Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2016-044

18 MAY 2016

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

SUBJECT: **Public Health Advisory on World Health Organization's Medical Product Alert No. 3/2016 Re: Falsified Hepatitis C Medicines circulating in South East Asia**

The Food and Drug Administration (FDA) hereby informs the public that the World Health Organization (WHO) has recently issued Medical Product Alert No. 3/2016 regarding falsified Hepatitis C Medicines circulating in South East Asia:

PRODUCT	BATCH NUMBER	MANUFACTURING DATE	EXPIRY DATE
SOFOSBUVIR + LEDIPASVIR (LEDSO) 400 mg/ 90 mg CAPSULE	**0022**	**5/2015**	**4/2017**
DACLATASVIR (DAKAVIR) 60 mg CAPSULE	**0322**		

(Attached is a copy of the WHO Alert)

Based on FDA records, the aforementioned products are unregistered drug products. Further, as stated in the WHO Alert, the said products are labeled to be manufactured by Pharco Corporation – Alexandria, Egypt. However, Pharco Corporation issued a statement that they do not manufacture any of these products.

All healthcare professionals and the general public are hereby warned to be vigilant of the falsified Sofosbuvir + Ledipasvir (Ledso) 400 mg/ 90 mg capsule and Daclatasvir (Dakavir) 60 mg capsule that may reach the Philippine market. The presence of these identified products pose potential danger or injury to the consuming public and 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.

In the interest of protecting public health and safety, the Officers of the Field Regulatory Operations Office (FROO) are hereby mandated to exercise their regulatory function pursuant to Section 14 of Republic Act No. 9711.

All establishments and outlets are hereby warned against selling and/or dispensing the identified products. Anyone found selling the said products will be penalized.

Likewise, 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 their medications only from FDA-licensed establishments. Please note that in addition to inspection of establishments, product evaluation, registration, and testing are measures that the government undertakes to ensure the quality, safety, and efficacy of health products. Moreover, please be reminded that drug products registered with FDA Philippines bear in their labels information in English and/or in Filipino for all consumers to understand.

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 you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report immediately to FDA through our website: www.fda.gov.ph. Look for the ADR Report tab and fill out all the required fields.

Dissemination of the information to all concerned is requested.

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World Health Organization

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Ref. RHT/SAV/Alert 3.2016

25 February 2016

Medical Product Alert N° 3/2016

Falsified Hepatitis C medicines circulating in South East Asia

This Medical Product Alert relates to the circulation of confirmed falsified versions of *Sofosbuvir 400mg + Ledipasvir 90mg* and *Daclatasvir 60mg* in South East Asia.

Both products are used to treat Hepatitis C. *Daclatasvir 30mg* and the fixed dose combination of *Sofosbuvir 400mg + Ledipasvir 90mg* are on the WHO list of Essential Medicines.

In February 2016, WHO was informed by a local NGO working in Myanmar that they had identified falsified versions of the two following products:

Product Name	**LEDSO capsules**	**DAKAVIR**
Batch Number	0022	0322
Expiry Date	4/2017	4/2017
Date of manufacture	5/2015	5/2015

Both products claim to be manufactured by ***PHARCO Corporation ; Alexandria, Egypt***.

Photographs of both falsified products are available in annex. Laboratory analysis is pending so as to better assess the threat posed to public health.

PHARCO Corporation has stated that:

- they do not manufacture the specific fixed dose combination of *Sofosbuvir 400mg + Ledipasvir 90mg*
- they do not manufacture any products under the names of *LEDSO* nor *DAKAVIR*
- they do not manufacture *Daclatasvir 60mg* at this moment in time.

It is necessary to ensure that all medical products are obtained from authentic and reliable sources. Their authenticity and origin should be carefully checked and verified with manufacturers before use.

No serious adverse reactions attributed to these falsified products have been reported at this stage. However, if you have taken this falsified product, or if you suffer an adverse event following its uptake, please seek immediate advice from a qualified healthcare professional and report the incident to your local Ministry of Public Health / National Medicines Regulatory Authorities/ National Pharmacovigilance Centre.

If you are in possession of these products, please do not use them, contact a healthcare professional as soon as possible for advice and report the incident as indicated above.

WHO requests increased vigilance for the supply chains of countries likely to be affected by these falsified products. Vigilance should include hospitals, clinics, pharmacies and any other suppliers of medical products.

