

File No. Enforc-11013(11)/10/2026-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi-110002
(Enforcement & Intelligence Cell)

Dated: 23.10.2026

PUBLIC ALERT

Subject: - WHO Alert on falsified DEFITELIO (Defibrotide) 80 mg/ml concentrate for solution for infusion, B. No. 24GC01A, Exp date 04/2027, Mfg by: Patheon, Il Trav. sx Via Morolense, 5, 03013 Ferentino (FR) Italy and Marketing authorisation holder: Gentium S.r.l, Piazza XX Settembre, 2, 22079 Villa Guardia (Como) Italy and identified in India-reg.

The World Health Organization (WHO), through its Market Surveillance and Control Regulation and Safety Department, has informed that a suspected falsified medicinal product bearing the following particulars may be available for sale and purchase in India:

- **Product Name:** DEFITELIO (Defibrotide) 80 mg/mL Concentrate for Solution for Infusion.
- **Batch Number & Expiry Date:** 24GC01A, 04/2027
- **Manufacturer:** Patheon, Il Trav. sx Via Morolense, 5, 03013 Ferentino (FR), Italy
- **Marketing Authorisation Holder:** Gentium S.r.l., Piazza XX Settembre, 2, 22079 Villa Guardia (Como), Italy

However, the manufacturer or its authorised agent has confirmed that the above-mentioned product batch was never supplied to India. Accordingly, any product bearing the aforementioned particulars that is found to be offered for sale or distribution in India shall be reported immediately to the concerned State/District Drugs Control Authority and this office through email at dci@nic.in for necessary action and the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder.

Risks associated:

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, 1940 and Rules made thereunder.

Encl. Copy of Rapid Alert Notification received from WHO.


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

Copy for information and necessary action:

- All State/UTs Drugs Controllers.
- Heads of Zonal/Sub-Zonal/Port offices of CDSCO.
- All India Organization of Chemists and Druggists (AIOCD), through email (aiocd@aiocd.com)- with a request to circulate the alert to all States/UTs Chemists and Druggists associations.
- Joint Secretary, Drugs Regulation Section, Ministry of Health and Family Welfare, Kartavya Bhawan-I, New Delhi- for information.
- CDSCO-IT Cell for publication on CDSCO website.



DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY!

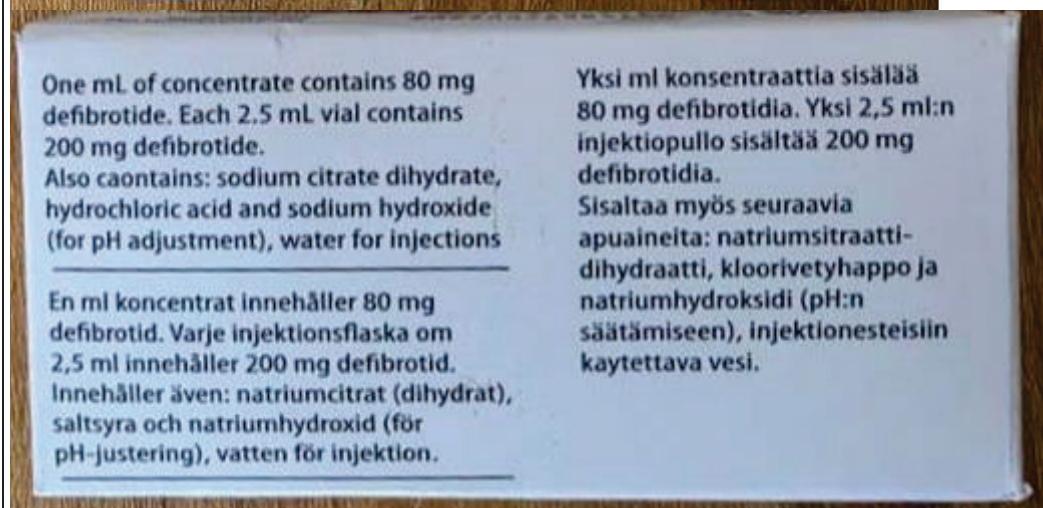
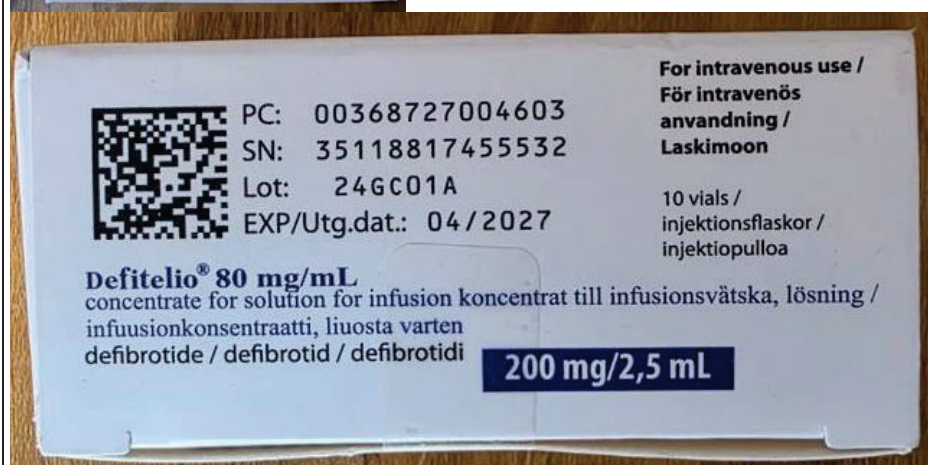
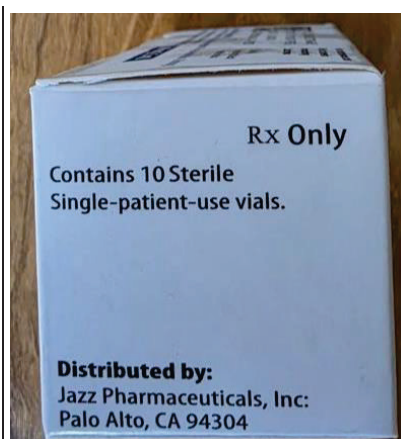
Rapid Alert Notification of a Medicinal Product Falsification

