Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. ~~2020-749~~

23 APR 2020

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

SUBJECT: **Product Recall of Specific Batches of Methotrexate 25 mg/mL (50 mg/2 mL) Solution for Injection (IM/IV) with Brand Names Alltrex and MPL Methoxil**

All healthcare professionals and the general public are hereby advised by the Food and Drug Administration (FDA) regarding the voluntary recall by the marketing authorization holders on the affected batches of the subject products from the market. The details of the products are as follows:

DRUG PRODUCT (1)	**METHOTREXATE 25 mg/mL (50 mg/2 mL) SOLUTION FOR INJECTION (IM/IV) (ALLTREX)**	
REGISTRATION NO.	**DRP-3138**	
BATCH NO./EXP. DATE	**NN8398B**	**SEPTEMBER 2020**
MANUFACTURER	**NAPROD LIFE SCIENCES PVT. LTD. – G-17/1, MIDC, TARAPUR INDUSTRIAL AREA, BOISAR, DIST. THANE 401 506, INDIA**	
IMPORTER & DISTRIBUTOR [Marketing Authorization Holder (MAH)]	**MULTICARE PHARMACEUTICALS PHILIPPINES, INC. – 26TH FLOOR RUFINO TOWER, 6784 AYALA AVENUE, MAKATI CITY**	

DRUG PRODUCT (2)	**METHOTREXATE 25 mg/mL (50 mg/2 mL) SOLUTION FOR INJECTION (IM/IV) (MPL METHOXIL)**	
REGISTRATION NO.	**DRP-3138-01**	
BATCH NO./EXP. DATE	**NN8398C**	**SEPTEMBER 2020**
MANUFACTURER	**NAPROD LIFE SCIENCES PVT. LTD. – G-17/1, MIDC, TARAPUR INDUSTRIAL AREA, BOISAR, DIST. THANE 401 506, INDIA**	
IMPORTER	**MULTICARE PHARMACEUTICALS PHILIPPINES, INC. – 26TH FLOOR RUFINO TOWER, 6784 AYALA AVENUE, MAKATI CITY**	
DISTRIBUTOR (MAH)	**MULTI PRODUCTS LINE PHARMA, INC. – UNIT 107 STERTEN PLACE CONDOMINIUM, 116 MAGINHAWA ST., TEACHER'S VILLAGE-EAST DILIMAN, QUEZON CITY**	

The MAHs pursued the voluntary recall of the drug products due to the microbial sterility issue found in certain batches provided to Columbia. The concerned batches were also exported to the Philippines. Therefore, the stated batches present quality and safety concerns.

Methotrexate is indicated in the treatment of gestational choriocarcinoma, acute lymphoblastic leukemia, and symptomatic control of psoriaris. The above-mentioned drug products are packed in a 3 mL flint glass vial (box of 1's).

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected batches of the drug products are instructed to discontinue further distribution, sale, and use. All consumers are likewise advised not to purchase or use the affected product batches and may contact Multicare Pharmaceuticals Philippines, Inc. at telephone number (02) 8811-0636 or mobile no. +639178854954 for any question or additional information regarding the recall.

All Local Government Units (LGU) and Law Enforcement Agencies (LEAs) are requested to ensure that the affected product batches are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph**. To report continuous sale or distribution of the abovementioned, 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 the products should be reported immediately to the FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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