World Health Organization

13 May 2024

# Targeted Market Surveillance list: Quarter 1–2024

## Global Surveillance and Monitoring System for substandard and falsified (SF) medical products

**DISCLAIMER: The information in this document is only for use by national or regional medical product regulatory authorities. It is not intended for the public and must not be shared beyond the GSMS network of regulatory focal points. National regulatory authorities are requested to increase vigilance and conduct market surveillance for the medical products listed below.**

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Products have been referenced in this issue because:

1. The product has been previously reported to the WHO GSMS database **AND/OR**
2. The product is likely to be available across one or more WHO Region(s) **AND/OR**
3. The product has previously appeared or may appear on a WHO Medical Product Alert **AND/OR**
4. A reporting focal point has requested information on the product is shared within the network.

### Notify WHO if you detect any of these products or have any suspicions.

Please increase surveillance when dealing with these products or when considering their procurement.

It is important to obtain photographs, samples for laboratory analysis, and information on the supply and/or distribution route. Please refer to the WHO guidance on how to take photographs of SF medical product samples and the WHO Aide-Mémoire for guidance on handling incidents of SF medical products. Both are available on the resources page on the GSMS Portal at https://sfreport.who.int/

Focal Points are encouraged to consult the GSMS Portal search tool for additional information and photographs of the products referenced in this issue.

Notifications may be done by using the GSMS Portal notification tool or by email rapidalert@who.int .

This issue references **six products** which, at this stage, have been detected in **five WHO regions, in six countries**. Widespread attention is required in all WHO regions, regardless of where the product referenced in this document was originally identified.

This issue primarily includes products reported to the GSMS between November 2023 and March 2024.

Please share or forward reports to the WHO GSMS if you detect products referenced in this issue in your markets/ jurisdictions.

It is important to detect and remove these products from circulation to prevent potential harm to patients.

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# 1 WHO Africa Region

## 1.1 FALSIFIED TANDAK IDENTIFIED IN NIGERIA

In March 2024, WHO was notified through media monitoring of the detection of falsified Tandak. The product was discovered by the marketing authorization holder and confirmed to be falsified. The product may still be available at the patient level. The national regulatory authority has released a public alert that can be accessed through the following link: https://nafdac.gov.ng/public-alert-no-011-2024-alert-on-the-sale-of-counterfeit-tandak-injection-in-nigeria/.

**HOW TO DETECT**:

- Lack of a hologram on the primary carton.
- A photocopied/scanned mobile authentication service label on the primary carton.
- No patient information leaflet.
- The falsified product has a white vial cap, while genuine products have green vial caps.
- The Prime Pharmaceutical Pvt Ltd logo is inconsistent with the genuine logo of the company.

| ***Product Name*** | **TANDAK INJECTION 1.5 G** |
|---|---|
| *Declared active ingredient* | Ceftriaxone and Sulbactam |
| *Stated Manufacturer* | Intracin Pharmaceuticals PVT. LTD |
| *Batch Number* | 22P21 |
| *Expiry Date* | 08/2026 |
| *Language on label* | English |
| *Available photograph* |  |

# 2 WHO Region of the Americas

## 2.1 FALSIFIED SOLIRIS IDENTIFIED IN MEXICO

In January 2024, WHO was notified by the genuine manufacturer that falsified versions of SOLIRIS were available at patient level, identified by health professionals in hospital/clinic. The genuine manufacturer has confirmed that Lot 1003556 does not correspond to the genuine manufacturing records. The WHO GSMS database holds previous records of other falsified versions of this product.

**HOW TO DETECT**:

| ***Product Name*** | **SOLIRIS** |
|---|---|
| *Declared active ingredient* | Eculizumab |
| *Stated Manufacturer* | ALEXION |
| *Batch Number* | 1003556 |
| *Expiry Date* | N/A |
| *Language on label* | N/A |
| *Available photograph* | N/A |

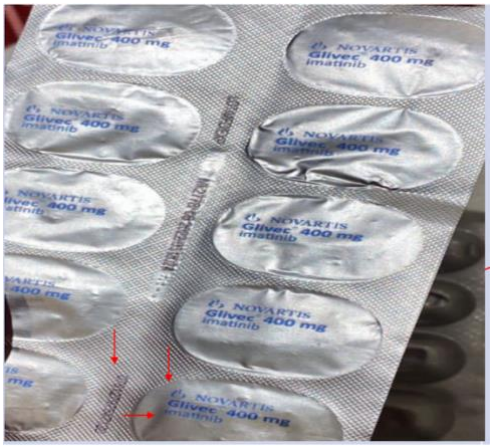
# 3 WHO Eastern Mediterranean Region

## 3.1 FALSIFIED GLIVEC IDENTIFIED IN EGYPT

In January 2024, WHO was notified by the genuine manufacturer that falsified GLIVEC (imatinib) was available at patient level in Egypt. The WHO GSMS database holds previous records of other falsified versions of this product.

