World Health Organization

**Executive Board**
**156th session**

Provisional agenda item 10 EB156/11

17 January 2025

# Substandard and falsified medical products

## Report by the Director-General

1. The Director-General has the honour to transmit to the Executive Board at its 156th session the reports of the twelfth and thirteenth meetings of the Member State mechanism on substandard and falsified medical products (see Annexes 1 and 2), which were held in a hybrid format on 15–17 November 2023 and 20–22 November 2024, respectively.[1]

## Action by the Executive Board

2. The Board is invited to note the report and consider the following draft decision:

> The Executive Board, having considered the report by the Director-General,[2]
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> Decided to recommend to the Seventy-eighth World Health Assembly the adoption of the following decision:
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> > The Seventy-eighth World Health Assembly,
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> > Having considered the report by the Director-General, in particular, the provisions pertaining to the independent evaluation of the Member State mechanism,
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> > Decided to request the Director-General to submit the report of the fourteenth meeting of the Member State mechanism to the Seventy-ninth World Health Assembly through the Executive Board at its 158th session.

[1] The goal, objectives and terms of reference for meetings of the Member State mechanism were established in the Annex to resolution WHA65.19 (2012).

[2] Document EB156/11. See also document EB156/12.

# Annex 1

# 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 Abdoo (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: Islamic Republic of 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.

# Appendix 1

## 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.<br>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.<br>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.<br>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.<br>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.<br>1(b) Roster of market control and surveillance expertise maintained based on assessed competency.<br>1(c) Consolidated and regularly updated list of training materials available to Member States.<br>2(a) At least 10 Member States adopting/adapting the Epione e-tool by the end of 2025.<br>2(b) At least 10 Member States maintaining their risk-based post-market surveillance data on the WHO electronic prequalification system (ePQS) platform.[1]<br>3. WHO technical guideline on risk-based market surveillance and control published by December 2025.<br>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.<br>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.<br>3. Member States with robust surveillance systems and capacities for planning, performing and assessing risk-based market surveillance and control of supply chains.<br>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.<br>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).<br>2. Develop a substandard and falsified incidents communication platform for focal points to facilitate information sharing and networking.<br>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.<br>1(b) Implement the proposed solutions in at least two pilot countries by the end of 2025.<br>2. Online communication portal developed by the end of 2024.<br>3(a) Key performance indicators developed by the end of 2024.<br>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.<br>2. Improved communication about substandard and falsified medical products among focal points.<br>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.<br>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(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.<br>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. |
| 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.<br>Lead: South Africa, 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.<br>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.<br>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.<br>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.<br>1(c) Yearly monitoring and evaluation report on the status of the implementation of national action plans.<br>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.<br>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.<br>2(b) Functional regional and international networks that foster cross-border collaboration and information exchange.<br>3(a) Increased knowledge and evidence-based recommendations and national policy development. |

| 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.<br>3(b) Position papers prepared for all research conducted to influence the development and implementation of appropriate policies and practices. | 3(b) Strengthened regulatory frameworks, enhanced international collaboration and greater public awareness and engagement. |
| 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.<br>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.<br>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.<br>1(b) Map and review effective communication activities and subsequently share findings and report to Member States by the end of 2025.<br>2(a) Convene at least one technical briefing session per year.<br>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.<br>1(b) Identification of gaps or areas for improvement in current risk communication activities, leading to targeted recommendations for enhancing communication efforts.<br>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.<br>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.<br>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.<br>1(b) Map/list of the weaknesses and vulnerabilities in the excipient supply chain.<br>2(a) Report on the status of data sharing on the control, quality and safety of excipients.<br>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.<br>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.<br>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.<br>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.<br>1(b) Pilot training programme launched in working group G by the end of 2024.<br>1(c) Training seminar delivered for each WHO region, via the internet training programme, by the end of 2025.<br>2(a) At least one informal technical briefing session delivered by the end of 2024.<br>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.<br>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.<br>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.<br>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.<br>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.<br>2. Finalize the workplan of technical activities to address knowledge gaps by the end of 2024.<br>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.<br>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.<br>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.<br>2. Convene 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.<br>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. |
| J. Improve Member States' implementation of national traceability systems.<br>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.<br>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.<br>3. Consumers with greater trust in the health care system and confidence in the medical products being distributed in Member States. |

