World Health Organization

December 2023

Targeted Market Surveillance list: Quarter 3–2023

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 .

Widespread attention is required in all WHO Regions, regardless of where the product referenced in this document was originally identified. It is important to detect and remove these products from circulation to prevent potential harm to patients.

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

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

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1 Corrigendum of TMS Q2-2023: falsified rabies vaccines in the Philippines

In the previous issue of the Targeted Market Surveillance list (Quarter 2 of 2023), there was a typographical error in the table with the details of the falsified Equirab vaccine identified in the Philippines. Please see below corrected table :

Product Name	Stated manufacturer	Batch Number	Expiry Date	Available photograph
EQUIRAB	Bharat Serums & Vaccines Limited	A06822010	03/24	
		A02721016	10/23	
		A02721012	06/23	
		A02721009	02/23	
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	

2 Products reported from multiple regions

2.1 LIQUID MEDICINES CONTAMINATED WITH DYETHYLENE GLYCOL

Since September 2022, WHO has received multiple reports worldwide of liquid medicines contaminated with ethylene glycol and diethylene glycol. These contaminants are toxic chemical substances used as antifreeze agents and industrial solvents that can be fatal even if consumed in small amounts with the potential to cause serious illness or deaths. Please refer to the full list of WHO global medical product alerts for further information.

Since June 2023, WHO has recorded the following additional contaminated liquid medicines.

Product Name	Stated manufacturer	Batch Number(s)	Identified in
Cold Out syrup	Fourrts (India) Laboratories PVT. LTD	SF001A02 ; SF001A01 ; SF001A03 ; SF001A04 ; SF001A05 ; SF001A06	Iraq
Sylpro Plus Syrup	Norris Medicines Limited	33002	India
Trimax Expectorant	Norris Medicines Limited	23009	India

2.2 FALSIFIED COVID19 VACCINES IN THE WHO REGIONS OF AFRICA AND EASTERN MEDITERRANEAN

In June 2023, WHO received information suggesting that falsified COVID-19 vaccines might be circulating in the WHO Eastern Mediterranean Region and the WHO African Region. The stated manufacturer has confirmed that the products displayed in the photographs do not correspond to their genuine manufacturing records. At this stage, there is no evidence of recent physical circulation of the products displayed in the photographs. Heightened vigilance is therefore requested from all.

Available photographs display two different COVID-19 products (see below table). *NOTE that the reliability of the photographic evidence is still being established.* However increased vigilance and reporting to WHO if similar products are detect ed are requested.

HOW TO DETECT:

Product Name	**Covid-19**	**CoronaVac**
Declared active ingredient	Ad26.CoV2-S recombinant IM injection	Inaktive SARS CoV2
Stated Manufacturer	Vaccine Janssen	Not visible from photograph
Batch Number	ACB0233 *but unclear to which vial version this corresponds to*	
Expiry Date	08-2023 *but unclear to which vial version this corresponds to*	
Available photograph		

2.3 FALSIFIED DEFITELIO IDENTIFIED IN INDIA AND TÜRKIYE

In September 2023, WHO published global medical product alert n°7/2023 which concerns a falsified batch of DEFITELIO (defibrotide sodium). This falsified product has been detected in India (April 2023) and Türkiye (July 2023) and was supplied outside of regulated and authorized channels.

HOW TO DETECT:

- Genuine DEFITELIO with Lot 20G20A was packaged in German/Austrian packaging.
- The falsified products instead are in UK/Ireland packaging.
- The stated expiry date is falsified and does not comply with the registered shelf life.
- The stated serial number is not associated with batch 20G20A.
- DEFITELIO does not have marketing authorization in India and Türkiye.

Product Name	**DEFITELIO 80 mg/mL concentrate for solution for infusion**
Declared active ingredient	defibrotide
Stated Manufacturer	Gentium Srl
Batch Number	20G20A
Expiry Date	08/2024
Available photograph	 *Photos of product detected in Türkiye*

Note that WHO has previously issued Alerts for falsified DEFITELIO detected in other countries and regions. Please refer to Medical Product Alert N°5/2020, and Medical Product Alert N°3/2023.

