

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

1. The tenth meeting of the Member State mechanism on substandard and falsified medical products was held virtually from 27–28 October 2021 and was chaired by Dr V.G. Somani (India) with the following Vice-Chairs: Mr Oluwakayodé Nils Daniel Kintin (Benin), Mr Leonardo Dutra Rosa (Brazil), Mr Liu Jingqi (China), Ms Meutia Hasan (Indonesia), Dr Yasmine J. Ameen Kannan (Iraq), Dr Leila Mousavi (Islamic Republic of Iran), Dr Wilbur Kariuki Gachoki (Kenya), Mr Roeslan bin Ishak (Malaysia), Mr Sergey Glagolev (Russian Federation), Dr Manuel Ibarra Lorente (Spain), and Mr Mark Abdo (United States of America). Representatives from 70 Member States participated in the meeting.

2. The WHO Deputy Director-General, Ms Zsuzsanna Jakab, opened the meeting and acknowledged the importance of global access to safe, efficacious, quality and affordable medical products. In this regard, the prevention and detection of, and response to, substandard and falsified medical products remain crucial to achieving this goal. The sustainability of the Member State mechanism is thus critical to ensuring that Member States retain a platform to coordinate, collaborate, and engage on substandard and falsified medical products. Outgoing Steering Committee members were thanked for all their contributions to the success of the mechanism. The Chair, Dr V.G Somani of India, was thanked for his excellent leadership during his three years as the chair of the mechanism.

3. The Assistant Director-General for Access to Medicines and Health Products, Dr Mariângela Simão, delivered the opening remarks, noting the progress made by the Member State mechanism over the years, and commended Member States for taking concrete action to address the challenges resulting from substandard and falsified medical products on the market. The Assistant Director-General also took the opportunity to introduce the new technical leadership team involved in coordinating the work of the Member State mechanism, including: Dr Rogério Gaspar, Director of the Department of Regulation and Prequalification; Mr Hiiti Sillo, Unit Head, Regulation and Safety Unit; and Mr Rutendo Kuwana, Team Lead for Incidents and Substandard/Falsified Medical Products Team.

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

4. The Secretariat provided an update on the activities and budget to implement the mechanism's workplan, including the estimated budget for 2021 and the main funding sources. Updates were also provided on the latest information technological improvements to the WHO Global Surveillance and Monitoring System (GSMS) and the planned enhancements to improve data quality by introducing new key performance indicators and continuing data curation. GSMS reporting trends were reported and the annual increase in reported incidents over the past three years was noted. Despite this increase in reported incidents, the number of incidents being reported by Member State focal points decreased while reports from other stakeholders increased during the same time period. Member State focal points, as the pre-eminent source for such notifications, were encouraged to continue reporting substandard and

falsified products to the GSMS for the benefit of all Member States. During the discussion, the importance of the information reported through GSMS on substandard and falsified COVID-19 vaccines was noted as particularly useful. Member States noted the update by the Secretariat on its activities and budget to implement the workplan of the Member State mechanism, as contained in document A/MSM/10/3.

Update on the list of prioritized activities for 2020–2021

5. The Secretariat provided an overview of the status of the activities and the actions outlined in the prioritized list of activities for 2020–2021, including the details of each of the working groups that had been established to carry out the various actions. Member States noted the update on the list of prioritized activities for 2020–2021, as contained in document A/MSM/10/4 and the agreed list of prioritized activities to implement the workplan of the Member State mechanism for the period 2020–2021, as contained in document A/MSM/10/5.

Activity A: Develop and promote training material and guidance documents to strengthen the capacity of national/regional regulatory authorities for the prevention and detection of, and response to, substandard and falsified medical products

6. The Secretariat introduced Activity A, noting the objectives of the WHO regulatory systems strengthening programme which are to: (1) build regulatory capacity in Member States consistent with good regulatory practices; and (2) promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance. WHO's five-step capacity-building model for national regulatory authorities was described along with the global status of benchmarking of regulatory systems (2016–2021). Other updates related to the current levels of maturity of national regulatory systems, WHO Global Benchmarking Tool indicators related to substandard and falsified medical products, and the status of implementation of indicators related to such medical products. An overview of WHO-listed authorities was presented and it was emphasized that the introduction of a framework for designating and publicly listing a regulatory authority as a WHO-listed authority provides a transparent and evidence-based pathway for regulatory authorities to be globally recognized as meeting WHO and other internationally recognized standards and practices. The Member State mechanism was noted as an important platform for advocacy for strong regulatory systems.

