



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



30 July 2014

FDA Advisory
No. **2014-059**

**SUBJECT: Public Health Warning Against the Use of Unregistered Product
“Prednisolone 5 mg per 5 mL Syrup (PRED)”**



The Food and Drug Administration advises the public against the use of an unregistered product named **PRED 5 mg per 5 mL Syrup**. The product which was labeled to be a Corticosteroid has the generic name “Prednisolone” and is claimed to be used “to control the acute exacerbations of bronchial asthma, severe osteoarthritis, severe allergic reactions, auto-immune diseases and in rheumatoid arthritis.”

PRED 5 mg per 5 mL Syrup was found to be distributed without FDA registration. The importer and distributor of the product, Sham Chem Pharmacals Inc., is not licensed by this Office.

The FDA warns the public that the use of this unregistered corticosteroid product presents safety risks and adverse health consequences. The safety, efficacy and quality of this product cannot be guaranteed.

Retailers and distributors of FDA regulated products are advised to source their supplies from authorized dealers so as to avoid processing fake and/or unregistered products.

The field Food and Drug Regulation Officers are ordered to confiscate all unregistered drug product, particularly PRED found in the market or in possession of individuals.

All local government units and law enforcement agencies are requested to ensure that these products are not sold or offered for sale in their localities or area of jurisdiction.

All consumers are advised to purchase and use only FDA-registered health products from FDA-licensed establishment. To verify if the product is registered with FDA, the general public may search the FDA website, www.fda.gov.ph by typing the product’s name in the search tab.

For more information and inquiries, please email us at info@fda.gov.ph. To report continuous sales or distribution of unregistered health products kindly email us via report@fda.gov.ph or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report at the FDA website: www.fda.gov.ph through the ADR Report tab.



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