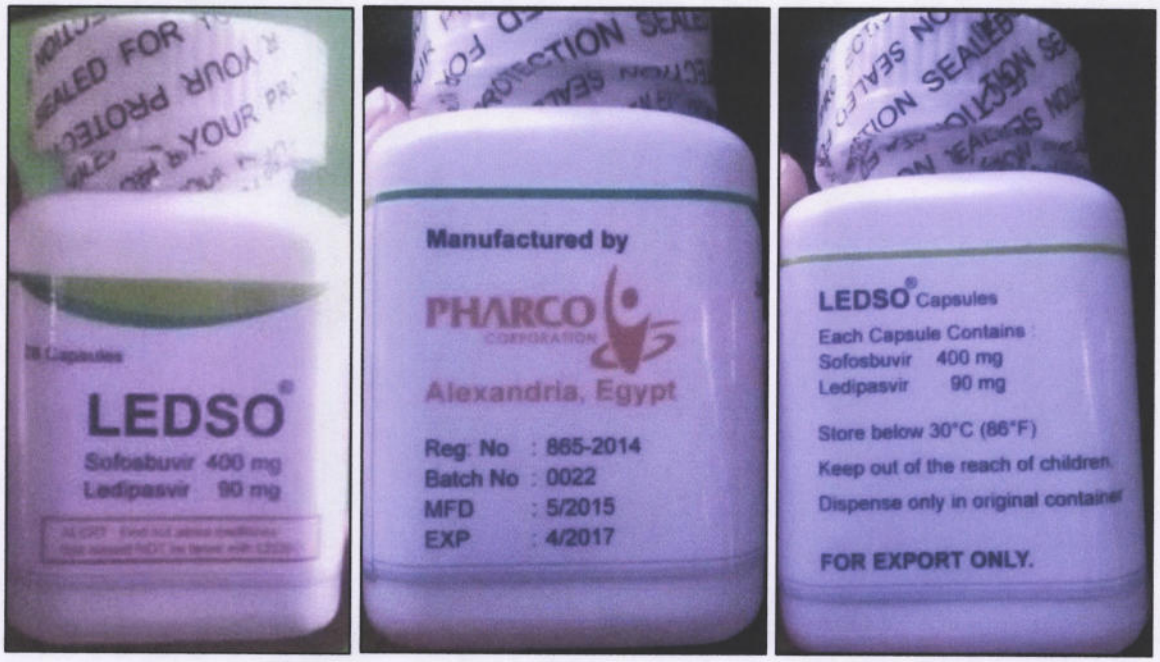
Health authorities are asked to immediately notify WHO if these falsified products are discovered in their country. If you have any information on their supply and/or distribution please contact rapidalert@who.int

WHO Surveillance and Monitoring – Rapid Alert

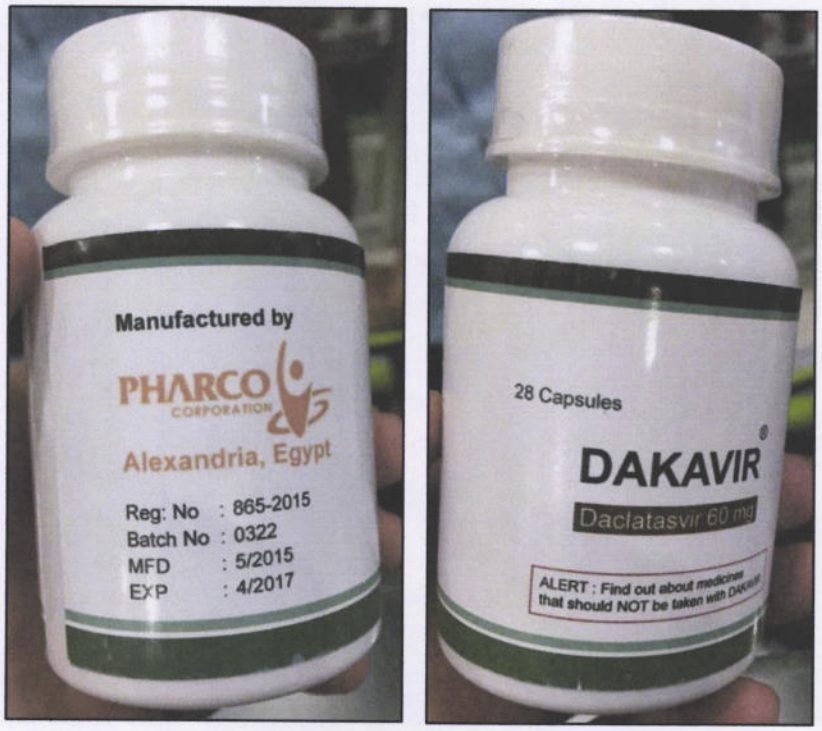
Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) Medical Products
All WHO Drug Alerts are available at the following link: http://www.who.int/medicines/publications/drugalerts/en/

ANNEX WITH PHOTOGRAPHS

1. Falsified LEDSO



2. Falsified DAKAVIR



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