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

1. The twelfth meeting of the Member State mechanism on substandard and falsified medical products was held in Geneva, Switzerland in a hybrid format from 15–17 November 2023. The meeting was chaired by Dr Paul Huleatt, Chair (Australia) and the following Vice-Chairs: Dr Celda Molake-Tiroyakgosi (Botswana), Ms Laila Mouawad (Brazil), Mr Zhou Naiyuan (China), Dr Raditya M. Kusumaningprang (Indonesia), Mrs Annam Visala (India), Dr Yasmine J. Ameen Kannan (Iraq), Dr Fatemeh Bashokouh (Islamic Republic of Iran), Dr Domenico Di Giorgio (Italy), Ms Iuliia Zarudska on behalf of Mrs Maryna Taran (Ukraine), Mr Mark Abdo (United States of America) and Mr Lyoko Nyambe (Zambia). Representatives from 54 Member States participated in the meeting.

2. The WHO Assistant Director-General (Access to Medicines and Health Products), Dr Yukiko Nakatani, opened the meeting and emphasized the importance of global access to safe, efficacious, quality and affordable medical products. In that regard, the prevention and detection of, and response to, substandard and falsified medical products remained crucial. The contributions of the mechanism in those areas were acknowledged. Outgoing Steering Committee members and working group chairs were thanked for all their contributions to implementing the workplan and prioritized activities of the mechanism for 2022–2023. Dr Huleatt of Australia was also thanked for his dedication and excellent leadership during his two years as the Chair of the mechanism.

### **Update by the Secretariat on activities and budget to implement the workplan of the Member State mechanism**

3. The Secretariat provided an update on the activities and budget to implement the workplan of the Member State mechanism, supplementing the information contained in document A/MSM/12/2, the contents of which was noted by the mechanism. Despite ongoing resource mobilization efforts, the Secretariat noted that the financial sustainability of the workplan for 2024–2025 remained a concern.

4. Updates were also provided on the WHO Global Surveillance and Monitoring System for substandard and falsified medical products noting that there had been a nearly 60% increase in recorded incidents over the past two years. Improved market surveillance by Member States national regulatory authorities was noted as a contributing factor leading to the increased detection and reporting. The Secretariat noted that incidents related to in vitro diagnostics were primarily reported by their manufacturer to the Global Surveillance and Monitoring System, which is expected for WHO recommended products and in Member States with legal provisions for reporting incidents and field safety corrective actions. In vitro diagnostics could still meet specifications but be unsafe, therefore incident reports should contain

information on health impacts so that benefit–risk assessments could be properly conducted by the respective manufacturers.

5. The Secretariat provided an update on the WHO Global Benchmarking Tool, focusing on the market surveillance and control indicators and the work performed in 2023. The Secretariat also provided an update on the WHO-listed authority initiative, including the additional performance evaluation required for such authorities. Recently designated WHO-listed authorities were also noted. During the discussion, it was clarified that a WHO-listed authority referred to a regulator or regulatory system that had been assessed to comply with all the relevant indicators and requirements specified by WHO for the requested scope for listing, based on an established benchmarking and a performance evaluation framework.

### **Update on incidents of over-the-counter syrups for children with confirmed or suspected contamination with high levels of diethylene glycol and ethylene glycol**

6. The Secretariat provided an overview of incidents of over-the-counter syrups for children with confirmed or suspected contamination with high levels of diethylene glycol and ethylene glycol, supplementing information contained in document A/MSM/12/3, the contents of which was noted by the mechanism. The overview included a description of the historical context and the recently reported incidents resulting in WHO medical product alerts as well as the Secretariat’s activities related to prevention, detection and response. The Secretariat provided an overview of the WHO pharmaceutical starting materials certification scheme aimed at addressing the root causes of such incidents, namely: inadequate supplier qualification, lack of origin information and limited identity testing. The Secretariat also provided an overview of tests for identification and quantification of diethylene glycol and ethylene glycol in liquid preparations for oral use, which were to be included in the general monographs of the International Pharmacopoeia.