2.4 SUBSTANDARD SABRIL PRODUCTS IDENTIFIED IN BRAZIL, GERMANY, THAILAND, AND THE UK

In July 2023, the WHO was notified by regulatory focal points of substandard versions of Sabril, a medication used to treat epilepsy. Forty-five different combinations of variable data (batch number and expiry and manufacturing dates), in tablet and powder forms, are reported to be contaminated with the impurity tiapride. The product was distributed in a regulated supply chain and the level of distribution, business level or consumer level, varies between countries.

The products are a part of a global recall of 45 batch numbers issued by the manufacturer, across four regions (European Region, Eastern Mediterranean Region, Western Pacific Region, and Region of Americas). For the complete list, please see Annex 1 (available in English).

2.5 OTHER

WHO continues to receive notifications of falsified Ozempic worldwide. Please refer to the previous target market surveillance list issued for Quarter 2 of 2023. Please continue to share or forward reports to the WHO Global Surveillance and Monitoring System (GSMS).

3 WHO African Region

3.1 SUBSTANDARD TAMEDOL PARACETAMOL IN KENYA

In September 2023, WHO was notified through media monitoring that several batches of TAMEDOL Paracetamol Oral Solution, including batch number BPL066A, had been recalled. Laboratory analysis indicates that the product fails to comply with specifications on description.

Note : At this stage, there is no information suggesting DEG/EG contamination.

HOW TO DETECT:

Product Name	**TAMEDOL Paracetamol Oral Solution**
Declared active ingredient	Paracetamol
Stated Manufacturer	BIOPHARMA LIMITED, Kenya
Batch Number	BPL066A
Expiry Date	05/2026
Available photograph	*N/A*

4 WHO Region of the Americas

4.1 FALSIFIED ADREN IDENTIFIED IN BRAZIL

In August 2023, WHO was notified by regulatory focal points of falsified Adren identified in Brazil. The product was discovered in the regulated supply chain at consumer level. Visual analysis by the manufacturer concluded the product was falsified.

HOW TO DETECT:

- The batch number is genuine, but expiry date has been altered from the genuine version (12/2022).
- The label of the falsified unit is different from the company's labelling standard

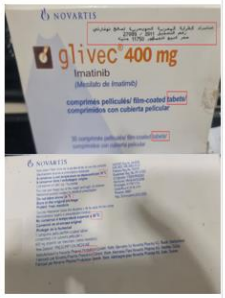
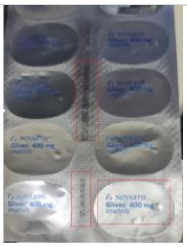
Product Name	**Adren**
Declared active ingredient	Dapagliflozin
Stated Manufacturer	AstraZeneca
Batch Number	D-038/21
Expiry Date	12/2023
Available photograph	N/A

5 WHO Eastern Mediterranean Region

5.1 FALSIFIED GLIVEC IN EGYPT

In June 2023, the WHO was notified by industry sources of two different falsified versions of Glivec. The product was discovered in the regulated supply chain at consumer level. 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

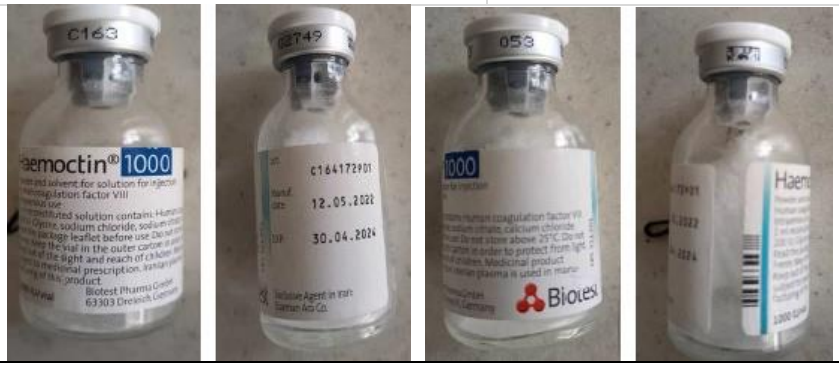
HOW TO DETECT:

