Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

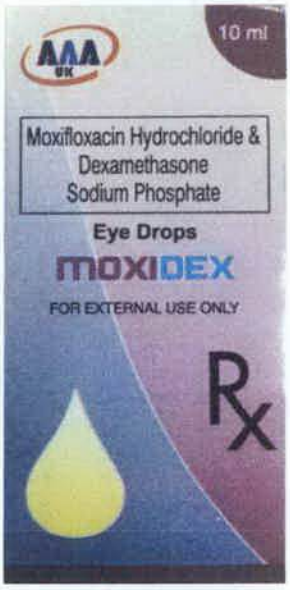
FDA ADVISORY
No. 2018-075

15 MAR 2018

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

SUBJECT : **Public Health Warning Against the Purchase and Use of the Unregistered Drug Product Moxifloxacin Hydrochloride & Dexamethasone Sodium Phosphate (Moxidex) 5.0 mg / 1.0 mg per ml Eye Drops**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the unregistered drug product:



Moxifloxacin Hydrochloride & Dexamethasone Sodium Phosphate (Moxidex) 5.0 mg / 1.0 mg per ml Eye Drops
Manufactured for AAA Ophthalmics Ltd. (UK) – 140 Addison Road, Enfield, Middlesex EN3 5LD (UK)

Figure 1. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug product has not gone through the registration process of the agency and has not been issued with proper authorization in the form of Certificate of Product Registration.

Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

Accordingly, since this unregistered drug product has not gone through evaluation and testing process of the FDA, the agency cannot guarantee its quality and safety. The

consumption of such violative product may pose potential danger or injury if administered.

In light of the above, the public is advised not to purchase the aforementioned violative product and to be vigilant against drug products that might not be duly registered with the FDA. Always check if a drug product has been registered with the FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at www.fda.gov.ph. You may also look for the FDA Registration number on the product label.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug product until it has already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this product is not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **info@fda.gov.ph**. To report continuous sale or distribution of unregistered health products, kindly e-mail us via **report@fda.gov.ph**, or through the online reporting facility, **eReport**, at **www.fda.gov.ph/ereport**. You may also call the Center for Drug Regulation and Research at telephone number **(02)809-5596**. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: **www.fda.gov.ph/adr-report-new** and fill out all the required fields.

Dissemination of the information to all concerned is requested.

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Director General

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