7. During the discussion, it was clarified that the primary investigators of such incidents were the national regulatory authorities upon which the WHO Secretariat relied for information. The Secretariat was engaging with the United Nations Office on Drugs and Crime to research global trade of excipients and their respective starting materials to try and identify where contamination occurred, including characterization as accidental or intentional, as well as any other illicit activity. The need to focus on prevention was emphasized, noting that detection and response efforts were enormously burdensome, particularly in low-capacity settings.

8. In terms of how Member States could be encouraged and supported to promptly, openly and comprehensively report incidents involving substandard and falsified medical products that could have an immediate and far-reaching impact on other Member States, a few suggestions were offered including on: (i) improving the capacity of Member States to investigate substandard and falsified medical products; (ii) creating a user-friendly communication platform for networking and information sharing among national focal points; (iii) simplifying the Global Surveillance and Monitoring System database; and (iv) providing guidance on reportable incidents. There was also a suggestion for the Steering Committee to address the question at a future meeting and make recommendations for consideration by the mechanism.

### **Update on the list of prioritized activities for 2022–2023**

9. The Secretariat and/or the respective working group chairs provided updates regarding each of the prioritized activities. There was a focus on progress in 2023, as detailed in the report contained in document A/MSM/12/4.

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

10. Brazil, as the Chair of the working group for Activity A, provided an update on the actions of the working group. The Secretariat provided further information about the WHO Global Competency Framework that had gone through consultations and would be published soon, as well as on the Epione e-tool pilot project, noting that the Epione e-tool was due to be available to Member States in the first half of 2024.

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

11. Eritrea, as the Chair of the working group for Activity B, provided an update including an overview of the reporting barriers faced by national focal points of the Global Focal Point Network for substandard and falsified medical products and possible solutions as contained in document A/MSM/12/5, the contents of which was noted by the mechanism.

12. During the discussion, difficulties in reporting to the Global Surveillance and Monitoring System were discussed. It was suggested that technical issues (e.g. bandwidth issues) might be easier to solve than policy issues within countries. A mobile application was proposed as a possible solution along with additional training of focal points on the System. Further reflections on the purpose of the Global Surveillance and Monitoring System (e.g. as a repository for incident response and management) could aid in determining what solutions might work best. It was also suggested that future work should address reporting barriers and not just disparities in reporting capacities because the reasons for not reporting were not limited to those that were capacity-related.

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

13. Rwanda, as a member of the working group on traceability for Activity C, provided an update on improving Member States' implementation of national traceability systems and described the ongoing survey of national traceability systems.

14. Montenegro, as the Chair of the working group on detection technologies for Activity C, provided an update on how to use detection technologies to detect contaminated medicines and described the ongoing survey on existing methodologies and tools used to screen and detect substandard and falsified medical products.

**Activity D: Leverage the competencies of relevant stakeholders, including policy-makers, procurers, distributors, practitioners, patients and consumers, and good governance to reduce the burden of substandard and falsified medical products**

15. The Secretariat provided an update on Activity D, noting that it was the only activity without a Member State lead and a working group. The Secretariat had drafted a handbook for Member States on developing/strengthening national action plans for prevention, detection and response strategies on substandard and falsified medical products. The Secretariat was circulating the draft for comment among a

select group of stakeholders and would conduct pilot implementation projects in a few countries before finalizing the handbook.

16. During the discussion, metrics for assessing the quality of the action plans were discussed. It was suggested that the plans should indicate several key parameters including outputs, outcomes, timelines and structures, which should be measurable over time. Member States interested in utilizing the handbook were encouraged to contact the Secretariat.

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

17. Zambia, as the Chair of the working group for Activity E, provided an update on the actions of the working group and an overview of next steps, including to finalize media campaign material on discouraging members of the public from accessing antibiotics from illegal outlets. During the discussion, the significant public health risk presented by antimicrobial resistance was emphasized.

