Targeted Market Surveillance list: Quarter 2–2023

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 **11 products** which, at this stage, have been detected in **all WHO regions, in 15 countries**. Widespread attention is required in all WHO Regions, regardless of where the product was originally identified.

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

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

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1 Products reported from multiple regions

1.1 FALSIFIED OZEMPIC IDENTIFIED IN CROATIA, IRAQ, NIGERIA, PAKISTAN, POLAND, AND UKRAINE

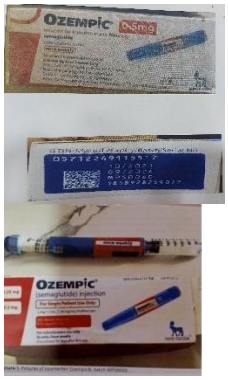
Since September 2022, WHO has been notified of multiple versions of falsified Ozempic, identified in six different countries. These products are most often available at patient level and distributed in the unregulated supply chain (mainly online).

Genuine Ozempic contains semaglutide and is indicated for the management of diabetes. It is manufactured by NovoNordisk, who have confirmed that these products are falsified because the variable data does not match genuine manufacturing records (deliberate misrepresentation of identify and source).

It is likely that there are multiple versions of falsified Ozempic in circulation. The combinations of batch number and expiry-manufacturing dates listed below are restricted to what has been reported to the GSMS to date.

HOW TO DETECT:

- Genuine Ozempic pens do not extend or increase in length when setting the dose.
- The information, such as batch number or expiry date, on the secondary packaging (box / carton) may not match the information on the primary packaging (pen).
- Genuine Ozempic pens are currently available in the following three configurations 0.25/0.5 mg; 1 mg; 2 mg.

Product Name	**Ozempic**			
Declared active ingredient	Semaglutide			
Stated Manufacturer	Novo Nordisk			
Batch Number	MP5A370	MP5B060	MP5B060	MP5D600
Expiry Date	Oct-24	09/2024	09/2024	May-25
Date of manufacture	Nov-21	10/2021	10/2021	N/A
Available photographs (check GSMS portal for larger versions)				

Please note that, separately, the WHO ISF team has issued a Threat Assessment on the risks of falsified versions of glucagon-like peptide 1 receptor agonist (GLP-1-RA) products, a class of pharmaceuticals which includes, but is not restricted to, semaglutide.

There has been an increase in reports to the GSMS of falsified versions falsified GLP-1-RA products. It is possible that falsified versions are sold and distributed through unregulated outlets, including social media platforms. There has been a recent surge in demand for, and reported shortages of, GLP-1-RA products indicated to manage diabetes type II. These products are also sought for weight loss.

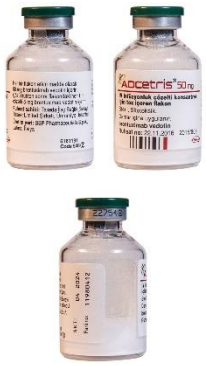
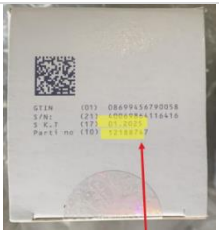
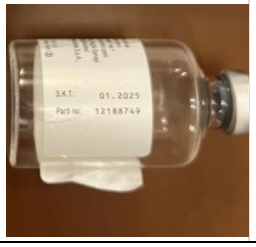
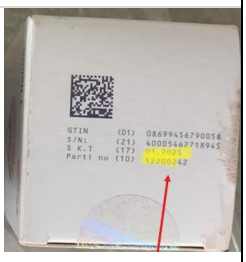
Healthcare professionals and members of the public should be reminded of the risks of procuring medical products from unauthorized sources, including online.

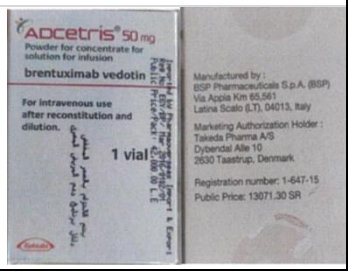
1.2 FALSIFIED ADCETRIS IDENTIFIED IN INDIA, IRAN, IRAQ, AND VIETNAM

Since February 2022, WHO has been notified of multiple versions of falsified ADCETRIS, identified in four different countries. The same batch numbers have been recorded multiple times as part of different incidents in different countries. These products are most often available at patient level and distributed in the unregulated supply chain (mainly online). The products have been identified in both regulated and illicit supply chain, sometimes at patient level.

HOW TO DETECT:

- There are at least 8 different batch numbers of falsified versions in circulation (for the purpose of readability, the following table is divided into two).

Product Name	**Adcetris**			
Declared active ingredient	Brentuximab vedotin			
Stated Manufacturer	TAKEDA			
Batch Number	11980412	12188747	12188749	12200242
Expiry Date	04 2024	01/2025	01/2025	01/2025
Date of manufacture	N/A	N/A	01/2022	N/A
Available photograph (check GSMS portal for larger versions)			 	

Product Name	**Adcetris**			
Declared active ingredient	Brentuximab vedotin			
Stated Manufacturer	TAKEDA			
Batch Number	12202389	12203322	12310404	512053
Expiry Date	01/2025	01/2025	09.2025	November 2024
Date of manufacture	N/A	N/A	N/A	N/A
Available photograph (check GSMS portal for larger versions)				

2 WHO region of Africa

2.1 CONTAMINATED NATURCOLD SYRUP IDENTIFIED IN CAMEROON

In July 2023, WHO obtained confirmation through lab analysis, that NATURCOLD syrup contained unacceptably high amounts of Diethylene glycol. The product has been detected in Cameroon, but may have been supplied through informal markets to other countries in the region.