# Appendix 2

| **Member State engagement**<br>The Member State mechanism is agile and forward-looking serving as a forum for discussion and the development of recommendations for policy-makers | | |
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| **Proposed goals** | **Proposed actions** | **Proposed indicators** |
| 1. The Member State mechanism is a critical and valued partner for international organizations and policy forums.<br>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.<br>3. All relevant sectors are integrated in a whole-of-government approach to prevent, detect and respond to substandard and falsified medical products.<br>4. All relevant stakeholders at the regional, national and local levels participate holistically to prevent, detect and respond to substandard and falsified medical products. | The mechanism<br>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.<br>2. Improve engagement by Member States, especially in respect of Steering Committee roles.<br>Regional engagement<br>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.<br>4. Establish regional pre- and post-Steering Committee meetings, led by the Vice-Chairs, to solicit input on Steering Committee agenda items.<br>Policy coherence<br>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.<br>6. Ensure all handbooks and guidelines emphasize the need for multisectoral collaboration and a whole-of-government approach.<br>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]<br>1. RS01.05: Legal provisions and relevant regulations to take actions.<br>2. RS04.03: Rapid alert and recall system.<br>3. MC01.02: Legal provisions and/or regulations to authorize market surveillance and control activities.<br>4. MC01.03: Legal provisions and/or regulations to address the role of national regulatory authorities.<br>General progress indicators<br>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.<br>6. The mechanism demonstrates increased collaboration, communication and cooperation with relevant organizations and stakeholders on issues related to substandard and falsified medical products. |

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

| **Technical capacity**<br>Member States have the tools and resources to prevent, detect and respond to substandard and falsified medical products | | |
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| **Proposed goals** | **Proposed actions** | **Proposed indicators** |
| 1. The legitimate medical product supply chain is secured by robust good manufacturing, distribution and pharmacy practices.<br>2. Import and export regulations protect the supply chain from substandard and falsified medical products.<br>3. Accredited laboratories support Member State efforts to prevent and detect substandard and falsified medical products.<br>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.<br>5. Detection technologies are deployed to survey, monitor and identify substandard and falsified medical products.<br>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<br>1. Work with relevant organizations and key Member State focal points on regulatory systems strengthening and capacity-building.<br>Laboratory testing<br>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).<br>Track and trace systems and detection technologies<br>3. Support the implementation of WHO handbooks and guidelines on track and trace systems and detection technologies.<br>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.<br>5. Consider options for Member States to pool financial and technical resources, etc., in order to access and implement technologies on the ground.<br>Internet sales and informal markets<br>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<br>1. MC01.05: Legal provisions and/or regulations exist for placement of a product's unique identification number.<br>2. MC01.07: Guidelines exist on the recall, storage and disposal of substandard and falsified medical products.<br>3. MC04.07: Documented and implemented procedures and mechanisms exist to prevent, detect and respond to substandard and falsified medical products.<br>4. MC04.08: Documented and implemented procedures and mechanisms exist to ensure safe storage and disposal of substandard and falsified medical products.<br>General progress indicators<br>5. Capacity is developed to test, track and trace substandard and falsified medical products.<br>6. Member States demonstrate laboratory capacity, as reflected in reaching the relevant national regulatory authority maturity levels. |