**HOW TO DETECT**:

- Overprinting texts (importer's name, registration number, registered price) with different font types in different locations on the packaging.
- Old Novartis logo on blister.
- In the genuine sample, Imatinib is written in italics.

| | |
|---|---|
| ***Product Name*** | **GLIVEC 400MG 30 Film Coated Tablets** |
| *Declared active ingredient* | Imatinib |
| *Stated Manufacturer* | Novartis Pharma Production GmbH, Wehr, Germany for Novartis Pharma AG Basel Switzerland |
| *Batch Number* | MK2778 |
| *Expiry Date* | 05 2024 |
| *Language on label* | English, French, Spanish |
| *Available photograph* |    |

# 4 WHO European Region

## 4.1 SUBSTANDARD VBLAAST IDENTIFIED IN POLAND

In March 2024, WHO was notified by the national regulatory authority that substandard versions of VBLAAST (injection 10mg/10ml) were recalled due to crystal formations.

**RISKS**

Injection of undissolved crystals can lead to tissue damage, irritation, inflammation, and blockage of blood vessels. This can result in pain, swelling, infection, and even tissue death at the injection site.

**HOW TO DETECT**:

- Visible crystal formation in the injection solution.

| ***Product Name*** | **VBLAAST 10** |
|---|---|
| *Declared active ingredient* | Vinblastine sulphate |
| *Stated Manufacturer* | BRUCK PHARMA PVT. LTD. |
| *Batch Number* | I23I011B |
| *Expiry Date* | 31.08.2025 |
| *Language on label* | N/A |
| *Available photograph* | N/A |

## 4.2 FALSIFIED OMNITROPE IDENTIFIED IN UKRAINE

In March 2024, WHO was notified by the genuine manufacturer that falsified versions OMNITROPE 10MG/1.5ML were identified in the unregulated supply chain (and at consumer level). The WHO GSMS database holds previous records of other falsified versions of this product.

**HOW TO DETECT**:

- The stated expiry date on the box - "11 2024" is wrong. Genuine OMNITROPE batch MT4711 expires 05/2024.
- Labelling errors of the secondary packaging.

| ***Product Name*** | **OMNITROPE 10MG/1.5ML** |
|---|---|
| *Declared active ingredient* | Somatropine |
| *Stated Manufacturer* | Sandoz GmbH |
| *Batch Number* | MT4711 |
| *Expiry Date* | Nov-24 |
| *Language on label* | Polish |
| *Available photograph* | N/A |

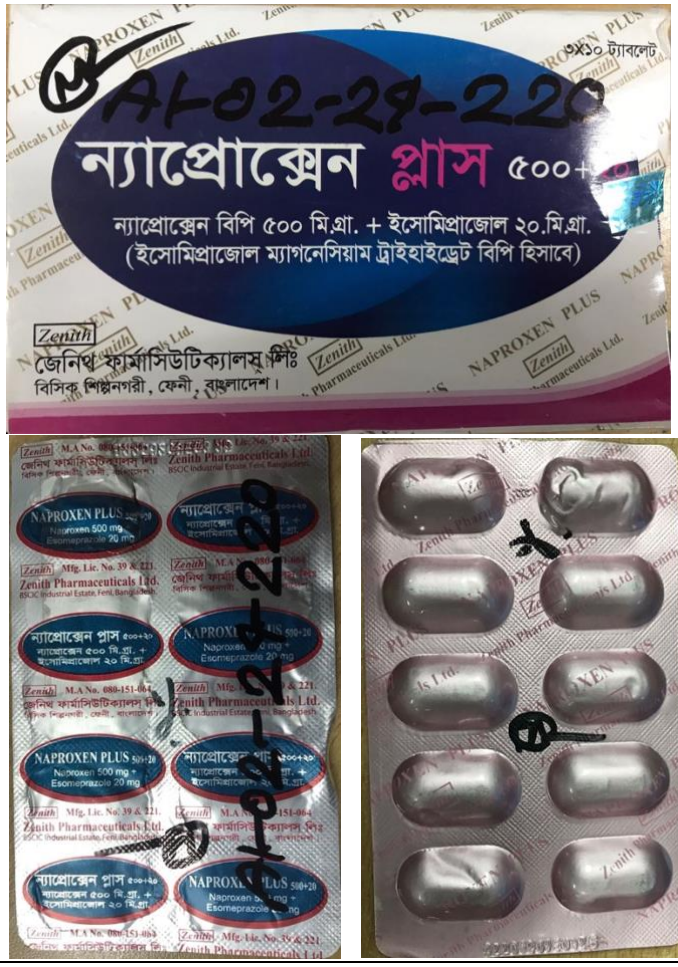
# 5 WHO South-East Asia Region

## FALSIFIED NAPROXEN IDENTIFIED IN BANGLADESH

In March 2024, WHO was notified by the national drug regulatory authority of the detection of falsified Naproxen. The product was discovered during routine market surveillance. Laboratory testing found the product contained no active pharmaceutical ingredient (API). The genuine manufacturer confirmed that the product is falsified. The product may still be available at the patient level.

**HOW TO DETECT**:

- The batch number and expiry date on the outer packaging differs from the batch number and expiry date on the blister strips.

| | | |
|---|---|---|
| ***Product Name*** | **NAPROXEN PLUS 500+20** | |
| *Declared active ingredient* | Naproxen and Esomeprazole | |
| *Stated Manufacturer* | Zenith Pharmaceuticals Ltd. Bisik Shilpanagari, Feni, Bangladesh. | |
| *Batch Number* | Outer packaging: 2023/001 | Blister strip: 2206209 |
| *Expiry Date* | Box: JAN-2025 | Blister strip: 03/25 |
| *Language on label* | Bengali, English | |
| *Available photograph* |  | |