

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 at August 2022, the WHO Global Surveillance and Monitoring System for substandard and falsified medical products has received almost 3500 reports of substandard and falsified medical products (medicines and vaccines) from all WHO regions.

3. As at August 2022, the Global Surveillance and Monitoring System has also been notified of approximately 360 complaints for WHO-recommended in vitro diagnostic medical devices (WHO prequalified, WHO emergency use listed or otherwise).

4. The database and online portal of the Global Surveillance and Monitoring System require continuous technical maintenance and upgrades to ensure that the systems are secure, accurate and fit for purpose. Financial costing for system maintenance and upgrade work is ongoing. This is in addition to further technical development and expansion of the database and online portal.

5. In 2022, two global medical product alerts¹ were issued for falsified Intratect (human normal immunoglobulin) and falsified DESREM (Remdesivir). A regional alert was also issued and limited only to national regulatory authorities in the Western Pacific Region and the South-East Asia Region for a falsified coronavirus disease (COVID-19) product.

6. During the same period, nine field safety notices were issued by the manufacturers of WHO-recommended in vitro diagnostic medical devices (WHO prequalified, WHO emergency use listed or otherwise).

7. Three targeted market surveillance requests were issued to regulatory authorities for a total of 25 substandard and falsified medical products.

¹ <https://www.who.int/teams/regulation-prequalification/incidents-and-SF/full-list-of-who-medical-product-alerts> (accessed 11 August 2022).

COVID-19

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,¹ targeted market surveillance requests and threat assessment information notes.

9. As at August 2022, a total of 93 substandard and falsified medical products related to COVID-19 have been recorded in the Global Surveillance and Monitoring System. The number of COVID-19-related products reported decreased in the first half of 2022 – with nine products reported as at August 2022. All but one of the reported products were antivirals. Two rounds of risk assessment considering the impact of omicron lineages on in vitro diagnostic medical devices used for the diagnosis of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) were assessed during the period of December 2021 to August 2022.

10. Underreporting remains an issue. Ongoing risks to accessing safe and effective COVID-19 products continue to include corruption; diversion of vaccines; suspicious and fraudulent offers to supply COVID-19 vaccines; cold chain vulnerabilities in supply chains leading to degradation; refilling and repurposing of empty vaccine vials due in part to inappropriate disposal of used COVID-19 vaccine vials; and inappropriate use of syringes used to administer COVID-19 vaccines.

Monkeypox

11. On 23 July 2022, the Director-General declared the current monkeypox outbreak a public health emergency of international concern under the International Health Regulations (2005). The Global Surveillance and Monitoring System is now monitoring information sources for any incidents of substandard and falsified therapeutics and vaccines recommended for monkeypox.

ACTION BY THE MEMBER STATE MECHANISM

12. The mechanism is invited to note the report and discuss ideas for improvements in respect of:

- Member State reporting on substandard and falsified medical products; and
- the resource requirements for the workplan.

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¹ Ibid.