| **Access to safe, effective, affordable and good quality medical products**<br>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 | | |
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| **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.<br>2. Data, experiences and best practices are shared via WHO regional entities or other relevant forums. | Reporting and data<br>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:<br>• focus on reaching a consensus on data quality, access and transparency standards;<br>• 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;<br>• 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;<br>• look at regional working groups to support and underpin improvements in data reporting and information sharing;<br>• train Member State focal points in the importance of reporting consistent and fit-for-purpose data;<br>• 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<br>Sharing data and best experiences<br>• consider the impacts of regulation and surveillance on access to substandard and falsified medical products. | WHO Global Benchmarking Tool indicators<br>1. MC04.05: Documented and implemented procedures exist to enable the public to report substandard and falsified medical products.<br>2. MC06.02: Findings and regulatory decisions are communicated to all national stakeholders, including the public.<br>3. MC06.03: Findings and regulatory decisions are communicated and shared with other countries and regional and international organizations.<br>General progress indicators<br>4. An increased number of national regulatory authorities are reporting substandard and falsified medical products to the WHO Global Surveillance and Monitoring System.<br>5. Post-marketing surveillance indicators.<br>Note: Working group B already has plans to develop performance indicators for the functionality of Member State focal points. |

# Annex 2

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

1. The thirteenth meeting of the Member State mechanism on substandard and falsified medical products was held in Geneva in a hybrid format from 20 to 22 November 2024. The meeting was chaired by Professor Emile Bienvenu, Chair (Rwanda) and the following Vice-Chairs: Dr Paul Huleatt (Australia), Ms Laila Mouawad (Brazil), Mrs Annam Visala (India), Mr Sherwin Tobing (Indonesia), Dr Fatemeh Bashokouh (Islamic Republic of Iran), Dr Ronny Berkovitz (Israel), Dr Mohammed Hamdan Al Rubaie (Oman), Mr Pavle Zelic (Serbia) and Mr Mark Abdoo (United States of America). Representatives from 63 Member States participated in the meeting.

2. The WHO Assistant Director-General (Access to Medicines and Health Products), Dr Yukiko Nakatani, opened the meeting, welcomed participants to Geneva and acknowledged the contributions of the Steering Committee over the past year. Dr Nakatani emphasized the importance of the independent evaluation as an essential step in understanding the mechanism's impact, assessing successes and identifying areas for improvement. She noted that the evaluation findings would inform strategic planning for the mechanism as well as the implementation of actions included in the WHO management response to the evaluation report. Additionally, Dr Nakatani highlighted the 19th International Conference of Drug Regulatory Authorities meeting, held in India (October 2024), where global regulatory recommendations, including those on combating substandard and falsified medical products, were made.

## 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/13/2, the contents of which were noted by the mechanism. The update included an overview of the Secretariat's workplan in relation to the prioritized activities; the Secretariat noted that the financial sustainability of the workplan remained a concern.

4. Updates were also provided on the WHO Global Surveillance and Monitoring System for substandard and falsified medical products, noting that training and other network engagement events had an impact on reporting to the WHO Global Surveillance and Monitoring System. The Secretariat also provided an update on the WHO medical product alerts issued in 2024, among other risk communication activities. With regard to emerging issues, the Secretariat pointed out the increase in reports of falsified opioid and benzodiazepine medicines and the high-quality packaging of falsified medical products. The Secretariat noted that 70% of incidents related to in vitro diagnostics were primarily reported to the WHO Global Surveillance and Monitoring System by the manufacturers. The Secretariat reported on how the use of WHO's Epidemic Intelligence from Open Sources Initiative (EIOS) tool contributed to the WHO Global Surveillance and Monitoring System database by detecting and monitoring media articles on substandard and falsified medical products.

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

5. The Secretariat and/or the respective working group chairs provided updates regarding each of the prioritized activities. There was a focus on progress in 2024, as detailed in the report contained in document A/MSM/13/3.

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

6. Brazil, as the Chair of the working group for Activity A, provided an update on the actions and next steps of the working group. The Secretariat presented the comparative analysis of national regulatory systems based on the WHO Global Benchmarking Tool and institutional development plan data used to identify common critical gaps and needs for effective market surveillance and control – as detailed in the executive summary in document A/MSM/13/4, the contents of which were noted by the mechanism.

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

7. The Secretariat, on behalf of Eritrea as the Chair of the working group for Activity B, provided an update on the actions, indicators and future activities of the working group. In 2025, the working group intended to conduct a review of the terms of reference of the Global Focal Point Network for substandard and falsified medical products.

