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## **Updates on the list of prioritized activities for the period 2022–2023**

### **Report by the Secretariat**

#### **BACKGROUND**

1. The agreed list of prioritized activities to implement the workplan of the Member State mechanism on substandard and falsified medical products for the period 2022–2023 contains eight prioritized activities,<sup>1</sup> of which seven are led by Member States and one is currently supported by the WHO Secretariat. This document provides a progress update on these activities.

2. In 2023, the Director-General transmitted to the Executive Board at its 152nd session and the Seventy-sixth World Health Assembly the reports of the tenth and eleventh meetings of the mechanism, which were held virtually from 27 to 29 October 2021 and in a hybrid format from 19 to 21 October 2022, respectively.

**Activity A: Strengthen the capacity of national/regional regulatory authorities for the prevention and detection of, and response to, substandard and falsified medical products.**

3. This activity is led by Brazil. The Secretariat has aligned its efforts with the WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems of medical products to ensure that training materials are accessible and readily available for national/regional regulatory authorities. Institutional development plans on training needs will be extracted from the GBT after the Global Competency Framework for regulators of medical products has been finalized. The Secretariat has continued to focus on building a modernized risk-based post-market surveillance process through the deployment of its e-tool, Epione, and the organization of a return-on-investment pilot study in the United Republic of Tanzania. Working Group A has developed a high-level guidance text on risk-based post-market surveillance and control that will be enhanced with the support of the Secretariat and finalized following the standard WHO consultation procedure.

**Activity B: Develop, expand and maintain global networks of stakeholders to facilitate cooperation and collaboration.**

4. This activity is led by Eritrea. The Secretariat has worked to strengthen the Global Focal Point Network, including by conducting regional training and through the regular monitoring and validation of focal point contacts. Working Group B has disseminated a questionnaire as part of a multinational

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<sup>1</sup> Document A/MSM/10/11 Rev.1, Annex 2.

study to identify (a) reporting barriers faced by national focal points in respect of the WHO Global Surveillance and Monitoring System for substandard and falsified medical products and (b) possible solutions.<sup>1</sup> The results of the study will provide indications of where, and at what level, training is required as well as the challenges that Member States face when reporting substandard and falsified medical products. Working Group B aims to develop a strategy and implementation mechanisms for the identified barriers in the next workplan of the mechanism.

**Activity 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.**

5. The working group on traceability, which is led by Nigeria, organized a technical briefing session to review how traceability enables adverse event reporting and efficient recall, particularly in the context of the contamination of medical products with diethylene glycol and ethylene glycol. A multinational survey on country experiences in respect of the traceability of medical products and the mapping of national traceability systems and associated technologies has been distributed to all Member States. An initial report on the findings of the survey will be presented at the twelfth meeting of the mechanism, which is scheduled to be held in a hybrid format on 15–17 November 2023. The working group on detection technologies, which is led by Montenegro, organized a technical briefing session to review existing detection technologies in response to the latest cases of the contamination of medical products with diethylene glycol and ethylene glycol. A multinational survey on existing detection methodologies and/or tools used by Member States within their respective jurisdictions has been distributed and an initial report on the findings of the survey will be presented at the twelfth meeting of the mechanism.

**Activity 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.**

6. Pending the identification of a Member State lead, this activity is currently supported by the Secretariat. The Secretariat has drafted a handbook for Member States on developing/strengthening national action plans for prevention, detection and response strategies on substandard and falsified medical products. This work is being carried out in line with the GBT and other stakeholder guidance (such as that published by the World Customs Organization and UNODC). The Secretariat is circulating the draft for comment among a select group of stakeholders and will implement pilot implementation projects in a few countries before finalizing the handbook.

**Activity E: Enhance Member States' capacity to run effective risk communication campaigns for substandard and falsified medical products.**

7. This activity is led by Zambia. In response to the latest cases of the contamination of medical products with diethylene glycol and ethylene glycol, Working Group E organized a technical briefing session on risk communication strategies and invited affected Member States to share their experiences with other Member States and stakeholders to facilitate the development of prevention, detection and response strategies that are built on the lessons learned from such incidents.

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<sup>1</sup> Document A/MSM/12/5.

**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 Australia. Working Group F focuses on linking national, regional and global awareness-raising efforts. The Secretariat continues to disseminate and promote the work of the mechanism proactively and encourages Member States to participate in this activity.

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

9. This activity is led by Colombia. As agreed at the tenth meeting of the mechanism, Working Group G aims to develop a strategic road map promoting interagency cooperation and collaboration with relevant stakeholders to respond to and promote awareness-raising and the policy visibility of the distribution of substandard and falsified medical products via the internet.<sup>1</sup> Regarding next steps, Working Group G plans to advocate for Member State capacity-building so that all Member States are able to respond effectively to the online distribution of substandard and falsified medical products.

**Activity 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.**

10. This activity is led by the United States of America. Working Group H proposed a definition of the term “informal market of medical products” that was agreed to at the eleventh meeting of the mechanism.<sup>2</sup> The Secretariat has facilitated the conduct of a comprehensive literature review on informal markets for medical products, with a focus on substandard and falsified medical products;<sup>3</sup> it has also performed a landscape analysis of existing knowledge gaps, including the known prevalence and regulatory interventions to control and limit the distribution of substandard and falsified medical products through informal markets. Working Group H will undertake a pilot survey of Member States participating in the working group to assess their experiences, challenges and responses in respect of informal markets. The findings of the survey will be presented at the twelfth meeting of the mechanism.

**ACTION BY THE MEMBER STATE MECHANISM**

11. The mechanism is invited to note the report. In its discussions, it is further invited to provide comments and guidance in respect of the following questions:

- reflecting on the low participation of Member States in the activities of the workplan for the period 2022–2023, in what ways could Member State engagement be increased, including ensuring that all future prioritized activities have a Member State lead?
- what is the mechanism's view on the continuation and promotion of technical briefing sessions, which have increased the visibility of the work of the mechanism within the Secretariat and among national regulatory authorities and other stakeholders?

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<sup>1</sup> See document A/MSM/10/11 Rev.1.

<sup>2</sup> Document A/MSM/11/4, Annex.

<sup>3</sup> Document A/MSM/12/6.