7. The Secretariat provided an update on action 3(a) regarding the risk-based post-market surveillance project in the United Republic of Tanzania as well as the e-Tool developed to facilitate its implementation. The next steps will include an evaluation of the survey design, planning and roll-out using the e-Tool, assessment of the need for further adaptation and evaluation of resource needs and consideration of the need for the tool to be made available in additional languages. The use of the “return on investment” models for advocating adequate resourcing of market surveillance by national regulators was encouraged along with the sharing of data.

8. Brazil, as lead for Activity A, provided an update on action 3(b) relating to the development of guidance documents to strengthen capacities of national/regional regulatory authorities to plan, perform, and assess risk-based post-market surveillance including the effective use of the tools. The tasks of the related working group were described including to: (1) develop guidelines on the design, implementation and management of risk-based post-market surveillance of medicines in the public and private supply chains, considering a stepwise approach; and (2) develop, if necessary, replicable training material on the guidelines applied to the risk-based post-market surveillance for national/regional regulatory authorities. It was explained that the preparation of the first draft is in progress and is

proposed to continue into the next biennium. Additional Member States were encouraged to join the related working group to continue this work.

9. During the discussion, the issue of indexing the sources of substandard and falsified products was brought up and the Secretariat reminded Member States of the Guidance for registers of manufacturers, importers, distributors and medical products authorized by Member States, which was shared during the seventh meeting of the Member State mechanism in 2018.¹

Activity B: Expand and maintain the Global Focal Point Network among national medicines regulatory authorities to facilitate cooperation and collaboration

10. Eritrea, as lead for Activity B, provided an update, explaining that the main purpose of this activity is to: identify barriers for reporting; propose practical solutions; and strengthen the Global Focal Point Network to facilitate reporting and information sharing. The two components of the project to identify barriers to reporting substandard and falsified medical products to the GSMS and possible solutions included: (1) a cross-sectional study using a quantitative approach to identify the main barriers to reporting substandard and falsified products and identify possible solutions; and (2) a qualitative study to further explore the possible solutions needed to bridge identified gaps. Additional Member States were encouraged to join the related working group to continue this work.

Activity C: Improve Member States' understanding of detection technologies, methodologies and "track and trace" models

11. The Secretariat provided an update on Activity C on improving understanding of "track and trace" models (actions 1a and 2) and on improving understanding of detection technologies and methodologies (action 1b). The working group on traceability met virtually in September 2021. Member States are encouraged to join this group, which remains in need of a Chair. Additional updates were provided on the open-ended expert session that was held during the International Conference of Drug Regulatory Authorities, the policy paper on traceability of medical products², the reformatting of a publication on country traceability experiences, and the collaboration with the International Coalition of Medicines Regulatory Authorities to publish recommendations on common technical denominators for traceability systems to allow for inter-operability. Furthermore, the working group on detection technologies met virtually in August 2021. Member States are encouraged to join this group, which also remains in need of a Chair. As per the request of Member States, an open-ended expert session on the topic of detection technologies was held during the International Conference of Drug Regulatory Authorities. During the discussion, Member States emphasized the importance of understanding track and trace models to address issues of substandard and falsified products on the market. Iraq expressed interest in joining the working group on detection technologies.

Activity D: Increase Member States' knowledge of the links between substandard and falsified medical products and access to quality, safe, efficacious and affordable medical products

12. The Secretariat provided an update on Activity D, noting that the Secretariat had completed the report on the link between constrained access to quality, safe, efficacious and affordable medical

¹ See https://apps.who.int/gb/sf/pdf_files/MSM7/A_MSM7_2-en.pdf (accessed 15 November 2021).