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

18. Australia, as the Chair of the working group for Activity F, provided an update on the actions of the working group, including on the proactive approach to disseminate and promote the materials and information developed by the Member State mechanism. Member States were encouraged to use the documentation developed by the Member State mechanism and WHO reports as tools to increase political awareness and advocacy at the highest policy levels about the need to support and dedicate resources to prevent, detect and respond to substandard and falsified medical products. The proposal to merge working groups E and F for the next biennium was noted. Engagement was an ongoing issue for the working group. Member States were encouraged to actively participate in working groups when nominated.

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

19. Colombia, as the Chair of the working group for Activity G, provided an update noting the work to develop a road map promoting inter-agency cooperation and collaboration with relevant stakeholders to respond to and promote awareness-raising and the policy visibility of the distribution of substandard and falsified medical products via the internet. There was an ongoing selection process for an expert consultant who would develop a training programme on dealing with the supply of substandard and falsified medical products on the internet. Regarding next steps, there were plans to advocate for Member State capacity-building so that all Member States were able to respond effectively to the online distribution of substandard and falsified medical products. During the discussion, Indonesia shared its experience in tackling substandard and falsified medical products available online, including through the use of a mobile application that received notifications from the public.

**Activity H: Develop strategies for national regulatory authorities to mitigate public health risks posed by the distribution of substandard and falsified medical products through informal markets**

20. The United States of America, as the Chair of the working group for Activity H as well as a consultant engaged for Activity H, provided an overview of substandard and falsified medical products and informal markets as contained in document A/MSM/12/6, the contents of which was noted by the mechanism. The comprehensive literature review on informal markets for medical products with a focus on substandard and

falsified medical products was described along with the landscape analysis of existing knowledge gaps, including the known prevalence and regulatory interventions to control and limit the distribution of substandard and falsified medical products through informal markets. Preliminary results of a pilot survey of Member States to assess their experiences, challenges and responses in respect of informal markets were presented.

21. During the discussion, the importance of such work was emphasized and several Member States reiterated the importance of working together and learning from each other given the common challenges faced in different countries.

### **WHO's participation in relevant global and regional initiatives**

22. The Secretariat provided an overview of WHO's collaborative participation in relevant global and regional initiatives. The Secretariat noted that in order to effectively coordinate and collaborate, insights on Member State engagement in other global and regional initiatives were needed. The importance of that work was emphasized in order to address substandard and falsified medical products through collaboration and coordination. A regional perspective was shared by a representative of the WHO Regional Office for the Americas.

### **Evaluation of the Member State mechanism**

23. The Secretariat provided an update on the status of the evaluation of the mechanism, which was moving forward in accordance with decision WHA76(10) (2023). Based on the evaluation terms of reference, the WHO Evaluation Office had initiated a bidding process among companies with which it had existing long-term agreements. Proposals would be jointly reviewed by the Evaluation Office and the responsible technical unit in the WHO Secretariat. If no proposal met the expected quality standards, the Evaluation Office would initiate a request for proposals. The current timeline was as follows: (i) selection of the evaluation team in November 2023; (ii) initial report due in January 2024; (iii) data collection phase from January 2024 to April 2024; (iv) stakeholder workshop in May 2024; and (v) final evaluation report in June 2024.

### **Governance matters**

24. With respect to the decision-making process of the mechanism, the possibility of approving a formalized silence procedure was considered (document A/MSM/12/7). The matter of decision-making of the mechanism arose following a request from the Steering Committee in March 2023 when it was explained that there was no standing arrangement for the mechanism to make intersessional decisions. In the light of the Steering Committee's interest in the mechanism enhancing its ability to react in a more agile way to emerging issues, the Secretariat prepared a paper for discussion at the Steering Committee meeting in June 2023. The document explained the steps that would be necessary to facilitate intersessional decision-making through the use of a written silence procedure when necessitated by circumstances that were to be further clarified. At the June 2023 meeting, while recognizing that a written silence procedure might rarely be needed, the Steering Committee members expressed support for its consideration by the mechanism.

