Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-0351

22 FEB 2021

TO: **DRUG DISTRIBUTORS AND DRUG WHOLESALERS**

SUBJECT: **Product Recall of Specific Lots of Neostigmine Methylsulfate 0.50 mg/mL Solution for Injection (IM/IV/SC) (Prostigmin)**

Drug distributors and drug wholesalers are hereby advised by the Food and Drug Administration (FDA) regarding the recall of the affected lots of the subject product. The details of the product are as follows:

DRUG PRODUCT	**NEOSTIGMINE METHYLSULFATE 0.50 mg/mL SOLUTION FOR INJECTION (IM/IV/SC) (PROSTIGMIN)**	
REGISTRATION NO.	**DR-4017**	
LOT NO./EXP. DATE	**113322**	**2023-05-31**
	F20BAX	**2024-11-30**
MANUFACTURER	**Legacy Pharmaceuticals Switzerland GmbH - Ruhrbergstrasse 21, CH-4127 Birsfelden, Switzerland**	
IMPORTER (MAH)	**A. Menarini Philippines, Inc. – 4F W Building, 11th Ave. cor. 28th St. Bonifacio High St., Bonifacio Global City, Taguig City**	

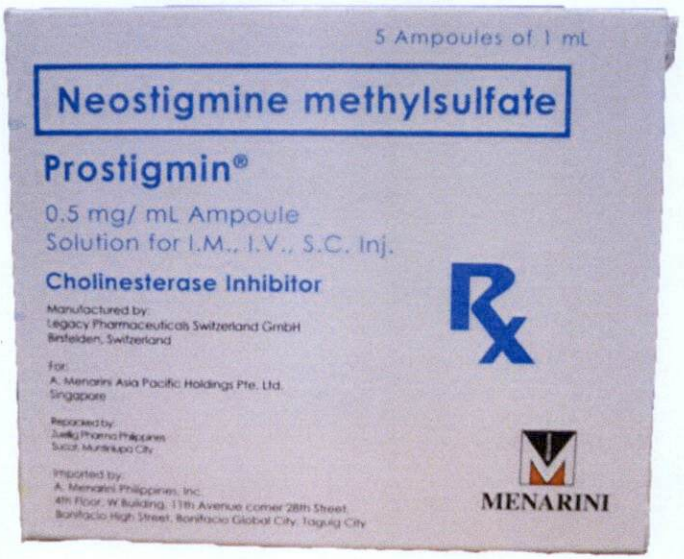

Figure 1. Neostigmine Methylsulfate 0.50 mg/mL Solution for Injection (IM/IV/SC) (Prostigmin) for recall

The recall is pursued due to the rating of Swissmedic on its sterile license manufacturer as non-compliant to Good Manufacturing Practice (GMP). Sterile products in the Swiss market were ordered for recall except for critical products, including the subject product, due to its therapeutic use. After due evaluation and assessment, recall of the subject product in the Philippines is ordered until distributor level only.

Neostigmine Methylsulfate is indicated for myasthenia gravis, antagonist to non-depolarizing neuromuscular blockade, palaytic ileus, post-operative urinary retention, and paroxysmal supraventricular tachycardia. Neostigmine Methylsulfate 0.50 mg/mL Solution for Injection (IM/IV/SC) (Prostigmin) is packed in a colorless glass ampoule x 1mL (Box of 5's).

Therefore, distributors that have the affected lots of the drug product are instructed to discontinue further distribution and may contact A. Menarini Philippines, Inc. at telephone numbers +(632) 333-3800 and +(632) 333-3888, or send an e-mail to **aaguinaldo@menariniapac.com** and/or **kristine.sagmon@menariniapac.com** 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 lots are not sold or made available by concerned distributors, after the issuance of this advisory, 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 product 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.


20210129150318

ROLANDO ENRIQUE D. DOMINGO, MD
Director General