² See <https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products> (accessed 15 November 2021).

products and substandard and falsified medical products. Two recommendations from the report were highlighted that the mechanism had previously agreed to implement during the ninth meeting of the Member State mechanism, namely: (1) strengthen collaboration across both strategic areas of the road map for access – specifically prevention and detection efforts, including in price determination; monitor shortages and supply disruptions; reduce cost-cutting; and ensure better targeting of risk communication; and (2) address gaps in data and reporting to generate broader evidence; continue and expand reporting to the relevant national authorities and WHO; and ensure connections are established between relevant databases in order to strengthen evidence and improve planning and response.

Activity E: Develop and leverage existing activity for effective risk communication and make recommendations for awareness campaigns on substandard and falsified medical products

13. The Secretariat provided an introduction to Activity E (action 1) and presented the status of the insight studies and risk communication campaigns. In this regard, it was reported that customized campaign materials were developed from earlier completed insight studies and were guided by the Member State mechanism IDEAS Global Communications Framework.¹ The status of the campaigns in four countries including Ghana, Nigeria, Sierra Leone and Uganda was described by the Secretariat, followed by updates from representatives of each of these four Member States. During their updates, the representatives highlighted lessons learned from their experiences, which included running communication campaigns using a variety of modalities. The Secretariat further noted that next steps will include an evaluation of the communication campaigns and the development of a practical guidance handbook for Member States. During the discussion, Member States congratulated the four Member States on their successful campaigns and requested that campaign materials be shared broadly so that other Member States could consider adapting and applying them in their own national contexts. The Secretariat noted that sharing information on what has worked in different countries is a great practice that should be encouraged. The Secretariat also noted that a forthcoming publication would include the results from the surveys conducted in the four countries.

14. The Secretariat provided an update on Activity E (action 2) related to the pharmacy school curriculum and explained that compulsory modules have been implemented in Cameroon, Senegal, Uganda and United Republic of Tanzania. The next steps were described, including: implementation in Nigeria; commencement of the evaluation phase; compilation of results and recommendations for increasing scope and scale.

15. The Secretariat further explained that this work involves a new working group and Indonesia and Panama expressed interest in joining. This working group is also in need of a Chair. Additional Member States were encouraged to join the related working group to continue this work.

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

16. The Secretariat provided an update on Activity F, noting that engagement and advocacy by WHO has continued in various national, regional and global policy and technical events with an aim to strengthen regional, subregional and global coordination and collaboration. Other updates were provided on the WHO website migration and the MedNet to make the interfaces more user-friendly. The Secretariat noted the Steering Committee's proposal to merge the related working group with the

¹ See https://apps.who.int/gb/sf/pdf_files/MSM7/A_MSM7_4-en.pdf (accessed 15 November 2021).

working group on “Regional and Global Initiatives” citing the similarity of their work. The Secretariat also noted this working group is in need of a Chair. Additional Member States were encouraged to join the related working group to continue this work.

Activity G: Promote shared understanding among Member States from a public health perspective regarding medical products in transit

17. The Secretariat provided an update on Activity G, noting that Member State survey responses and experiences have been analysed and reported on in the information note on promoting a shared understanding among Member States, from a public health perspective, regarding medical products in transit, as contained in document A/MSM/10/8. Some of the main conclusions from the information note were highlighted, including the idea that delays affecting medicines in transit could be addressed by increased international cooperation (including between national regulatory authorities and customs) to ensure that: (1) medicines in transit reach their country of destination with minimum delays; and (2) substandard and falsified medical products are subject to the appropriate oversight wherever they are detected. Next steps outlined in the information note were also described, including: (1) national regulatory authorities’ engagement in active cooperation, support for and technical advice to customs; and (2) measures to resolve issues of access to and regulatory oversight of medical products in free-trade zones through internal arrangements. During the discussion, the subject of jurisdiction for determining substandard and falsified products was raised. The Secretariat explained that regulatory authorities in the country through which the goods transit would make an assessment and pass that information on to a recipient country to facilitate intervention and assessment at the point of entry.

