World Health Organization

**NINTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS**
**28–30 October 2020**

**A/MSM/9/7**
**23 December 2020**

# Report of the ninth meeting of the member state mechanism on substandard and falsified medical products

1. The ninth virtual meeting of the Member State mechanism on substandard and falsified medical products was held in Geneva on 28 and 29 October 2020 and was chaired by Dr V.G. Somani (India), with the following Vice-Chairpersons: Mr Oluwkyodé Nils Daniel Kintin (Benin); Mr Wilberforce Kariuki Gachoki (Kenya); Ms Laila Mouawad on behalf of Mr Leonardo Dutra Rosa (Brazil); Mr Mark Abdoo (United States of America); Dr Leila Mousavi (Islamic Republic of Iran ); Ms Yasmine Jamal Ameen Kannan (Iraq); Mr Manuel Ibarra Lorente (Spain); Mr Sergey V. Glagolev (Russian Federation); Ms Ratna Irawati on behalf of Ms Meutia Hasan (Indonesia); Mr Liu Jingqi (China); and Mr Roeslan bin Ishak (Malaysia).The meeting was attended by representatives of 82 Member States.

2. The WHO Deputy Director-General opened the meeting and acknowledged the burden of substandard and falsified medical products as an unacceptable global public threat. Efforts to ensure access to safe, quality, affordable and effective medical products would be undermined if patients and end users received products that were substandard or falsified. She reiterated her support for the WHO Member State mechanism as a forum for developing global approaches to the prevention and detection of, and response to, substandard and falsified medical products.

## Update by the Secretariat on the 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 mechanism's workplan, including on the new incidents and substandard and falsified medical products team structure, information technology improvements to the WHO Global Surveillance and Monitoring System, WHO global medical product alerts, the medicine quality surveys, the post-market and market surveillance of medical devices, and the smartphone reporting application, as well as an update on the global situation of substandard and falsified medical products related to the coronavirus disease (COVID-19) pandemic. Member States reiterated the value of ensuring the sustainability of the Secretariat's work given its link to regulatory systems strengthening. They 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/9/4.

## Update on the list of prioritized activities for 2020–2021

4. The Steering Committee requested the Secretariat to update the plenary session on their recommendations and open discussion points for each prioritized activity within the workplan, including the possibility of creating dedicated working groups to address those points. Member States wishing to lead or join the prioritized activities and/or a working group were encouraged to contact the Secretariat. Member States noted the update on the list of prioritized activities for 2020–2021, as contained in document A/MSM/9/5.

### 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

5. The Secretariat provided an update on actions 1 and 2 under Activity A that focused on identifying training needs and developing capacity strengthening activities/material. Member States noted that such activities must match country needs to ensure effective knowledge transfer. Comments were made around ensuring impact and the possibility of developing a concept that detailed how training contributed to building regulatory capacity. Staff turnover was expressed as a challenge; the Train-the-Trainer approach – namely to have trained regulatory staff train others in their respective region – was noted as a means of ensuring sustainability in that regard. Member States agreed on the importance of taking a risk-based approach complemented with multistakeholder engagement to ensure practical implementation and widespread impact.

6. The Secretariat provided an update on action 3(a) regarding the risk-based post-market surveillance project. Innovative tools and approaches for risk-based post-market surveillance were being piloted in the United Republic of Tanzania. That work area comprised four different workstreams: an update of survey protocol, the development of IT tools (mobile application and database), the strengthening of laboratory capacity, and the conducting of a return on investment study that was expected to leverage support for national regulatory authorities.

7. Brazil, as Chair of the working group, provided an update on action 3(b) regarding the development of draft guidance on risk-based post-market surveillance, including a proposed framework and time frame of next steps with the final document to be submitted at the tenth meeting of the Member State mechanism. It was agreed that the Secretariat would issue a call for additional Member States to join the working group.

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

8. The Secretariat provided an update on its activities to maintain the Global Network of Focal Points, including ongoing efforts to ensure that the focal point lists were current and up-to-date. Member States were reminded that the Global Focal Point Network was a distinct entity from, but worked in a complementary manner with, the Member State mechanism, and close and regular communication should be maintained between the two bodies.

