World Health Organization

TWELFTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS
Provisional agenda item 8

A/MSM/12/9
26 October 2023

Draft list of prioritized activities to implement the workplan of the Member State mechanism for the period 2024–2025

Updated following the Steering Committee meeting in June 2023

BACKGROUND

1. In May 2014, the Sixty-seventh World Health Assembly noted the workplan of the Member State mechanism on substandard and falsified medical products as published in Appendix 2 to document A67/29.[1] Since 2014, the mechanism has agreed on a biennial list of prioritized activities to implement the workplan. The current list of prioritized activities covers the period 2022–2023,[2] and the draft list of prioritized activities for the period 2024–2025 will be considered at the twelfth meeting of the mechanism in November 2023.

CURRENT STATUS

2. For the period 2024–2025, the following changes have been made to the draft list of prioritized activities:

(a) addition of three new prioritized activities (F, I and J);

(b) merging of prioritized activities E and F for the period 2022–2023 into one new prioritized Activity E, with revised text;

(c) addition of a "Metrics/Success indicators" column to reflect the performance and impact of the proposed actions;

(d) addition of an "Expected outcomes" column to reflect the results of the proposed actions;

(e) changes to the wording of the "Proposed actions" and "Metrics/Success indicators" columns, including the addition of an "Expected outcomes" column, have been made in coordination with the respective working-group chairs; and

(f) the technical team have made changes to the wording of the "Proposed actions", "Metrics/Success indicators" and "Expected outcomes" columns for working groups D, F and I.

[1] See document WHA67/2014/REC/3, summary record of Committee B, fourth meeting, section 2.

[2] Document A/MSM/10/11 Rev.1, Annex 2.

DRAFT LIST OF PRIORITIZED ACTIVITIES TO IMPLEMENT THE WORKPLAN OF THE MEMBER STATE MECHANISM FOR THE PERIOD 2024–2025

Prioritized activities	Proposed actions	Metrics/Success indicators	Expected outcomes
A. Strengthen the capacity of national/regional regulatory authorities for the prevention and detection of, and response to, substandard and falsified medical products. Lead: Brazil, with the support of the Secretariat.	1. Use global standard tools to assist in the identification of training needs and existing expertise and in the update of training materials for Member States in order to prevent, detect and respond to substandard and falsified medical products. 2. Roll out the tool and database that have been developed to automate the conduct of medical product quality surveys and enhance the quantity and quality of data captured to inform risk-based post-market surveillance programmes based on existing WHO guidance, providing support to Member States to ensure their correct use. 3. Develop a technical guideline, following the standard WHO consultation procedure, with the aim of strengthening the capacities of national/regional regulatory authorities to plan, perform and assess risk-based post-market surveillance. 4. Improve the availability and usability of the WHO knowledge base on substandard and falsified medical products for Member States.	1(a) Consolidated list of market control and surveillance training needs for all benchmarked countries available to Member States via a shared platform. 1(b) Roster of market control and surveillance expertise maintained based on assessed competency. 1(c) Consolidated and regularly updated list of training materials available to Member States. 2(a) At least 10 Member States adopting/adapting the Epione e-tool by the end of 2025. 2(b) At least 10 Member States maintaining their risk-based post-market surveillance data on the WHO ePQS platform.[1] 3. WHO technical guideline on risk-based market surveillance and control published by December 2025. 4. e-Library of training materials, guidance documents and other relevant resources published on a user-friendly shared platform.	1. Member States have targeted training programmes and materials to improve competencies to meet the regulatory challenges posed by substandard and falsified medical products effectively. 2. Automated risk-based post-market surveillance tool and database for medical product quality surveys available to support robust national, regional and global systems for monitoring and enhancing the quantity and quality of data that enable regulatory authorities to identify and respond more efficiently to the risks associated with substandard and falsified medical products. 3. Member States with robust surveillance systems and capacities for planning, performing and assessing risk-based market surveillance and control of supply chains. 4. Improved availability and effective use of a global knowledge base that provides reliable and up-to-date information on substandard and falsified medical products, empowering Member States to take proactive measures within their respective jurisdictions to combat them.

[1] The WHO ePQS platform is a piece of cloud-based software.