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

18. Colombia, as lead for Activity H, provided an update on the work carried out by the related working group and highlighted several key points from the guidance on strategies to enable national/regional regulatory authorities to address the distribution or supply of substandard and falsified medical products via the internet. The structure of the guidance was explained, and the recommendations were elaborated. Italy provided an update on the development of the internet “good practices” bookshelf initiative, which aims to collect the existing “good practices documents” related to internet investigations and to create a WHO virtual bookshelf for sharing them, in order to support the Member States in developing activities by optimizing the use of resources. A first draft is under development for consideration by the working group and will be shared with all Member States for comments, suggestions, and to stimulate the sharing of more documents, before developing a more structured release of the virtual bookshelf. During the discussion, Member States expressed appreciation for the work conducted in this regard, noting its importance for improving Member States’ capacities to address substandard and falsified products.

19. Member States took note of the report on identifying experiences, best practices and/or regulation of the distribution or supply of medical products via the internet to prevent and reduce the risk of substandard and falsified medical products reaching consumers, as contained in document A/MSM/10/9, as well as the report on the development of guidance on strategies to enable national/regional regulatory authorities to address the distribution or supply of substandard and falsified medical products via the internet, as contained in document A/MSM/10/10. Additional Member States were encouraged to join the related working group to continue this work.

WHO's participation in relevant global and regional initiatives

20. The Secretariat provided an overview of WHO's participation in relevant global and regional initiatives, noting the ongoing collaboration and participation in various global, subregional and regional initiatives. Furthermore, the Secretariat described the ongoing alignment and coordination across other technical initiatives such as COVID-19 response, antimicrobial resistance and the WHO Global Benchmarking Tool. The Secretariat noted that to maximize coordination and collaboration, insights on Member State engagement in other global and regional initiatives were needed. During the discussion, the importance of this work was emphasized in order to address substandard and falsified products through collaboration and coordination.

Draft list of prioritized activities to implement the workplan of the Member State mechanism for the period 2022-2023.

21. The Member States considered the draft list of prioritized activities for the period 2022–2023, submitted by the Steering Committee. Member States agreed the draft list of prioritized activities and actions to implement the workplan of the Member State mechanism for the period 2022–2023 (see Annex) while noting that working groups would be tasked with proposing additional actions for agreement by the Member State mechanism through the Steering Committee. It was agreed that although robust technical work will always be the foundation of the Member State mechanism, the Steering Committee and the mechanism itself should be more strategic and policy-focused. For the new Activity H, the following Member States have expressed interest in joining the working group: Botswana, El Salvador, Ghana, India, Indonesia, Iraq, Malaysia, Nepal, Nicaragua, Niger, Nigeria, Panama and the Republic of Korea.

22. To aid the working groups in their task of developing new actions, Member States are invited to send any proposals for new actions to the Secretariat by the end of November 2021, for compilation and sharing with all Member States. Taking into account any proposals thus received, the working groups will then submit proposals for additional actions to the Steering Committee for consideration at its next meeting. The Steering Committee will make a recommendation thereon, for approval by the Member State mechanism through a written silence procedure, the details of which will be determined by the Steering Committee in consultation with the Secretariat. The written silence procedure will involve the list of prioritized activities to implement the workplan of the Member State mechanism for the period 2022–2023, containing the proposed new actions being circulated to all Member States for a comment period. If no objections are received within that period, the proposed new actions will be considered agreed by the Member State mechanism.

Update on governance issues

23. The Secretariat provided an overview of the governance of the Member State mechanism and its Steering Committee, based on relevant resolutions and decisions of the World Health Assembly and decisions adopted by the mechanism in previous years. The Secretariat explained the contents of the report on governance, as contained in document A/MSM/10/7, including information about the establishment of the mechanism, the composition and chairmanship of the Steering Committee, the workplan and prioritized activities of the mechanism, its reporting, the definitions endorsed by the Health Assembly, and working groups. The Secretariat emphasized that the report does not propose new procedures or ways of working, for which a separate mandate would be required. Member States took note of the report.

