LET_LSE_PMS_0001/09/23

All correspondence should be addressed to the Director General

In reply, please quote .....

ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 5th September, 2023

To: Distributors, Wholesalers, Retailers, Healthcare Professionals, General Public

MEDICAL PRODUCT ALERT:

FALSIFIED DEFITELIO (DEFIBROTIDE) IDENTIFIED IN THE WHO REGIONS OF EUROPE AND SOUTH-EAST ASIA

FOR IMMEDIATE RELEASE – The World Health Organisation (WHO) through the Global Surveillance and Monitoring System for Substandard and Falsified Medical Products has alerted Zambia Medicines Regulatory Authority (ZAMRA) of the circulation of one (1) batch of falsified **DEFITELIO (defibrotide sodium)** for Injection 80mg/ml. This falsified product has been detected in India (April 2023) and Turkey (July 2023) and was supplied outside of regulated and authorized channels.

DEFITELIO (defibrotide) is used in the treatment of severe hepatic veno-occlusive disease (VOD) also known as sinusoidal obstructive syndrome (SOS), a condition in which the veins in the liver become blocked and stop the liver working correctly. It is used in adults, adolescents, children and infants over 1 month of age.

The genuine manufacturer of DEFITELIO has confirmed that the product referenced in this Alert is falsified (see product details below). The genuine manufacturer has advised that:

- 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 Turkey

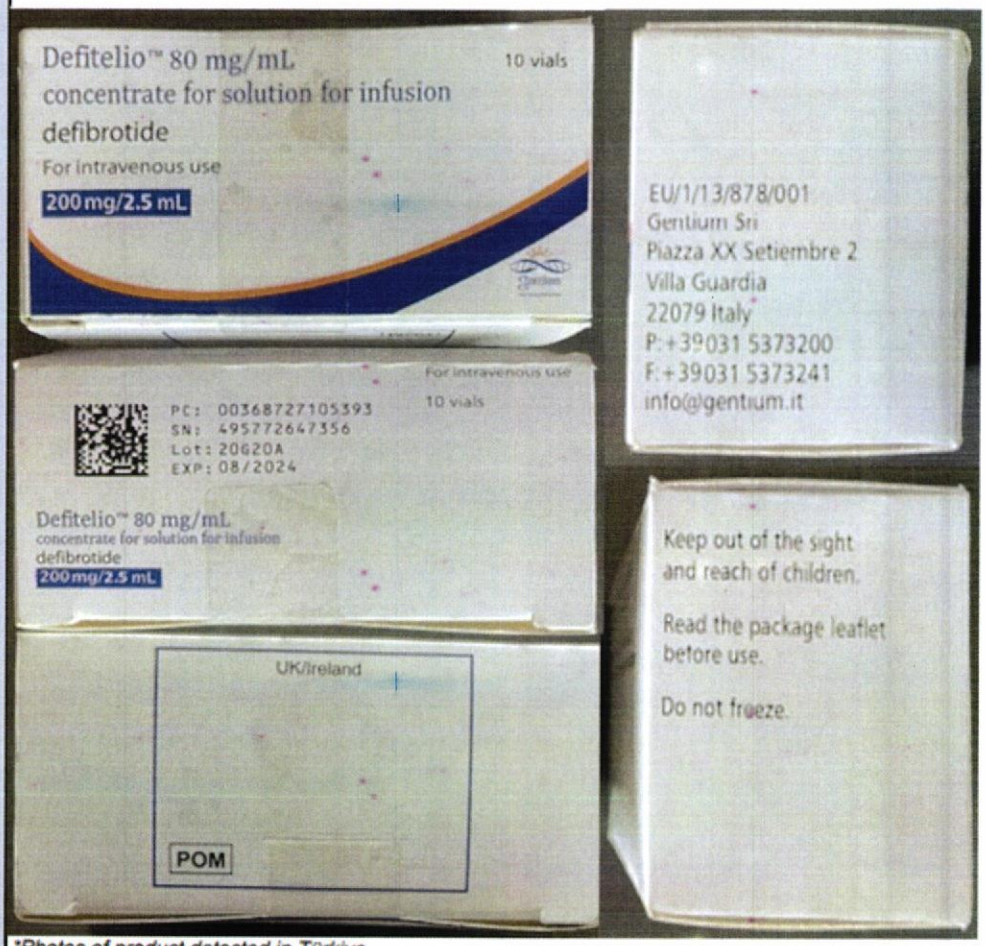
Falsified products pose a risk to global public health and hamper efforts to patients to receive safe and effective treatment they deserve.

Considering the possibility that this product could have been distributed through informal (illegal) markets, the Authority has intensified countrywide vigilance for this product through public notification and inspection of pharmaceutical outlets. Further, the Authority wishes to caution members of the public to also be vigilant and only buy medicines from authorised entities.

Head Office
Plot No: 2350/M
Off Kenneth Kaunda International Airport Road
P.O. Box 31890, Lusaka, ZAMBIA
Tel: +260 211 432 350 /432 351
E-mail: pharmacy@zamra.co.zm

Report Adverse Reactions to:
Pharmacovigilance Unit, Lusaka
Tel: +260 211 432 356
E-mail:npvu@zamra.co.zm
Website: www.zamra.co.zm

Annex: Products subject of WHO Medical Product Alert No. 7/2023

Product Name	DEFITELIO 80 mg/mL concentrate for solution for infusion
Stated manufacturer	Gentium Srl
Packaging	UK/ Ireland packaging
Lot	20G20A
Expiry date	08 / 2024
Identified in	India and Türkiye
Available photos*	 *Photos of product detected in Türkiye*

If you are in possession of the above-mentioned products, please return them to your healthcare provider who should in turn notify ZAMRA.

If you suffer any adverse drug reaction/event having used this product, you are advised to seek immediate medical advice and report the incident to the National Pharmacovigilance Unit at Zambia Medicines Regulatory Authority by phone: +260 211

432 356/+260 //956 521 094 or email address at: npvu@zamra.co.zm or pharmacy@zamra.co.zm.

Should you need further clarification, please do not hesitate to contact our Secretariat.

Makomani Siyanga (Mr.)
ACTING DIRECTOR-GENERAL