World Health Organization

NINTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS
Provisional agenda 4

A/MSM/9/5
20 October 2020

Update on the list of prioritized activities for 2020–2021

Report by the Secretariat

BACKGROUND

1. Resolution WHA65.19 (2012) adopted by the Sixty-fifth World Health Assembly established the Member State mechanism on substandard and falsified medical products. The Member State mechanism reports to the Health Assembly though the Executive Board on progress in the prevention and control of substandard and falsified medical products and provides policy recommendations.[1] The WHO Secretariat supports the Steering Committee of the Member State mechanism.[2] The Chairperson may present reports of the Member State mechanism to the Health Assembly. In case of issues, other than policy matters, which require the attention of the Health Assembly before the annual session of the mechanism, the Steering Committee may report directly to the Health Assembly.[3]

2. Through effective collaboration among Member States and the WHO Secretariat, the Member State mechanism aims to: (a) protect public health and promote access to affordable, safe, efficacious, and quality medical products; and (b) promote prevention and control of substandard and falsified medical products and associated activities. To this end, the Member State mechanism establishes a list of priority activities, revised every two years based on the recommendations of the Steering Committee. To advance the workplan, subsidiary working groups may be established and may generate knowledge products supporting Member States' combat against substandard and falsified medical products. Preventing, detecting and responding to substandard and falsified medical products require global coordination and cross cutting approaches. The policy work of the Member State mechanism is informed by technical input, centred around the WHO global surveillance and monitoring system.

3. The 2020–2021 agreed list of prioritized activities to implement the workplan of the Member State mechanism contains eight prioritized activities; six are led by the WHO Secretariat, one is co-led by the WHO Secretariat with a Member State, and one is led by a Member State. This document provides a progress update on these activities as agreed by the Member State mechanism workplan.[4]

---

[1] Reports of the eighth and ninth meetings will be transmitted to the WHO Executive Board and Health Assembly in 2021.

[2] The Steering Committee is composed of two vice-chairpersons for each WHO region. Chairmanship of the Member State mechanism rotates among the regions in English alphabetical order.

[3] Document A66/22.

[4] Document A/MSM/8/4 Annex. List of prioritized activities to implement the workplan of the Member State mechanism for the period 2020–2021.

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.

4. Brazil and the Secretariat co-lead this activity, which contains three actions: (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, (3.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 and (3.b) Develop guidance documents to strengthen capacities of regulatory authorities to plan, perform, and assess risk-based post-market surveillance including the effective use of the tools.

5. Actions (1) and (2) are integrated as part of WHO's technical work and the global surveillance and monitoring system. Considering the focus on building national regulatory capacity, this is implemented in coordination with other technical teams. The coronavirus disease (COVID-19) crisis has halted physical delivery of training, however distance learning and synchronized materials are being developed. These will be partly hosted on the public WHO web pages and the enhanced online portal. Staff time has been allocated and external suppliers contracted in order to advance this ongoing background work.

6. COVID-19 related restrictions have delayed operational implementation of action (3). Nonetheless, the Secretariat has continued work to simplify and accelerate the various phases of risk-based post-market surveillance: design, planning, execution, analysis and response. The tool will now cater to different users, each responsible for a specific phase of the survey. Improved data management, in addition to the physical tracing of samples, will eventually allow regulatory authorities to better target interventions.

7. In parallel, the return on investment in post-market surveillance activities has been studied. The Secretariat will present preliminary findings to the Steering Committee and seek guidance on how to leverage advocacy and support. The Secretariat has allocated staff time and contracted external suppliers for this work.

8. With regard to action (3.b), considering the operational delays, the Steering Committee agreed that the working group would aim to finalize the guidance by the tenth meeting of the Member State mechanism (2021). The group working on developing guidance calls for additional Member States to join the group.

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

9. This activity is led by the Secretariat and contains three actions: (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; and (3) Facilitate the exchange of information in the Global Focal Point Network.

10. In 2015, terms of reference[1] for a global network of regulatory focal points were developed. Focal points are trained on the use of the global surveillance and monitoring system and report incidents of substandard and falsified medical products to WHO. The technical unit is responsible for maintaining the list of nominated focal points and administering a secure online platform.

11. The Secretariat liaises with WHO regional offices to update lists as necessary. A large ongoing information technology upgrade will enhance resources available to focal points via the online platform. Validated data and analyses are key to generate evidence and sound strategies. However, a number of reporting barriers remain, namely the misconception that national reporting rates could be extrapolated to prevalence rates – in reality, high reporting rates indicate good detection capacity and efficient information management processes. Staff time has been allocated and external resources contracted to progress this work.

– *The Secretariat seeks guidance and support from the Member State mechanism to: (i) encourage timely and regular reporting from focal points to the global surveillance and monitoring system; (ii) ensure that focal points have relevant authority to execute their roles; and (iii) encourage focal points to exchange appropriate information with their peers within the WHO-hosted network.*

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

12. This activity is led by the Secretariat and contains two actions: (1) Convene open-ended expert sessions to review existing field detection devices and "track and trace" models, (1.a) provide updates on existing "track and trace" and authentication technologies in use by Member States and (1.b) report on existing field detection devices in use or available to Member States; and (2) Working group to continue to develop the policy paper on "track and trace" and submit a finalized document to the Member State mechanism.