9. Member States noted that they had been able to use the Global Focal Point Network to share information during the COVID-19 pandemic and underscored the importance of the WHO Global Surveillance and Monitoring System – including the Global Focal Point Network – to maintaining strong links with regional networks and communities. In line with the agreed terms of reference for the Global Focal Point Network,[1] there was consensus that focal points should be empowered and encouraged to report substandard and falsified medical products as early as possible to the WHO Global Surveillance and Monitoring System, with any reporting barriers being removed. It was noted that a webinar on the roles and responsibilities of the Global Focal Point Network would be useful. The possibility of creating a dedicated working group to identify solutions to reporting barriers was discussed.

[1] Document A69/41, Appendix 1.

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

10. The Secretariat provided an update on action 1 under Activity C, specifically the open-ended expert session that had taken place on 26 October 2020 to share the latest knowledge on the topic, which had included presentations by representatives from Oxford University, the United States Pharmacopeial Convention and WHO. Member States reiterated the value of such work in helping to inform selection, procurement and deployment decisions, and supported further open-ended expert sessions being held. It was agreed that the Secretariat should continue to promote evidence-based decision-making, including through additional reviews and assessments. The Secretariat reminded Member States that WHO did not promote nor advocate any product (neither technology format nor device). Member States discussed the need to continue such open-ended briefings, but noted that the objectives of each session should be better defined. Member States called for technical guidance from WHO in the area of detection technologies. It was noted that a dedicated working group would be required to define the scope and objectives of such guidance. Member States interested in joining that working group were encouraged to contact the Secretariat.

11. The Secretariat provided an update on action 2 concerning the traceability of health products and noted that the corresponding documents had been drafted with the support of 19 Member States. It was agreed that the technical traceability paper would become a WHO publication, with Annex 3 on country and regional experiences serving as a stand-alone document so that it could be updated more regularly. Member States agreed on the convening of open-ended expert sessions and noted the update by the Secretariat on Activity C, as contained in document A/MSM/9/3.

### 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 summarized the report on the links between substandard and falsified medical products and access to medicines including for accessibility, affordability, availability and acceptability. Member States noted the report by the Secretariat on Activity D, as contained in document A/MSM/9/6, and agreed upon the recommendations outlined in paragraphs 19 and 20 of that report.

### 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 update on action 1 under Activity E regarding the insight studies and risk communication campaigns conducted in Ghana, Nigeria, Sierra Leone and Uganda, as well as the pharmacy school curriculum pilot with five universities in Cameroon, Nigeria, Senegal, the United Republic of Tanzania and Uganda. Once the operational work had been completed, the results would be published and shared in order to raise global and regional awareness and strengthen learning.

14. The Secretariat provided a further update on action 1 regarding the attitudinal and behavioural factors for, as well as the demographic groups at higher risk of, buying and/or using substandard and falsified medicines. The Secretariat continued to work with the national medicines regulatory authorities in the four countries involved in the insight studies in order to plan for and launch the evidence-based risk communication campaigns, including by developing practical evaluation models.

15. The Secretariat provided an update on action 2 regarding the pharmacy school curriculum pilot, describing the completion of virtual training and the sharing of teaching materials via an online resource platform. Despite the implementation delays owing to the COVID-19 pandemic, it was noted that the curriculum would be rolled out once universities resumed. Member States requested access to the post-pilot project expansion, as well as to the training materials.

16. Member States further requested that the Secretariat provide reports on how both the risk communication campaigns and the pharmacy school pilot project had been developed and implemented, once those activities had been completed. Member States discussed the possibility of creating a dedicated working group to identify ways in which Member States and other relevant stakeholders could build on the lessons learned from such projects.

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

17. The Secretariat had taken a proactive approach to disseminating and promoting the work of the Member State mechanism, with the aim of supporting Member States to increase awareness and advocacy at the highest policy levels. The issue of substandard and falsified medical products had been recognized as an urgent global health challenge and a WHO health topic, with ongoing efforts to strengthen high-level advocacy, increase social media engagement, and develop resources (including an information booklet). Member States were encouraged to deploy those communication and advocacy products within their respective regional and national contexts. Member States discussed the possibility of creating a dedicated working group designed to link national, regional and global awareness-raising efforts.

