Targeted Market Surveillance Request

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 World Health Organization (WHO) Global Surveillance and Monitoring System (GSMS) and must not be shared beyond the network. National regulatory authorities are requested to increase vigilance and conduct market surveillance for the medical products listed below.

These products have been listed because:

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

Notify WHO by emailing rapidalert@who.int if you detect any of these products or have any suspicions.

Increase vigilance when dealing with these products or when considering their procurement.

It is important to obtain photographs, samples for laboratory analysis, and information on supply and/or distribution route. Please refer to the WHO guidance document on how to take photographs of SF medical product samples and the 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 (https://sfreport.who.int/) search tool for detailed photographs of the listed products.

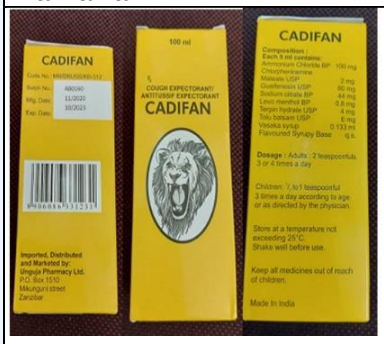
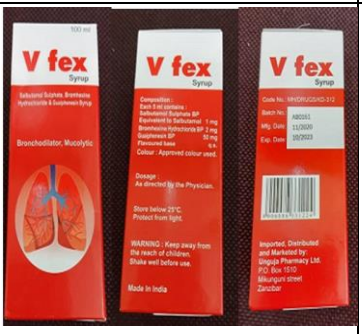
This issue references **seven products**, which at this stage, have been detected in **three regions**. Widespread vigilance is required from Member States in all WHO Regions, regardless of where the product was originally identified.

Table of contents

Falsified products identified in the WHO region of Africa

1. Falsified cough medicines identified in Tanzania.

In March 2021, WHO was notified by the Zanzibar Food, Drug and Cosmetics Agency of three falsified cough medicines in Zanzibar, United Republic of Tanzania. All three products were identified within the regulated supply chain in February 2021. The three falsified products do not carry any details of a manufacturer and their packaging deliberately / fraudulently misrepresents the products' identity and source.

Product Name	CADIFAN SYRUP	V FEX SYRUP	PHARMKOF SYRUP
Stated Manufacturer	none	none	none
Batch Number	AB0160	AB0161	AB0162
Mfg. Date	11/2020	11/2020	11/2020
Expiry Date	10/2023	10/2023	10/2023
Identified in	Tanzania	Tanzania	Tanzania
Available photos			

Falsified products identified in the WHO region of the Americas

2. Falsified VIDANZA identified in Brazil

In March 2021, WHO was notified by the Brazilian Health Regulatory Agency (ANVISA) of falsified VIDANZA (Azacitidine). The falsified product was discovered in March 2021 within the regulated supply chain. The local marketing authorization holder confirmed that products with batch number 9C169A and expiry date 02/2022 are falsified. Genuine VIDANZA (Azacitidine) batch 9C169A carried an expiry date of 02/2021.

VIDANZA is a high value chemotherapy drug used to treat a group of blood/bone marrow disorders.
While the distribution of this falsified product appears to be limited to Brazil at this stage, widespread vigilance is requested from all Member States, regardless of where the product was originally identified.

Product Name	VIDANZA
Stated Manufacturer	United Medical Ltda.
Batch Number	9C169A
Mfg. Date	03/2020
Expiry Date	02/2022
Identified in	Brazil
Available photo	

3. Falsified SOLIRIS identified in Brazil

In April 2021, WHO was notified by the Brazilian Health Regulatory Agency (ANVISA) of falsified SOLIRIS (eculizumab) in Brazil. The falsified product was identified at pharmacy level within the regulated supply chain – but had not been procured from the approved supply chain.

The genuine manufacturer has confirmed that the products are falsified. Lot 1000490 is a genuine lot number; however, the genuine expiry date is 07 2020. The cartons and labels of the falsified product instead carry a falsified expiry date of 07 2022. The genuine manufacturer also concluded that the product cartons and vial labels showed signs of physical tampering – the original expiration date appeared to have been cut out and over-labelled with the falsified expiry date.

While the distribution of this falsified product appears to be limited to Brazil at this stage, widespread vigilance is requested from all Member States, regardless of where the product was originally identified.

Product Name	SOLIRIS
Stated Manufacturer	ALEXION
Lot Number	1000490
Mfg. Date	n/a
Expiry Date	07 2022
Identified in	Brazil
Available photos	Photo not available

Falsified products identified in the WHO region of Europe

4. Falsified OXALIPLATIN SOLUTION identified in Armenia

In February 2021, WHO was notified by the German Federal Institute for Drugs and Medical Devices (BfArM) of two falsified medicines identified in Armenia – OXALIPLATIN SOLUTION AQVIDA 100 mg and OXALIPLATIN SOLUTION AQVIDA 50 mg.

Oxaliplatin is a chemotherapy medicine used to treat cancer of the bowel, stomach, pancreas and oesophagus. Both products were identified at patient level and were reported by a healthcare provider.

The manufacturer of genuine OXALIPLATIN SOLUTION AQVIDA has confirmed that batch numbers AG190302 and AF190402 were only supplied to the Georgian market. The falsified products can be clearly distinguished from genuine products as follows:

- The falsified products have German language labelling and are not serialized.
- The primary packaging of the falsified products are brown glass vials. Genuine OXALIPLATIN SOLUTION AQVIDA is presented in clear glass vials.
- The metal crimp on the falsified products is a brass colour and the flip-off vial cap is blue. Genuine OXALIPLATIN SOLUTION AQVIDA has an aluminum colour crimp and a white flip-off cap.

To date, distribution of this falsified product appears to be limited to Armenia. However, widespread vigilance is requested from all Member States, regardless of where the product was originally identified.

Product Name	OXALIPLATIN SOLUTION AQVIDA 100 mg - 5 mg/ml	OXALIPLATIN SOLUTION AQVIDA 50 mg - 5 mg/ml
Stated Manufacturer	AqVida GmbH	AqVida GmbH
Batch Number	AG190302	AF190402
Mfg. Date		
Expiry Date	03/2023	11/2023
Identified in	Armenia	Armenia
Available photo		

WHO Global Surveillance and Monitoring System
for Substandard and Falsified Medical Products

For more information, please visit the web pages of the WHO Global Surveillance and Monitoring System or Email: rapidalert@who.int