EIGHTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS
24–25 October 2019

A/MSM/8/4
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Report of the eighth meeting of the Member State mechanism on substandard and falsified medical products

1. The eighth meeting of the Member State mechanism on substandard and falsified medical products was held in Geneva on 24 and 25 October 2019 and chaired by Dr V.G. Somani of India, with the following Vice-Chairpersons:[1] Mr Oluwkyodé Nils Daniel Kintin (Benin); Mr Wilberforce Kariuki Gachoki (Kenya); Ms Bianca Zimon Giacomini Ribeiro on behalf of Mr João Paulo Ortega Terra (Brazil); Ms Mary Lou Valdez (United States of America); Ms Yasmine Jamal Ameen Kannan (Iraq); Mr Manuel Ibarra Lorente (Spain); Mr Sergey V. Glagolev (Russian Federation); Ms Meutia Hasan (Indonesia); Mr Liu Jingqi (China) and Dr Ramli Zainal (Malaysia). The meeting was attended by representatives of 52 Member States and one regional economic integration organization.

2. The WHO Director-General opened the meeting and reiterated his support for the WHO Member State mechanism as the forum for developing global approaches to the prevention, detection 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 (including grants and proposals) to implement the mechanism's workplan, including on the WHO transformation agenda, the WHO Global Surveillance and Monitoring System, medicine quality surveys, and global medical product alerts. It was noted that the data emerging from the various sources would be useful in guiding the work of the Mechanism and should be made accessible to Member States, including through publications. Concerning medicine quality surveys, the importance to Member States of receiving this data as soon as possible was noted.

4. In line with the WHO transformation agenda and Thirteenth General Programme of Work, WHO will prioritize work based on country needs, including those identified as WHO global public health goods and requests included in country support plans as developed by ministries of health, in coordination with WHO country and regional offices.

5. The Mechanism requested WHO to ensure continuity of support to strengthen the Secretariat substandard and falsified medical products group as it is important for the workplan.

[1] Dr Abdol Majid Cheraghali (Islamic Republic of Iran) was unable to attend the meeting.

Update on the list of prioritized activities for 2018–2019

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. Brazil, as Chair of the working group, provided an update on Activity A. Following discussions with the Steering Committee, a new action on risk-based post-market surveillance was proposed, containing two distinct, but complementary approaches (as described in the Annex). It was agreed that the development of the tool should proceed under the chairmanship of the Secretariat and a parallel technical working group chaired by Brazil should be established to develop the guidance. An informal background document on risk-based post-market surveillance had been shared with Member States via MedNet before the eighth meeting of the Member State mechanism.

7. For the new action proposed on risk-based post-market surveillance and led by Brazil, a working group of Member States would be formed, with next steps to include the development of terms of reference for the working group on guidance. Any Member State interested in joining this working group on the development of guidance on risk-based post-market surveillance was encouraged to contact the Secretariat as soon as possible. The following Member States had expressed an interest: Algeria, Angola, Colombia, Guinea, India, Indonesia, Kenya, Mozambique, Nigeria, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania and United States of America.

8. An informal technical meeting of the risk-based post-market surveillance technical working group of experts developing the survey tool chaired by the Secretariat was convened on 21 October 2019. The meeting was attended by Algeria, Brazil, India, Indonesia, Nigeria, Spain, United Republic of Tanzania, United States of America, and experts from Oxford University, the University of North Carolina and the United States Pharmacopeial Convention. The terms of reference for the working group on tools were agreed upon and would be circulated by the Secretariat on MedNet. The tool and guidance would be piloted in the United Republic of Tanzania. Progress would be reported to the Steering Committee, with the final report being shared with the ninth meeting of the Member State mechanism.

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

9. The Secretariat provided an update on its activities to maintain the global network of focal points. The value of active participation in the Global Focal Point Network was underscored, including the importance of having the support of the heads of national medicines regulatory authorities in reporting to the WHO Global Surveillance and Monitoring System. In line with the agreed terms of reference for the Global Focal Point Network, the Secretariat noted that the list and contact information would require regular updating and all Member States would be contacted to ensure the list was current. Member States were also reminded to communicate any changes to the Secretariat. Members of the Global Focal Point Network were encouraged to interact with each other in order to fulfil the objectives of the Mechanism.

