates awareness; provides norms, standards and technical support on country situation assessment; supports national policy development; capacity-building; product development and domestic production.

medicines” in the less than two pages of the resolution and its annex, according to key informants, there was not always sufficient collaboration between the MSMech and parts of WHO working on access to medicines during the evaluation period (e.g. in relation to medicine shortages), although there are signs that this may now be improving.

WHO regions nominate MSMech vice-chairs, and the MSMech’s structure and history of chairs involves good geographical representation, coming from every region. The WHO regional offices are not always as well integrated into MSMech activities as they could be,⁷² which may reflect the challenge for the mechanism to fully achieve the regional involvement called for by the Resolution. This was considered important for providing visibility to the SF medical product issue and potentially for accessing funding.⁷³

There were divergent opinions in evaluation interviews regarding how welcome other SF medical products stakeholders (e.g. global health partnerships, NGOs, private sector) were to participate within the MSMech, although the founding Resolution suggests that engagement with other relevant stakeholders is a Member State responsibility (see Table 6). As per Member States’ decisions during the foundation of the MSMech, other SF medical products-related stakeholders⁷⁴ are not invited to MSMech meetings. This may be because a definition of “relevant stakeholders” (as per the Resolution) has not been agreed. Sensitivity surrounds the pharmaceutical industry, with mixed views amongst stakeholders of the extent to which it should participate in the MSMech. Some agree that its participation could help, especially given the industry’s desire to build trust in non-SF medicines, whilst others are cautious of its involvement.^{75 76}

To enhance political commitment from Member States, some stakeholders⁷⁷ suggested that the governance structure should include at least mMinisterial level representation. Additionally, having representatives from each region attend steering committee meetings (as currently happens) was deemed by many to be very useful. It was proposed that experts from the pharmaceutical industry and customs authorities should be included in some sessions to provide practical insights (while noting the need to comply with the requirements of the WHO FENSA). There was also a call to increase the number of steering committee members from LMICs (which regions currently nominate) to address their specific challenges with SF products. Respondents emphasized the need for a governance structure that allows more flexibility and reactivity to emerging challenges to ensure timely responses to public health concerns – where changes would require consideration and decision by the WHA.

EQ1.3 To what extent has the mechanism been flexible, able to adapt to changing circumstances and respond to emerging issues?

The MSMech is considered to lack agility and flexibility, an inherent weakness linked to its current format. For example, the “process of adopting decisions through the plenary”⁷⁸ is not conducive to agility and adaptation to changing circumstances. It is a slow process, in part because many representatives lack technical expertise.⁷⁹ Some interviewees also reported that the MSMech was inevitably slow-moving since it is an intergovernmental body (subsidiary to the WHA),⁸⁰ and also since there are geopolitical differences in perspective relating to SF

⁷² KIIs

⁷³ Key informants also commented on the MSMech’s biannual report to the WHA as important in this respect.

⁷⁴ For example, NGOs, the pharmaceutical industry and the media.

⁷⁵ KIIs.

⁷⁶ It is important to note that engagement with non-state actors, including the private sector, needs to be in accordance with FENSA.

⁷⁷ KIIs.

⁷⁸ KIIs.

⁷⁹ KIIs.

⁸⁰ KIIs.

medical products,⁸¹ such as on issues of intellectual property (especially in earlier years) or the origin of SF medical products.⁸² The MSMech responded slowly to the diethylene glycol and ethylene glycol emergency of 2022–2023.⁸³

“We weren’t able to act promptly when it came to glycol, causing frustrations on the part of Member States.” (stakeholder interview)⁸⁴

Working Group I, which was established in the 2024–2025 workplan (Identification of a Response to Emerging Issues), was conceived during the evaluation period but adopted just after it and is led by the MSMech chair, to specifically accelerate the response to future emergencies arising between plenaries. This reflects recognition of the problem and an attempt to improve flexibility, although it has not yet been tested.

The increase in rate of change in working groups (each corresponding to a “prioritized activity”) also demonstrates efforts to improve flexibility. For example, whereas there were no revisions to working groups in 2018–2019 and 2020–2021, one new working group was added for 2022–2023, and three were added for 2024–2025. However, this may be an indicator of flexibility and responsiveness to specific issues of interest to particular countries, rather than to changing circumstances or urgent/emerging issues within SF medical products.

The guidance note for new steering committee members (see above) could also be seen as an indication of flexibility. Several stakeholders, who had been involved with the MSMech from its earliest days, drew attention to differences in the nature of the issues it has faced over time. In the initial years, significant efforts were dedicated to clarifying definitions and smoothing relations among Member States. The success of this has allowed the MSMech to focus more on operational issues relating to the risks of SF medical products.⁸⁵ This has increased the need for flexibility.

EQ1.4 Overall what are the advantages and disadvantages of the current MSMech format?

Views about the advantages and disadvantages of the MSMech’s format differ significantly, depending on the timeframe considered and the category of respondents. Perspectives may be influenced by the level of knowledge about its format (e.g. extensive Member State responsibilities), the nature of WHO intergovernmental bodies and their relationship with the WHO Secretariat (and respective roles and responsibilities) and the structure of comparable entities/organizations and mechanisms (e.g. degree of technical proficiency and accountability).⁸⁶ Member State representatives who have had little direct contact with the MSMech tended to have more supportive views of the status quo than those who served on the steering committee or WHO staff from various departments who have worked closely with the mechanism.

There is less consensus and satisfaction regarding the MSMech’s governance structure than there is with its objectives. Views again varied according to familiarity with the MSMech and category of respondent. While most steering committee members and WHO staff who work closely with the MSMech saw a need for change, other Member State representatives were more positive about the current structure. Of the ministry of health representatives, 38% saw “no need for change” while 25% called for either “some” or “substantial” changes.

⁸¹ KIIs.

⁸² KIIs and also evaluation team judgement in interpreting “geopolitical”.

⁸³ Evaluation team judgement, but it was also mentioned by key informants.

⁸⁴ KIIs.

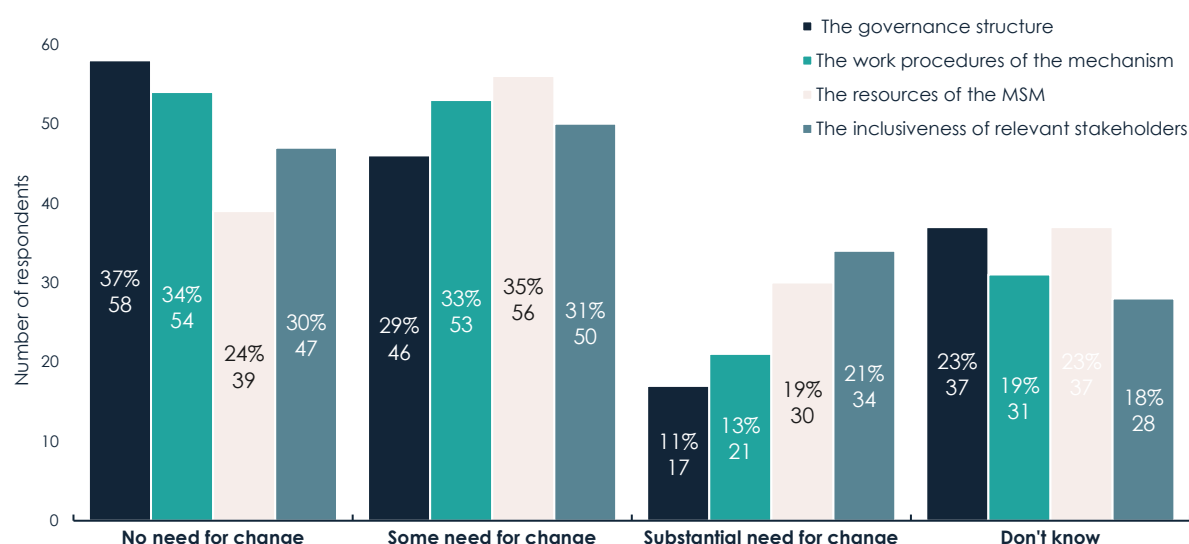
⁸⁵ KIIs.

⁸⁶ The evaluation produced an analysis of comparable mechanisms, available upon request from the WHO Evaluation Office at evaluation@who.int

For National Regulatory Agencies (NRA) representatives, 39% indicated “no need for change” compared to 42% who desired “some” or “substantial” changes.

This represents a deterioration in satisfaction compared to the 2017 review survey, when the governance structure and the composition of the steering committee were considered highly adequate or adequate by 59% and 55% of the respondents respectively (15) (see Fig. 10)

Fig. 10. Perceptions on MSMech aspects that need to change to more effectively support activities to address SF medical products, 2017



Source: 2024 MSM FS Survey - Evaluation

Suggestions for change in the governance structure from the survey respondents were diverse. Some called for increased political representation, for example by ministers. Others focused on maintaining broad geographical representation or having increased LMIC representation on the steering committee to bring greater familiarity with LMIC contexts. Others still suggested that there should be more inclusion of other SF medical products stakeholders, allowing experts from the pharmaceutical industry and customs authorities to attend some sessions to provide practical insights (in accordance with FENSA requirements). Some 20% of respondents reported substantial change was needed in the degree of inclusivity of relevant stakeholders – which would need to be further defined and would likely require consideration and decision by the WHA. There were also calls for a future structure that allowed flexibility and reactivity, to ensure timely responses to emerging concerns.

It is widely considered that the current format delivered important benefits in the earlier years of the MSMech, when it was important to have access to Member State political decision-makers to address sensitive issues, such as definitions. However, a substantial number of interviewees, especially those who work most closely and frequently with the MSMech, report that the current format is disadvantageous given the mechanism’s changed focus since agreement was reached on definitions. In many cases, key informants expressed interest in alternative formats for the MSMech, especially ones that would introduce a more technical focus and greater agility.⁸⁷ Some reported advantages and disadvantages of the MSMech format are given in Table 7 below.

⁸⁷ KIIs.

Table 7. Reported advantages and disadvantages of the MSMech format

Reported advantages of the current MSMech format	Reported disadvantages of the current MSMech format
• In principle open to all Member States on an equal basis and providing a forum to bring Member States together to tackle common concerns (which clearly worked well with the discussions on definitions);⁸⁸ • Can engage with the full range of government representatives of Member States (for example, diplomatic expertise can be applied to ensure that no undesired precedents are set. In theory, law enforcement or customs representatives could also be provided by Member States in addition to diplomatic resources, but in practice this has not been seen) • The political involvement in the current format could prove useful in the future should any⁸⁹ contentious issues arise.	• Lack of clear accountability of Member States within the MSMech's working processes (see also sections on effectiveness and efficiency); • Absent or inappropriate Member State representation such that participation remains limited and uneven;⁹⁰ • Dependence on Member State willingness and proactiveness to engage with other key SF stakeholders who could assist in meeting MSMech objectives (e.g. NGOs, pharmaceutical industry). Other SF stakeholders, such as UNODC, were mentioned as being able to achieve this with comparative ease;⁹¹ • Lack of assurance that MSMech recommendations will be taken up by Member States (due to lack of accountability), despite political representation as well as technical,⁹² including the basic requirement of reporting SF incidents.⁹³

2.2 Effectiveness

EQ2: To what extent has the MSMech achieved its objectives, and what factors have supported/hindered progress?

Summary of key findings 2: While an activity-based workplan exists and progress on reporting has recently been made, the MSMech does not have a results framework that clearly outlines outputs and outcomes, corresponding to the activities and objectives or a ToC that shows linkages between these. It lacks baselines, processes and indicators to monitor progress towards objectives and does not report on this, so it is difficult to assess the extent to which it has achieved its objectives. The evaluation team considered available evidence on progress with activities, in addition to feedback from key informants and survey respondents, and, based on this, infers that some progress has been made towards achieving MSMech objectives.

⁸⁸ KIIs.

⁸⁹ KIIs.

⁹⁰ KIIs.

⁹¹ KIIs.

⁹² KIIs.

⁹³ KIIs.

The MSMech reports regular progress relating to the implementation of activities. It has successfully implemented some planned activities and products, but there has been slower progress with others. Some activities and products are perceived to have had a positive influence at country level, but there is a lack of robust evidence on their effectiveness and impact.

Key factors that have hindered MSMech progress and effectiveness include: sub-optimal Member State participation; variable effectiveness of working groups and lack of accountability; limited engagement with other (non-state) stakeholders; and lack of funding. There are also country-specific factors, some of which are outside the control of the MSMech, although the MSMech can help to address others, such as weak regulatory systems.

The secretariat has clear value and provides good support to ensure the effective functioning of the MSMech, although there are concerns about its overstretched capacity and the efficiency of its communication.

Aspects of the MSMech that have worked well include bringing a global perspective and consensus on key SF issues and enhancing country interaction, collaboration and information sharing. Aspects that have worked less well include promoting active engagement and participation of all Member States, responsiveness to priority and emerging issues and processes for communicating information.

EQ 2.1 (a) To what extent has the MSMech achieved its objectives?

The MSMech does not report on progress towards objectives and lacks indicators to monitor this. MSMech reporting is activity- rather than outcome-focused, and available evidence reflects this. There are calls for clearer linkages between activities and objectives.⁹⁴ In some instances it is difficult to determine the extent to which progress towards objectives is attributable to the MSMech or WHO or a combination of both.

