Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Enforcement Division)

Dated: - 06 SEP 2023

Subject: - WHO Alert on falsified DEFITELIO (DEFIBROTIDE) 80 mg/ml concentrate for solution for infusion, B. No. 20G20A, Exp date 08/2024 mfg by: Gentium Srl and identified in India-reg.

The World Health Organization (WHO) has issued Medical Product Alert No. 7/2023 dated 04.09.2023 for falsified product DEFITELIO (DEFIBROTIDE) 80 mg/ml concentrate for solution for infusion, B. No. 20G20A Exp date 08/2024, Manufactured by M/s Gentium Srl . This falsified product has been detected in India (April 2023) and Türkiye (July 2023) and was supplied outside of regulated and authorized channels. Because of the significant threat to public health posed by these falsified products, and the risk posed to more than one Country and Region – the WHO GSMS has issued a Medical Product Alert to highlight the detection of this product in the WHO Regions of Europe and South East Asia.

The genuine manufacturer of DEFITELIO has confirmed that the product referenced in this Alert is falsified. 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 Türkiye.

Risks:

The use of falsified DEFITELIO will result in the ineffective treatment of patients and may pose other serious risks to health because of its intravenous administration and could be life-threatening in some circumstances. Based on the above, the following advisory is provided:

a. **To Doctors and Healthcare Professionals**: The doctors and healthcare professionals should carefully prescribe and educate their patients for reporting of any ADRs.
b. **To consumers and patients:** To be careful and only procure the medical products from authorized sources with proper purchase Invoice.
c. **To Regulatory Authorities (All States/UTs Drugs Controllers and all Zonal and Sub-Zonal Offices of CDSCO, all Port Offices of CDSCO):** Instruct your officers to keep strict vigil on the movement, sale, distribution, stock of the said drug products in the market, draw samples if said product lying in market and initiate necessary action as per the provisions of the Drugs and Cosmetics Act and Rules made thereunder.

Encl. Copy of WHO Medical Product Alert No. 7/2023.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (I)

Copy for information and necessary action:

- All Zonal/Sub-zonal offices/Port offices of CDSCO.
- All State/UTs Drugs Controllers.
- All India Organization of Chemists and Druggists (AIOCD), 201, Safalya Building, Opp Jaigopal Industrial Estate, Dadar (W), Maharashtra 400028 (aiocd@aiocd.com)
- JS (R), Drugs Regulation Section, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
- CDSCO-IT Cell for publication on website.

World Health Organization

4 September 2023

Medical Product Alert No. 7/2023

Falsified DEFITELIO (defibrotide) identified in the WHO Regions of Europe and South-East Asia

Alert Summary

This WHO Medical Product Alert refers to one 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.

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

The genuine manufacturer of DEFITELIO has confirmed that the product referenced in this Alert is falsified. 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 Türkiye.

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.

Please refer to the Annex of this Alert for full details of the affected products.

Risks

The use of falsified DEFITELIO will result in the ineffective treatment of patients and may pose other serious risks to health because of its intravenous administration and could be life-threatening in some circumstances.

WHO is not currently aware of any reports of adverse events following the use of this reported falsified DEFITELIO, however, the safety, sterility, and quality of the falsified products referenced in this alert are unknown.