25. Following a discussion on the matter where views were expressed by a number of Member States, it was decided not to approve the written silence procedure but rather to focus on the creation of a new prioritized activity on the identification of and response to emerging issues on substandard and falsified medical products, which would enable the mechanism to operate in a more agile way. New proposals on the establishment of a written silence procedure if it were deemed necessary after future discussions, should

be addressed to the WHO bodies responsible for governance matters. The report contained in document A/MSM/12/7 was noted by the mechanism.

26. With respect to possible engagement with non-State actors in the work of the mechanism, the Chair provided an overview in line with the report contained in document A/MSM/12/8, the contents of which was noted by the mechanism. The importance of multisectoral engagement was emphasized. It was discussed that stakeholder mapping would be an important step during the evaluation of the mechanism that could provide additional insight into the ways in which non-State actors might be engaged by the mechanism in the future. It was proposed that modalities for engaging with non-State actors could be considered over the next biennium by the Steering Committee. New proposals on that matter could be submitted to the mechanism for its consideration.

27. The mechanism noted that the new composition of the Steering Committee, beginning from the closure of the twelfth meeting of the Member State mechanism, would be as follows.

- African Region: Ethiopia and Rwanda
- Region of the Americas: Brazil and the United States of America
- South-East Asia Region: India and Indonesia
- European Region: Israel and Serbia
- Eastern Mediterranean Region: To be determined
- Western Pacific Region: Australia and the Republic of Korea

28. As recommended by the Sixty-sixth World Health Assembly in decision WHA66(10) (2013) and agreed to by the Member State mechanism, the position of chair rotated among the six WHO regions, in English alphabetical order. Following regional consultations, the next chair had been appointed from Rwanda in the African Region.

29. It was noted that regional consultations on the matter had not yet concluded for the Eastern Mediterranean Region and would be reported on a later date, as soon as possible.

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

30. The mechanism considered the draft list of prioritized activities for the period 2024–2025, submitted by the Steering Committee. Ten prioritized activities were proposed, including seven continued from 2022–2023 and three new ones. Following consideration and discussion of the activities, Member States approved the draft list of prioritized activities and actions to implement the workplan of the Member State mechanism for the period 2024–2025, including the strategic plan (See Annexes 1 and 2). The Chair commended Member States for preparing a list of prioritized activities and strategic plan that would enable the mechanism to be more agile and forward-looking.

31. An expression of interest in leading or joining working groups was made by the following Member States and welcomed by the mechanism:

- Activity C – new member: Iran
- Activity D – Chair of newly established working group D: South Africa; new members: Ethiopia, Kenya, Liberia, Morocco, Nigeria, Rwanda, and the United Republic of Tanzania
- Activity E – new members: Botswana and Chad
- Activity F – Chair of newly established working group F: the United States of America; new members: Australia, Benin, Morocco, Nigeria, Rwanda and the United Republic of Tanzania
- Activity G – new members: Benin, Morocco, Rwanda and South Africa
- Activity H – new members: Chad, Rwanda and South Africa
- Activity I – new member: Eritrea
- Activity J – new members: Benin, Botswana, Liberia, Morocco and South Africa.

32. All working groups remained open to all Member States and could be joined at any time. The Secretariat would send an overview of all working groups together with a call for enrolment in due course.

### **Proposed dates of the thirteenth meeting of the Member State mechanism**

33. The Member State mechanism decided that its thirteenth meeting should take place in the week of 18 November 2024. Should exigent circumstances preclude the holding of the meeting during that week, it was agreed that adjustments to the timing of the meeting would be made by the Chair, in consultation with Steering Committee members and the Secretariat.