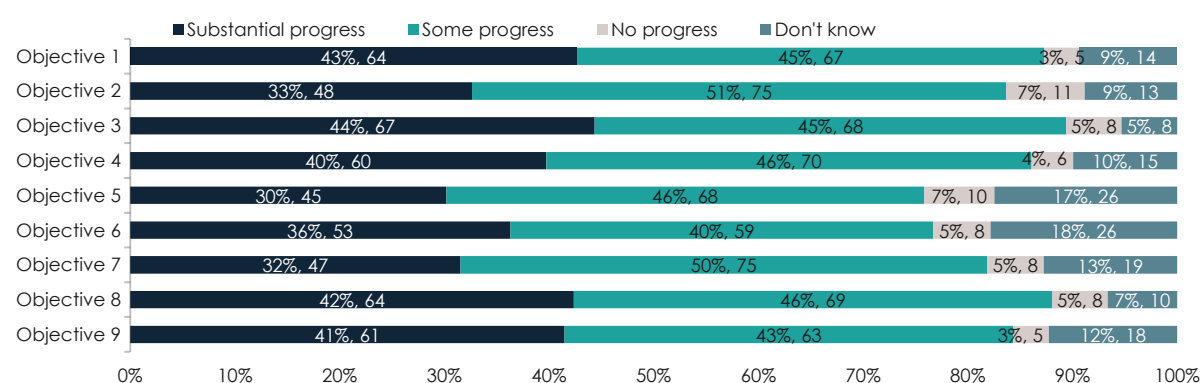
Despite lack of reporting against objectives, some evidence gathered through this evaluation – mainly progress with activities that are likely to contribute to the objectives (see Table 8 below) but also survey feedback – suggests there has been some progress towards objectives 1 (identify needs and develop policy recommendations); 2 (strengthen capacity); 3 (exchange experience, best practices and information); 4 (identify actions, activities and behaviours that result in SF medical products and make recommendations); 5 (strengthen regulatory capacity and quality control laboratories); 8 (promote cooperation and collaboration on surveillance and monitoring) and 9 (develop definitions). Progress towards objectives 6 (collaborate with and contribute to the work of other areas of WHO) and 7 (facilitate consultation, cooperation and collaboration with relevant stakeholders) is less clear. While some survey feedback suggests that there has been progress on these two objectives, there is little other supporting evidence.

Survey feedback suggests that stakeholders perceive progress towards MSMech objectives but respondents were not asked to provide evidence to substantiate their views, so caution should be exercised in drawing conclusions. Approximately 80%⁹⁵ of survey respondents reported some or substantial progress for all objectives. More respondents (over 40%) reported substantial progress towards Objectives 1, 3, 4, 8, 9 (see Fig. 11 below).

⁹⁴ KIIs.

⁹⁵ Total of “substantial” and “some” progress towards MSMech objectives 1(89%), 2 (85%), 3 (91%), 4 (87%), 5 (78%), 6 (78%), 7 (83%), 8 (90%), 9 (85%), as per survey.

Fig. 11. Perception of progress towards MSMech objectives



Source: 2024 MSM FS Survey - Evaluation

Table 8 includes available evidence indicating progress towards the MSMech's objectives.

Table 8. Evidence of progress towards achievement of MSMech objectives

MSMech Objectives	Progress with activities likely to contribute to achievement of MSMech objectives
1. Identify major needs and challenges and make policy recommendations, and develop tools in areas of prevention, detection methodologies and control of SF medical products to strengthen national and regional capacities	Contribution of activities under: Activity A: Tools for post-market surveillance. Activity B: Handheld devices for reporting by health workers. Activity C: Guidance on selection of detection technologies; collation of existing tools and methodologies; track and trace policy.
2. Strengthen national and regional capacities to ensure the integrity of the supply chain	Contribution of activities under Activity A: National Action Plan (NAP) handbook and benchmarking; assessing training needs and mapping training materials; regional meetings and trainings; technical guidance on risk-based market surveillance and control. Activity D: Handbook on strengthening NAPs, including implementing/accelerating regulatory system strengthening and country pilots.
3. Exchange experiences, lessons learned, best practices and information on ongoing activities at national, regional and global levels	Contribution of activities under Activity E: Sharing lessons learned from risk communication campaigns in four countries; pilot implementation of compulsory pharmacy school modules in four countries. Activity G: Identifying and sharing experience of regulation of distribution via the internet and good practices. Activity B: Planned contribution but limited activity to date on facilitating exchange of information and networking among the Global FP Networks. Feedback from key informants and survey respondents suggests that the MSMech has facilitated collaboration and information sharing between Member States (see EQ 2.3 and EQ 4.2).

4. 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	Contribution of activities under Activity E: Surveys on patient/consumer attitudes and behaviours; risk communication campaigns in four countries. Activity G: Understanding and addressing distribution of SF medical products via the internet; pilot internet training programme.
5. Strengthen regulatory capacity and quality control ⁹⁶ laboratories at national and regional levels, for developing countries and least developed countries	Contribution of activities under Activity A: NAP handbook and benchmarking; assessing training needs and mapping training materials; regional meetings and trainings; technical guidance on risk-based market surveillance and control. Activity B: Training for national FPs
6. 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	Feedback from most key informants who are in a position to comment indicates there is good collaboration between the MSMech secretariat and WHO headquarters teams working on related issues, including regulation and prequalification, product testing standards, and regulatory system strengthening (see EQ 4.3). However, some key informants commented that there is scope for greater engagement of WHO regional offices.
7. 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	Contribution of activities under Activity C: Coordination with the International Coalition of Medicines Regulatory Authorities and the European Directorate for the Quality of Medicines & HealthCare on track and trace policy paper. Activity G: Roadmap for interagency collaboration on online distribution of SF medical products There was a consensus among key informants that there is limited MSMech engagement and collaboration with non-Member State stakeholders (see EQ 4.1). Survey respondents also highlighted the need to foster cooperation and collaboration among regulatory authorities and other stakeholders, enhance interagency cooperation and use a more coordinated approach through networks like the African Network on SF medical products.
8. Promote cooperation and collaboration on surveillance and monitoring of SF medical products	Contribution of activities under Activity A: Improvements to the GSMS and reporting. Activity B: Identifying and addressing barriers to reporting by national FPs; training for national FPs.
9. Further develop definitions of SF medical products that focus on the protection of public health	Contribution of activities under Activity C: Technical expert sessions developing harmonized definitions. Activity G: Definition of informal markets

Source: KIs and survey.

⁹⁶ Work on strengthening quality control laboratories is conducted by the Laboratory Networks and Services team in WHO and is not included in MSMech activities.

There are several key factors influencing progress towards MSMech objectives.⁹⁷

MSMech processes and ways of working

- **Uneven Member State engagement and participation:** The active engagement of Member States in the MSMech steering committee, working groups and plenary meetings is a critical factor in taking forward activities.⁹⁸ The effectiveness of participation is influenced by who is nominated as a representative by countries and whether or not these representatives have a good understanding of issues related to SF medical products.
- **Uneven effectiveness of working groups:** Effective working groups are critical to engaging Member States, ensuring that activities and products are relevant and adaptable to specific regional and country contexts and that planned activities and products are delivered.⁹⁹ Working groups that have most successfully delivered planned activities have been those whose chair has the right expertise and understanding, has provided active leadership and has made substantial efforts to engage with the working group members and the MSMech secretariat to drive progress.¹⁰⁰ The effectiveness of Working Groups is also determined by having a clear plan and timeframe for activities. Another key factor is the “voluntary” nature of the working groups: Working group members have other full-time jobs, which is not conducive to rapid progress.¹⁰¹ Survey respondents suggested holding more regular working group meetings and providing orientation for new members so that they understand their roles. Some respondents emphasized the need for working groups to have more resources. This could catalyse more rapid action and support innovative and collaborative projects.
- **Lack of robust MSMech monitoring and accountability:** This is reported to be limiting progress.¹⁰² For example, although working groups track and provide updates on activities, there is no accountability for not progressing with implementation.¹⁰³
- **Complex WHO and Member State processes:** Some key informants highlighted delays in communicating key information, such as meeting invitations.^{104,105} As for other governing bodies and Member State meetings, invitations are sent by WHO at least eight weeks before meetings to Member State contacts, copied to the missions in Geneva. Delays may be due to processes in country. For example, in one country, key informants reported that information goes via the mission, the ministry of foreign affairs and then the ministry of health, and often reaches the NRA too late or not at all. Key informants also reported that WHO processes can make contracting consultants or other external experts to provide specific inputs more time-consuming, delaying the progress of working group activities.
- **Lack of engagement of other (non-state) stakeholders:** Key informants and survey respondents highlighted the need for improved cooperation and collaboration among relevant actors, and for MSMech engagement with a wider range of stakeholders. This could include donors, technical agencies, civil society organizations and health professional networks. In some instances, there may

⁹⁷ MSMech does not systematically capture or document factors supporting or hindering progress towards objectives. These are largely based on KIIs and survey.

⁹⁸ KIIs.

⁹⁹ KIIs.

¹⁰⁰ KIIs.

¹⁰¹ KIIs.

¹⁰² KIIs.

¹⁰³ KIIs.

¹⁰⁴ KIIs.

¹⁰⁵ KIIs.

be value in collaborating with the pharmaceutical industry – albeit with caution and due diligence in accordance with FENSA – and, with regard to a public health perspective, with law enforcement and customs entities addressing SF medicines, such as Interpol. It would be appropriate for the MSMech to consult with the WHO Due Diligence and Non State Actors Unit/Compliance, Risk Management and Ethics Office (DAN/CRE) about the circumstances in which such interactions would be appropriate.¹⁰⁶ According to some key informants, the MSMech could have engaged more effectively with other stakeholders supporting or working on the same issues. For example, the Bill and Melinda Gates Foundation is supporting countries to take forward NAPs and the development of handheld devices for use in screening, detection and reporting of SF medical products.¹⁰⁷ Any changes in this regard would require WHA consideration and decision.

Lack of funding: Lack of resources – such as funding for external consultants, workshops and meetings, and training for country level implementation – is reported to affect progress with MSMech activities. Reduced financial contributions from Member States, with a few exceptions, have resulted in growing reliance on non-MS donor funding.^{108,109} The scope to increase external donor funding for the work of the MSMech may be undermined by the lack of participation by such donors in the mechanism’s meetings.

“I believe there's a need for more support from Member States, including experts to assist with specific tasks and reviews.”¹¹⁰

Contextual challenges and country factors

- **Country-specific factors:** Key factors that affect progress and that the MSMech could help to address include the extent of country-level leadership and commitment, the strength of regulatory systems, laboratories and other relevant systems (for example, the supply chain) and the availability and capacity of human resources and funding.
- **Limited information sharing – in some cases – about SF medical products:** Another factor is the unwillingness of national authorities and officials in some instances to share information about SF medical products, including through the GSMS and with the MSMech, because of national regulations or concerns about the legal, institutional or reputational implications of doing so.¹¹¹ Key informants suggested that, to address resistance to reporting and sharing information, there is a need for a cultural shift or change in mindset that will enable more acknowledgement and openness about the problem of SF medicines.¹¹²

EQ 2.1 (b) To what extent have MSMech activities and products been implemented?

Many stakeholders interviewed could not comment on progress with implementation of MSMech activities – although some perceive that progress is quite slow¹¹³ – and most were only able to comment on the specific activities or working groups that they have been involved with. Many were also unable to distinguish between MSMech and WHO activities and products. For example, WHO training and other capacity-building support were frequently cited as making an important contribution to progress in-country.¹¹⁴

¹⁰⁶ KIIs.

¹⁰⁷ KIIs.

¹⁰⁸ KIIs.

¹⁰⁹ See Efficiency section for a more detailed discussion of MSMech funding.

¹¹⁰ KIIs.

¹¹¹ KIIs.

¹¹² KIIs.

¹¹³ KIIs.

¹¹⁴ KIIs.

Overall, based on available evidence and MSMech reporting, the evaluation team concludes that there has been mixed progress with implementation of MSMech activities and products. Table 9 provides an overview of progress against MSMech activities, and Annex 4 provides more detailed evidence on this.

Table 9. Progress against MSMech activities

Overall, there has been more progress within: ¹¹⁵	Progress appears to have been slower ¹¹⁶ within:
Activity Area A: Capacity-building, although attribution to the MSMech rather than WHO is difficult to determine.	Activity Area B: Global networks, where the focus of activity has been strengthening networking between MSMech FPs, with little or no focus on networking with a wider range of stakeholders.
Activity Area C: Member State understanding and uptake of technologies and national traceability systems, ¹¹⁷ especially in relation to policy and tools.	Activity Area D: Leveraging stakeholder competencies, where the focus of activity has been NAPs.
Activity Area E: Communication campaigns and pharmacy school modules, but only in specific pilot countries.	Activity Area F: Member State capacity to expand awareness.
Activity Areas G and H: Addressing distribution of SF medicines via the internet and informal markets. ¹¹⁸	

Some MSMech activities and products are reported to have been more helpful than others in reducing the presence and use of SF medical products. Key informants said that the development of agreed definitions was one of the most helpful of the MSMech's activities. In their view, other helpful activities include those related to technologies and traceability systems and to internet and informal market distribution of SF medical products.

Feedback from survey respondents on the most helpful activities was slightly different. Activities identified as very helpful were: recommendations for a strategic approach promoting interagency cooperation and collaboration with relevant stakeholders to respond to online distribution of SF medical products (80%); recommendations for health authorities responsible for detecting SF medical products and training materials and guidance documents (63%); and documents on existing technologies and track and trace models (50%) (see Fig. 12 below).