Prioritized activities	Proposed actions	Metrics/Success indicators	Expected outcomes
B. Develop, expand and maintain global networks of stakeholders to facilitate cooperation and collaboration. Lead: Eritrea, with the support of the Secretariat.	1. Implement the proposed solutions for bridging reporting barriers to the WHO Global Surveillance Monitoring System for substandard and falsified medical products (continuation of Action 2 of Activity B for the period 2022–2023). 2. Develop a substandard and falsified incidents communication platform for focal points to facilitate information sharing and networking. 3. Develop key performance indicators for monitoring the functionality of the Global Focal Point Network.	1(a) Mechanisms for implementing the proposed solutions for bridging reporting barriers developed by January 2024. 1(b) Implement the proposed solutions in at least two pilot countries by the end of 2025. 2. Online communication portal developed by the end of 2024. 3(a) Key performance indicators developed by the end of 2024. 3(b) Update Global Focal Point Network (document A/MSM/4/2) by the end of 2025.	1. Member States are ready to implement the proposed solutions for bridging reporting barriers, improving the quality and quantity of reporting. 2. Improved communication about substandard and falsified medical products among focal points. 3. Enhanced and strengthened international collaboration within the Global Focal Point Network, with clear actions and objectives to prevent, detect and respond to substandard and falsified medical products.
C. Improve Member States' understanding and uptake of technologies to screen and detect substandard and falsified medical products. Lead: Montenegro, with the support of the Secretariat.	1. Develop user requirements for ideal handheld devices for screening substandard and falsified medicines to inform target product profiles and/or preferred product characteristics.	1. User requirements developed by the end of 2024.	1. Improved screening of substandard and falsified medical products in the supply chain through the use of devices equipped with the necessary features and capabilities. 2. Greater standardization and interoperability among devices, allowing for improved data sharing and collaboration among Member States in combating substandard and falsified medical products.
D. Leverage the competencies of relevant stakeholders, including policy-makers, procurers, distributors, practitioners, patients and consumers, and good governance to reduce the burden of substandard and falsified medical products. Lead: TBC, with the support of the Secretariat.	1. Support the roll-out, implementation, monitoring and evaluation of the uptake by Member States of the WHO handbook on developing and strengthening national action plans for prevention, detection and response strategies on substandard and falsified medical products. 2. Organize or support regular meetings, workshops and conferences among Member States to promote dialogue, share best practices and develop joint strategies to prevent, detect and respond to substandard and falsified medical products. 3. Support the conducting of research and data collection on the prevalence, impact and consequences of substandard and falsified medical products to generate evidence-based recommendations for national policy development.	1(a) At least 19 Member States with national regulatory systems at maturity level 3 as at December 2023, with established national action plans to prevent, detect and respond to substandard and falsified medical products by December 2025. 1(b) At least nine Member States with national regulatory systems below maturity level 3 as at December 2023, with established national action plans to prevent, detect and respond to substandard and falsified medical products by December 2025. 1(c) Yearly monitoring and evaluation report on the status of the implementation of national action plans. 2. At least one annual meeting conducted on the implementation of national action plans.	1. A significant proportion of Member States ready and better prepared to combat substandard and falsified medical products effectively through the use of more coordinated and comprehensive approaches. 2(a) A collaborative global environment that fosters dialogue, knowledge sharing and the development of joint strategies to prevent, detect and respond to substandard and falsified medical products. 2(b) Functional regional and international networks that foster cross-border collaboration and information exchange. 3(a) Increased knowledge and evidence-based recommendations and national policy development. 3(b) Strengthened regulatory frameworks, enhanced international collaboration and greater public awareness and engagement.