**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
<p>A. Strengthen the capacity of national/regional regulatory authorities for the prevention and detection of, and response to, substandard and falsified medical products.</p> <p>Lead: Brazil, with the support of the Secretariat.</p>	<ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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.</li> <li>4. Improve the availability and usability of the WHO knowledge base on substandard and falsified medical products for Member States.</li> </ol>	<ol style="list-style-type: none"> <li>1(a) Consolidated list of market control and surveillance training needs for all benchmarked countries available to Member States via a shared platform.</li> <li>1(b) Roster of market control and surveillance expertise maintained based on assessed competency.</li> <li>1(c) Consolidated and regularly updated list of training materials available to Member States.</li> <li>2(a) At least 10 Member States adopting/adapting the Epione e-tool by the end of 2025.</li> <li>2(b) At least 10 Member States maintaining their risk-based post-market surveillance data on the WHO electronic prequalification system (ePQS) platform.<sup>1</sup></li> <li>3. WHO technical guideline on risk-based market surveillance and control published by December 2025.</li> <li>4. e-Library of training materials, guidance documents and other relevant resources published on a user-friendly shared platform.</li> </ol>	<ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>3. Member States with robust surveillance systems and capacities for planning, performing and assessing risk-based market surveillance and control of supply chains.</li> <li>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.</li> </ol>

<sup>1</sup> The WHO ePQS platform is a piece of cloud-based software.



Prioritized activities	Proposed actions	Metrics/Success indicators	Expected outcomes
<p>B. Develop, expand and maintain global networks of stakeholders to facilitate cooperation and collaboration.</p> <p>Lead: Eritrea, with the support of the Secretariat.</p>	<ol style="list-style-type: none"> <li>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).</li> <li>2. Develop a substandard and falsified incidents communication platform for focal points to facilitate information sharing and networking.</li> <li>3. Develop key performance indicators for monitoring the functionality of the Global Focal Point Network.</li> </ol>	<ol style="list-style-type: none"> <li>1(a) Mechanisms for implementing the proposed solutions for bridging reporting barriers developed by January 2024.</li> <li>1(b) Implement the proposed solutions in at least two pilot countries by the end of 2025.</li> <li>2. Online communication portal developed by the end of 2024.</li> <li>3(a) Key performance indicators developed by the end of 2024.</li> <li>3(b) Update Global Focal Point Network (document A/MSM/4/2) by the end of 2025.</li> </ol>	<ol style="list-style-type: none"> <li>1. Member States are ready to implement the proposed solutions for bridging reporting barriers, improving the quality and quantity of reporting.</li> <li>2. Improved communication about substandard and falsified medical products among focal points.</li> <li>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.</li> </ol>
<p>C. Improve Member States' understanding and uptake of technologies to screen and detect substandard and falsified medical products.</p> <p>Lead: Montenegro, with the support of the Secretariat.</p>	<ol style="list-style-type: none"> <li>1. Develop user requirements for ideal handheld devices for screening substandard and falsified medicines to inform target product profiles and/or preferred product characteristics.</li> </ol>	<ol style="list-style-type: none"> <li>1. User requirements developed by the end of 2024.</li> </ol>	<ol style="list-style-type: none"> <li>1(a) Improved screening of substandard and falsified medical products in the supply chain through the use of devices equipped with the necessary features and capabilities.</li> <li>1(b) Greater standardization and interoperability among devices, allowing for improved data sharing and collaboration among Member States in combating substandard and falsified medical products.</li> </ol>
<p>D. Leverage the competencies of relevant stakeholders, including policy-makers, procurers, distributors, practitioners, patients and consumers, and good governance to reduce the burden of substandard and falsified medical products.</p> <p>Lead: South Africa, with the support of the Secretariat.</p>	<ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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.</li> </ol>	<ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>1(c) Yearly monitoring and evaluation report on the status of the implementation of national action plans.</li> <li>2. At least one annual meeting conducted on the implementation of national action plans.</li> </ol>	<ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>2(b) Functional regional and international networks that foster cross-border collaboration and information exchange.</li> <li>3(a) Increased knowledge and evidence-based recommendations and national policy development.</li> <li>3(b) Strengthened regulatory frameworks, enhanced international collaboration and greater public awareness and engagement.</li> </ol>