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)	  

5.2 FALSIFIED HAEMOCTIN IN IRAN

In August 2023, WHO was notified by regulatory focal points of two different falsified versions of Haemoctin. Both versions have different batch numbers. The product was discovered in an unregulated supply chain at the consumer level. The packaging features that state the batch numbers given on the label of the vial do not match the batch number on the crimp cap. The stated manufacturer has confirmed that the products are falsified.

HOW TO DETECT:

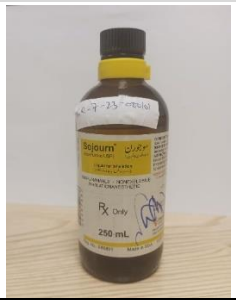
Product Name	**Haemoctin 1000**	
Declared active ingredient	Human coagulation factor VIII	
Stated Manufacturer	Biotest	
Batch Number	C164172P01	C163053P07
Expiry Date	30.04.2024	N/A
Manufacturing date	12.05.2022	N/A
Available photographs (check GSMS portal for larger versions)		

5.3 FALSIFIED SOJOURN LIQUID FOR INHALATION IN PAKISTAN

In July 2023, WHO received information from regulatory focal points of two falsified versions of Sojourn Liquid for Inhalation. The product was discovered in the regulated supply chain at consumer level. Visual and laboratory analysis concluded the product was falsified with chloroform detected in the product.

HOW TO DETECT:

- No hyphen between NONFLAMMABLE and NONEXPLOSIVE is observed in the given sample. The spelling for NONEXPLOSIVE is wrongly written as "NONEXPLOSVE" without "I".
- Font size of information for composition, dosage, administration and instruction is larger compared to the genuine product.
- Manufactured by Allied Distributors, instead of Marketed by Allied Distributors.
- Colour of "Piramal is Black in logo".
- The gap between MRP and yellow panel is less.
- The price is written in bold letters.
- P is written instead of R in "MRP Ps. 17032.35".
- Font colour is black dark shaded (instead of light shaded like the genuine product) for Lot No, Mfg Date and Exp Date.
- The bottom of glass bottle is written "PG" & "5".

Product Name	**Sojourn Liquid for Inhalation**	
Declared active ingredient	Sevoflurane	
Stated Manufacturer	Allied Distributors	
Batch Number	S0502C11	S0512C14
Expiry Date	March 2027	
Manufacturing date	March 2022	
Available photographs (check GSMS portal for larger versions)	 	

6 WHO European Region

6.1 FALSIFIED AVASTIN IDENTIFIED IN UKRAINE AND UZBEKISTAN

In July 2023, WHO was notified from industry sources that falsified Avastin, batch number H0223B08, was detected in Uzbekistan. Some adverse events were associated to an off-label use of the product. Good procurement practice was not followed for the importation. The stated manufacturer confirmed that the product is falsified on the basis of photographic evidence.

HOW TO DETECT:

Product Name	AVASTIN 100mg
Declared active ingredient	Bevacizumab
Stated Manufacturer	Roche
Batch Number	H0223B08
Expiry Date	01/2024
Available photographs	*N/A*

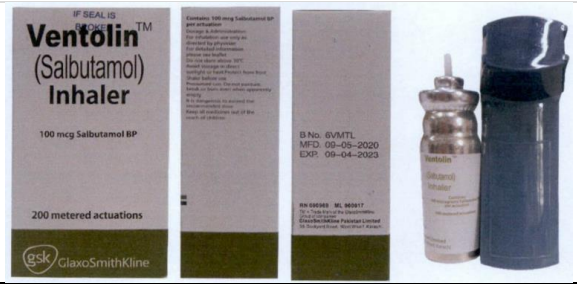
7 WHO Western Pacific Region

7.1 FALSIFIED VENTOLIN IN THE PHILIPPINES

In May 2023, WHO was notified by regulatory focal points of a falsified Ventolin Inhaler. The product was discovered in the regulated supply chain at consumer level. The stated manufacturer has confirmed that the product was falsified

HOW TO DETECT:
The symbol, watermark element of logo and structure are not comparable with the standard features of the registered product.