Prioritized activities	Proposed actions	Metrics/Success indicators	Expected outcomes
		3(a) Research findings tabled at Member State mechanism plenary meetings and regional policy forums and consultations. 3(b) Position papers prepared for all research conducted to influence the development and implementation of appropriate policies and practices.	
E. Enhance Member States' capacities to develop and utilize effective risk communication strategies, with the aim of expanding awareness of substandard and falsified medical products. Lead: Italy, with the support of the Secretariat.	1. Map and review examples of relevant effective national or regional risk communication activities, with the aim of assisting in the development of effective risk communication strategies among Member States. 2. Convene technical briefing sessions (at least one per year) to review existing communication activities and discuss strategies, learnings and/or outcomes related to serious incidents of substandard and falsified medical products.	1(a) Conduct a survey of Member State communication activities by the end of 2024. 1(b) Map and review effective communication activities; share findings and report to Member States by the end of 2025. 2(a) Convene at least one technical briefing session per year. 2(b) Issue technical briefing session report(s), to be shared with appropriate/responsible authorities.	1(a) Identification of effective risk communication strategies and techniques employed by Member States. 1(b) Identification of gaps or areas for improvement in current risk communication activities, leading to targeted recommendations for enhancing communication efforts. 2(a) Sharing of knowledge, experiences and lessons learned from serious incidents of substandard and falsified medical products, leading to an improved understanding of effective communication strategies in such scenarios. 2(b) Increased awareness and understanding among Member States regarding the importance of effective risk communication in the context of serious incidents of substandard and falsified medical products, leading to improved preparedness and response capabilities.
F. Strengthening the supply chain of high-risk excipients and related raw materials. Lead: TBC, with the support of the Secretariat.	1. Conduct a comprehensive global risk assessment, based on recent incidents, to identify excipients at a high risk of being substandard or falsified in order to identify trends, risk factors and vulnerabilities throughout the supply chain, including manufacturing, distribution and storage. Identify critical control points and vulnerabilities in the excipient supply chain that contribute to substandard medical products.	1(a) Risk assessment report that includes a list of excipients at a high risk of contamination based on recent incidents. 1(b) Map/list of the weaknesses and vulnerabilities in the excipient supply chain. 2(a) Report on the status of data sharing on the control, quality and safety of excipients 2(b) Report on survey of Member State good practices, policies and guidelines by the end of 2025.	1. Enhanced understanding of high-risk excipients and improved identification and mitigation of risks in the excipient supply chain. 2. Increased awareness and understanding of the risks of substandard or falsified excipients through, for example, the dissemination of guidelines and research findings and the availability of training programmes.

Prioritized activities	Proposed actions	Metrics/Success indicators	Expected outcomes
	2. Collaborate with Member States, regulatory authorities, other specialized agencies of the United Nations and industry stakeholders to (a) collect and share data on excipient control, quality and safety, including routine testing results to establish standards and specifications, and (b) develop good practices, policies and guidelines to ensure excipient quality and safety.		
G. Identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet. Lead: Colombia, with the support of the Secretariat.	1. Improve capacity-building among Member States to respond to the distribution of substandard and falsified medical products via the internet, including the use of policy recommendations from the Member State mechanism internet guidance. 2. Develop strategic guidance to promote interagency cooperation and collaboration with relevant stakeholders to respond to the distribution of substandard and falsified medical products via the internet.	1(a) Internet training programme developed by the end of 2024. 1(b) Pilot training programme launched in Working Group G by the end of 2024. 1(c) Training seminar delivered for each WHO region, via the internet training programme, by the end of 2025. 2(a) At least one informal technical briefing session delivered by the end of 2024. 2(b) Strategic guidance available by the end of 2025.	1. Member States equipped with the knowledge, tools and resources to identify, track and combat the sale of substandard and falsified medical products via the internet, resulting in the reduction of the related public health risks. 2. Member States collaborating and sharing best practices, intelligence and resources, allowing for a more unified and effective response to combat the prevalence of substandard and falsified medical products. 3. Member States aligned in their respective approaches to combat the distribution of substandard and falsified medical products via the internet, with minimal potential regulatory gaps and variations that could be exploited by illicit actors.
H. Develop strategies for national regulatory authorities to mitigate the public health risks posed by the distribution of substandard and falsified medical products through informal markets. Lead: United States of America, with the support of the Secretariat.	1. Establish and implement a workplan for activities to address knowledge gaps in respect of informal markets. 2. Develop strategies and policy recommendations for Member States to combat the distribution of substandard and falsified medical products through informal markets.	1. Deliver one technical briefing session with experiences and input from at least one Member State and/or non-State actor (for example, a technical expert) by the end of 2024 and another by the end of 2025. 2. Finalize the workplan of technical activities to address knowledge gaps by the end of 2024. 3. Initiate at least one activity from the workplan to address knowledge gaps by the end of 2025.	1. Member States with a better understanding of the scope, scale and potential harm of the sale of substandard and falsified medical products through informal markets. 2. National regulatory authorities with the tools to identify the nature and scope of the distribution of substandard and falsified medical products through informal markets in their respective jurisdictions.

