Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20220487

08 MAR 2022

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

SUBJECT: **Voluntary Product Recall of Specific Lot of Ciclosporin 1 mg / mL Ophthalmic Emulsion [Ikervis]**

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

DRUG PRODUCT	**CICLOSPORIN 1 mg/mL OPHTHALMIC EMULSION [IKERVIS]**	
REGISTRATION NO.	**DR-XY46077**	
LOT NO./EXP. DATE	**1L14S**	**MAY 2022**
MANUFACTURER	**Excelvision – 27 Rue de la Lombardiere 07100 Annonay, France**	
IMPORTER [MARKETING AUTHORIZATION HOLDER (MAH)]	**Santen Philippines Inc. – 2801-2802, 28th Floor, SM Aura Tower, 26th Street corner McKinley Parkway, The Fort, Taguig City**	

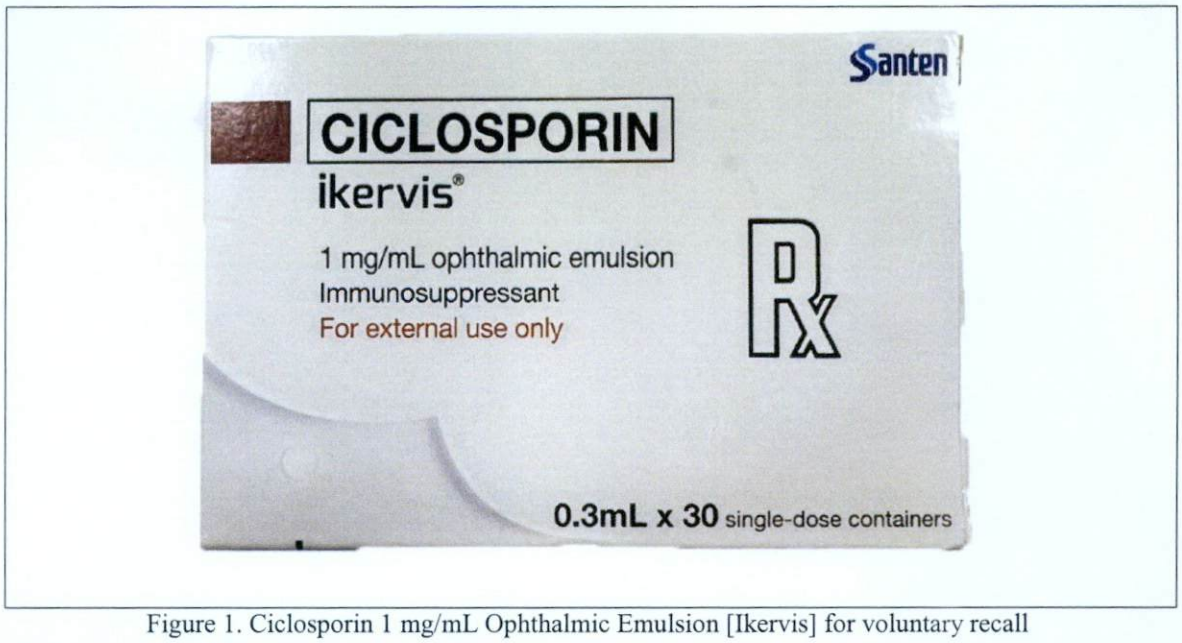

Figure 1. Ciclosporin 1 mg/mL Ophthalmic Emulsion [Ikervis] for voluntary recall

The voluntary recall is pursued by the MAH, as advised by the Santen EMEA, due to the detection of Active Pharmaceutical Ingredient (API) crystallization in the stated lot of the drug product.

Ciclosporin is indicated for the treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes. Ciclosporin 1 mg/mL Ophthalmic Emulsion [Ikervis] is packed in an aluminum pouch with LDPE dropper with net content of 0.3 mL (Boxes of 30's and 90's).

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected lot 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 and may contact Santen Philippines Inc. by sending an e-mail to **SPHRegulatoryAffairs@santen.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 lot is 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.

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

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