24. The Member States noted that the new composition of the Steering Committee, beginning from the closure of the tenth meeting of the Member State mechanism, would be as follows:

- African Region: Botswana and Zambia;
- Region of the Americas: Brazil and the United States of America;
- Eastern Mediterranean Region: Islamic Republic of Iran and Iraq;
- European Region: Italy and Ukraine;
- South-East Asia Region: India and Indonesia; and
- Western Pacific Region: Australia and China.

25. As recommended by the Health Assembly in decision WHA66(10) (2013) and agreed by the Member State mechanism, the chairmanship rotates among the six WHO regions, in English alphabetical order. Following regional consultations, the next Chair has been appointed from Australia.

Proposed dates of the eleventh meeting of the Member State mechanism

26. The Member State mechanism decided that its eleventh meeting would take place in the week of 17 October 2022.

ANNEX

**DRAFT LIST OF PRIORITIZED ACTIVITIES TO IMPLEMENT
THE WORKPLAN OF THE MEMBER STATE MECHANISM
FOR THE PERIOD 2022–2023**

Prioritized activities	Status	Actions	Alignment of actions to strategic prioritized activity areas (see Appendix)
Note: Further actions are to be proposed by the working groups.			
<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>	In progress	<ol style="list-style-type: none"> 1. (Ongoing) Develop training material for national/regional regulatory authorities, focused on promoting the technical and knowledge documentation approved by the Member State mechanism. 2. (Ongoing) Assist in the identification of the training needs, existing expertise and training materials of Member States and other institutions in order to build capacity concerning the prevention and detection of, and response to, substandard and falsified medical products. 3. Risk-based post-market surveillance: <ol style="list-style-type: none"> (a) (In progress) develop tools and a database to automate the conduct of medical products quality surveys and enhance the quantity and quality of data captured to inform risk-based post-market surveillance programmes based on existing WHO guidance; and (b) (In progress) develop guidance documents to strengthen the capacities of national/regional regulatory authorities to plan, perform, and assess risk-based post-market surveillance, including the effective use of the tools. 	<ol style="list-style-type: none"> 1. 3.1 2. 3.1 3a. 2.3 3b. 2.3
<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>	In progress	<ol style="list-style-type: none"> 1. (Ongoing) Continue to follow up with Member States to nominate focal points. 2. (Ongoing) Continue to train new focal points and provide refresher training for existing focal points. 3. (Ongoing) Facilitate the exchange of information in the Global Focal Point Network. 	<ol style="list-style-type: none"> 1. 2.2 2. 2.2 3. 2.2

Prioritized activities	Status	Actions	Alignment of actions to strategic prioritized activity areas (see Appendix)
Note: Further actions are to be proposed by the working groups.			
<p>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.</p> <p>Lead: TBC with the support of the Secretariat</p>	In progress	<p>1. (Ongoing) Convene open-ended expert sessions to review existing field detection devices and "track and trace" models, and, as needed:</p> <ul style="list-style-type: none"> (a) (Ongoing) provide updates on existing "track and trace" and authentication technologies in use by Member States; and (b) (Ongoing) report on existing field detection devices in use or available to Member States. <p>2. (Completed) Working group to continue to develop the policy paper on "track and trace" and submit a finalized document to the Member State mechanism.</p>	<p>1a. 1.2</p> <p>1b. 2.1</p> <p>2. 1.2</p>
<p>D. Leverage the competencies of relevant stakeholders, including policy-makers, procurers, distributors, practitioners, patients and consumers, and good governance to reduce the burden of substandard and falsified medical products</p> <p>Lead: TBC with the support of the Secretariat</p>	Proposed	<p>1. (New) Develop a handbook to accelerate sustainable implementation, monitoring and evaluation of national prevention, detection and response strategies on substandard and falsified medical products.</p>	<p>1.1 3.1</p>
<p>E. Enhance Member States' capacity to run effective risk communication campaigns for substandard and falsified medical products.</p> <p>Lead: TBC with the support of the Secretariat</p>	In progress	<p>1. (Completed) Conduct surveys on patient or consumer attitudes and behaviours on accessing medical products in four African countries, and</p> <ul style="list-style-type: none"> (i) (Completed) develop or leverage recommendations for effective risk communication and awareness campaigns; (ii) (Completed) produce samples of hard and soft copy material and video and broadcast material; (iii) (Completed) assess the use of social media for raising awareness; (iv) (Completed) identify the full range of stakeholders and audiences; and (v) (Completed) develop key, innovative advocacy material. 	<p>1i-v. 1.3</p>