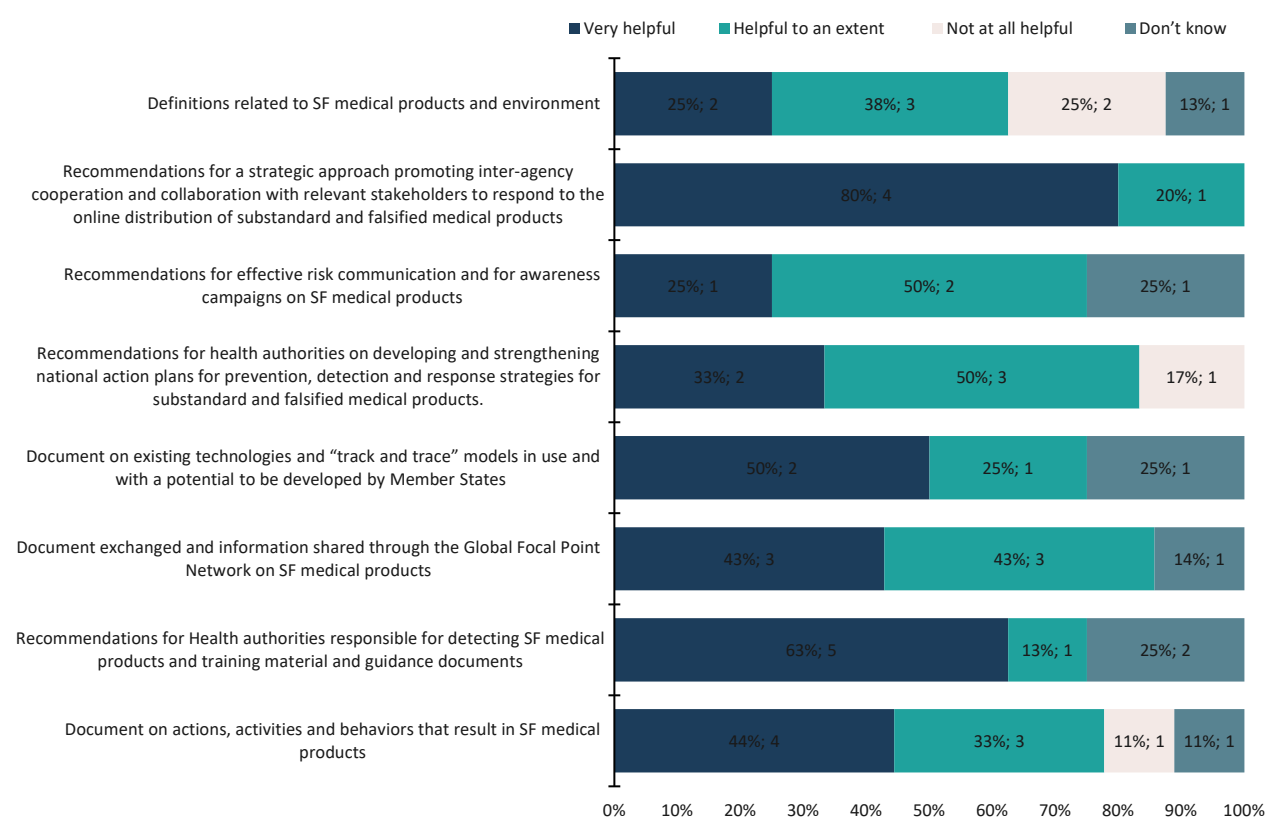
¹¹⁵ KII.s.

¹¹⁶ KII.s.

¹¹⁷ KII.s.

¹¹⁸ KII.s.

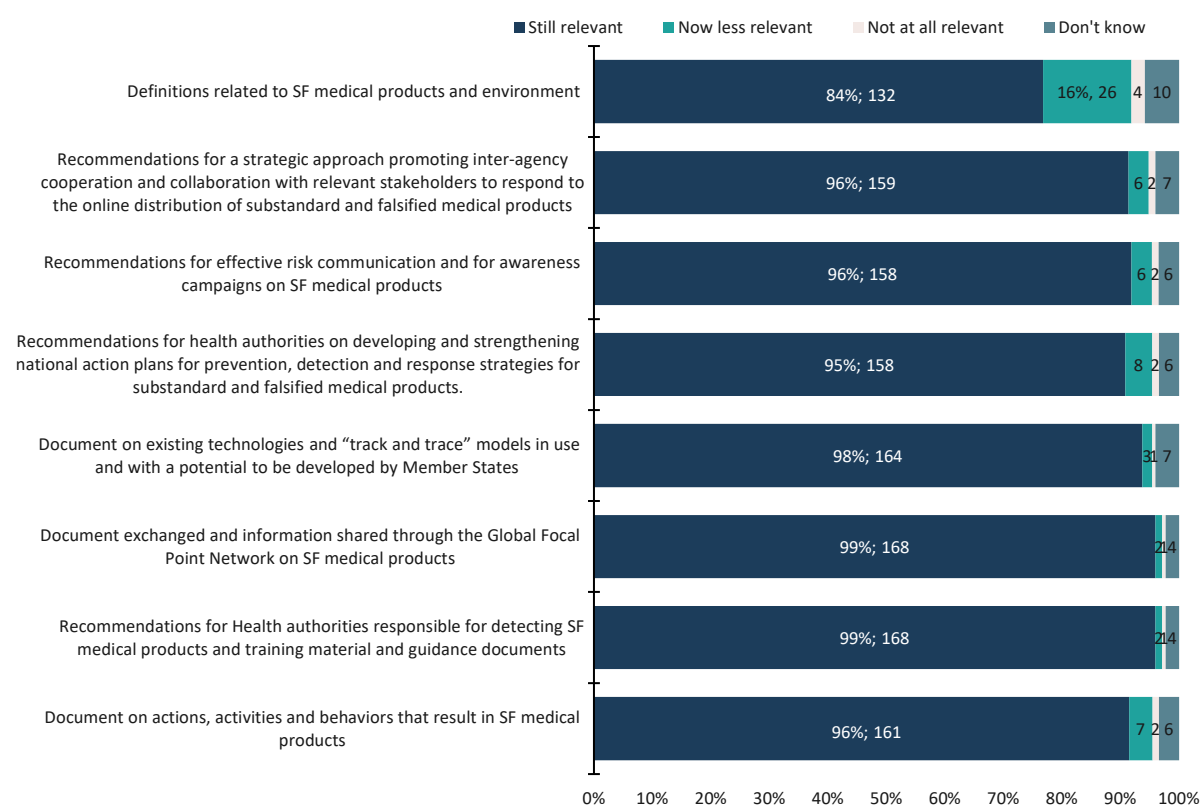
Fig. 12. Extent to which MSMech activities/products are considered helpful by survey respondents



Source: 2024 MSM FS Survey - Evaluation

Most survey respondents also broadly see the majority of MSMech activities and products as relevant in promoting the prevention, detection of and response to SF medical products (see Fig. 13 below), in particular recommendations for health authorities (99%) and information sharing through the Global FP Network (99%).

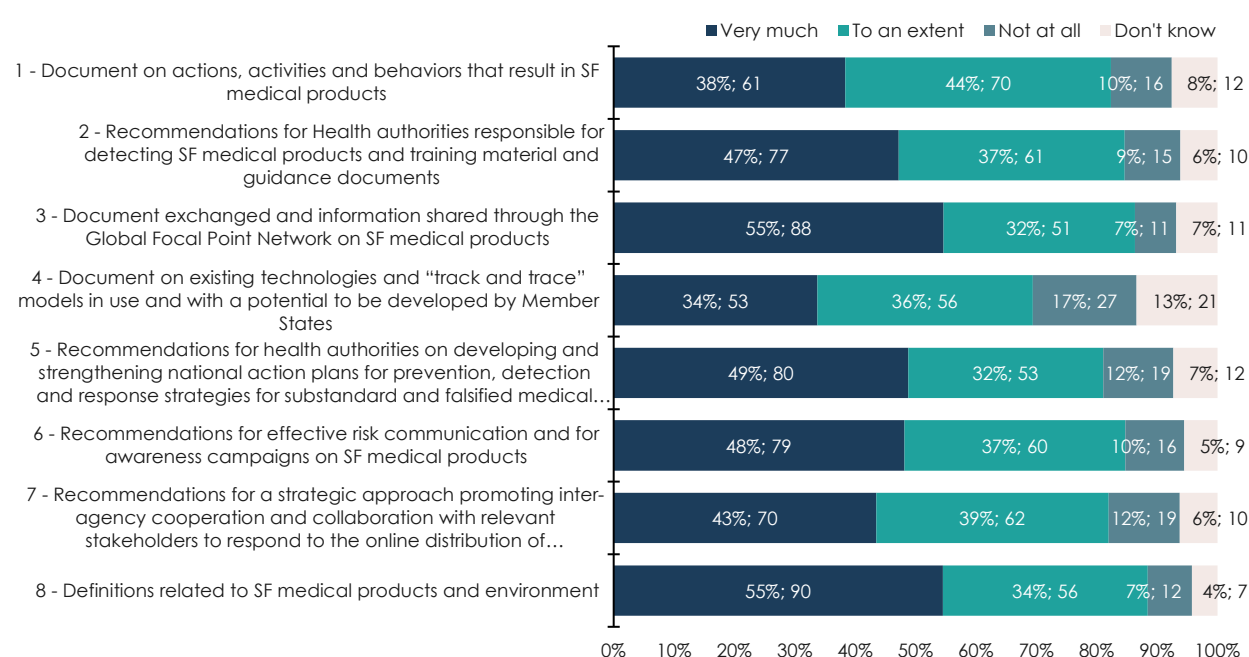
Fig. 13. Extent to which MSMech activities/products are considered relevant by survey respondents



Source: 2024 MSM FS Survey - Evaluation

Some MSMech activities/products are reported to have had a positive influence (on policy and practice) at country level, particularly definitions, guidelines and recommendations. Just over half (55%) of survey respondents reported that the definitions related to SF medical products, as well as documents exchanged and information shared through the Global FP Network, significantly influenced country-level policy and practice. Almost half of respondents (48%) reported that recommendations for health authorities on developing and strengthening NAPs have been very influential. Other activities are reported to have been less influential (see Fig. 14).

Fig. 14. Extent of influence of MSMech activities on country level policy and practice



Source: 2024 MSM FS Survey - Evaluation

In some areas of MSMech activity, pilot projects have been implemented or are being implemented in several countries. These include, for example, developing and strengthening NAPs, including regulatory system strengthening in line with WHO Global Benchmarking Tools in Burkina Faso, Gambia, Guinea, Nigeria and South Africa; and implementation of a compulsory element in the pharmacy school curriculum in Cameroon, Nigeria, Senegal, Tanzania and Uganda. Some interview respondents suggested that there is a need for funding to support pilot projects in countries that are interested in adopting traceability systems.

*"Implementation of traceability systems in many countries remains a challenge – while the MSMech has done well in terms of providing the foundations for traceability systems, traceability requires a lot of technology and expertise, it could perhaps do more to make technologies more affordable for countries with limited resources and to advocate with governments for adequate financing of traceability systems."*¹¹⁹

It is difficult to assess the impact of MSMech activities. Some stakeholders reported that they could not comment on the extent to which MSMech activities have had an impact at country level, due to the lack of clarity about the role of the MSMech at country level and how "success" is defined, and the absence of Key Performance Indicators and of evidence of effectiveness.¹²⁰

*"Those deliverables, have they been used by countries? Have they been implemented or not? Have they been found useful ultimately by regulators? I don't know. We don't really have any information on the impact of the MSMech activities."*¹²¹

¹¹⁹ KIIs.

¹²⁰ KIIs.

¹²¹ KIIs.

Others highlighted the need for follow-up to assess the extent to which MSMech recommendations and products are being adopted and implemented by countries.

It was reported both in stakeholder interviews and in the survey that more focus is required on some areas of activity, as given in Table 10 below.

Table 10. Suggestion for increasing focus on certain activities (stakeholder interviews and survey)

Areas of activity focus suggested by stakeholders during interviews that could be strengthened or implemented to help further reduce the presence and use of SF medical products	Areas of activity focus suggested by survey respondents that could be strengthened or implemented to help further reduce the presence and use of SF medical products
- Improving data quality and timeliness. Some key informants reported that data from some countries on the prevalence of SF medicines is out of date and suggested that the MSMech could do more to support these countries to collect more up-to-date data for an accurate picture of the situation.¹²² - Wider stakeholder engagement. The MSMech coordinates with relevant global and regional initiatives¹²³ but could do more to engage with external actors and to support effective global networking. Respondents also suggested that the MSMech could do more to foster a whole-of-government approach and collaboration between NRAs and other key country stakeholders to strengthen efforts to tackle SF medicines. - Capacity-building. Key informants highlighted the need for increased support for LMICs, including capacity-building, equipment and training for NRAs and quality control laboratories. - Public awareness campaigns are seen as vital to educate consumers about the risks of SF medical products, and this is an area where some Member States could be doing more. Some key informants suggested increased engagement with the media, civil society organizations and communities, as well as making better use of social media, which is often the main source of information for young people.¹²⁴ - Enforcement. Key informants also highlighted the need for stricter penalties for the production, distribution, and sale of SF medical products and for more effective enforcement in some countries. Whether this is a role for the MSMech requires consideration by Member States.	- Enhanced detection and reporting mechanisms and use of advanced technologies for monitoring and detecting SF medical products. - Strengthening international collaboration and regulatory frameworks to establish a unified approach to tackling SF medical products, in parallel with enhancing post-market surveillance and supply chain integrity, and implementing pharmaceutical serialization and track-and-trace systems. - Strengthening monitoring and regulation of online marketplaces and implementing strategies to combat online distribution. - Capacity-building, especially for national laboratories and NRAs, and training: “more efforts are required in capacity-building of NRAs, particularly those in low and middle-income countries”. - Public awareness campaigns. - Increased access to affordable medicines. - Greater community and stakeholder engagement.

Overall, Table 10 underscores the importance of a multifaceted strategy involving detection, regulation, capacity-building, public awareness and enforcement to effectively combat SF medical products.

EQ 2.2 To what extent is secretariat support adequate to facilitate MSMech functioning and reach? What areas of MSMech secretariat support work well or less well?