☐ **ASSUMED**

☐ **REASONABLY SUSPECTED**

☒ **VERIFIED**

Sender: Regierung von Oberbayern Maximilianstraße 39 80538 München				1. Reference no.: DE_BY_04/verified falsification/2026/963/1 2. Recall no. assigned: (if available)	
3. To: ☒ BfArM ☐ BVL ☐ PEI ☐ OLGB ☐ OLVB ☐ OLVB					
4. Files attached? no					
5. For use in human		6a. Class of defect <please choose> 6b. Product recall? <please choose>		7. Reason <please choose>	
I.	8. Product Defitelio 80 mg/mL concentrate for solution for infusion	9. Strength 80mg/mL	10. INN or Generic name Defibrotide		11. Pack size and presentation 1 carton with 10 vials
	12. Brand/Trade name Defitelio 80 mg/mL concentrate for solution for infusion		13. Dosage form Powder for concentrate and solution for solution for infusion		14. Marketing authorisation number EU/1/13/878/001
	15. Batch number(s) and bulk (if different) 24GC01A (of the counterfeit product)		16. Date(s) manufactured N/A		17. Expiry date(s) 04/2027 (of the counterfeit product)
18. Marketing authorisation holder Name Gentium S.r.l. Address Piazza XX Settembre, 2 22079 Villa Guardia (Como) Italy E-mail manuela.camisa@jazzpharma.com Phone +390315373418			19. Manufacturer Name Patheon Address Il Trav. sx Via Morolense, 5 03013 Ferentino (FR) Italy E-mail Not applicable Phone Not applicable		
20. Recalling firm (if different) Name <text> Address <text> E-mail <text> Phone <text>			21. Site where the defect occurred (where the defect is attributed to a manufacturing site and if different from 19) Name Not applicable Address Not applicable E-mail Not applicable Phone Not applicable		
22. Details On September 21, 2026, Gentium S.r.l., the Marketing Authorisation Holder (MAH), received an authenticity inquiry from India concerning a product purported to be Defitelio® (defibrotide) 80 mg/mL with Batch Number 24GC01A, Serial Number 35118817455532, and an Expiry Date of April 2027. It should be noted that Defitelio does not have marketing authorisation in India. A comparative assessment of photographic images of the carton against an authentic retention sample revealed multiple discrepancies in text layout, font, artwork, and overall presentation. While the batch and serial numbers correspond to a genuine, legitimate batch of Defitelio, the packaging is clearly fraudulent.					



The MAH has therefore concluded this is an attempt at falsifying the product.

The authentic batch 24GC01A was distributed to the United Arab Emirates, Cyprus, Spain, Finland, Israel, Portugal, Sweden, Slovenia, Turkey, and Uruguay.

Currently, this is a single reported incident. The MAH has not received a physical sample for laboratory testing and is still working to obtain the product and confirm details about its source and disposition. A search of the Jazz Global Safety Database found no other reports associated with this batch number. Based on the currently available information, there is no evidence that other units are affected, and thus no product recall is being initiated at this time. The investigation by MAH is ongoing.

23. Information on distribution including exports (type of customer, including parallel distribution/importation)

The genuine batch 24GC01A (expiry date 04/2027) was packaged for the European market (FI/SE/IR); however, the product complaint originated from India.

The original 14 digit Serial Number (SN) displayed on the falsification was decommissioned in Movianto Netherlands on February 26th, 2025 and shipped to Gen Ilac in Turkey on February 28th, 2025.



24. Action taken by the issuing authority		25. Proposed action	
Referral of the information to the BfArM		Forwarding of the information to the authority in Italy by the BfArM	
26. Issuing authority			
From (issuing authority)	Government of Upper Bavaria	Phone	Philipp.Altnoeder@reg-ob.bayern.de
Contact person	Philipp Altnoeder	E-mail	+49 (89) 2176-3730
Signature	sign. Xenia Dimont o.b.o. Philipp Altnoeder		
27. Date/Time	12.10.2026/ 16:15		

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