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 and subsequently 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: United States of America, 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, and 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 inter-agency 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(a) 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. 1(b) 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. 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.
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
<p>I. Identification of and response to emerging issues on substandard and falsified medical products.</p> <p>Lead: Member State mechanism Chair, with the support of the Secretariat.</p>	<p>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.</p> <p>2. Convene on an ad hoc basis to respond to emerging issues.</p>	<p>1. Risk assessment framework developed by the end of 2024.</p>	<p>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.</p> <p>2. An effective response to address the issue of concern based on selection of an appropriate modality such as technical briefing sessions, recommendations or other actions as appropriate.</p>
<p>J. Improve Member States' implementation of national traceability systems.</p> <p>Lead: Nigeria, with the support of the Secretariat.</p>	<p>1. Convene at least one technical briefing session per year to review existing traceability models, including approaches and enabling technologies.</p>	<p>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.</p>	<p>1. Member States with improved capacity to monitor and identify substandard and falsified medical products in their respective supply chains.</p> <p>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.</p> <p>3. Consumers with greater trust in the health care system and confidence in the medical products being distributed in Member States.</p>

## ANNEX 2

<b>Member State engagement</b>		
The Member State mechanism is agile and forward-looking serving as a forum for discussion and the development of recommendations for policy-makers		
<b>Proposed goals</b>	<b>Proposed actions</b>	<b>Proposed indicators</b>
<ol style="list-style-type: none"> <li>1. The Member State mechanism is a critical and valued partner for international organizations and policy forums.</li> <li>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.</li> <li>3. All relevant sectors are integrated in a whole-of-government approach to prevent, detect and respond to substandard and falsified medical products.</li> <li>4. All relevant stakeholders at the regional, national and local levels participate holistically to prevent, detect and respond to substandard and falsified medical products.</li> </ol>	<p>The mechanism</p> <ol style="list-style-type: none"> <li>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.</li> <li>2. Improve engagement by Member States, especially in respect of Steering Committee roles.</li> </ol> <p>Regional engagement</p> <ol style="list-style-type: none"> <li>3. Improve regional engagement by leveraging regional committee meetings for the Vice-Chairs to present and report on regional substandard and falsified medical product data and communicate alerts about regional trends.</li> <li>4. Establish regional pre- and post-Steering Committee meetings, led by the Vice-Chairs, to solicit input on Steering Committee agenda items.</li> </ol> <p>Policy coherence</p> <ol style="list-style-type: none"> <li>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.</li> <li>6. Ensure all handbooks and guidelines emphasize the need for multisectoral collaboration and a whole-of-government approach.</li> <li>7. Foster the inclusion of regional, national and local officials to prevent, detect and respond to substandard and falsified medical products.</li> </ol>	<p>WHO Global Benchmarking Tool indicators<sup>1</sup></p> <ol style="list-style-type: none"> <li>1. RS01.05: Legal provisions and relevant regulations to take actions.</li> <li>2. RS04.03: Rapid alert and recall system.</li> <li>3. MC01.02: Legal provisions and/or regulations to authorize market surveillance and control activities.</li> <li>4. MC01.03: Legal provisions and/or regulations to address the role of national regulatory authorities.</li> </ol> <p>General progress indicators</p> <ol style="list-style-type: none"> <li>5. The mechanism engages with and develops policy coherence in respect of substandard and falsified medical products with relevant organizations and stakeholders at the regional and international levels.</li> <li>6. The mechanism demonstrates increased collaboration, communication and cooperation with relevant organizations and stakeholders on issues related to substandard and falsified medical products.</li> </ol>

<sup>1</sup> The WHO Global Benchmarking Tool indicators are available at <https://www.who.int/tools/global-benchmarking-tools> (accessed on 27 November 2023).