The available evidence indicates that MSMech secretariat support is adequate to facilitate MsMech functioning. There was a consensus among key informants that the secretariat has a clear value and provides good support to ensure the functioning of the MSMech. This includes coordinating and organizing meetings,

¹²² KIIs.

¹²³ For example, collaboration with UNODC, International Medical Device Regulators Forum, African Medicines Quality Forum and the Asia-Pacific Economic Cooperation.

¹²⁴ KIIs.

providing support and guidance to the working groups and making information available to Member States through the MSMech website, including resolutions and reports on meetings.

KIIs report that the MSMech secretariat has facilitated the establishment of shared MSMech objectives and a collaborative environment for collective efforts. It is also viewed as supportive and respectful of Member States. Interaction with the secretariat is reported to be positive. Country-level interviewees also highlighted the importance of collaboration with and support provided by WHO country offices.¹²⁵

“The (MSMech) secretariat performs a tremendous amount of work with a relatively small team of dedicated experts’. ‘They are very professional’.¹²⁶ ‘The mechanism can lean on the professionalism, dedication and expertise of the ISF teams’.¹²⁷ ‘What really contributes to keep the mechanism alive is the secretariat.’¹²⁸

“Communication by the secretariat is open and respectful of the country context and the sensitivity of some information.”¹²⁹

There are some concerns about the MSMech secretariat’s capacity and communication. Although the secretariat provides significant support for implementing working group activities, some key informants noted that the secretariat’s capacity is limited, with staff balancing WHO technical roles and support for the MSMech. Some suggested that the Secretariat could be more effective if it had additional human and financial resources.¹³⁰ The need for greater clarity on the secretariat’s roles and responsibilities was also highlighted, as well as more transparency about WHO resources and staff time allocated to managing and supporting the MSMech.¹³¹

Views about the secretariat’s communication across Member States vary, with some reporting that it provides timely feedback and useful and helpful advice; for example, secretariat support to some countries is said to have been excellent. However, others report that the secretariat is slow to respond.¹³² Some interviewees suggested that, with additional capacity, the secretariat could be more proactive in supporting global networking and in regularly engaging with national FPs.

EQ 2.3 Which aspects of the MSMech have worked well?

Many aspects of the MSMech that were identified by key informants as working well are in fact implemented by the WHO Secretariat. For example, the WHO Global Surveillance and Monitoring System for SF medical products (GSMS) and rapid alert system were reported as aspects of the MSMech that are working well, even though the GSMS is not an MSMech activity.¹³³ Similarly, survey respondents identified a range of areas where the MSMech has been effective – including the rapid alert system and timely dissemination of information, networking, support and training, development of tools and guidelines, regional and national cooperation, supportive leadership and resource availability – but many of these are primarily WHO activities.

The evaluation did identify several aspects of the MSMech that are seen as having worked well since 2017, based on feedback from key informants and document review, as described below.

¹²⁵ KIIs.

¹²⁶ KIIs.

¹²⁷ KIIs.

¹²⁸ KIIs.

¹²⁹ KIIs.

¹³⁰ KIIs.

¹³¹ KIIs.

¹³² KIIs.

¹³³ KIIs.

The MSMech has brought a global perspective and consensus on some key issues. This is invaluable as, without it, efforts to combat SF medicines would be limited to local or regional levels, missing broader interconnectedness at global, regional and country levels. There is also consensus that an early, and important, achievement of the MSMech was reaching agreement among Member States on the definition of SF medicines, which is crucial for global cooperation on SF medical products.

“A global approach is essential ... very few products are manufactured, distributed, and used within the same country or region.”¹³⁴

The MSMech has enhanced country interaction, collaboration and information sharing. It is seen as providing an important forum for countries to share experience and information and address common challenges. The MSMech has also improved communication and collaboration among Member States. The role played by the Global Network of FPs was also highlighted to be an important aspect of the MSMech.

“I think the focal points have been very effective, as without this, there wouldn’t have been the visibility of the system [GSMS].”¹³⁵

Specific examples of regional and country collaboration and information sharing that have been initiated by the secretariat or catalysed by the MSMech include regional meetings in Indonesia and Cambodia.¹³⁶ Examples include the activities of Working Group C, which have contributed to information sharing between African countries. Delegations from Botswana, Ghana and Uganda have visited Nigeria to learn from its experiences and to better understand how interventions related to traceability systems are implemented. Nigeria has also shared information on this with the National Regulatory Authority in South Africa.¹³⁷

“They have done well on risk communication to countries and encouraging information sharing on this between countries.”¹³⁸

Which aspects of the MSMech have worked less well?

Survey respondents reported aspects of the MSMech that have worked less well, including participation and engagement, communication, capacity-building, resource allocation, effective implementation and follow-up, development of technological tools, consideration of regional differences, and interagency cooperation. Some of these – for example, capacity-building and development of technological tools – are not the remit of the MSMech.¹³⁹ Stakeholders interviewed also highlighted similar issues, in particular engagement and participation of Member States, responsiveness and communication. Key aspects that have worked less well are discussed in more detail below.

Engagement and participation of Member States is suboptimal. While some Member States are active participants in the MSMech, others are not.¹⁴⁰ A key challenge is the relatively small number of Member States that engage in the working groups. Reasons cited for limited country-level participation include the low visibility of the MSMech, the perception that participation does not result in any tangible benefits for Member States, frequent turnover of nominated representatives and national FPs, lack of resources for travel to meetings and barriers to participation in virtual meetings associated with technology and time zones.¹⁴¹

¹³⁴ KIIs.

¹³⁵ KIIs.

¹³⁶ KIIs.

¹³⁷ KIIs.

¹³⁸ KIIs.

¹³⁹ As reported by survey respondents.

¹⁴⁰ KIIs.

¹⁴¹ KIIs.

Member State engagement is also influenced by the relevance, or perceived relevance, of MSMech activities to their regional and country context. Some interviewees reported that balancing diverse interests and priorities is a challenge,¹⁴² and some survey respondents suggested that the MSMech's strategies and recommendations do not adequately take account of regional differences and specific challenges and are sometimes disconnected from the practical realities of the fight against SF medicines faced by NRAs.

The MSMech has not been sufficiently responsive to all priority and emerging issues. Although the MSMech has been responsive to some emerging areas of interest, such as its increased focus on traceability,¹⁴³ some interviewees reported that it has not been sufficiently rapid in its response to urgent issues. Survey respondents also highlighted the need for a governance structure that allows more flexibility and responsiveness to emerging challenges. A working group has been established to address urgent emerging issues, but the criteria for selection of issues that it might address have not yet been defined.

*"It's vital to consider whether the MSMech's approach has evolved sufficiently to address the current landscape effectively."*¹⁴⁴

A range of priority issues were highlighted – including issues where Member State action is critical – that the MSMech is not currently addressing. These include the need to strengthen international collaboration and regulatory frameworks, an increased focus on the constituents of medicines and post-market testing and on online and informal markets,¹⁴⁵ and, in less well-resourced countries, the constituents of medicines and post-market testing and more effective laws and enforcement measures.

*"Access to quality medicines is the responsibility of every Member State. There needs to a strong message sent that they have an obligation to protect the interest of the countries that they're exporting to. I don't think that's been done very well. We need to have some real commitment – that's something that the MSMech can push from the top."*¹⁴⁶

*"In many countries NRAs and laboratories focus on the official supply chain – they only sample the good guys – so the picture presented is only half the story."*¹⁴⁷

Communication of information is not efficient or user friendly. The communication chain can be lengthy and sometimes inefficient,¹⁴⁸ highlighting the need for communication of information to be streamlined.¹⁴⁹

The WHO MedNet secured platform has provided MSMech members with access to recent discussions, relevant documents and other information. This has been replaced by a new SharePoint platform, but this was reported to be not yet fully available to Member States. There has been no progress as yet with facilitating or establishing a platform for communication, information sharing and networking among the Global FPs Network. Survey respondents highlighted the lack of a robust communication platform for national FPs as an issue.¹⁵⁰

A quarter of survey respondents (24%) report that there has been full implementation of the 2017 review recommendation to establish or enhance virtual fora and communication tools to disseminate information

¹⁴² KIIs.

¹⁴³ KIIs.

¹⁴⁴ KIIs.

¹⁴⁵ KIIs.

¹⁴⁶ KIIs.

¹⁴⁷ KIIs.

¹⁴⁸ KIIs.

¹⁴⁹ KIIs.

¹⁵⁰ This is identified as an action for the 2024–2025 biennium.

between the MSMech and Member States, but almost half (47%) report that there has only been partial implementation of this recommendation. Survey respondents also made suggestions for improving the effectiveness and efficiency of communication and information sharing, including linking the GSMS with other reporting mechanisms such as the World Green Economy Forum and with regional platforms such as the ASEAN Post Market Alert System.

The MSMech shares knowledge and guidance, making information available via the WHO MSMech website (17). There were requests to improve the website and access to and dissemination of information. For example, at country level it was reported that there was limited knowledge of MSMech tools and technologies and that more could be done to ensure relevant stakeholders are aware of these.¹⁵¹

“The website is not very comprehensive. The working groups have elaborated many good materials, but they are not easy to find. I think that perhaps Member States do not use these and other materials because they are not easily available.”¹⁵²

Other suggestions to improve MSMech communication and sharing of updates, best practices and lessons included producing short accessible reports and policy briefs for decision makers,¹⁵³ participation in international and regional conferences and meetings, targeted outreach and networking, making use of the media, online platforms and professional networks to share information, collaborating with NGOs, research institutions and other key stakeholders and establishing an accessible online portal with data and resources.

EQ 2.4 What strategies would enhance national engagement in MSMech discussions and activities?

Strategies suggested by the evaluation team to enhance Member State engagement¹⁵⁴ are given in Table 11.

Table 11. Stakeholders’ suggestions to enhance Member State engagement

Suggestions by interviewed stakeholders	Suggestions by survey respondents
- Identifying and addressing differing priorities and interests among Member States. - Increasing the visibility of the MSMech and Member State awareness of its role and the potential benefits of participation, including through improving reporting on and communication of its activities and outcomes: “Demonstrating success and the practical outcomes of the	- Including heads of state or ministers in the governance structure. - Increasing the budget to support engagement of Member States. - More proactive advocacy for the MSMech in global and regional forums. - Holding more regular working group meetings and providing orientation for new members.

¹⁵¹ Klls.

¹⁵² Klls.

¹⁵³ Klls.

¹⁵⁴ These suggestions have been considered by the evaluation team in developing the evaluation recommendations.

mechanism's work is critical for engagement.”¹⁵⁵

- Encouraging Member States to nominate participants who understand and are familiar with the issue of SF medical products.
- Orientating MSMech national FPs and other participants on the MSMech, roles and responsibilities and providing FPs with regular opportunities for interaction and capacity-building.
- Strengthening efforts to engage Member States at regional level through WHO regional offices, regional meetings and regional bodies.
- Mobilizing resources to support Member State participation and the effective functioning of MSMech working groups and to support Member States to implement working group outputs.

2.3 Efficiency

EQ3: How efficiently¹⁵⁶ has the MSMech used the resources at its disposal?

Summary of key findings 3: It is difficult to fully ascertain efficiency in the absence of systematic monitoring and evaluation (some progress has been made in 2024, with the development of outcome level indicators) and budgetary detail. At the same time, there is no evidence of major visible inefficiencies in how the Member State mechanism uses its resources.

MSMech resources have increased over the evaluation period, especially for working group activities. However, they come from a very narrow donor base (and also involve some restrictions in their use due to being earmarked). Over 98% of funding (flowing through WHO, largely via the RPQ Department) comes from three donors, with little sign of the broad funding which was envisaged from all Member States in 2012 – although some contribute indirectly, e.g. through meeting attendance. Key informants view activity spend as well-targeted and the secretariat's work as efficient. While meeting costs are not out of line with comparable events, technology has not been fully embraced and the low participation rate also represents reduced efficiency. But less obvious inefficiencies may exist, due to there being little M&E of activities and outputs over

¹⁵⁵ Kils.

¹⁵⁶ Efficiency is interpreted in this report as the extent to which appropriate outputs are obtained given the inputs used.

the period. There is also little collaboration with other SF medical products stakeholders (e.g. NSAs or private sector entities that have both data on SF medical products and channels for public information dissemination) to create synergies and avoid duplication, which could potentially have hindered maximizing on the efficiency/effectiveness of the work done by the MSMech. Most MSMech members are unfamiliar with any financial information related to MSMech. The secretariat does not have clearly defined comprehensive budget information for the MSMech.

Note: In the absence of any agreed MSMech-specific budget, only approximations are possible and only for certain cost centres. In particular, while financial/cost data is available for working group activities¹⁵⁷ and for MSMech meetings it is more challenging to identify costs for the MSMech secretariat and other WHO staff time and activities that are also related to the work of the MSMech. The evaluation team has made an approximation of the latter by applying an estimate of the proportion of the ISF team's staff time devoted to supporting the MSMech work and multiplying this by the ISF's total activity budget (as data on staff costs was not available). It is recognized that this approximation could well under-estimate the actual total WHO staff and activity costs that support the work of the mechanism. Other approaches could be possible.

EQ3.1 How have MSMech resources and their sources evolved? Are there any resource gaps and have they significantly evolved?

Financial resources to directly support the work and functioning of the MSMech which are measurable – working group activities and MSMech meetings – have increased substantially over the period within the scope of this evaluation. Expenditures increased from US\$ 106 000 in 2018 to US\$ 322 000 in 2023, as shown in Table 12.

In addition, an estimate of MSMech secretariat costs in support of the MSMech was made, as also shown in Table 12.