Prioritized activities	Proposed actions	Metrics/Success indicators	Expected outcomes
I. Identification of and response to emerging issues on substandard and falsified medical products. Lead: Member State mechanism Chair, with the support of the Secretariat.	1. Develop a robust and comprehensive risk assessment framework that includes identifying potential risks, analysing their likelihood and impact and regularly updating the assessment based on emerging trends. 2. Convene technical briefing sessions on an ad hoc basis to respond to emerging issues.	1. Risk assessment framework developed by the end of 2024.	1. An agile mechanism capable of responding swiftly and effectively to acute and emerging trends, incidents, events and issues associated with the detection and prevention of, and response to, substandard and falsified medical products.
J. Improve Member States' implementation of national traceability systems. Lead: Nigeria, with the support of the Secretariat.	1. Convene at least one technical briefing session per year to review existing traceability models, including approaches and enabling technologies.	1. At least one technical briefing session convened per year, with the tally of attending Member States noted and reported to the Steering Committee and Member State mechanism plenary meetings.	1. Member States with improved capacity to monitor and identify substandard and falsified medical products in their respective supply chains. 2. Member States with better access to good quality, safe and effective medical products through efficient supply chain management and logistics, with real-time insights into their movement, minimized delays and a reduced likelihood of diversions to unauthorized channels. 3. Consumers with greater trust in the health care system and confidence in the medical products being distributed in Member States.

ACTION BY THE MEMBER STATE MECHANISM

3. The mechanism is invited to note the report and approve the draft list of prioritized activities to implement the workplan of the Member State mechanism for the period 2024–2025, together with the strategic plan.

ANNEX

STRATEGIC PLAN

Member State engagement The Member State mechanism is agile and forward-looking, serving as a forum for discussion and the development of recommendations for policy-makers		
Proposed goals	**Proposed actions**	**Proposed indicators**
1. The Member State mechanism is a critical and valued partner for international organizations and policy forums. 2. All WHO regions engage in the work of the mechanism to provide regional data and trends on substandard and falsified medical products, as well as policy coherence. 3. All relevant sectors are integrated in a whole-of-government approach to prevent, detect and respond to substandard and falsified medical products. 4. All relevant stakeholders at regional, national and local levels participate holistically to prevent, detect and respond to substandard and falsified medical products.	The mechanism 1. Raise the mechanism's profile and improve policy alignment, with the Chair attending relevant policy forums to advocate and communicate on behalf of the mechanism. 2. Improve engagement by Member States, especially in respect of Steering Committee roles. Regional engagement 3. Improve regional engagement by leveraging regional committee meetings for vice-chairs to present and report on regional substandard and falsified medical product data and communicate alerts about regional trends. 4. Establish regional pre- and post-Steering Committee meetings, led by vice-chairs, to solicit input on Steering Committee agenda items. Policy coherence 5. Focus on regulatory systems strengthening and multisectoral support, including legal and law enforcement sectors, to address the issue of substandard and falsified medical products adequately and comprehensively. 6. Ensure all handbooks and guidelines emphasize the need for multisectoral collaboration and a whole-of-government approach. 7. Foster the inclusion of regional, national and local officials to prevent, detect and respond to substandard and falsified medical products.	WHO Global Benchmarking Tool indicators 1. RS01.05: Legal provisions and relevant regulations to take actions. 2. RS04.03: Rapid alert and recall system. 3. MC01.02: Legal provisions and/or regulations to authorize market surveillance and control activities. 4. MC01.03: Legal provisions and/or regulations to address the role of national regulatory authorities. General progress indicators 5. The mechanism engages with and develops policy coherence in respect of substandard and falsified medical products with relevant organizations and stakeholders at regional and international levels. 6. The mechanism demonstrates increased collaboration, communication and cooperation with relevant organizations and stakeholders on issues related to substandard and falsified medical products.

