Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2023-1933

14 SEP 2023

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning on Falsified Drug Product "Defitelio" Confirmed by the World Health Organization (WHO)**

The Food and Drug Administration (FDA) notifies the public on the WHO Medical Product Alert on falsified Defibrotide with brand name "Defitelio" which were detected in Europe and South-East Asia regions last April and July 2023:

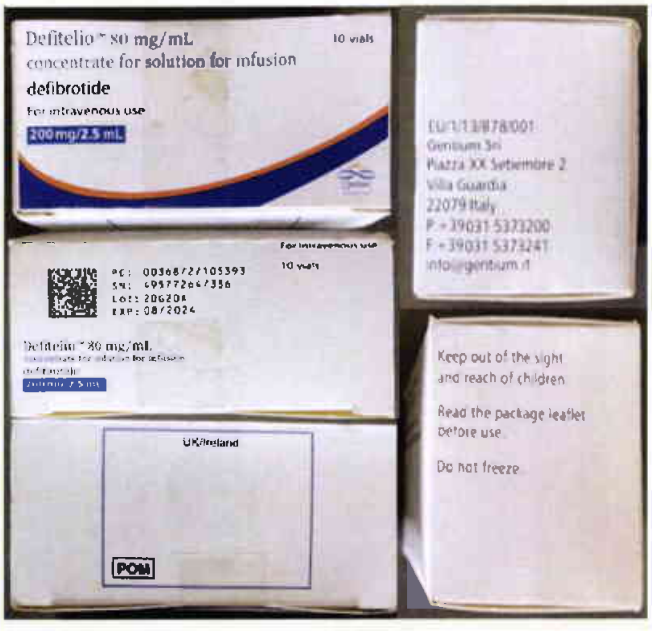
PRODUCT NAME	Defibrotide 80 mg/mL Concentrate for Solution for Infusion [Defitelio]
STATED MANUFACTURER	Gentium Sri – Piazza XX Setiembre 2 Villa Guardia 22079 Italy
LOT	20G20A
EXP. DATE	08/2024
PACKAGING LANGUAGE	English
IDENTIFIED IN	India and Turkey
AVAILABLE PHOTO	

Figure 1. Defibrotide 80 mg/mL Concentrate for Solution for Infusion [Defitelio] detected in Turkiye

The FDA strongly advises the public to be vigilant on the circulation of this falsified drug product since this poses a particular risk to patients as they are administered intravenously, and their sterility, quality, and safety are unknown. A falsified drug product deliberately or fraudulently misrepresents its identity, composition, or source and its safety and quality are unknown. The genuine manufacturer, Gentium Sri, confirmed that this product and its variable data (lot number, serial number, and expiry date) referenced are falsified, including the packaging of the product.

This is to emphasize that Defibrotide 80 mg/mL Concentrate for Solution for Infusion [Defitelio] is not registered with FDA. Authentic Defitelio is used for the treatment of severe hepatic veno-occlusive disease (VOD) also known as sinusoidal obstruction syndrome (SOS) in haematopoietic stem-cell transplantation (HSCT) therapy.

Therefore, all Local Government Units (LGU) and Law Enforcement Agencies (LEAs), after the issuance of this advisory, are requested to ensure that this falsified drug product is not sold or not administered to patients in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph**. To report unauthorized sale or distribution of the abovementioned, kindly e-mail us via **cdrr.od@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**.

Dissemination of the information to all concerned is highly requested.

DR. SAMUEL A. ZACATE
Director General

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