- The falsified products are presented in a box with white and green colour, with GSK logo written on the lowermost part of the box.
- The falsified product`s description of “200 metered actuation” is in the lower part of the box.
- The inhaler tube was coloured in a darker shade of grey.

Product Name	**Ventolin (Salbutamol) Inhaler**
Declared active ingredient	Salbutamol
Stated Manufacturer	GlaxoSmithKline
Batch Number	6VMTL
Expiry Date	09-04-2023
Manufacturing date	09-05-2020
Available photographs (check GSMS portal for larger versions)	

8 WHO South-East Asia Region

8.1 FALSIFIED SOLIRIS IN INDIA

In July 2023, WHO was notified by regulatory focal points of falsified Soliris sold in India. The product was discovered in an unregulated supply chain at the consumer level. Visual analysis by the manufacturer concluded the product was falsified. The WHO GSMS holds previous similar record of the same product identified in India.

HOW TO DETECT:
- There is no hologram, 2D barcode, GTIN and serial number in the cardboard box.
- The cardboard material number on the cardboard box is incorrect.
- The vial label contains a typographical error and has a faded appearance

Product Name	**SOLIRIS 300 mg / 30 mL**
Declared active ingredient	Eculizumab
Stated Manufacturer	ALEXION
Batch Number	1002160
Expiry Date	31.05.2024
Manufacturing date	08.12.2021

8.2 FALSIFIED IMMUNOGLOBULIN IN SRI LANKA

In October 2023, WHO was notified by the national regulatory authority that three different batches of Human Normal Immunoglobulin for Intravenous Administration I.P 5g (5g in 100ml (5%) vial) were associated to adverse reactions in patients. The stated manufacturer, LIVEALTH BIO PHARMACEUTICALS PVT LTD, confirmed that the reported product does not match their manufacturing records. There is no market authorization for this specific product in Sri Lanka.

HOW TO DETECT:

Product Name	Human Normal Immunoglobulin for Intravenous Administration I.P 5g (5g in 100ml (5%) vial)
Declared active ingredient	Human Normal Immunoglobulin
Stated Manufacturer	Livealth Bio Pharmaceuticals Pvt Ltd, Int Company
Batch Number	A732230401 ; A732230402 ; A732230403

8.3 SUBSTANDARD BUPIVACAINE IN SRI LANKA

In June 2023, WHO was notified by the national regulatory authority that two versions of substandard Bupivacaine were available at patient level in the regulated supply chain. Laboratory analysis showed the sample does not conform with specification.

HOW TO DETECT:

Product Name	**Bupivacaine Hydrochloride in Dextrose Injection USP 4 ml**	
Declared active ingredient	Bupivacaine	
Stated Manufacturer	DIVINE LABORATORIES PRIVATE LIMITED (India)	
Batch Number	DP2202	DP2203
Expiry Date	11-2025	
Manufacturing date	12-2022	

8.4 SUBSTANDARD PROPOFOL IN SRI LANKA

In June 2023, the WHO was notified by the NMRA of Sri Lanka of three versions of substandard Propofol sold in Sri Lanka. The product was discovered in the regulated supply chain at consumer level. The product was analysed and it was determined that it does not comply with the requirements for sterility and bacterial endotoxin test.

HOW TO DETECT:

Product Name	**PROPO SPAL 500**		
Declared active ingredient	Propofol Injection Emulsion USP 500 mg/50 ml		
Stated Manufacturer	SP Accure Labs Pvt. Ltd, India		
Batch Number	23CPF01	23CPF02	23CPF03
Expiry Date	N/A	N/A	02/2025
Manufacturing date	N/A	N/A	03/2023
Available photographs (check GSMS portal for larger versions)