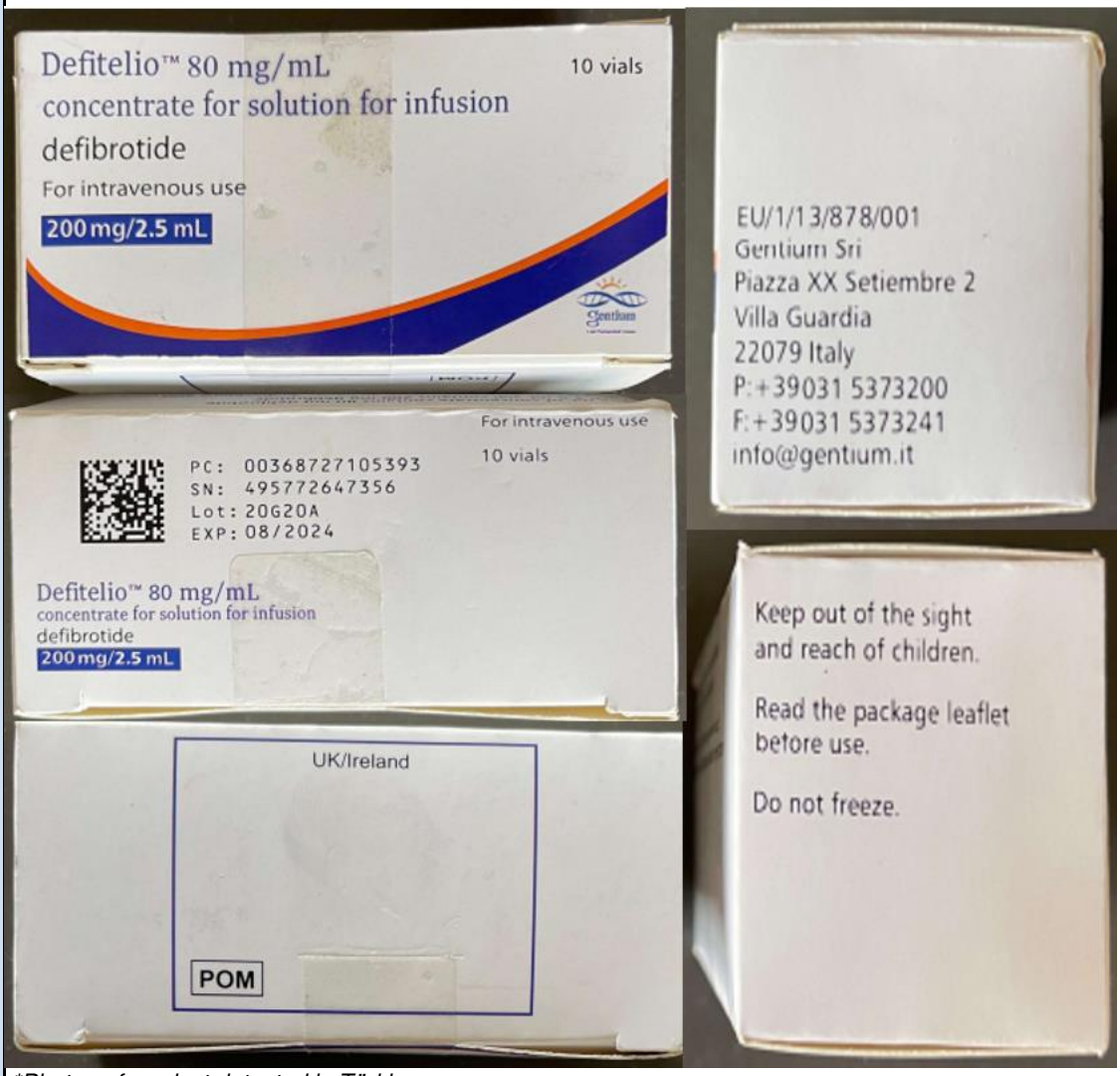
Advice to regulatory authorities and the public

If you have any of the affected products, WHO recommends that you do not use them. If you, or someone you know, has or may have used the affected product, or suffered an adverse reaction or unexpected side-effect after use, you are advised to seek immediate medical advice from a healthcare professional.

Healthcare professionals should report the incident to the National Regulatory Authorities/National Pharmacovigilance Centre. National regulatory/health authorities are advised to immediately notify WHO if they identify these falsified products.

All medical products must be obtained from authorized/licensed suppliers. If you have any information about the manufacture or supply of these products, please contact WHO via rapidalert@who.int.

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*