Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20220486

08 MAR 2022

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

SUBJECT: **Product Recall of Specific Batch of Atracurium Besilate 10 mg / mL Solution for Injection (IV) [Atrium]**

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

DRUG PRODUCT	**ATRACURIUM BESILATE 10 mg/mL SOLUTION FOR INJECTION (IV) [ATRIUM]**	
REGISTRATION NO.	**DRP-7642**	
BATCH NO./EXP. DATE	**1320259**	**06/2022**
MANUFACTURER	**BioRx Pharma Labs LLP – 809 Kerala Industrial Estate, G.I.D.C., Bayla Road, Ahmedabad-382220, Gujarat, India**	
IMPORTER & DISTRIBUTOR	**Ambica International Corporation – #9 Amsterdam Extension, Merville Park Subd., Parañaque City**	

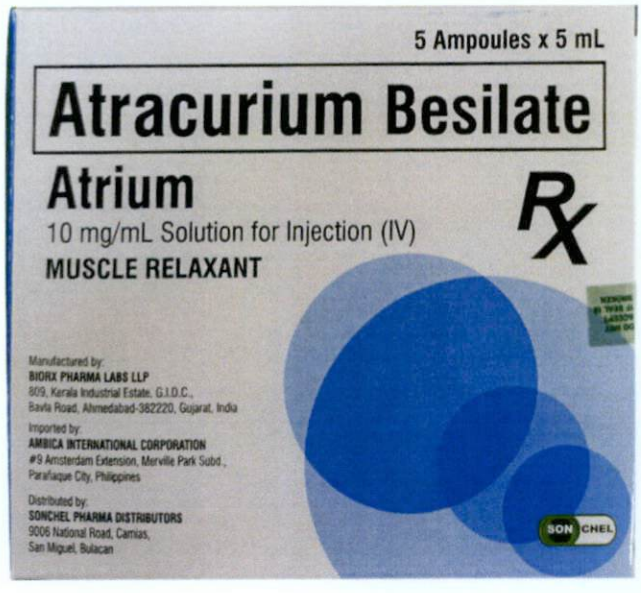

Figure 1. Atracurium Besilate 10 mg/mL Solution for Injection (IV) [Atrium] for recall

Based on the results of the laboratory analyses conducted by the FDA, it was found that the affected batch did not conform to the set specification of assay test. The assay of a drug product determines the (1) presence of a substance and the amount of that substance, or (2) the pharmaceutical potency of a drug. Therefore, the stated batch presents safety, quality, and efficacy concerns.

Atracurium Besilate is indicated as an adjunct to general anesthesia during surgery to relax skeletal muscles and to facilitate endotracheal intubation and mechanical ventilation. It is also indicated to facilitate mechanical ventilation in intensive care unit (ICU) patients. Atracurium Besilate 10 mg/mL Solution for Injection (IV) [Atrium] is packed in an USP Type I glass ampoule with net content of 5 mL (Box of 5's).

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected batch 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 batch and may contact Ambica International Corporation at telephone no. 8828-6617 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 is 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.

DR. OSCAR G. GUTIERREZ, JR
Officer-in-Charge Director General

20220224153830