Prioritized activities	Status	Actions	Alignment of actions to strategic prioritized activity areas (see Appendix)
		Note: Further actions are to be proposed by the working groups.	
		2. (Completed) Pilot the implementation of a compulsory element in the pharmacy school curriculum in five African countries.	2. 1.3
F. Enhance Member States' capacity to expand awareness, effectiveness, impact and outreach in their work on substandard and falsified medical products. Lead: TBC with the support of the Secretariat	In progress	1. (Ongoing) Secretariat, working with Member States, to enable a proactive approach to disseminate and promote the materials and information developed by the Member State mechanism. 2. (Ongoing) Member States to use 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.	1. 1.1 2. 1.1
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	In progress	1. (Completed) A working group was established to: (a) (Completed) develop terms of reference; (b) (Completed) provide a problem statement identifying the range of issues that facilitate the sale and supply of substandard and falsified medical products through the Internet, both nationally and across borders; (c) (Completed) identify experiences or regulation of the distribution or supply of medical products via the Internet to prevent and reduce the risk of substandard and falsified medical products reaching consumers; and (d) (Completed) develop guidance on strategies to enable national/regional regulatory authorities to address the distribution or supply of substandard and falsified medical products via the internet.	1a-d. 2.3

Prioritized activities	Status	Actions	Alignment of actions to strategic prioritized activity areas (see Appendix)
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. Lead: United States of America with the support of the Secretariat	New	Note: Further actions are to be proposed by the working groups. (New) To be determined by the working group, including developing a working definition of informal markets.	2.3

Appendix

PUBLIC HEALTH OUTCOMES AND STRATEGIC PRIORITIZED ACTIVITY AREAS

Public health outcomes

1. Increased technical capacity
 2. Improved access to safe, effective, affordable and quality medical products
 3. Strengthened governance
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Strategic prioritized activity area 1: Prevention

1.1 Increase multistakeholder engagement to maximize impact and outreach, including through regional and global networks and collaboration across both strategic areas of the [Roadmap for access to medicines, vaccines and health products 2019–2023: comprehensive support for access to medicines, vaccines and other health products](#).¹

1.2 Increase supply chain integrity including by improving Member States implementation of national traceability systems and strategies to mitigate risks of the informal markets² to sell or distribute medical products.

1.3 Promote effective education and awareness for relevant stakeholders, including non-health professionals, the general public and civil society groups.

Strategic prioritized activity area 2: Detection

2.1 Increase access and uptake of technologies for screening and detecting substandard and falsified medical products, testing including by improving Member States' understanding of detection and screening technologies.

2.2 Increase reporting of substandard and falsified medical products by health care professionals and the general public to national regulatory authorities and by these authorities to national, regional and global networks, including the WHO Global Surveillance and Monitoring System and the WHO Global Focal Point Network.

2.3 Promote a risk-based strategy for national regulatory authorities to conduct market surveillance for substandard and falsified medical products within the regulated and unregulated supply chains, including the internet and the informal markets.²

Strategic prioritized activity area 3: Response

3.1 Strengthen the capacity of national/regional regulatory authorities to respond to incidents of substandard and falsified medical products, including engaging in relevant partnerships such as with law enforcement and customs authorities.

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¹ The strategic areas include: (1) Ensuring quality safety and efficacy of health products; (2) Improving equitable access.

² Working definition of informal markets to be established by the working group.