Statement of Recall on (Betamethasone dipropionate / Betamethasone sodium phosphate 5 mg / 2 mg Suspension) [Diprospan®]

Due to a potentially corroded stainless-steel part in the manufacturing line a Class II recall has been initiated for the following batches of Betamethasone dipropionate / Betamethasone sodium phosphate (DIPROSPAN®) 5 mg / 2 mg Suspension for Injection (DRP-6247).

This recall will be carried out up to the retail level; hence it is requested that distributors, hospitals, retailers, pharmacies, or clinics that have the affected lots of the product are instructed to discontinue further distribution, sale, and use.

All batches manufactured since investigation into the particulates have been thoroughly monitored for quality in accordance with Organon's practices and industry standards, and all batches released were compliant with quality standards, site procedures, product specifications, and in accordance with their marketing authorizations.

To date, there have been no reported adverse events attributable to particulate matter in the potentially impacted and distributed product batch.

Recall List:

DRUG PRODUCT	Betamethasone dipropionate / betamethasone sodium phosphate (DIPROSPAN®) 5 mg / 2 mg Suspension for Injection	
REGISTRATION NO.	DRP-6247	
BATCH NO. and EXPIRATION DATE	U038437	March 2023
	W005751	May 2023
	W025758	December 2023
	W036602	March 2024
MANUFACTURER	Schering-Plough Labo NV Industriepark 30, Heist-op-en-Berg, 2220, Belgium	
IMPORTER [MARKETING AUTHORIZATION HOLDER (MAH)]	Organon (Philippines) Incorporated 23w117 & 23w118, Menarco Tower, 32nd Street, BGC, Taguig City, Metro Manila	

You may contact Organon (Philippines) Incorporated by sending an e-mail to regulatoryph@organon.com for any questions regarding the recall. For any suspected adverse reaction experienced from the use of the product or any product complaint kindly send an e-mail to dpoc.philippines@organon.com.

For more information and inquiries, you may also reach out to the Food and Drug Administration at cdrr_postmarketsurveillance@fda.gov.ph. To report continuous sale or distribution of the abovementioned, kindly e-mail the Food and Drug Administration 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.