Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2022-1967

09 DEC 2022

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Voluntary Product Recall of Additional Batches of Vancomycin Hydrochloride 500 mg (500,000 IU) Powder for Intravenous Infusion In Relation to FDA Advisory No. 2022-1092

All healthcare professionals and the general public are hereby advised by the Food and Drug Administration (FDA) that the additional affected batches of the subject product are being recalled from the market. The details of the product are as follows:

DRUG PRODUCT	**Vancomycin Hydrochloride 500 mg (500,000 IU) Powder for Intravenous Infusion**	
REGISTRATION NO.	**DR-XY12581**	
BATCH NO./EXP. DATE	**J026913AAR**	**JUN 2023**
	J026913AAR1	
	J026913AAR2	
	J026913BAR	
	J026913BAR1	
MANUFACTURER	**Hospira Australia Pty. Ltd. – 1-5, 7-23 and 25-39 Lexia Place, Mulgrave VIC 3170, Australia**	
IMPORTER [MARKETING AUTHORIZATION HOLDER (MAH)]	**Pfizer, Inc. – 19F-20F 8 Rockwell Building, Hidalgo Drive, Rockwell Center, Poblacion, Makati City**	

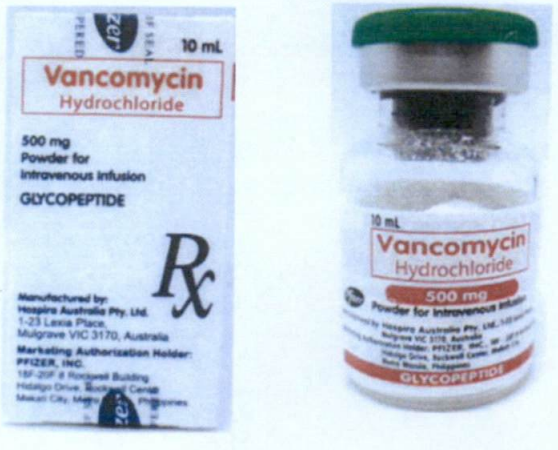

Figure 1. Vancomycin Hydrochloride 500 mg Powder for Intravenous Infusion for voluntary recall

The voluntary recall is pursued by the MAH due to the predicted Out-of-Specification (OOS) stability results which do not meet the shelf-life specification of not less than 95% for potency. Based on regression analysis, it is predicted that the mean assay result would be 95% at 23.1 months and the Upper Fiducial Limit (UFL) is predicted to be at 95% at 25.6 months. To date, there were no complaints or adverse events reported within the scope of this incident. Further investigation is ongoing to determine the root cause and identify preventive actions to avoid future impact on other Vancomycin Hydrochloride 500 mg batches.

The potential risk to a patient arising from using an impacted product towards the end of its shelf life has a reasonable probability of resulting in a lack of effect or development of resistance to susceptible organisms. Therefore, the MAH is recalling these batches prior to the end of shelf life. The amount of drug delivered may be insufficient to effectively treat the patient and therefore appropriate follow-up and monitoring of patients should be considered.

Vancomycin Hydrochloride for Intravenous Infusion is indicated for potentially life-threatening infections which cannot be treated with another effective, less toxic antimicrobial drug, including the penicillins and cephalosporins. Vancomycin Hydrochloride 500 mg (500,000 IU) Powder for Intravenous Infusion is packed in Clear Type I Glass Vial with green flip-off seal (Box of 1's).

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected lots of the product are instructed to discontinue further distribution, sale, and use. Likewise, all consumers are advised not to use or purchase the affected product lot. You may contact Pfizer, Inc. by sending an e-mail to Pfizer Product Quality via **pcom-qophl@pfizer.com** for any questions or additional information regarding the recall.

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 the 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.

DR. SAMUEL A. ZACATE
Director General

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