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

10. The Secretariat provided an update on three strands of work under this activity: traceability of health products,[1] the smartphone application reporting project, and field detection and screening technologies and devices. The draft policy brief on traceability of health products and the smartphone application for reporting substandard and falsified medical products pilot study report had been shared with Member States via MedNet before the eighth meeting of the Member State mechanism. Member States interested in leading Activity C were encouraged to notify the Secretariat.

11. An informal technical meeting on traceability of health products was convened by the Secretariat on 22 October 2019. The Secretariat reported that the draft policy brief would undergo additional consultation and comments would be welcomed from Member States. Transparency of the received feedback was encouraged, with the understanding that confidentiality would need to be considered if requested. A final version of this policy brief would be submitted to the ninth meeting of the Member State mechanism, and, for the benefit of all, would be made available by WHO as a draft until it had been finalized and adopted.

12. On the smartphone reporting application project, it was noted that this pilot study report had been completed and would be published, with additional insights on the impact of the type and settings of health facilities. Member States welcomed the project's expansion to additional countries, reiterating the importance of integrating sustainability in WHO's request for proposals soon to be issued.

13. An informal technical meeting on detection and screening technologies was convened by the Secretariat on 23 October 2019. The Secretariat reported on the ongoing work of Oxford University, the United States Pharmacopeial Convention and WHO. Member States welcomed the continued coordination of such activities.

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.

14. The Secretariat provided an update on the emerging links between access to medicines and substandard and falsified medical products, using the data collected and analysed from the WHO Global Surveillance and Monitoring System. A draft document had been prepared that would benefit from scientific validation. Member States supported the alignment with the WHO road map on access to medicines and vaccines 2019–2023, which included the prevention, detection and response to substandard and falsified medical products, and noted the need for a more in-depth assessment of the impact of this issue on the affordability, availability and acceptability of medical products. Member States encouraged the Secretariat to report progress to the Steering Committee.

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

15. The Secretariat provided an update on the country insight studies, aligned to the IDEAS (insight, data, engagement, action and solutions) global communications campaign framework to help combat

[1] Health products include finished medicines, including vaccines and pharmaceuticals.

the threat of substandard and falsified medical products under way in four Member States (Ghana, Nigeria, Sierra Leone and Uganda). The other deliverables/actions (1 to 5) under this activity will be based on the results of the studies. An update was also provided on the progress of the pharmacy school project under way in five Member States (Cameroon, Nigeria, Senegal, Uganda and United Republic of Tanzania). The value of increasing education and awareness, one of the key pillars of prevention of substandard and falsified medical products, was emphasized. Member States interested in leading Activity E were encouraged to notify the Secretariat.

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 the policy and technical coverage in all WHO regions of the work of the Member State mechanism, including the draft of an advocacy document which would be updated with the agreed prioritized activities so as to implement the workplan of the Member State mechanism for the period 2020–2021. The document would be made available in all United Nations languages and published in hard copy and a web version. Member States interested in leading Activity F were encouraged to notify the Secretariat.

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 medicines in transit. A technical working group had been convened, and a questionnaire established, translated into six languages and circulated to the Global Focal Point Network. Responses to the survey had been requested by 5 November 2019, with the aim of reporting progress and results to the Steering Committee. The Member State mechanism had requested the Secretariat to circulate the results to members of the Mechanism. Member States interested in leading Activity G were encouraged to notify the Secretariat.

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 Chair of the working group, provided an update on Activity H. An informal technical meeting on the internet was convened by Colombia on 22 October 2019. 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: executive summary had been published as an official document before the eighth meeting of the Member State mechanism. As next steps to completing an assessment of the experiences of national medicine regulatory authorities (action 1(c)), a timeline had been agreed, and a drafting group of Member States (Brazil, India, Indonesia, Ireland, Malaysia, Nigeria, Spain, United Republic of Tanzania and United States of America) formed to develop and disseminate a survey to the Global Focal Point Network and members of the Mechanism.