13. On the margins of the eighth meeting of the Member State mechanism, two open-ended technical sessions on detection technologies and traceability were delivered by external experts and the Secretariat. The Chairperson of the Steering Committee requested that a similar short update on detection technologies be provided for the week of the ninth meeting of the Member State mechanism. The Secretariat has allocated staff time to progress this work.

14. A working group (19 Member States) was established to develop the traceability paper. Submitted for the consideration of the ninth plenary meeting of the Member State mechanism, the paper provides guidance on developing workable traceability regulation.

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.

15. This activity is led by the Secretariat. Substandard and falsified medical products obstruct access to safe, quality, efficacious and affordable medical products. The COVID-19 crisis further complicates the matter with challenging policy and scientific issues.

[1] Document A69/41.

16. Following the request of the Steering Committee, the Secretariat conducted a thematic analysis of the global surveillance and monitoring system. The data were mapped to accepted criteria of affordability, availability and acceptability, and subsequently aligned to WHO's *Roadmap for access to medicines, vaccines and other health products 2019–2023*.

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

17. This activity is led by the Secretariat and contains two actions: (1) Conduct surveys on patients' or consumers' attitudes and behaviours on accessing medical products in four African countries; and (2) Pilot the implementation of a compulsory element in the pharmacy school curriculum in five African countries. Both actions are being implemented in the form of projects in collaboration with Member States. Staff time has been allocated and external suppliers have been contracted to ensure delivery of both actions.

18. Insight studies, conducted in Ghana, Nigeria, Sierra Leone and Uganda, demonstrate that access constraints, in particular affordability and limited alternatives, increase the risk of substandard and falsified medical products. Attitudinal and behavioural factors identified in five demographic groups were linked to the risk of patients using substandard and falsified medical products. The findings were used to develop national awareness campaigns, currently ongoing in the four Member States. Among other elements, the campaigns focus on trust of health care professionals, appropriate media sources and protective measures. The data collected through the insight studies will also be analysed by contracted academics.

19. The pharmacy school curriculum project aims to formalize and structure information available to pharmacists to prevent, detect, and respond to substandard and falsified medical products. An informal technical working group developed a competency framework and six teaching modules that cover different aspects of the prevent-detect-respond strategy. All materials are accessible in French and English. The initial plan for a physical train-the-trainers meeting was replaced with twelve hours of virtual sessions. Due to restrictions related to COVID-19, implementation of modules at student level has been delayed.

– *The Secretariat seeks guidance from the Member State mechanism on how to leverage and apply this knowledge so that other Member States and stakeholders could benefit from these projects.*

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

20. This activity is led by the Secretariat and contains two actions: (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; and (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.

21. The Secretariat allocates staff time and resources throughout the year to disseminate and promote the work of the Member State mechanism. As a result, substandard and falsified medical products have

been recognized as an urgent global health challenge and a WHO health topic,[1] with ongoing efforts to strengthen high level advocacy. Despite travel restrictions related to COVID-19, the Secretariat has continued to participate in both technical and strategic international forums increasing awareness on substandard and falsified medical products. Communication material is continuously improved. It is made available to Member States and other relevant stakeholders to facilitate a coordinated messaging strategy in as many languages as possible, in formats such as information booklets, bulletins and presentations.

22. Member States are encouraged to take ownership of these various outreach products and leverage support within their respective regional and national networks.

– *The Secretariat seeks feedback from the Member State mechanism on how these materials have been received and directions for improvement in both content and coordination efforts.*

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

23. This activity is led by the Secretariat who has been tasked with providing an information note regarding medical products in transit. In order to collect the necessary data, a questionnaire was sent to Member States but current response rates are below 50%, so the questionnaire is to be re-circulated. The questionnaire responses should be systematically analysed to further investigate the matter from a public health perspective. Staff time has been allocated to progress this work and contracting external resources is under consideration.

– *The Secretariat seeks guidance and support from the Member State mechanism to: (i) increase response rates for this and any other questionnaire related to the workplan for the Member State mechanism; and (ii) use and apply the insights provided by analysing responses to the transit questionnaire.*

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

24. This activity is led by Colombia who will provide an update to the Steering Committee and the ninth plenary meeting.

COVID-19 Impact

25. The COVID-19 pandemic has caused delays in the implementation of the prioritized activities. The Steering Committee has supported the Secretariat in a flexible approach, adapting workplan timelines and implementation plans as needed according to the evolution of the pandemic.

ACTION BY THE MEMBER STATE MECHANISM

26. The Member State mechanism is invited to note this update.

= = =

[1] https://www.who.int/news-room/photo-story/photo-story-detail/urgent-health-challenges-for-the-next-decade, accessed 7 October 2020.