HOW TO DETECT:

Product Name	**NATURCOLD SYRUP**
Declared active ingredient	Paracetamol; phenylephrine hydrochloride; chlorpheniramine maleate
Stated Manufacturer	FRAKEN
Batch Number	E22053
Expiry Date	Feb-25
Available photographs (check GSMS portal for larger versions)	

3 WHO region of the Americas

3.1 FALSIFIED FORXIGA IDENTIFIED IN MEXICO

In June 2023, the WHO was notified of two different versions of falsified Forxiga identified in Mexico. These products were available at patient level.

Genuine Forxiga contains Dapagliflozin and is indicated for the management of diabetes. It is manufactured by AstraZeneca, who have confirmed to WHO that these products are falsified because the variable data does not match genuine manufacturing records (deliberate misrepresentation of identify and source).

The WHO GSMS holds previous similar records of the same product, notified in 2021 and 2020, identified in the WHO Americas and Western Pacific regions.

HOW TO DETECT:

- The batch number is genuine, but expiry date has been altered from the genuine version (Apr-20).

Product Name	**Forxiga**
Declared active ingredient	Dapagliflozin
Stated Manufacturer	AstraZeneca
Batch Number	KK0036
Expiry Date	Nov-24 and Nov25
Available photograph	N/A

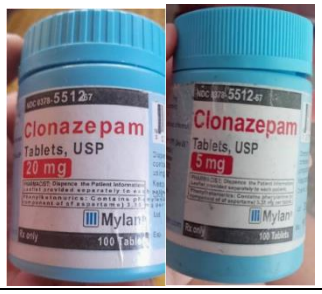
3.2 FALSIFIED CLONAZEPAM IDENTIFIED IN CUBA

In June 2023, the WHO was notified of different versions of falsified Clonazepam identified in Cuba. These products were available at patient level and have been associated with adverse reactions.

There are several different falsified versions which display either Mylan or Boeringher Ingelheim as the stated manufacturer. These products are classified as falsified on the basis that there is a deliberate misrepresentation of identify and source.

HOW TO DETECT:

- The falsified products present in plastic bottles with screw-caps. Each container / bottle holds 100 tablets.
- The color of the plastic bottle may either be blue or white
- *Note that there are several different versions that have been reported but details on variable data will be updated in the GSMS portal at a later stage*

Product Name	**Clonazepam**	
Declared active ingredient	Clonazepam	
Stated Manufacturer	Mylan Pharmaceuticals Inc.	Boeringher Ingelheim
Batch Number	Details will be updated in the GSMS portal later	
Expiry Date		
Available photograph (check GSMS portal for larger versions)		

4 WHO region of the Eastern Mediterranean

4.1 FALSIFIED GLIVEC IN EGYPT

In June 2023, the WHO was notified of two different falsified versions of Glivec . Both versions have the same batch number and the same falsified expiry date but display different manufacturing dates. The stated manufacturer has confirmed that the products are falsified

HOW TO DETECT:

Product Name	**Glivec 400mg Film Coated Tablets**
Declared active ingredient	Imatinib mesylate
Stated Manufacturer	Novartis
Batch Number	MF8865
Expiry Date	2/2024
Manufacturing date	2/2021 or 03 2022
Available photographs (check GSMS portal for larger versions)	

5 WHO region of Europe

5.1 SUBSTANDARD HAEMOCOMPLETTAN IDENTIFIED IN CZECHIA

In June 2023, the WHO was notified of 13 different batches of Haemocomplettan that were substandard. The products were discovered to have microbial contamination on 31 May 2023 by manufacturer and MAH, CSL Behring (Germany). The products are being recalled from wholesalers, hospitals and pharmacies. No adverse event has been reported.

HOW TO DETECT:

Product name	Declared active ingredient	Stated Manufacturer	Batch Number	Expiry Date	Manufacturing date
Haemocomplettan P	fibrinogenum humanum	CSL Behring GmbH, Marburg	P100543177	28.Feb.2027	07.Feb.2023
			P100522588	31.Oct.2026	13.Dec.2022
			P100529771	31.Oct.2026	10.Jan.2023
			P100533667	31.Oct.2026	17.Jan.2023
			P100541035	31.Oct.2026	17.Jan.2023
			P100541039	31.Oct.2026	24.Jan.2023
			P100507729	30.Sep.2026	15.Nov.2024
			P100513554	30.Sep.2026	15.Nov.2022
			P100542545	31.Jan.2027	15.Nov.2022
			P100518143	30.Sep.2026	23.Nov.2022
			P100519749	30.Sep.2026	05.Dec.2022
			P100507717	30.Oct.2026	15.Nov.2023
			P100544787	28.Feb.2027	15.Nov.2022

6 WHO region of the Western Pacific

6.1 FALSIFIED RABIES VACCINES IDENTIFIED IN THE PHILIPPINES

In March 2023, the WHO was notified of three different falsified rabies vaccines identified in the Philippines. These products were distributed in dispensing outlets in the regulated supply chain. The Philippines FDA has confirmed these products are falsified.

HOW TO DETECT:

Product Name	Stated manufacturer	Batch Number	Expiry Date	Available photograph
EQUIRAB	Bharat Serums & Vaccines Limited	A06822010	45381	
		A02721016	45230	
		A02721012	45107	
		A02721009	44985	
Speeda Purified Rabies Vaccine (Vero Cell)	Liaoning Cheng Da Biotechnology Co., Ltd.	202106207AY	06/01/2024	
		28210309-1	Not reported	
Vaxirab N (Purified Chick Embryo Cell Culture Rabies Vaccine)	Cadila Healthcare Limited, Sovereign Pharma Pvt. Ltd (diluent)	RV00020	JAN.24	
		AMU1010	Oct.2024	