19. An information session with internet platforms was convened by the Secretariat on 23 October 2019. Member States expressed their appreciation for the information shared by the platforms and requested continued engagement by the Mechanism with similar stakeholders, as appropriate.

WHO's participation in relevant global and regional initiatives

20. The Secretariat provided an update on WHO's engagement in relevant global and regional initiatives, highlighting areas of coordination with the Member State mechanism. The Secretariat was encouraged to continue to share information on the various initiatives via MedNet.

Draft list of prioritized activities to implement the workplan of the Member State mechanism for the period 2020–2021

21. The Member States considered the draft list of prioritized activities for the period 2020–2021 submitted by the Steering Committee. The agreed list of prioritized activities for the period 2020–2021 is attached in the Annex.

22. The Mechanism also acknowledged the proposal to compile a list of the various regional initiatives to tackle the issue of distribution and supply of substandard and falsified medical products via the internet and include it in Activity H, in coordination with the Secretariat.

23. Furthermore, as a potential future activity, Member States were supportive of informal discussions with interested Member States, facilitated by Italy, with a view to generating a scoping paper on the need to establish a similar network on medical devices, for consideration by the ninth Member State mechanism, through the Steering Committee.

Proposed dates of the ninth meeting of the Member State mechanism

24. The Member State mechanism decided that its ninth meeting would take place in the week of 26–30 October 2020.

ANNEX

AGREED LIST OF PRIORITIZED ACTIVITIES TO IMPLEMENT THE WORKPLAN OF THE MEMBER STATE MECHANISM FOR THE PERIOD 2020–2021

Agreed 25 October 2019

Prioritized activities	Status	Actions
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. Lead: Brazil and Secretariat	In progress	1. Develop training material for national/regional regulatory authorities, focused on promoting the technical documentation approved by the Member State mechanism. 2. Assist in the identification of training needs, existing expertise and training material from 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: (a) 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. (b) Develop 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.
B. Expand and maintain the Global Focal Point Network among national medicines regulatory authorities to facilitate cooperation and collaboration. Lead: Secretariat	In progress	1. Continue to follow up with Member States to nominate focal points. 2. Continue to train new focal points and provide refresher training for existing focal points. 3. Facilitate the exchange of information in the Global Focal Point Network.

Prioritized activities	Status	Actions
C. Improve Member States' understanding of detection technologies, methodologies and "track and trace" models. Lead: Secretariat	In progress	1. Convene open-ended expert sessions to review existing field detection devices and "track and trace" models, and, as needed: (a) provide updates on existing "track and trace" and authentication technologies in use by Member States; (b) report on existing field detection devices in use or available to Member States. 2. Working group to continue to develop the policy paper on "track and trace" and submit a finalized document to the Member State mechanism.
D. Increase Member States' knowledge of the links between substandard and falsified medical products and access to quality, safe, efficacious and affordable medical products. Lead: Secretariat	In progress	1. Secretariat to review and report on future WHO activities on access to quality, safe, efficacious and affordable medical products, from the angle of links with substandard and falsified medical products.
E. Develop and leverage existing activity for effective risk communication and make recommendations for awareness campaigns on substandard and falsified medical products. Lead: Secretariat	In progress	1. Conduct surveys on patients' or consumers' attitudes and behaviours on accessing medical products in four African countries, and (i) Develop or leverage recommendations for effective risk communication and awareness campaigns. (ii) Produce samples of hard and soft copy material and video and broadcast material. (iii) Assess the use of social media for raising awareness. (iv) Identify the full range of stakeholders and audiences. (v) Develop key and innovative advocacy material. 2. Pilot the implementation of a compulsory element in the pharmacy school curriculum in five African countries
F. Enhance Member States' capacity to expand awareness, effectiveness, impact and outreach in their work on substandard and falsified medical products. Lead: Secretariat	In progress	1. 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. 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.

Prioritized activities	Status	Actions
G. Promote shared understanding among Member States from a public health perspective regarding medical products in transit. Lead: Secretariat	In progress	1. Secretariat to provide an information note on the current situation regarding medical products in transit, within the public health domain.
H. 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. A working group was established to: (a) develop terms of reference (completed); (b) 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 (completed); (c) 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) 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.

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