Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20201876

13 OCT 2020

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

SUBJECT: **Product Recall of Specific Batch of Glibenclamide 5 mg Tablet (Glimide)**

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 holder (MAH) on the affected batch of the subject product from the market. The details of the product are as follows:

DRUG PRODUCT	**GLIBENCLAMIDE 5 mg TABLET (GLIMIDE)**	
REGISTRATION NO.	**DR-XY45762**	
BATCH NO./EXP. DATE	**180174**	**01/2021 or January 2021**
MANUFACTURER	**Jiangxi XierKangtai Pharmaceutical Co., Ltd. – North Zone, High New Technology Industrial Zone, Pingxiang City, Jiangxi, China**	
IMPORTER (MAH)	**PhilRx Pharma Inc. – AMB Bldg., No. 6 Felipe Pike St., Bagong Ilog, Pasig City**	

Figure 1. Glibenclamide 5 mg Tablet (Glimide) for recall – BLISTER PACK

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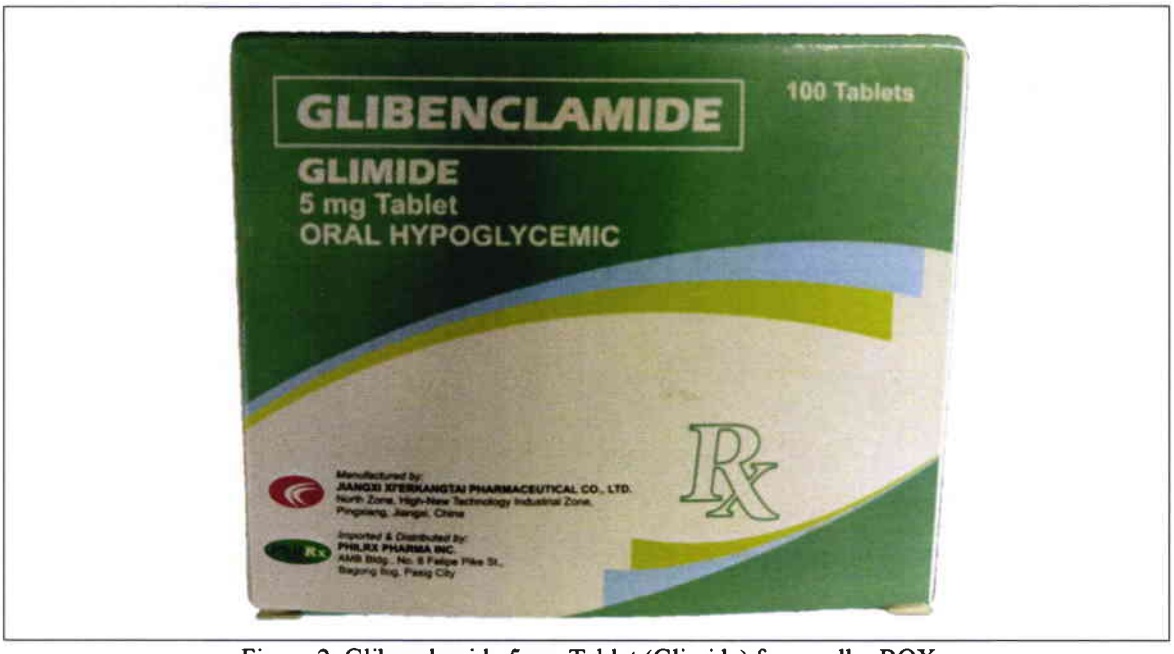

Figure 2. Glibenclamide 5 mg Tablet (Glimide) for recall – BOX

The MAH pursued the voluntary recall of the drug product due to the misprinting of the expiration dates on the blister pack as discovered by the manufacturer. It was found that "01/2020" is printed on units of the blister pack and "01/2021" is printed on the edge of the whole blister pack. Therefore, the stated batch presents quality issues.

Glibenclamide is an antidiabetic drug indicated in the management of non-insulin dependent diabetes to lower the level of sugar in the blood. Glibenclamide 5 mg Tablet (Glimide) is packed in an Alu/PVC Blister Pack x 20's (Box of 100 tablets).

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected batch of the drug product are instructed to discontinue further distribution, sale, and use. All consumers are likewise advised not to purchase or use the affected batch and may contact PhilRx Pharma Inc. at telephone number (02) 655-5492 or send an e-mail to **philrx.regulatory@ambpharma.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 batch 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 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.

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Director General