The aggregate has varied significantly over the evaluation period, rising or falling by more than 30% in three of the six years. It increased from US\$ 329,000 in 2018 to US\$ 515,000 in 2023 (an increase of 64%). This does not include indirect costs, such as those borne by Member States in arranging for delegates to attend MSMech meetings or in collaborating with the implementation of working group activities.¹⁵⁸

Table 12. Estimated total expenditures for the MSMech – rounded (US\$), 2018–2023

	2018	2019	2020	2021	2022	2023
Total direct MSMech expenditure: WGs and meetings (activity)	106 000	146 000	183 000	202 000	170 000	322 000
Change over previous year		38%	25%	10%	-16%	90%
Estimated MSMech secretariat expenditure (activity)	223 000	224 000	327 000	327 000	193 000	193 000
Change over previous year		0.4	46%	0	-41%	0
Total MSMech expenditures	329 000	370 000	510 000	529 000	363 000	515 000
Change over previous year		12%	38%	4%	-31%	42%

Source: Evaluation team analysis based on secretariat data

¹⁵⁷ This includes only direct cost for working group activities, and not ISF staff support, for example, hiring a consultant for the working group.

¹⁵⁸ No data were available for this.

Expenditures noted above are composed of two direct cost components and one estimate of the ISF activity budget. Direct costs are: 1) for MSMech meetings (annual) and 2) for the MSMech working group activities. The estimate, component 3, is of the ISF staff time for the MSMech applied to the ISF's activity budget.

Component 1: MSMech working group activities. While the secretariat presents data on the funding of working group activities at steering committee meetings, these are not included in the MSMech annual report nor in the “Secretariat activities and budget to implement the workplan of the Member State mechanism”, produced at the plenary meeting and available on the MSMech website (for 2023, see (18)) or any other document available there.

Working Group Activity funding has increased markedly, especially since 2022. In 2018, expenditure was only on a management information platform (with similar payments of around US\$ 2000 every year). Details of how the expenditure has evolved for Working Group activities is given in Table 13.

Table 13. Evolution of expenditures for Working Group activities, 2019–2024

Year	Amount and activities
2019	US\$ 13 000 for translation for Activity E (risk communication and awareness in Member States) and US\$ 14 000 for development of an advocacy brochure.
2020	US\$ 28 000 for Activity C (spreading use of detection technology and traceability models), US\$ 13 000 for Activity E (risk communication), US\$ 24 500 for Activity G (medical products in transit) and US\$ 18 000 for video, brochure and associated interpretation.
2021	US\$ 26 000 was spent on document translation, layout and consulting for Activity C, US\$ 27 000 for Activity G (products in transit) and US\$ 28 000 for Activity H (internet distribution).
2022 and 2023	US\$ 80 000 of consultancy expenditure for Activity A (strengthening NRAs), US\$ 58 000 for Activity B (Global FP Network) and US\$ 101 000 for Activity H (internet distribution). The marked increase in working group funding in 2022 likely coincided with substantial new donor contributions (see below).
2024	US\$ 200 000 has been earmarked for the current evaluation. Activities D (leveraging stakeholders), F (excipients), J (traceability) and I (emergencies) did not receive any allocations over the period 2017–2024.

Source: WHO secretariat data.

Component 2: MSMech meetings. The MSM secretariat provided data on expenditures related to supporting the organization and conduct of the annual plenary meetings and the two annual steering committee meetings (all held in Geneva). Working group meetings tend to be online only. Overall expenditure per year is approximately US\$ 115 000, with small fluctuations from year to year (approximately 10%).

Overall, the cost breakdown includes:

- the annual plenary/steering committee meetings, which represent 70% to nearly 80% of all annual meeting costs;
- interpretation costs for all meetings during the year, which are the major cost centre (varying between 60% and ~75%)
- remaining costs to cover document editing and translation for the plenary meeting (~20% on average of annual meeting costs), facility and IT costs. Travel costs for LMICs began to be supported in 2022 (approximately 12–15% of total annual meeting costs).

Component 3: Other MSMech secretariat support for the MSMech. Table 14 shows how ISF's overall activity budget has evolved by biennium. For example, the budget increased by 47% from 2018–2019 and then decreased by 41% from 2020–2021 to 2022–2023.

Table 14. ISF activity budget by biennium (US\$)

Biennium	Budget	Change
2018–2019	996 318	
2020–2021	2 919 382	+47%
2022–2023	1 724 292	-41%

Source: MSMech secretariat.

In addition to direct financial support provided for the work of the MSMech noted above, WHO allocates in-kind staff time as part of the MSMech secretariat (ISF unit) and from other departments.¹⁵⁹ A greater investment by WHO is in the form of activity and staff resources that support a range of activities to implement workstreams related to following up on MSMech recommendations/advice and/or the themes of MSMech working groups.

Examples include providing technical support for countries, WHO's normative work, operation of the GSMS, technical support for capacity-building for NRAs, etc. Regarding MSMech secretariat staff, a precise estimate of the amount of time devoted to the MSMech is not possible. However, with input from the ISF Unit, the evaluation team estimated that approximately 22.4% (unweighted average¹⁶⁰) of the time of the currently seven ISF staff members (annualized) was spent on MSMech related work. This percentage was used to broadly estimate the contribution of the ISF overall activity budget to the cost of the MSMech secretariat, as shown in Table 16.

Table 16. Estimated use of ISF activity budget for MSMech (US\$)

	2018	2019	2020	2021	2022	2023
ISF activity budget - annualized	996 318	996 318	1 459 691	1 459 691	862 146	862 146
Estimate of ISF activity budget for MSMech (per staff time 22.4%)	223 175	223 175	326 971	326 971	193 121	193 121

Source: MSMech secretariat.

Source of funding

The main funding sources supporting the MSMech, via WHO, are a small number of Member States and other donors which make financial contributions.

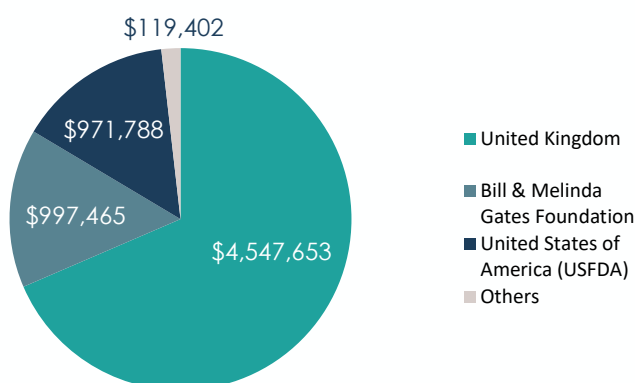
It is challenging to precisely identify donors' contributions to the MSMech as they normally do not explicitly earmark funds for the MSMech, but rather to broader WHO work involving SF medical products and related issues. According to MSMech Secretariat data, US\$ 6 636 308 was contributed for activities for the WHO ISF team over the period covered by the evaluation. About 69% of funds came from the UK, with a further 15% from each of the US Food and Drug Administration and the Bill and Melinda Gates Foundation. Less than 2%

¹⁵⁹ Such as the Legal Office, the Department for Governing Bodies and specific services as needed, e.g. the IT department.

¹⁶⁰ The evaluation team has not weighted this by salary due to a lack of information on remuneration.

came from other donors, including all Member States in their capacity as MSMech members. The need for further resource mobilization was noted in the MSMech's *Update on the activities and budget to implement the workplan of the Member State mechanism (19)*

Fig. 17. Donors to WHO ISF (2018–2023)



Source: MSMech secretariat

Some donors place restrictions on the use of their funds, either in terms of activities or countries (earmarked funding).

Donors interviewed confirmed that they would be willing to provide more funding if there were better evidence of results.¹⁶¹

The WHA resolution creating the MSMech urged Member States to provide “sufficient financial resources for the mechanism”. Some Member States do contribute by covering travel costs for delegates attending MSMech meetings and through their human resource inputs to activities. However, Member States funding has not translated into direct funding and this has been a longstanding problem, first raised in the 2017 review.¹⁶²

Funding gaps are not explicitly visible because the MSMech adapts its activities (especially for working groups) to available funds on an annual basis. To note that there are some activities that take place but do not require financial resources or that the WHO Secretariat is supporting. Key informants observed that more could be done by each working group if additional funds were available, as limited resources influence both their efficiency and effectiveness.¹⁶³ Based on the staff time estimates above, the MSMech secretariat is only able to provide around 1.5 full time equivalent (distributed across several staff members) to support the MSMech and to carry out a range of duties, including some that should be the responsibility of Member States (see the section on Relevance, above).

However, the MSMech’s limited collaboration with external stakeholders (see below) does not appear to be due to resource constraints.¹⁶⁴

¹⁶¹ KIIs.

¹⁶² This recommended that “The mechanism should support secretariat efforts to secure additional resources from Member States and the international donor community”. The latter part has been more successfully addressed than the former.

¹⁶³ KIIs.

¹⁶⁴ Evaluation team judgement.

EQ3.2 To what extent have the resources been used appropriately? Has there been unnecessary use of resources, duplication/complementarity (i.e. synergy), timeliness of MSMech responses?

The MSMech uses resources (made available by WHO) to implement working group activities, organize and conduct meetings and for analytical support (e.g. by consultants), as discussed below. The WHO MSMech secretariat devotes staff time, which is supported by WHO's overall programmatic budget and operational planning and relies on the availability of voluntary contributions. Indirect or "in-kind" support is also provided by WHO for activities that support the overall programmatic areas covered by the MSMech. Thus, overall the limited existing resources have been used efficiently, but there is a need for additional resources to fulfil the expectations of the MSMech as defined by the WHA resolution and subsequent MSMech plans.

Use of resources to implement working group activities: Key informants active in working groups generally report that use of funds associated with specific activities has been appropriate, although one highlighted overlap between the actions of different working groups.¹⁶⁵ Some also noted that working groups are only gradually taking advantage of opportunities to analyse data (including from the GSMS) and to use it to inform and drive actions.¹⁶⁶ But it was notable that few outside of the MSMech secretariat had knowledge of what the expenditures were, how they had been decided on or what the alternatives might have been. Some key informants commented on the lack of transparent funding and performance measurement of activities, suggesting that this may reduce efficiency.¹⁶⁷ Many key informants pointed out that efficiency can vary significantly depending on the individuals chairing working groups or indeed the MSMech itself.¹⁶⁸

There may be scope for greater efficiencies in the MSMech's geographical focus, particularly in balancing an equity focus on countries with the greatest needs and with lower resources and/or capacity, as at present these are sometimes driven by donor requirements, existence/lack of Member State interest or greatest need (e.g. in Africa – although this is, of course, also a valid alternative criterion).¹⁶⁹

Use of resources to conduct meetings: Key informants highlighted a few time inefficiencies related to MSMech meetings. These include online access not being as effective as in-person attendance for the quality of discussion and relationship-building, as participation and attention are not always as high with online attendance versus face-to-face;¹⁷⁰ and timings for a Geneva meeting being challenging for the Americas and eastern Asia. The efficiency of MSMech meetings is also influenced by the level of Member State participation. Some reported that meetings might not need to be as frequent as they currently are (e.g. three steering committee meetings annually);¹⁷¹ others said the meeting format does not encourage accountability, debate, agreed action points or follow-up. Instead, it offers mainly unstructured narrative and unchallenged working group updates.¹⁷²

Table 18 below shows a fluctuating number of attendees per plenary meeting, with less than half of all Member States (194) in attendance at any given meeting.¹⁷³

Table 14. MSMech plenary meeting attendance

¹⁶⁵ KII.

¹⁶⁶ KII.

¹⁶⁷ KII.

¹⁶⁸ KII.

¹⁶⁹ KII.

¹⁷⁰ KII.

¹⁷¹ KII.

¹⁷² KII.

¹⁷³ Based on meeting reports.

Year	Number of Member States in attendance	Notes
2018	53	In-person only ¹⁷⁴
2019	52	In-person only
2020	82	Online only
2021	70	Online only
2022	66	Hybrid: in-person and online
2023	54	Hybrid: in-person and online

Source: MSMech secretariat

The limited attendance at plenaries relative to the total MSMech membership is to an extent indicative of the costs and logistics of travel to Geneva, combined with infrastructure challenges, such as unreliable internet access.¹⁷⁵ The advent of online participation from 2020 represents one form of technological innovation that may serve meetings, but there may be other opportunities.¹⁷⁶ It is also clear that some of the reduced attendance is due to lack of interest, evidenced by the fact that some high-income countries do not attend plenaries. It should be noted that the 2017 review made two recommendations that the MSMech should “encourage active engagement of more Member States in the work of the mechanism” and “expand the number of Member States that are involved in the process”, neither of which seems so far to have been effectively addressed.

It is difficult to find appropriate Member State comparators for the meeting costs referred to above. The evaluation team explored one possible parallel example for meeting costs in a UN agency (while noting that there are also differences). This example is the UN Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, which the UN also convenes in Geneva and which is open to all countries. A rough comparison of some costs from this Conference’s 2023 budget is provided in Table 19.

Table 15. Estimated meeting costs for the UN Biological Weapons Conference and MSMech

Item	Budget (US\$) / working day (2023)	Comparison with MSMech / working day (2020–2023) (US\$)
Interpretation and meeting servicing	18 000	24 000 (plenary)
Documentation (translation, reproduction, distribution)	7 000	12 000 (plenary)
IT and audio support	800	500 (plenary and steering committees)

Note: No travel costs data are available for the UN conference.

¹⁷⁴ For 2018 and 2019, participation included one regional economic integration organization.

¹⁷⁵ KIIs.

¹⁷⁶ Evaluation team’s judgement.

The comparison suggests that MSMech meeting costs are generally in line with those of one other UN comparable entity, although interpretation, translation and other such costs are higher (both use all six UN languages), which could well reflect differences in agencies' organizational and cost contexts.

Use of resources for operationalizing the MSMech secretariat: Resources appear to be well used within the secretariat, in that key informants universally saw staff members providing valuable support and outputs, always on time and to schedule and of good quality. However, currently secretariat reporting to the MSMech on anticipated budgetary envelopes, identified planned resource needs and expenditures is lacking and can be improved.

