World Health Organization

**TENTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS**
**Provisional agenda item 3**

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# Secretariat activities and budget to implement the workplan of the Member State mechanism

## Update by the Secretariat

1. The Secretariat remains committed to providing support as required to implement the workplan of the WHO Member State mechanism. Despite ongoing resource mobilization efforts, the financial sustainability of the workplan remains a concern.

### Global surveillance and monitoring

2. As of August 2021, the WHO Global Surveillance and Monitoring System for substandard and falsified medical products has received more than 3000 reports of substandard and falsified medical products from all WHO regions, including 39 complaints regarding in vitro diagnostics. In order to ensure that the reporting process remains fit for purpose, the Secretariat has continued to upgrade the database and portal of the Global Surveillance and Monitoring System and has developed more efficient processes and tools.

3. In 2021, five global medical product alerts[1] were issued regarding falsified Vitamin A, falsified coronavirus disease (COVID-19) vaccine BNT162b2, falsified misoprostol (CYTOTEC), falsified remdesivir and falsified COVISHIELD vaccine. One information notice was issued for users of in vitro diagnostic medical devices for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in the context of COVID-19 testing. Targeted market surveillance requests and threat assessment information notes were also issued to regulatory authorities, as appropriate.

### COVID-19

4. 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,[2] targeted market surveillance requests, and threat assessment information notes.

[1] https://www.who.int/teams/regulation-prequalification/incidents-and-SF/full-list-of-who-medical-product-alerts (accessed 13 September 2021).

[2] Ibid.

5. As of August 2021, nearly 80 substandard and falsified medical products related to COVID-19 have been recorded in the WHO Global Surveillance and Monitoring System. The number of COVID-19 products reported to the Global Surveillance and Monitoring System have increased this year; however, underreporting is still considered to be an issue. Related risks include: corruption and diversion of COVID-19 vaccines; suspicious and fraudulent offers to supply COVID-19 vaccines; supply chain vulnerabilities (in the cold chain) leading to degradation; refilling and repurposing of empty vaccine vials (in part perpetuated by inappropriate disposal of used COVID-19 vaccine vials); and inappropriate use of syringes used to administer COVID-19 vaccines. Following a surge in Delta variant infections, a spike in media reports of falsified remdesivir has also been observed.

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