

Update on the list of prioritized activities for 2020–2021

Report by the Secretariat

BACKGROUND

1. The agreed list of prioritized activities to implement the workplan of the Member State mechanism for the period 2020–2021¹ contains eight prioritized activities, of which five are led with the support of the WHO Secretariat, two are led by a Member State, and one is co-led by the WHO Secretariat and a Member State. This document provides a progress update on these activities. More information on the overall status of completion of the prioritized activities is provided in document A/MSM/10/5.

2. The Director-General transmitted to the Executive Board at its 148th session and the World Health Assembly at its Seventy-fourth session the reports of the eighth and ninth meetings of the Member State mechanism on substandard and falsified medical products, which met in Geneva from 24 to 25 October 2019 and virtually from 28 to 29 October 2020, respectively. During discussions at the Seventy-fourth World Health Assembly, there were numerous interventions from Member States highlighting the importance of the Member State mechanism and its work.

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.

3. Brazil and the Secretariat co-lead this activity. To ensure that training materials for national/regional regulatory authorities are accessible and readily available, the Secretariat has aligned its efforts with the WHO Global Benchmarking Tool. The prevention and detection of, and response to substandard and falsified medical products are critical for strong regulatory systems. The Secretariat has therefore continued to focus on building a modernized risk-based post-market surveillance process, including through the development of tools and the conducting of a return on investment study. Brazil, the lead of the working group, intends to draft risk-based post-market surveillance guidance after the completion of the pilot study.

¹ Document A/MSM/8/4, Annex.

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

4. This activity was led by the Secretariat until June 2021, after which point a new working group was established with Eritrea assuming the lead. The Secretariat has worked to strengthen the Global Focal Point Network, including by conducting regional trainings and through regular monitoring and validation of focal points. As agreed at the ninth meeting of the Member State mechanism, the working group aims to identify solutions to reporting barriers.¹

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

5. This activity is led by the Secretariat. As agreed at the ninth meeting of the Member State mechanism, a new working group on detection technologies was established and tasked with devising WHO technical guidance on this topic.² The Secretariat also published a policy paper on traceability of medical products³ and is conducting ongoing work to update the mapping of country and regional experiences. A working group on traceability continues to meet. Open-ended expert sessions on detection technologies and traceability are on track to be completed in 2021.

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.

6. This activity is led by the Secretariat. A report on Activity D by the Secretariat was considered at the ninth meeting of the Member State mechanism⁴ and it was agreed that the recommendations outlined in paragraphs 19 and 20 of that report should be implemented.

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

7. This activity is led by the Secretariat. Risk communication campaigns and pharmacy school curriculum pilot projects have been rolled out, the results of which will be shared with the Member State mechanism upon completion of the pilots. A new working group was established to identify ways in which Member States and other relevant stakeholders could build on the lessons learned from such projects.⁵

¹ Document A/MSM/9/7, paragraph 9.

² Ibid., paragraph 10.

³ <https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products> (accessed 14 September 2021).

⁴ Document A/MSM/9/6.

⁵ Document A/MSM/9/7, paragraph 16.

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

8. This activity is led by the Secretariat. As agreed at the ninth meeting of the Member State mechanism, a new working group was established to link national, regional and global awareness-raising efforts.¹ The establishment of a new working group for regional/global initiatives was also discussed at the ninth meeting of the Member State mechanism.² However, given the similar mandates of the two proposed working groups and in order to avoid any duplication of effort, the Steering Committee agreed to establish a single working group on these matters under Activity F. The Secretariat continues to proactively disseminate and promote the work of the WHO Member State mechanism.

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

9. This activity is led by the Secretariat. With the support of the working group, a questionnaire was disseminated to Member States, the results of which were used to draft the information note on the current situation regarding medical products within the public health domain.³ As agreed at the ninth meeting of the Member State mechanism, the Secretariat has increased coordination and collaboration with the World Customs Organization.⁴

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

10. This activity is led by Colombia. With the support of the working group, a questionnaire was disseminated to Member States, the results of which were used to draft the document on identifying experiences and regulations of the distribution or supply of medical products via the internet⁵ and the guidance on strategies to enable regulatory authorities to address this issue.⁶ Italy has continued to work on developing the online “good practices” initiative, which aims to collect and share existing good practices related to internet investigations.

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¹ Document A/MSM/9/7, paragraph 17.

² Ibid., paragraph 22.

³ Document A/MSM/10/8.

⁴ Document A/MSM/9/7, paragraph 19.

⁵ Document A/MSM/10/9.

⁶ Document A/MSM/10/10.