Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration
PHILIPPINES

FDA ADVISORY
No. 2024-0532

15 MAR 2024

SUBJECT: PUBLIC WARNING ON ALL BATCHES OF METHOTREXATE 100 mg/mL SOLUTION FOR INJECTION (I.M/I.V) [TREXASAPH]

The FDA Philippines is advising all hospitals, health facilities, healthcare professionals and the public in general to stop the use of Methotrexate 100 mg/mL Solution for Injection (I.M/I.V) [Trexasaph] manufactured by Bruck Pharma Private Limited, India, and imported by Nelpa Life Sciences, Inc., Parañaque City regardless of the batch. Likewise, this advisory extends to all government and private drug retail outlets to stop dispensing this drug.

The FDA has determined the nature of the quality problem of Trexasaph 100 mg/mL with Batch Number I23J001A which was found positive with *Pseudomonas aeruginosa*. In the interest of public health and safety, all available batches should not be used or administered until further notice from this Office.

Methotrexate is a chemotherapy agent and immune system suppressant. It is indicated in the treatment of neoplastic disease, such as trophoblastic neoplasms and leukemia, and the symptomatic treatment of recalcitrant disabling psoriasis which is not adequately responsive to other forms of therapy. It may be given intrathecal, intramuscular, intravenous, or intra-arterial routes. Patients receiving methotrexate treatment may have weakened immune systems and be more vulnerable to opportunistic infections.

Pseudomonas aeruginosa bloodstream infection is a serious infection that may lead to death and any product that has any contamination and is administered directly in the body would present serious risks to patients.

Further, drug establishments involved with this product are required to implement their risk management plans, to monitor their own product's safety profile and to take rapid action when there is a probable cause of safety breaches. The accountability of drug establishments in product quality and safety in this case is being studied by FDA with an end in view for levying appropriate penalties.

The FDA enjoins medical professionals, administrators of the health facilities and the public to monitor FDA Philippines website for alerts, warnings and recalls.

Consumers may contact Nelpa Life Sciences, Inc. thru email at **rao.nelpalifesciences@gmail.com.** For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph**. To report continuous sale or distribution of the abovementioned product, kindly e-mail us via **ereport@fda.gov.ph**. You may also call the Center for Drug Regulation and Research at telephone number **(02) 8809-5596**. Any suspected adverse reaction experienced from the use of this product should be reported immediately to the FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill-out all the required fields.

Dissemination of the information to all concerned is requested.

DR. SAMUEL A. ZACATE
Director General

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