Timeliness

WHO, and by association the MSMech, was criticized over the timeliness of its response to the diethylene glycol/ethylene glycol contamination emergency (see the sections on Context and Relevance). However, this was largely out of MSMech's control given its focus and commitment to discussions and recommendations only at one annual plenary meeting and an uneven openness on the part of Member States to publicize and act upon incidents. Steps have also been taken to improve response times (see Relevance).

As discussed in the Effectiveness section, WHO procedures (such as contracting, which can be slow) have been viewed by some as reducing efficiency, while recognizing there may be various factors influencing a given situation.¹⁷⁷ While WHO aids efficiency at times – in that regional and country offices can assist in interactions with Member States and in disseminating information between them¹⁷⁸ – some key informants saw the need to work through regional and national WHO offices as affecting timeliness.¹⁷⁹

EQ 3.3 Is the MSMech's M&E adequate for performance measurement?

The M&E system has improved in the current biennium but is not yet adequate for robust performance measurement. However, at this time, a ToC does not exist nor does a results framework to define the work and anticipated results of the MSMech, from which an M&E framework derives.

During the evaluated period, the MSMech has lacked formal M&E processes, beyond brief verbal/written narration of working group actions at meetings. This has tended to be activity-centric and not subject to challenge.¹⁸⁰

However, there has been a gradual move towards improving MSMech performance measurement. For the first time, for 2024–2025, expected outcomes are stated for each working group in biennial plans (see (20)Annex 1, p. 8.); there are no activity or output indicators yet. Each working group also works to at least one metric/success indicator, although in some cases these lack detail. This is seen as a positive step and welcomed as a move towards measuring the progress of working groups.¹⁸¹ Overall, a ToC and results framework for the MSMech would contribute to enhancing defining, documenting and reporting on the mechanism's work and results. There are calls for more independent assessment of progress rather than having members assess their own achievements.¹⁸²

¹⁷⁷ Klls.

¹⁷⁸ Klls.

¹⁷⁹ Klls.

¹⁸⁰ Klls.

¹⁸¹ Klls.

¹⁸² Klls.

2.4 Coherence

EQ4: How does the MSMech ensure coherence and continue to bring value to address SF medical products in relation to other agencies and their approaches with a similar mandate?

Summary of key findings 4: Externally the MSMech model has good potential for ensuring coherence via collaboration globally, regionally, nationally and between working groups, but this is not yet fully realized.

Externally, good harmonization has been achieved on definitions across a wide range of SF medicine stakeholders as well as ensuring alignment with WHO guidelines. However, there has also been a lack of sufficient engagement with international organizations and non-state actors. Engagement with non-state actors and other stakeholders (in line with FENSA) is deemed important to ensure the coherence of the mechanism's work.

The Member State mechanism could expand consideration of greater SF and multisectoral issues, where relevant, such as antimicrobial resistance and animal, agricultural and environmental health (as included in the One Health agenda).

The Member State mechanism's secretariat links well with WHO departments and offices, although coordination and information sharing could be further developed in some cases to support the work of the mechanism.

EQ4.1 How does the MSMech align with approaches of other organizations, including multilateral/bilateral and Non-State Actors (NSAs), which are also active in the field of SF medical products?

The MSMech aligns with existing WHO guidance and considers the work of other relevant organizations, such as UNODC and the World Custom Organization. Other organizations (see table 21) have also aligned their work with the MSMech, particularly around the MSMech's definition of these products (21).¹⁸³

The MSMech secretariat has coordinated with some external entities, such as the World Organization for Animal Health, on antimicrobial resistance, including the detection of substandard antibiotics,¹⁸⁴ and the World Custom Organization and UNODC, on a collaboration and sharing of information concerning falsified medical products (14). The MSMech steering committee has also recognized the importance for the secretariat and for Member States of engaging in regional, cross-regional and global Member States' initiatives (22).

However, the MSMech,¹⁸⁵ does not have a wide range of collaborations with other international organizations, and its collaboration with NSAs has been limited. There is, for example, no mention of any NSAs or other international organizations in the list of participants for plenary meetings or meetings of the steering committee,¹⁸⁶ although some external actors have been able to participate in the work done by MSMech

¹⁸³ KIIs

¹⁸⁴ WHO, June 2023. *Note for the record - Meeting of the steering committee of the Member State mechanism on substandard and falsified medical products*. Geneva.

¹⁸⁵ KIIs.

¹⁸⁶ Cf. all lists of participants and steering committee notes for records.

working groups.¹⁸⁷ To date, this reflects WHO's rules for entities such as the MSMech. Overall, many key informants report that there is significant untapped potential for external collaborations,¹⁸⁸ whether with international organizations or NSAs¹⁸⁹ (while noting that such interactions are governed by FESNA and relevant WHO rules or procedures).

When the MSMech does interact with external stakeholders, it primarily engages with multilateral governmental organizations rather than NSAs or the private sector, and it remains unclear whether these relationships are between WHO and these organizations, or between the MSMech and these organizations,¹⁹⁰ as relevant to the established roles and mandates for WHO and for the MSMech. For instance, when developing trainings or guidance on SF medical products for customs officers, UNODC works with WHO ISF, not the MSMech.¹⁹¹ However, the will to engage is there: the last four MSMech plenary meetings included dedicated time for discussing engagement with external mechanisms, platforms and stakeholders (16, 18, 19, 24). The steering committee was also in favour of continuing to participate in or observe relevant organizations and initiatives, such as UNODC and the MEDICRIME Convention, but there is no information available on the MSMech's participation or observer status.¹⁹²

Several UN agencies and global health initiatives, such as UNODC¹⁹³ and US Pharmacopeia,¹⁹⁴ voiced their desire to work or collaborate more with the MSMech, to avoid working in silos and to also share relevant information that they might have. The MSMech also recognizes that there is potential for stronger collaborations with Interpol, the Global Fund and Gavi.¹⁹⁵

Relationships with large international organizations can sometimes be complicated due to differing scopes of work and mandates. The MSMech would benefit from collaboration with organizations that focus on areas such as border control (e.g. World Customs Organization, Interpol), which remains essential for addressing SF medical products.¹⁹⁶ Despite the exclusion of intellectual property from the MSMech's mandate, collaboration with organizations working on intellectual property, such as the World Trade Organization, could still benefit from the MSMech's expertise on SF medical products. This is supported by existing agreements between NRAs and international organizations (e.g. UNODC and Brazil's NRA, the IVIMA).¹⁹⁷

The MSMech is least engaged with NSAs such as NGOs, patients' associations and the pharmaceutical industry and wholesalers.¹⁹⁸ Some engagement occurs with academia, though this is generally the secretariat conducting essentially ISF WHO work. Since 2017, there have been some efforts to include NSAs in working groups, but their integration and inputs into the MSMech's work are limited. They can be invited to collaborate or be consulted on specific topics but they are not permitted as observers in high-level meetings.¹⁹⁹

The inclusion of NSAs is likely to be crucial to the realization of the MSMech's objectives. For instance, in the case of internet sales of medicines, countries need to cooperate with companies that are often outside of their jurisdiction to remove falsified products from their listings, since they cannot enforce it by law (e.g. eBay or

¹⁸⁷ WHO, 2017. *Member State mechanism on SFMC - Meeting of the steering committee* 29–30 March 2017: Note for the record.

¹⁸⁸ KIIs.

¹⁸⁹ KIIs.

¹⁹⁰ KIIs.

¹⁹¹ KIIs.

¹⁹² WHO, 2020. *Member State mechanism on substandard and falsified (SF) medical products - Meeting of the steering committee*, 24–25 June 2020: Draft note for the record.

¹⁹³ KIIs.

¹⁹⁴ KIIs.

¹⁹⁵ KIIs.

¹⁹⁶ KIIs.

¹⁹⁷ Government of Colombia, Ministry of Health, INVIMA Institute (2018) *WHO Member State mechanism on substandard and falsified (SF) medical products, plenary session* [PowerPoint presentation]. (Accessed: 20 May 2024).

¹⁹⁸ KIIs.

¹⁹⁹ KIIs.

Amazon).²⁰⁰ NSA participation in the MSMech process would have to respect WHO's FENSA framework (6), which lists the overall principles, benefits, risks and rules of engagement with NSAs. Currently, this legal framework does not prevent the MSMech from building a closer relationship with NSAs.²⁰¹

One other perceived challenge to the wider inclusion of NSAs is the governing structure²⁰² -- options for broadening engagement would have to account for WHO rules, FENSA requirements and, if change is desired, WHA review and decisions. Some Member States are also worried about how their information would be used if shared to a wider audience outside other Member States.

Even though there is appetite for interaction with external stakeholders,²⁰³ the current governance structure does not allow for NSAs to participate more meaningfully in meetings. External members can only participate on specific agenda items. For instance, during the October 2018 steering committee meeting, the chairman of the Global Steering Committee for Quality Assurance of Health Products presented on this initiative and the participation of WHO. The chairman only accessed the room for the presentation and left as soon as his presentation/discussion was over (3). In 2019, the steering committee supported the invitation of big platforms, including Facebook, Google, Amazon and eBay, to share information and views.²⁰⁴ The evaluation team found no information about whether or not this happened.

However – and in addition to the collaboration between Member States and NSAs in working groups²⁰⁵ – some initiatives have been implemented to increase NSA participation. Side meetings have occasionally been organized to discuss technical subjects, and NSAs with relevant expertise were invited.²⁰⁶

NSAs are generally not seeking full inclusion in the MSMech. Rather, most are seeking the opportunity to share their findings and technical expertise to increase Member States' awareness of certain issues.²⁰⁷ Some would also like to stay updated on the MSMech's work, so as to continue contributing their expertise where needed.²⁰⁸ However, the current structure and WHO standard rules of engagement – in particular the high level of scrutiny that protects WHO from possible conflicts of interest and ensures that organizations correspond to the rules of due diligence (which some key informants noted can be administratively demanding)²⁰⁹ – make it challenging for NSAs to engage with the MSMech.

²⁰⁰ KIIs.

²⁰¹ KIIs.

²⁰² KIIs.

²⁰³ KIIs.

²⁰⁴ WHO. (2019). *WHO Member State mechanism on substandard and falsified (SF) medical products, steering committee virtual meeting*, 24–25 June, Geneva.

²⁰⁵ KIIs.

²⁰⁶ KIIs.

²⁰⁷ KIIs.

²⁰⁸ KIIs.

²⁰⁹ KIIs.

Table 16. Summary of current provisions for stakeholder engagement in the Member State mechanism

Type of engagement open to non-state actors	Is this type of engagement currently provided for in the mechanism's governance structure under WHA65.19?	The means by which engagement is enabled
Attending meetings of the mechanism to consult on specific topics	Yes	Upon invitation from the chair of the mechanism and if no objection to proposal at the start of each meeting.
Attending meetings of the steering committee to consult on specific topics	Yes	Upon invitation from the chair of the mechanism and if no objection to proposal at the start of each meeting.
Attending meetings of the working group to consult on specific topics	Yes	Upon invitation from the respective working group chair and if no objection to proposal at the start of each meeting.
Standing invitation to observe mechanism meetings	No	By decision of the WHA
Standing invitation to observe steering committee meetings	No	By decision of the WHA
Standing invitation to observe working group meetings	No	By decision of the WHA

Source: Document A/MSM/12/8.

This lack of engagement with non-state stakeholders can result in the MSMech missing out on expertise and technical knowledge.²¹⁰ It also creates issues regarding the comprehensiveness and effectiveness of the work done for certain defined issues, in particular when access to knowledge and expertise is limited.²¹¹ For example, some Member States would benefit from additional support supported by the MSMech and WHO to implement regulations and test medical products.²¹² Failing to engage with external stakeholders (especially the media) also results in reduced visibility of the MSMech, adversely affecting public awareness of its work²¹³ as well as funding opportunities. Expanding involvement of NSAs can bring new opportunities. For example, as part of its activity to develop guidance on selection of detection technologies, the MSMech published a questionnaire without realizing that the University of Oxford, which is working on a similar initiative, already had a questionnaire in circulation. Greater up-front collaboration could lead to greater effectiveness.²¹⁴ Several key informants referred to the vast information on SF medical products and potential capacities of the pharmaceutical industry, with which the MSMech does not currently engage.²¹⁵ In another example shared by key informants, some NGOs and academic institutions could deliver trainings that would be designed or shared by the MSMech.²¹⁶

²¹⁰ KII.

²¹¹ KII.

²¹² KII.

²¹³ KII.

²¹⁴ KII.

²¹⁵ KII.

²¹⁶ KII.

Donors are also not engaged in the MSMech beyond the provision of funds. Apart from their donor role, some entities such as the Bill and Melinda Gates Foundation can also contribute their experience supporting countries to develop NAPs (as relevant to broader engagement opportunities),²¹⁷ which would also benefit the MSMech's work.

Over the years, the MSMech has succeeded in developing definitions of SF medical products that were then used by many international stakeholders, not only in the health sector. Table 19 presents a non-exhaustive list of stakeholders that adopted the definitions developed by the MSMech.

