World Health Organization

TWELFTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS
Provisional agenda item 2

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Update on the activities and budget to implement the workplan of the Member State mechanism

Report by the Secretariat

1. The Secretariat remains committed to providing support as required to implement the workplan of the Member State mechanism. Despite ongoing resource mobilization efforts, the financial sustainability of the workplan remains a concern, especially with the addition of new prioritized activities and proposed actions for the period 2024–2025 in response to prevailing global public health situations and events.

Global surveillance and monitoring

2. As at August 2023, the WHO Global Surveillance and Monitoring System for substandard and falsified medical products (GSMS) had records of almost 4500 substandard and falsified medical products (medicines and vaccines) from all WHO regions.

3. As at August 2023, GSMS also had records of 469 complaints for WHO-recommended (WHO-prequalified, WHO-emergency-use-listed or otherwise) in vitro diagnostic medical devices (IVDs).

4. The GSMS database and online portal require continuous technical maintenance and upgrades to ensure that they are secure, accurate and fit-for-purpose. Technical developments are ongoing to improve the ease of use of the database and online portal and enhance record views and reporting.

5. As at September 2023, a total of seven WHO medical product alerts had been issued over the year; of those, three had been issued for substandard (contaminated) syrup medicines, two for falsified defibrotide sodium, one for substandard (contaminated) liquid dosage medicines and one for substandard tetracycline hydrochloride ophthalmic ointment**.**

6. As at September 2023, five field safety notices had been issued over the year by the manufacturers of WHO-recommended IVDs, covering a total of six products.

7. As at September 2023, two targeted market surveillance requests had been issued over the year to national regulatory authorities for a total of 18 substandard and falsified medical products.

Substandard and falsified coronavirus disease (COVID-19) medical products

8. Substandard and falsified COVID-19 medical products pose risks to global public health and place additional burdens on vulnerable populations and health systems; it is important to detect and remove these products from circulation to prevent harm to patients. WHO has requested additional

surveillance for substandard and falsified COVID-19 medical products, particularly those that are included in global medical product alerts, targeted market surveillance requests and threat assessment information notes.

9. As at August 2023, a total of four COVID-19 vaccines had been reported to GSMS over the year, which was fewer than in 2022, and two complaints had been received during the same period for IVDs for the detection of severe acute respiratory syndrome coronavirus 2.

10. The underreporting of substandard and falsified COVID-19 medical products is an ongoing issue. During 2022, major risks to accessing safe and effective COVID-19 medical products included: the diversion of COVID-19 vaccines; suspicious and fraudulent offers to supply COVID-19 vaccines; cold chain vulnerabilities in supply chains, leading to the degradation of COVID-19 vaccines; the refilling and repurposing of used COVID-19 vaccine vials owing in part to their inappropriate disposal; and the inappropriate use of syringes to administer COVID-19 vaccines. The same major risks were observed in 2023.

Development of guidance and knowledge products

11. In collaboration with the mechanism working groups, the Secretariat has been supporting the development of guidance and handbooks to support Member States to combat substandard and falsified medical products. Topics include: market surveillance and control; the selection of detection technologies; the control of the sale of medical products via the internet; the development of national action plans to prevent, detect and and respond to substandard and falsified medical products; and the identification of reporting barriers by national focal points.

ACTION BY THE MEMBER STATE MECHANISM

12. 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:

- what is needed to encourage Member States to improve the reporting of substandard and falsified medical products to GSMS?
- how can resource mobilization efforts for the financial sustainability of the workplan be best targeted?
- what is required to motivate Member States to provide technical expertise to develop guidance and knowledge products that support the prioritized activities and proposed actions of the workplan?
- how prepared are Member States to participate in the establishment of baseline situation analyses and surveys, including the evaluation of the mechanism?

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