Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2017-243

11 AUG 2017

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the Counterfeit Version of Dydrogesterone (Duphaston) 10 mg Film-coated Tablet**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit version of Dydrogesterone (Duphaston) 10 mg Film-coated Tablet collected from several clinics of Chinese General Hospital:

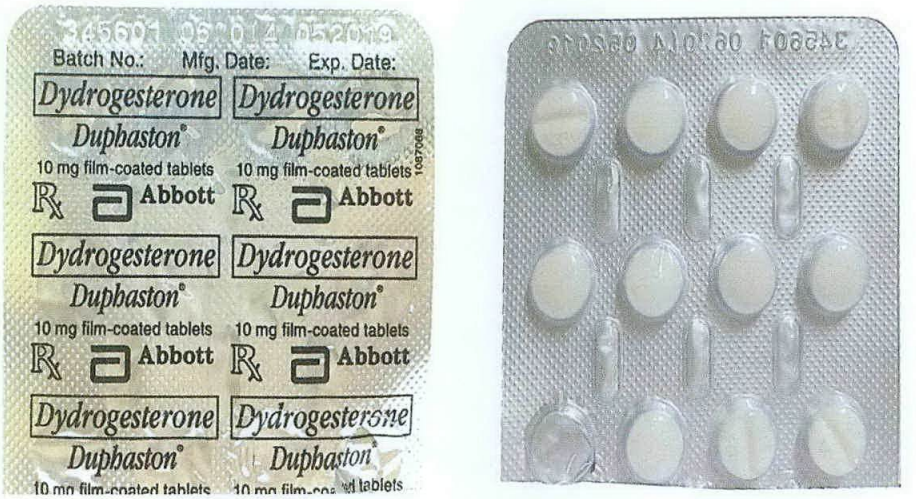

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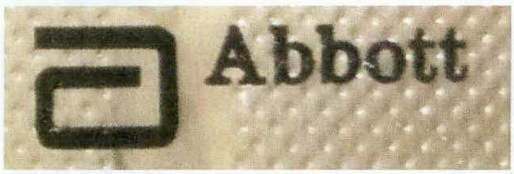
Figure 1. Blister foil of the counterfeit Dydrogesterone (Duphaston) 10 mg Film-coated Tablet

The FDA together with the Marketing Authorization Holder (MAH), Abbott Laboratories Philippines, have verified that the abovementioned sample drug product is counterfeit. The comparisons of the collected product and the registered and authentic one are as follows:

AUTHENTIC	COUNTERFEIT
• The letters "tt" from Abbott logo are connected	• The letters "tt" from Abbott logo are not connected
	

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• As per Abbott database Batch No.: 345601 Manuf. Date: 06-2014 Expiry Date: 05-2019	• Batch number does not correspond to the manufacturing date and expiry date Batch No.: 345601 Manuf. Date: 12-2013 Expiry Date: 11-2018
• Absence of black spots on the tablet 	• Presence of black spots on the tablet 
• Contains active pharmaceutical ingredient	• No active pharmaceutical ingredient

All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which pose potential danger or injury to consumers. Consumers are also reminded to purchase drug products only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing of this drug product with the abovementioned features of a counterfeit drug product. The importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009, and Republic Act No. 8203, or the Special Law on Counterfeit Drugs. Anyone found selling the said counterfeit drug products will be penalized.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this counterfeit 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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