Table 21 17Non-exhaustive list of stakeholders using the MSMech definition of SF medical products

Type	Names
Governmental organizations	International
	- Interpol (23) - UNODC (24) (worked with WHO, but not MSMech, on SF medical products subject) - IAP – The interacademy partnership (25)
	Regional
	- the European Medical Agency (26) - the Africa Medicines Agency (27) - European Union – Medisafe project (28)
Health professional organizations	National
	- National health agencies (have been invited to participate in MSMech working groups) - National medical academies (IAP) (29)
	International
	- International Council of Nurses (30) - International Pharmaceutical Student Federation (31) - International Pharmaceutical Federation (32, 33) - World Medical Association (but did not change “counterfeit” for “falsified”) (34) - World Health Professions Alliance (35) - ASOP Global – Alliance for Safe Online Pharmacies (35) (has been invited to participate in MSMech working groups)
Donors	- Bill and Melinda Gates Foundation (36) - The Global Fund (37) - USAID (38) - IFPW Foundation (39)
	- International Federation of Pharmaceutical Manufacturers and Associations (40) - European Federation of Pharmaceutical Industries and Associations (41) - International Federation of Pharmaceutical Wholesalers (42)
	- Sanofi (43) - Pfizer; BESAFE Project with Johns Hopkins University (44) - GSK (45) - Legitscript (46)
	- Médecins Sans Frontières (47) - US Pharmacopeia (48) (has been invited to participate in MSMech working groups) - Fight the Fakes Alliance (49) - Global Pharma Health Fund; GPHF-Minilab (50) - Centre for Social Impact and Philanthropy (51) (has been invited to participate in MSMech working groups)
Private sector	
NGOs	
Academics	- University of Oxford (36, 52) (has been invited to participate in MSMech working groups)

²¹⁷ Kils,

	- academic journals (53) - London School of Hygiene & Tropical Medicine Antimicrobial Resistance Centre (54) - Johns Hopkins Bloomberg School of Public Health; BESAFE Project (44) - University of Edinburgh, Scotland (55) (worked with WHO, but not MSMech, on SF medical products subject) - Pancasila University, Indonesia²¹⁸
Patient associations	International - International Alliance of Patients' Organizations²¹⁹ Regional - European Patients Forum (56)
Media	- BBC health (57) - The New York Times (58) - The Guardian (59) - Reuters (60) - CNN (61) - Forbes (62)

Source: Evaluation team Internet search

Though non-exhaustive, this list is extensive and shows the broad range of actors interested in the issue of SF medical products. It also illustrates that the MSMech interaction with these actors is currently limited. Broader MSMech engagement could tap into a wide array of expertise.

EQ4.2 To what extent have Member States cooperated at global, regional and national levels, and how has the mechanism facilitated this collaboration?

The MSMech model has good potential for collaboration globally, regionally, nationally and between working groups, but this potential is not fully capitalized upon.

Overall, Member States have collaborated at all three levels, and the MSMech has facilitated this collaboration, although there is room for further improvements. Feedback to the evaluation suggests that the MSMech has facilitated collaboration (see Fig. 15).

²¹⁸ <https://www.dropbox.com/scl/fi/z140ra1cu4gp5g5q5ahsr/KII-Yusi-Angriani-NSA-28.05.24.docx?rlkey=hhzjuhfui1b6ltvi8jr548t1t&e=1&st=o0nxnopb&dl=0>

²¹⁹ <https://www.ifpma.org/news/eb152-statement-on-substandard-and-falsified-medical-products/>

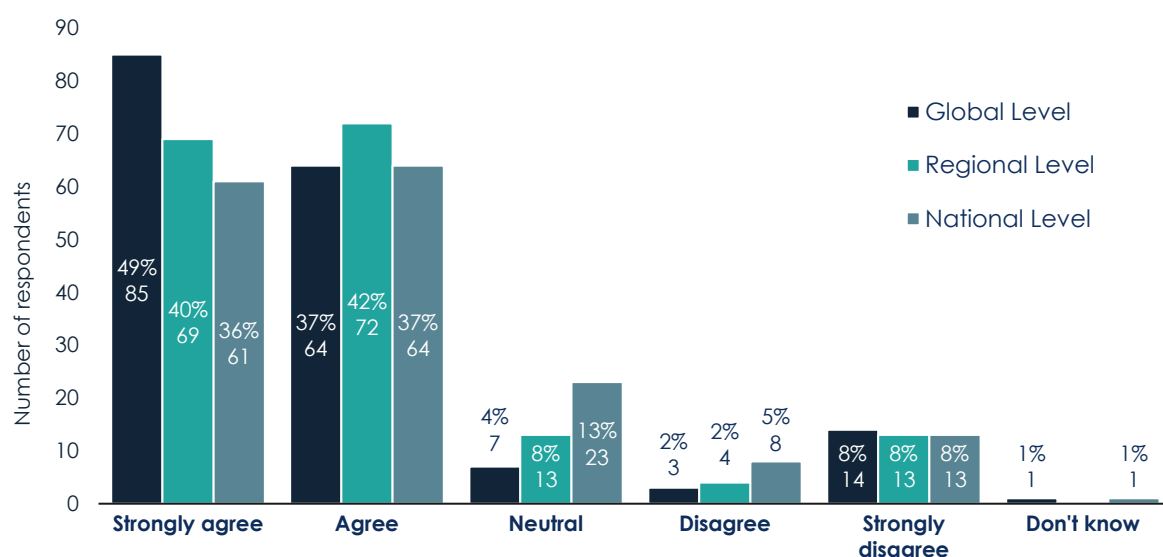


Fig. 1515. Perception of the MSMech as a platform for fostering collaboration at global, regional and national levels²²⁰

Source: 2024 MSM FS Survey - Evaluation

Regional-level engagement is important to foster country collaboration and strengthen relationships and actions on SF medical products,²²¹ although some regions seemed to be collaborating more than others.²²² Of survey respondents, 82% either strongly agreed (40%) or agreed (42%) that the MSMech is a platform for fostering collaboration at regional level, but this varied across regions. The African and Eastern Mediterranean regions displayed strong support, with 55% and 50%, respectively, strongly agreeing that the MSMech fosters regional collaboration. The Region of the Americas showed lower support, with 10% strongly agreeing and 25% agreeing, while 59% (the highest in any region) remained neutral. The Western Pacific Region also shows low levels of strong agreement (20%), but 40% agree. Overall, this suggests the need for improvement in efforts for regional collaboration.²²³

The paucity of interaction between the MSMech and external SF medical products stakeholders (like the pharmaceutical industry and NGOs, which both also combat SF medical products) raises questions regarding possible duplication and lack of synergy – while also noting the need to control for differing roles and mandates of the MSMech, WHO and individual stakeholders. Many such stakeholders are working on the same respective issues as specific working groups (e.g. detection and traceability technologies, public education), yet the MSMech rarely seeks to collaborate on these with some exceptions, e.g. with certain multilaterals, such as UNODC).²²⁴ The limited collaboration with external SF medical products stakeholders means that duplication can occur and complementarity is less likely. The effectiveness of working groups is reported to be affected by the absence of partners with whom to collaborate,²²⁵ including the pharmaceutical industry and Interpol, as appropriate.²²⁶

²²⁰ MSMech evaluation survey.

²²¹ KIIs.

²²² KIIs.

²²³ MSMech evaluation survey.

²²⁴ Examples are the Quadripartite Organization re. OneHealth – F7, and some UNODC and Interpol interactions.

²²⁵ KIIs.

²²⁶ KIIs.

Some actions could be capitalized upon. For example, in each plenary meeting the MSMech secretariat shares a list of relevant global and regional initiatives in which WHO is participating (16, 24). This has the potential to foster further international and regional collaboration in the domain of SF medical products.²²⁷

Over two-thirds of survey respondents also agreed that the MSMech is a platform for fostering collaboration at national levels (36% strongly agreed and 38% agreed). There are examples confirming this opinion: events such as the glycol crisis have increased collaboration, even though it was slow to start. The MSMech secretariat had a major role in this and was able to connect countries when it was needed.²²⁸

Member States also collaborate within the MSMech's working groups on prioritized issues related to SF medical products.²²⁹ However, this collaboration between countries through MSMech Working Groups does not necessarily mean that the SF issue for those participating is being fully addressed (lack of other actors' expertise lessens the relevance of the work).²³⁰ Working groups are also operating in isolation, with no collaboration between them.²³¹ Table 22 shows a list of working groups, their activities and lead Member States, during the evaluated period.

Table 18. MSMech working groups, period of activity and lead Member State

Working group	Lead by activity period		
	2018–2019	2020–2021	2022–2023 (63)
A – Strengthen the capacity of national/regional regulatory authorities for the prevention and detection of, and response to, SF medical products (Name changed in 2022)	Brazil	Brazil and secretariat	Brazil
B – Develop, expand and maintain global networks of stakeholders to facilitate cooperation and collaboration	Secretariat	Secretariat	Eritrea
C – Improve Member States' understanding and uptake of technologies to screen and detect SF medical products and the implementation of national traceability systems	Argentina and secretariat	Secretariat	Nigeria
D – Leverage the competencies of relevant stakeholders, including policy-makers, procurers, distributors, practitioners, patients and consumers, and good	Secretariat	Secretariat	Secretariat

²²⁷ KIIs.

²²⁸ KIIs.

²²⁹ World Health Organization, (n.d.) *Working Group - Activity H, WHO Member State Mechanism (MSMECH) on Substandard and Falsified (SF) Medical Products, Deliverable II*.

²³⁰ KIIs.

²³¹ KIIs.

governance to reduce the burden of SF medical products			
E – Enhance Member States’ capacity to run effective risk communication campaigns for SF medical products	UK	Secretariat	Zambia
F – Enhance Member States’ capacity to expand awareness, effectiveness, impact and outreach in their work on SF medical products	Secretariat	Secretariat	Australia
(2018–2021) G – Promote shared understanding among Member States from a public health perspective regarding medical products in transit.	Secretariat	Secretariat	NA
(2022–2023) G – Identify and develop appropriate strategies to understand and address the distribution or supply of SF medical products via the internet	NA	NA	Colombia
(2018–2021) H – Identify and develop appropriate strategies to understand and address the distribution or supply of SF medical products via the internet	Secretariat (interim)	Colombia	NA
(2022–2023) H – Develop strategies for NRAs to mitigate public health risks posed by the distribution of SF medical products through informal markets	NA	NA	USA

It was observed that collaboration has sometimes been hindered by established communication protocols that required documents (notably invitations to meetings) to pass through numerous individuals before reaching their destination. This issue is further exacerbated by some countries' lack of capacity.²³² Another significant obstacle to collaboration within the MSMech is the low level of country participation (as explained previously).²³³

²³² Klls.

²³³ Klls.

EQ4.3 To what extent is the coordination adequate across the MSMech secretariat, WHO headquarters technical departments (e.g. HQ/Health Product Policy and Standards (HPS); Antimicrobial Resistance Division (AMR)), regional and country offices?

The MSMech secretariat has proved to be effective in liaising with most relevant WHO technical teams,²³⁴ including the teams responsible for pre-qualification, product testing standards, clinical trials and regulatory systems (16, 24).²³⁵ However, more ongoing communication is needed, notably outside of annual and steering committee meetings. Two areas where cooperation could improve somewhat are controlled substances and shortages.²³⁶

The involvement of diverse WHO technical teams, notably by the secretariat, has been pivotal in ensuring that the MSMech's work has a comprehensive approach and brings relevant solutions to the issues at hand.²³⁷ However, communication and information sharing between Member States and WHO technical teams through the MSMech is lacking: information exchange is not ongoing and happens primarily at meetings. This can be problematic as SF medical products are a multifaceted challenge that sometimes requires timely reaction and, therefore, timely sharing of information and guidance.²³⁸

Overall, MSMech is making an effort to harmonize with the WHO technical teams and notably not to duplicate efforts and to promote WHO's standards. The MSMech's work is aligned to WHO guidelines, notably the guidelines of the WHO GSMS for SF medical products (5). At present, the GSMS gathers reports from national regulatory FPs, but in the future it is expected that this database will be connected to other internal and external datasets (e.g. the Global Benchmarking Tool, model lists of essential medicines and health products, pharmacovigilance, etc.) (64).

2.5 Sustainability

EQ5: To what extent are achievements of the MSMech work likely to remain (in the absence of an MSM) and its work continued on SF medical products?

Summary of key findings 5: From 2024, the MSMech is starting to apply longer term planning via use of basic outcome indicators, which may contribute to more sustainable achievement. Many of its activities are already inherently sustainable in their likely effects (e.g. assisting in the revision of national regulations, capacity-building). However, financial security for the mechanism itself only exists for the short term (approximately the current biennium), and the narrowness of the donor base brings risks, which, combined with a lack of well-developed long-term planning, undermines future sustainability.

There is short-term financial sustainability, but the narrow donor base risks the sustainability of the MSMech in the long term. So far, the MSMech has had adequate funding to support its activities (16), but in the long run, limited external donors' financial support could jeopardize the MSMech's work and achievement of objectives (20).²³⁹ In addition, since 2018, the ISF donor base, on which the MSMech depends, decreased from eight

²³⁴ KII.

²³⁵ KII.

²³⁶ KII.

²³⁷ KII.

²³⁸ KII.

²³⁹ KII.

donors to five. France and Germany stopped donating after the 2018–2019 biennium (but European Commission funding increased), and Brazil stopped donating after the 2020–2021 biennium.²⁴⁰

The MSMech is starting to incorporate long-term planning in the way it works. Some countries have proposed increasing the sustainability of the MSMech's work by encouraging a more long-term approach. During the March 2022 steering committee meeting, the Working Group on Activity H formalized their objective to address knowledge gaps and develop long-term strategies and policy recommendations.²⁴¹ However, this objective was repeated at the 12th plenary meeting in 2023 without any information on actions taken to reach it. Additionally, during the same meeting, a steering committee member presented their ideas for the "development of a longer-term strategic plan for the mechanism" to be considered by the committee.²⁴² There is, however, no concrete evidence that this has happened.