18. Member States supported the idea of observing world health or regional health days on substandard and falsified medical products. The Secretariat recalled that the matter of world health days would be considered at the resumed session of the Seventy-third World Health Assembly. It was also noted that initiatives could be developed at the regional level. Member States committed to exploring that process and moving it forward in their respective regions.

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

19. The Secretariat provided an update on Activity G regarding medicines in transit, including the re-circulation of the questionnaire to the Global Focal Point Network. The results of the questionnaire would be used in the development of the information note on the current situation regarding medical products in transit within the public health domain. Member States were supportive of increasing coordination and collaboration with the World Customs Organization and noted the need to ensure a public health focus using the agreed substandard and falsified medical product definitions. In response to Member States' request, it was agreed that the submission deadline for the questionnaire would be extended until the end of January 2021 to allow more time for Member States to respond. Member States discussed the need to better define the application of the information resulting from the analysis of the questionnaire responses.

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

20. Colombia, as Chair of the working group, provided an update on Activity H, describing the development of the report on Member States' experiences or regulations, which had been compiled using the survey responses from the mechanism. The draft report would be shared with the mechanism for consultation before being finalized. The next step for the working group would be to develop guidance on strategies designed to enable national/regional regulatory authorities to address the issue.

21. The representative of Italy provided an update on the development of the online "good practices" bookshelf that was aimed at collecting and sharing existing good practices related to internet investigations. Such work complemented the efforts made in that area by the working group chaired by Colombia.

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

22. The Secretariat provided an update on WHO engagement in relevant global and regional initiatives, highlighting the linkages with the Member State mechanism. The Member State mechanism supported WHO's continued engagement in those initiatives. To avoid duplication of work and ensure greater strategic coordination, wherever possible, it was agreed that both the Secretariat and Member States would engage in regional, cross-regional and global initiatives that would help to elevate the profile of the WHO Member State mechanism to the highest levels. Member States discussed the possibility of creating a dedicated working group aimed at coordinating input and strategic impact in such forums.

## Update on governance issues

23. Responding to the request made by the Member State mechanism at its eighth meeting, the Secretariat provided an update on the progress made during the informal discussions with interested Member States on the drafting of a scoping paper and the need to establish a similar network on medical devices. Member States acknowledged that COVID-19 had highlighted the need for safe, quality and effective medical devices, in particular personal protective equipment. It was clarified that the working definitions for substandard, falsified and unregistered medical products endorsed by the Seventieth World Health Assembly provided that "a medical product is defined as a medicine, vaccine or in vitro diagnostic (…) and it may also include medical devices at an appropriate time in the future."[1] It was agreed that medical devices other than in vitro diagnostics fell outside the scope of the Member State mechanism at present, and it was decided that the Secretariat would convene with interested Member States to discuss how to take such work forward.[2]

24. Member States acknowledged that the Member State mechanism delegates changed often. It was agreed that a procedural document to assist Member States in better understanding and navigating the intergovernmental process (e.g. terms of reference and working processes) should be developed. It was agreed that the Secretariat would convene with interested Member States to discuss how to take that work forward in collaboration with the Steering Committee. The draft report would be considered by the Steering Committee and submitted to the Member State mechanism.

[1] Document A70/23, Annex, Appendix 3, footnote 2.

[2] The representative of the United States of America expressed their reservation to this paragraph of the report.

25. It was noted that the terms of the current Steering Committee members had commenced at the closure of the seventh meeting of the Member State mechanism in 2018 and were set to expire at the closure of the ninth meeting of the Member State mechanism. It was further noted that the current list of prioritized activities covered the biennium 2020–2021 and that the next list of prioritized activities would be considered at the tenth meeting of the Member State mechanism in 2021.

26. The Member State mechanism agreed with the Steering Committee's recommendation to align the terms of the current Steering Committee members with the time frame established for the application of the list of prioritized activities. Accordingly, the mechanism agreed to extend the terms of the current Chairperson and Vice-Chairpersons by one year, such that their terms would expire at the closure of the tenth meeting of the Member State mechanism in 2021. It was understood that the subsequent terms of Chairpersons and Vice-Chairpersons would continue to expire at the closure of every second regular session of the Member State mechanism.

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

27. The Member State mechanism decided that its tenth meeting would take place in the week of 25–29 October 2021.

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