<b>Technical capacity</b>		
Member States have the tools and resources to prevent, detect and respond to substandard and falsified medical products		
<b>Proposed goals</b>	<b>Proposed actions</b>	<b>Proposed indicators</b>
<ol style="list-style-type: none"> <li>1. The legitimate medical product supply chain is secured by robust good manufacturing, distribution and pharmacy practices.</li> <li>2. Import and export regulations protect the supply chain from substandard and falsified medical products.</li> <li>3. Accredited laboratories support Member State efforts to prevent and detect substandard and falsified medical products.</li> <li>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.</li> <li>5. Detection technologies are deployed to survey, monitor and identify substandard and falsified medical products.</li> <li>6. Member States track and respond to substandard and falsified medical products that are sold via the internet and/or through informal markets.</li> </ol>	<p>Supply chain security and regulatory system strengthening</p> <ol style="list-style-type: none"> <li>1. Work with relevant organizations and key Member State focal points on regulatory systems strengthening and capacity-building.</li> </ol> <p>Laboratory testing</p> <ol style="list-style-type: none"> <li>2. Prioritize building national and regional capacity for testing by, for example, including laboratory qualifications as part of meeting WHO Global Benchmarking Tool milestones and/or relevant international standards (such as ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories).</li> </ol> <p>Track and trace systems and detection technologies</p> <ol style="list-style-type: none"> <li>3. Support the implementation of WHO handbooks and guidelines on track and trace systems and detection technologies.</li> <li>4. Ensure that 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 and/or deploy them.</li> <li>5. Consider options for Member States to pool financial and technical resources, etc., in order to access and implement technologies on the ground.</li> </ol> <p>Internet sales and informal markets</p> <ol style="list-style-type: none"> <li>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.</li> </ol>	<p>WHO Global Benchmarking Tool indicators</p> <ol style="list-style-type: none"> <li>1. MC01.05: Legal provisions and/or regulations exist for placement of a product's unique identification number.</li> <li>2. MC01.07: Guidelines exist on the recall, storage and disposal of substandard and falsified medical products.</li> <li>3. MC04.07: Documented and implemented procedures and mechanisms exist to prevent, detect and respond to substandard and falsified medical products.</li> <li>4. MC04.08: Documented and implemented procedures and mechanisms exist to ensure safe storage and disposal of substandard and falsified medical products.</li> </ol> <p>General progress indicators</p> <ol style="list-style-type: none"> <li>5. Capacity is developed to test, track and trace substandard and falsified medical products.</li> <li>6. Member States demonstrate laboratory capacity, as reflected in reaching the relevant national regulatory authority maturity levels.</li> </ol>

**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
<ol style="list-style-type: none"> <li>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.</li> <li>2. Data, experiences and best practices are shared via WHO regional entities or other relevant forums.</li> </ol>	<p>Reporting and data</p> <ol style="list-style-type: none"> <li>1. Focus on improving the quality and consistency of data reported to the WHO Global Surveillance and Monitoring System for substandard and falsified medical products and ensure data access and transparency. The Member State mechanism should:               <ul style="list-style-type: none"> <li>• focus on reaching a consensus on data quality, access and transparency standards;</li> <li>• reach a consensus on the purpose of WHO Global Surveillance and Monitoring System reporting – for example, whether it is for event management or knowledge generation;</li> <li>• work with the Secretariat to ensure that WHO Global Surveillance and Monitoring System 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;</li> <li>• look at regional working groups to support and underpin improvements in data reporting and information sharing;</li> <li>• train Member State focal points in the importance of reporting consistent and fit-for-purpose data;</li> <li>• 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</li> </ul> </li> </ol> <p>Sharing data and best experiences</p> <ul style="list-style-type: none"> <li>• consider the impacts of regulation and surveillance on access to substandard and falsified medical products.</li> </ul>	<p>WHO Global Benchmarking Tool indicators</p> <ol style="list-style-type: none"> <li>1. MC04.05: Documented and implemented procedures exist to enable the public to report substandard and falsified medical products.</li> <li>2. MC06.02: Findings and regulatory decisions are communicated to all national stakeholders, including the public.</li> <li>3. MC06.03: Findings and regulatory decisions are communicated and shared with other countries and regional and international organizations.</li> </ol> <p>General progress indicators</p> <ol style="list-style-type: none"> <li>4. An increased number of national regulatory authorities are reporting substandard and falsified medical products to the WHO Global Surveillance and Monitoring System.</li> <li>5. Post-marketing surveillance indicators.</li> </ol> <p>Note: Working group B already has plans to develop performance indicators for the functionality of Member State focal points.</p>