Technical capacity Member States have the tools and resources to prevent, detect and respond to substandard and falsified medical products		
Proposed goals	**Proposed actions**	**Proposed indicators**
1. The legitimate medical product supply chain is secured by robust good manufacturing, distribution and pharmacy practices. 2. Import and export regulations protect the supply chain from substandard and falsified medical products. 3. Accredited labs support Member State efforts to prevent and detect substandard and falsified medical products. 4. Track and trace systems and end-to-end product security and supply chain solutions are implemented to help to ensure that medical products are legitimate and enhance the detection of substandard and falsified medical products. 5. Detection technologies are deployed to survey, monitor and identify substandard and falsified medical products. 6. Member States track and respond to substandard and falsified medical products that are sold via the internet and/or through informal markets.	Supply chain security and regulatory system strengthening 1. Work with relevant organizations and key Member State focal points on regulatory systems strengthening and capacity-building. Lab testing 2. Prioritize building national and regional capacity for testing by, for example, including lab qualifications as part of meeting WHO Global Benchmarking Tool milestones and/or relevant international standards (for example, ISO/IEC 17025:2017). Track and trace systems and detection technologies 3. Support the implementation of WHO handbooks and guidelines on track and trace systems and detection technologies. 4. Ensure handbooks and guidelines include a compendium of available track and trace systems and detection technologies, as well as advisory guidelines for health ministries and national regulatory agencies to work with other sectors to implement/deploy them. 5. Consider options for Member States to pool financial and technical resources, etc., in order to access and implement technologies on the ground. Internet sales and informal markets 6. Ensure a multisectoral approach to and raise awareness about the sale of substandard and falsified medical products via the internet and/or through informal markets.	WHO Global Benchmarking Tool indicators 1. MC01.05: Legal provisions and/or regulations exist for placement of a product's unique identification number. 2. MC01.07: Guidelines exist on the recall, storage and disposal of substandard and falsified medical products. 3. MC04.07: Documented and implemented procedures and mechanisms exist to prevent, detect and respond to substandard and falsified medical products. 4. MC04.08: Documented and implemented procedures and mechanisms exist to ensure safe storage and disposal of substandard and falsified medical products. General progress indicators 5. Capacity is developed to test, track and trace substandard and falsified medical products. 6. Member States demonstrate lab capacity, as reflected in reaching relevant national regulatory authority maturity levels.

Access to safe, effective, affordable and good quality medical products Member States provide and use good quality, comprehensive data to mitigate the harm posed by substandard and falsified medical products, thereby improving access to safe, effective, affordable and good quality medical products		
Proposed goals	**Proposed actions**	**Proposed indicators**
1. Member States contribute to and utilize databases with good quality and up-to-date data and fit-for-purpose reporting on substandard and falsified medical products. 2. Data, experiences and best practices are shared via WHO regional entities or other relevant forums.	Reporting and data Focus on improving the quality and consistency of data reported to the WHO Global Surveillance and Monitoring System for substandard and falsified medical products (GSMS) and ensure data access and transparency. The Member State mechanism should: 1. focus on reaching a consensus on data quality, access and transparency standards; 2. reach a consensus on the purpose of GSMS reporting – for example, whether it is for event management or knowledge generation; 3. work with the Secretariat to ensure that GSMS pulls data from existing reporting systems for substandard and falsified medical products to reduce the duplication of reporting and improve the breadth of data collection; 4. look at regional working groups to support and underpin improvements in data reporting and information sharing; 5. train Member State focal points in the importance of reporting consistent and fit-for-purpose data; 6. establish reporting mechanisms that both share and collect data on incidents of substandard and falsified medical products as reported by the public, health workers and/or relevant stakeholders; and Sharing data and best experiences 7. consider the impacts of regulation and surveillance on access to substandard and falsified medical products.	WHO Global Benchmarking Tool indicators 1. MC04.05: Documented and implemented procedures exist to enable the public to report substandard and falsified medical products. 2. MC06.02: Findings and regulatory decisions are communicated to all national stakeholders, including the public. 3. MC06.03: Findings and regulatory decisions are communicated and shared with other countries and regional and international organizations. General progress indicators 4. Increased number of national regulatory authorities reporting substandard and falsified medical products to GSMS. 5. Post-marketing surveillance indicators. NB: Working Group B already has plans to develop performance indicators for the functionality of Member State focal points.