Threat Assessment Information Note 2/2021
Global Surveillance and Monitoring System for Substandard and Falsified (SF) Medical Products

DISCLAIMER: This document is intended exclusively for national regulatory Focal Points of the WHO Global Surveillance and Monitoring System (GSMS) and must not be shared beyond the national regulatory authority.

IDENTIFIED THREAT: ILLICIT REFILLING OF USED COVID-19 VACCINE VIALS

Key points
- **Criminal groups may seek to obtain empty COVID-19 vaccine vials which have been disposed of inappropriately**
- **Inappropriate or insecure disposal of vaccine vials may create risk that empty vials are refilled to produce falsified COVID-19 vaccines**
- **Secure waste management systems must be put in place to ensure waste vials are appropriately disposed of**

Background and driving forces

The increased global demand for COVID-19 vaccines (and therapeutic products such as remdesivir), has resulted in the creation of significant amounts of empty waste vials.

Inappropriate or insecure disposal of used vials may create opportunities for criminal groups to obtain and refill vials and produce falsified vaccines and medical products. Such activity may increase the risk that falsified COVID-19 vaccines and therapeutic products are introduced into legitimate supply chains.

The WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products has reports of historical incidents where empty vials of medical products were illicitly recovered and reused. The expiry date of those vials was also altered to lengthen the life of those products.

While WHO is not aware of any refilled COVID-19 vaccines vials in circulation, WHO recommends heightened scrutiny and vigilance in the purchasing and distribution of vaccines and calls for the secure and appropriate disposal of empty vials.

Identifying the issue

Reused and repurposed vials may sometimes be identified by physical examination. Some indicators that a vial is falsified and may have been illicitly refilled may include:
- Vials have scratches or signs of tampering
- Labels show signs of water damage
- The metal cap is dented, scratched or broken
- Rubber seals are scratched or punctured
- Foreign materials/particles visible inside the vial
- Visible signs the expiry date has been changed or tampered with
- The expiry date does not match the authentic batch number
- Suspiciously large amount of the product available for private sale

Preventive measures

To reduce the risk that used empty vials are available to criminal groups and are refilled, secure waste management systems must be put in place and maintained. Waste vials must be properly stored and disposed of, or destroyed by appropriate health-care waste management systems. Healthcare workers handling vaccines should be aware of and adhere to waste disposal guidelines. When in doubt, consult the products' manufacturer for guidance on secure disposal of empty vials.

If empty vials cannot be immediately destroyed or securely disposed of, the following measures should also be considered:

- If possible, deface, mark or peel off the vial labels after use
- Long term on-site storage of waste empty vials should be avoided
- If safe to do so, waste vials should be crushed at an appropriate waste management facility

To best ensure empty vials are not at risk of illicit repurposing, used vials should be transported to dedicated waste management facilities, where disposal and or destruction can be guaranteed.

National regulatory/health authorities are advised to immediately notify WHO of substandard/falsified medical products. If you have any information concerning the manufacture, distribution, or supply of these products, please email rapidalert@who.int .

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products
For more information, please visit: https://www.who.int/health-topics/substandard-and-falsified-medical-products **Email:**
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