Many of the MSMech's activities deliver on aspects of sustainability, but there is room for improvement. Capacity-building activities are recognized as potentially significant contributors to the sustainability of results (65). Some trainings were provided by WHO in relation to SF medical products, notably during the pilot study on smartphone application for reporting SF medical products. The MSMech's role in those trainings is unclear.²⁴³ As some countries lack adequate resources for risk-based sampling, testing and faster detection technologies,²⁴⁴ trainings provided by WHO were considered to be long-term investments in the regulatory framework of participating countries.²⁴⁵ The MSMech did not provide training sessions²⁴⁶ but developed at least one training handbook that was published in 2019.²⁴⁷ It covers various tools and methodologies for prevention, detection and response, including track and trace systems, authentication technologies and risk communication strategies.

Since 1997, WHO has had a programme of benchmarking and strengthening regulatory systems that provides training for NRAs. MSMech's work in this regard must be complementary and not overlap with the activities already carried out by WHO.²⁴⁸ This example illustrates that more outreach work is needed to ensure that MSMech's work is properly disseminated to groups or organizations already delivering training.

Half of the survey respondents (49%) recognize that the capacity strengthening of country FPs has been implemented to some extent, with 22% reporting full implementation. However, 11% reported that it has not been implemented at all, indicating that further efforts are needed to make sure that all FPs are aware of available capacity strengthening opportunities. There is also a perceived need for more capacity-building activities, notably for regulatory activities and laboratory quality control at national and regional levels.²⁴⁹ The need is particularly pronounced in LMICs,²⁵⁰ and this, if strengthened, could support the sustainability of countries' mechanisms. These activities have been hindered by lack of funds and human resources to follow up on capacity-building, at WHO and by countries.²⁵¹

²⁴⁰ Financial data shared by the secretariat.

²⁴¹ 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.

²⁴² WHO (2023). *Note for the record: Meeting of the steering committee of the Member State mechanism on substandard and falsified medical products*. Geneva.

²⁴³ WHO *Substandard and falsified medical products, Tanzania Food & Drugs Authority, BPOM, 2019. Smartphone application for reporting substandard and falsified medical products - Pilot Study Report*.

²⁴⁴ Evaluation survey analysis.

²⁴⁵ KIIs

²⁴⁶ KIIs

²⁴⁷ The handbook is available on WHO's MedNet platform and compiles existing training resources and reference documents: *WHO Member State mechanism on substandard and falsified (SF) medical products, 2019. Online Handbook on existing training resources and reference documentation for the prevention, detection and response to SF medical products*.

²⁴⁸ WHO (2018). *Regulatory system strengthening update. Steering committee, Member State mechanism on SF medical products*.

²⁴⁹ Evaluation survey analysis.

²⁵⁰ Evaluation survey analysis.

²⁵¹ KIIs.

The MSMech itself contributes to sustainability by developing and disseminating guidelines on a range of relevant topics for NRAs in the field of SF medical products (Table 23).²⁵² Guidance shared by the MSMech has helped some countries to establish and develop structures and systems.²⁵³ This contributes to sustainability, notably by improving the quality of their data, evidence and working tools.²⁵⁴ Some Member States were reported to have incorporated insights and strategies from the MSMech in their approach to SF medical products as a result of the data and evidence (e.g. Tanzania with the pilot study on a “*Smartphone application for reporting substandard and falsified medical products*”).^{255 256}

Table 19. Guidance and training documents on SF medical products shared by the MSMech on the Mednet Platform between 2017 and 2023

Author	Guidance and training document
MSMech	1. WHO Member State Mechanism on Substandard and Falsified (SF) Medical Products, 2019. Online handbook on existing training resources and reference documentation for the prevention, detection and response to SF medical products. 2. World Health Organization, 2018. Guidance for registers of manufacturers, importers, distributors and medical products authorized by Member States (No. A/MSM/7/2). 3. MSMech, A.C., 2019. WHO Health care Track & Trace Policy Brief Development.
WHO	1. World Health Organization, 2021. Policy paper on traceability of medical products. 2. World Health Organization, Tanzania Food & Drugs Authority, n.d. Identifying suspect substandard and falsified medical products. 3. World Health Organization, 2020. Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics. 4. World Health Organization, 2019. WHO work on detection technologies in PMS – NIR screening pilot and library development. 5. Kuwana, R., 2020. Pooling resources and technology – the role for MeSDAS, global libraries and Artificial Intelligence.

Some respondents reported that the lack of efforts to raise awareness about the importance of preventing the distribution of SF medical products at national and regional levels has reduced national authorities' engagement in the subject.²⁵⁷ In the long term, lack of engagement can become a sustainability issue if fewer Member States are interested in the matter or aware of its importance. Hence, efforts to increase engagement should also be implemented to ensure MSMech's sustainability.

²⁵² KIIs.

²⁵³ KIIs.

²⁵⁴ WHO Substandard and falsified medical products, Tanzania Food & Drugs Authority, BPOM, 2019. Smartphone application for reporting substandard and falsified medical products - Pilot study report.

²⁵⁵ Ibid.

²⁵⁶ KIIs.

²⁵⁷ KIIs.

2.6 Equity

EQ6: How is the MSMech considering issues of gender equality, health equity, disability and 'leaving no one behind', and human rights in its functioning?²⁵⁸

Summary of key findings 6: The MSMech's aims are inherently health equity-focused. The MSMech's governance structure is inclusive and open to all Member States, but some (mainly high- or middle-income countries) Member States participate more actively than others. There is a reasonable gender balance in the steering committee, among national FPs and within the mechanism's secretariat. There is limited evidence that the MSMech has been proactive in considering issues of gender equality, disability, human rights or other equity dimensions in planning and implementing its activities. Given that the risks associated with SF products are inequitably distributed, with countries with limited resources and the poorest populations most likely to be affected, the MSMech may need to consider giving higher priority to the needs of these countries.

The MSMech's governance structure is inclusive and open to all Member States and is structured in a way that promotes equal participation of all countries, including low-income countries.²⁵⁹ However, in practice, representation is a challenge, as Member States with fewer resources are less likely to attend meetings in person and, in some regions, differences in time zones are a challenge to virtual participation.²⁶⁰ Key informants who had a view on the inclusivity of working groups noted that they are suboptimal.²⁶¹

I know countries in my region that would be very interested in attending those meetings that would be willing to give a lot of input to the plenary of the mechanism. But they simply don't have the resources to pay for that.²⁶²

There were mixed views about gender equality within the MSMech, with some informants reporting that there is balanced gender representation, especially among national FPs, but others noted that MSMech leadership – for example, of the steering committee and working groups – has been male-dominated.²⁶³ For instance, all the steering committee chairs since 2012 have been men. There is, however, a reasonable gender balance in the current steering committee, which has seven male and five female regional representatives (refer to MSMech Governance Structure in the section on The object of the evaluation).

The MSMech's contribution to access to health care as a human right implies addressing equity issues.²⁶⁴ However, there is no explicitly stated focus on gender equality, equity, disability or human rights in planned activities, meeting agendas or discussions and MSMech reporting.²⁶⁵ Most key informants were unable to comment on whether or how the MSMech considers these issues.

²⁵⁸ Specific additional question as requested in the ToR to evaluate the extent to which differences in need, vulnerability, gender, disability and human rights are taken into account in the MSMech's work, as well as differences in interactions between the MSMech and various member states.

²⁵⁹ KIIs.

²⁶⁰ KIIs.

²⁶¹ KIIs.

²⁶² KIIs.

²⁶³ KIIs.

²⁶⁴ KIIs.

²⁶⁵ For example, from a search of selected documents on the MSMech website, Working Group products (e.g. IDEAS. A global communications framework to help combat the threat from SF medical products, 20 November 2018; Report on Activity H, 10th meeting of the MSMech, 7 October 2021); reports on activities (e.g. *Report of the 4th meeting of the MSMech, Report by the Director-General*, 69th WHA, 4 March 2016; *Update on the activities and budget to implement the workplan of the MSMech*, 12th meeting of the MSMech, 24 October 2023; *Future work of the MSMech*, 11th meeting of the MSMech, 28 September 2022).

“The MSMech has not done an adequate job on equity issues and the diversity of Member States beyond a broad north-south perspective.”

Some informants also suggested that there has been an insufficient focus on equity and gender in relation to populations most at risk, such as the poorest wealth quintiles; women affected by changing legislation on reproductive health that could drive demand for medicines in unregulated markets; women during pregnancy and labour; children with specific illnesses and diseases; as well as other vulnerable and marginalized populations who may have less access to quality medicines, information and services.²⁶⁶ Key informants also recognized the need to prioritize MSMech efforts, with some suggesting that more priority be given to supporting countries with the weakest systems and where people in the poorest wealth quintiles are most likely to be adversely affected by SF medical products.²⁶⁷

²⁶⁶ Kils.

²⁶⁷ Kils.

Chapter 3: Conclusions and Recommendations

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

3.1 Conclusions

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

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

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

Conclusion 4: The alignment between the Member State mechanism and external SF medical products stakeholders on definitions of SF medical products has led to useful consensus. However the mechanism's limited interaction with other (especially non-state) stakeholders reduces coordination and potentially fragments global action. There is generally strong support for increased engagement and involvement of

external stakeholders, both from those working in the mechanism (Member States and the secretariat) and from donors and other stakeholders. However, caution is urged with respect to both dissemination of country-specific information (e.g. in relation to SF incidents) and to engaging non-state actors, including the private sector in accordance with FENSA. **(Coherence)**.

Conclusion 5: The reliance of the Member State mechanism (and its secretariat) on two main external donors, who could easily change their funding priorities, risks its financial sustainability beyond the current biennium. This is compounded by the currently very small Member State contributions. Uncertainty regarding donor funding is a major threat to the future of the mechanism, and a stronger investment case for donors is required if its long-term future is to be secured. Changes to legislation, regulation and regulatory capacity in Member States, because of Member State mechanism support, are likely to positively affect the sustainability of its results. **(Sustainability)**.

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

3.2 Recommendations

Recommendations 1 to 5 are for the MSMech to consider.

Recommendations 6 and 7 are for WHO to consider.

Recommendation 1 is the most fundamental, and an early decision to pursue either option A or B within it will be helpful in setting the context and scope for implementation of recommendations 2–7.

Note that recommendations do not correspond only to single conclusions. These recommendations take into account the inputs provided during the recommendations workshop that took place on 9 September 2024, in which evaluation reference group members and other key personnel participated.

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

- **Option A:** Dissolving the current MSMech and establishing a new format, which would report to the WHO Director-General but would still have significant input from Member States. This could be an advisory group or a more bespoke hybrid²⁶⁸ format. Such revision would need to be proposed by the Member State mechanism and approved by the WHA through the Executive Board. A taskforce could be established to guide this process.

²⁶⁸ The WHO global coordination mechanism on the prevention and control of noncommunicable diseases is an example of a hybrid body, with a format other than an advisory group.

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

(Informed mainly by Conclusions 1, 2 and 5)

Further detail and suggestions regarding Recommendation 1 can be found at Annex 3.

Recommendation 2: Develop an integrated planning and review approach to further develop the Member State mechanism's work planning, costing/budgeting, prioritization and reporting processes (in line with results-based management approaches). Actions to develop a more comprehensive integrated planning and review system should include refining the draft Member State mechanism strategy, to include a ToC and results framework with clear output and outcome indicators to track performance, costing potential activities to help to prioritize and resource these, developing workplans with timelines and milestones and establishing a feedback system to help to disseminate learning. Resource constraints may mean that this approach developed to a less than comprehensive extent initially (unless the mechanism's secretariat capacity is significantly expanded). **(Informed mainly by Conclusions 2, 3 and 5)**

Recommendation 3: Clarify and communicate roles and responsibilities with a strong focus on strengthening Member State engagement and accountability. This would include making a clear distinction between Member State responsibilities and working group participation, and those of the WHO Secretariat. With this clarity the Member State mechanism should ensure processes are in place to strengthen accountability for the fulfilment of these responsibilities. The mechanism should also consider approaches, including the role of its secretariat in facilitating the link between national regulatory authorities and Member States' representation, to incentivize and support Member State meetings and working group participation (especially those from low-income countries). **(Informed mainly by Conclusions 1 and 2)**

Recommendation 4: Strengthen the Member State mechanism's visibility via stronger external communication (including benefits due to, and performance of, the mechanism) to Member States, potential donors and other stakeholders. This should communicate clearly the benefits to Member States of Member State mechanism participation, and the objectives, achievements and what can be offered by the mechanism and its secretariat in the substandard and falsified products field to external stakeholders. **(Informed mainly by Conclusions 3, 4 and 5)**

Recommendation 5: Improve external engagement by developing differentiated engagement strategies (in line with the Framework of Engagement with Non-State Actors). This will include ways to engage with donors, strategic and operational partners. As a basis for developing a stakeholder engagement strategy that targets strategic and operational partners, a full mapping of stakeholders should be conducted. The Member State mechanism, in consultation with the Due Diligence and Non-State Actors unit of the WHO Office of Compliance, Risk Management and Ethics, should specifically develop guidance for engagement with external stakeholders, such as the pharmaceutical industry which have much to offer in the fight against substandard and falsified products, but caution is required due to potential or perceived conflicts of interest. At the regional level, efforts should be made to seek increased collaboration, such as by increasing regional involvement in some Member State mechanism working groups and with national FPs. **(Informed by Conclusions 1, 3, 4, 5, 6)**

Recommendation 6: Further enhance WHO technical support for the work of the Member State mechanism.

This should include increasing coordinated communication, information sharing and technical support by WHO at the headquarters and regional levels for the Member State mechanism, including for issues of product shortages and local production (pursuant to resolution WHA65.19). **(Informed by Conclusion 4)**

Recommendation 7: Explore ways to further increase the capacity of the Member State mechanism's secretariat.

Support for additional human resources should be discussed with donors and senior managers within the WHO Secretariat. Better definition and recognition of Member State (and potential additional technical expertise) responsibilities versus those of the Member State mechanism's secretariat may reduce the burden on the secretariat and capacity requirements. **(Informed by Conclusion 3)**

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