### Activity C: Improve Member States' understanding and uptake of technologies to screen and detect substandard and falsified medical products

8. Montenegro, as the Chair of the working group for Activity C, provided an update on the status of actions, interim milestones on key activities and performance indicators of the working group. The Chair of the working group also presented the results of a Member State survey on the use of technologies – as detailed in the executive summary in document A/MSM/13/5, the contents of which were noted by the mechanism.

### 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

9. South Africa, as the Chair of working group for Activity D, provided an update on the progress on implementation of actions for that prioritized activity. The working group Chair raised concerns regarding reduced attendance and called for the addition of new members to the group, particularly from countries implementing national action plans on substandard and falsified medical products. The Secretariat also provided information on the status of the development of a handbook to support the development and implementation of national action plans and a pilot in South Africa, as well as the validation of existing plans for the Gambia and Nigeria.

### Activity E: Enhance Member States' capacity to develop and utilize effective risk communication strategies, with the aim of expanding awareness of substandard and falsified medical products

10. The Secretariat, on behalf of Italy, 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 a survey to be conducted in 2025 to assess the current status, challenges and best practices in risk communication and awareness-raising activities by Member States. The working group Chair reiterated the importance of Member States sharing successful risk communication and awareness-raising models on the virtual information sharing platform. That material could then be adapted and reused by other Member States.

### Activity F: Strengthening the supply chain of high-risk excipients and related raw materials

11. The United States of America, as the Chair of the working group for Activity F, provided an update on the status of the working group's actions, including next steps to complete outputs for 2025. A representative from UNODC presented the tentative findings from an ongoing study to establish the drivers and weaknesses in the pharmaceutical excipient supply chain that led to the proliferation of oral liquid medicines contaminated with diethylene glycol and ethylene glycol. The mechanism would further consider the matter when the UNODC report was finalized. The Secretariat provided information on existing WHO-coordinated model certification schemes on the quality of pharmaceutical products and pharmaceutical starting materials. The schemes were voluntary administrative instruments to certify core details of pharmaceutical products and pharmaceutical starting materials entering international trade and could be used by Member States to assure product quality.

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

12. Colombia, as the Chair of the working group for Activity G, provided an update on the status of the group's actions. The Chair of the working group emphasized the importance of first developing normative guidance, to be followed by training programmes. The working group would continue to support the development, delivery and implementation of training programmes in collaboration with the Secretariat.

### 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

13. The United States of America, as the Chair of the working group for Activity H, provided an overview of the status of the implementation of its actions. Key updates included the planned publication of results from a recent literature review of published information on informal markets, as well as a new Member State survey to be rolled out during 2025. Two new actions were highlighted: developing a research methodology toolkit for adaptable, scalable studies, and exploring use of a tool to gather household-level data. Plans for 2025 would focus on completing initiatives to bridge knowledge gaps and strengthen responses to informal markets.

### Activity I: Identification of and response to emerging issues on substandard and falsified medical products

14. The Secretariat, on behalf of the Chair of the mechanism, who was also serving as the Chair of the working group for Activity I, provided an update on efforts to address emerging issues on substandard and falsified medical products. A stepwise approach was agreed upon, including identifying criteria to define "emerging issues", determining when such issues fell within the mechanism's scope, to be followed by testing those definitions using case studies. The group noted the need for a more balanced membership from across the six WHO regions. Guidance was requested on refining the approach, criteria and strategies for addressing identified issues. Next steps to focus on were expanding membership and operationalizing the agreed framework.

### Activity J: Improve Member States' implementation of national traceability systems

15. Nigeria, as the Chair of the working group for Activity J, provided an update on the results of a survey to better understand country experiences regarding traceability systems – as detailed in the executive summary in document A/MSM/13/6, the contents of which were noted by the mechanism. The report of country experiences implementing traceability for medical products would be made available on the WHO website.

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

16. The Secretariat provided an overview of WHO's participation in relevant global and regional initiatives, noting both ongoing and upcoming initiatives. The importance of international collaboration and coordination was emphasized, in order to address substandard and falsified medical products. The Secretariat presented the recommendations made during the 19th International Conference of Drug Regulatory Authorities held in New Delhi in October 2024. The mechanism noted the report.

## Evaluation of the Member State mechanism

17. The Secretariat introduced the independent evaluation of the Member State mechanism and outlined the objective, purpose and methodology employed, as detailed in the executive summary of the report contained in document A/MSM/13/7. The evaluation team described the key relevance, effectiveness, coherence, sustainability and equity findings and recommendations. In presenting the management response, the Access to Medicines and Health Products Division welcomed the evaluation, noted that the management response was a management tool and explained that actions to implement some of the recommendations had implications for structural reforms and would require decisions by the governing bodies. The Division explained that recommendations that were more operational in nature could be taken forward without delay.

18. The Chair reported on the Steering Committee's discussion of the report on the evaluation. He explained that the Steering Committee considered that most of the recommendations were straightforward and operational in nature. With respect to recommendation 1 on a possible revision to the format of the mechanism and recommendation 5 on improving external engagement, the Steering Committee was of the opinion that it would be useful to take more time for their consideration. In that regard, the Steering Committee recommended that the Member State mechanism: (1) propose that the governing bodies refrain from taking any decisions on the evaluation at their forthcoming meetings in 2025; (2) request that the Steering Committee take such additional time as needed, for example through one or more extended meetings next year, to engage with the Secretariat to develop and consider a new theory of change and results

framework, along with other follow-up actions, and only then formulate any recommendations for the consideration of the Member State mechanism at its fourteenth meeting; (3) request that the report of the fourteenth meeting of the Member State mechanism be submitted to the Executive Board at its 158th session and to the Seventy-ninth World Health Assembly, so that the governing bodies may consider the outcomes of the Member State mechanism's deliberations on those matters and take any action that might be required.

19. The Member State mechanism expressed appreciation for the evaluation, agreed that further time was needed to consider the recommendations, and endorsed the proposal by the Steering Committee.

## Governance matters

20. At the invitation of the Chair, the Secretariat explained that, in accordance with resolution WHA65.19 (2012), the report of the Member State mechanism was submitted to the governing bodies on a biennial basis. In that regard, the next report of the Member State mechanism would be submitted to the Executive Board at its 156th session and Seventy-eighth World Health Assembly, and would contain the reports of the twelfth and thirteenth meetings of the Member State mechanism, held in November 2023 and November 2024, respectively. In addition, further to the proposal in paragraph 18 above, and if agreed by the governing bodies, the report of the fourteenth meeting of the Member State mechanism will be submitted to the Executive Board, at its 158th session, and the Seventy-ninth World Health Assembly.

21. The Chair of the mechanism explained a proposal considered by the Steering Committee to invite a stakeholder to make a presentation at an upcoming Steering Committee meeting. He noted that paragraph 2 of the section on relations with other stakeholders and experts in the annex to resolution WHA65.19, which contained the goals, objectives and terms of reference of the Member State mechanism, provided that "as needed, the Member State mechanism will invite other stakeholders to collaborate and consult with the group on specific topics".

22. In that regard, there had been a proposal to invite the Bill & Melinda Gates Foundation to give a briefing at a future meeting of the Steering Committee on the Foundation's activities that were relevant to prioritized activity D, relating to reducing the burden of substandard and falsified medical products, and the Steering Committee had agreed to proceed in that manner.

23. The Chair further noted that as the Steering Committee continued its work in support of the mechanism, including oversight of the implementation of the mechanism workplan, it could be expected that the Steering Committee may identify additional matters on which consultations with other stakeholders may be desirable, and might take place. Such consultations would take place consistent with the WHO Rules of Procedure and the Framework for Engagement with Non-State Actors. The Steering Committee reports on such consultations would be a valuable addition to mechanism discussions. The mechanism expressed support for the Steering Committee proceeding in that manner.

## Proposed dates of the fourteenth meeting of the Member State mechanism

24. The Member State mechanism decided that its fourteenth meeting should take place in the week of 10 November 2025. 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.

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