105B-0188

正本

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保存年限：

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受文者：新北市藥師公會

發文日期：中華民國105年3月14日
發文字號：新北衛食字第1050381259號
速別：普通件
密等及解密條件或保密期限：
附件：相關資料影本1份

主旨：有關「LEDSO、DAKAVIR」等C型肝炎治療藥之仿冒品於東南亞流通一案，惠請轉知所屬會員，如有案內批號產品請立即下架勿再販售，請查照辦理。

說明：

一、依據衛生福利部105年3月3日FDA企字第1051200769號函辦理。

二、為保障民眾用藥安全，惠請轉知所屬會員，如有案內批號產品請立即下架勿再販售。

三、檢附相關資料影本1份。

正本：新北市藥師公會
副本：

局長 林奇宏

本案依分層負責規定授權業務主管決行

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.

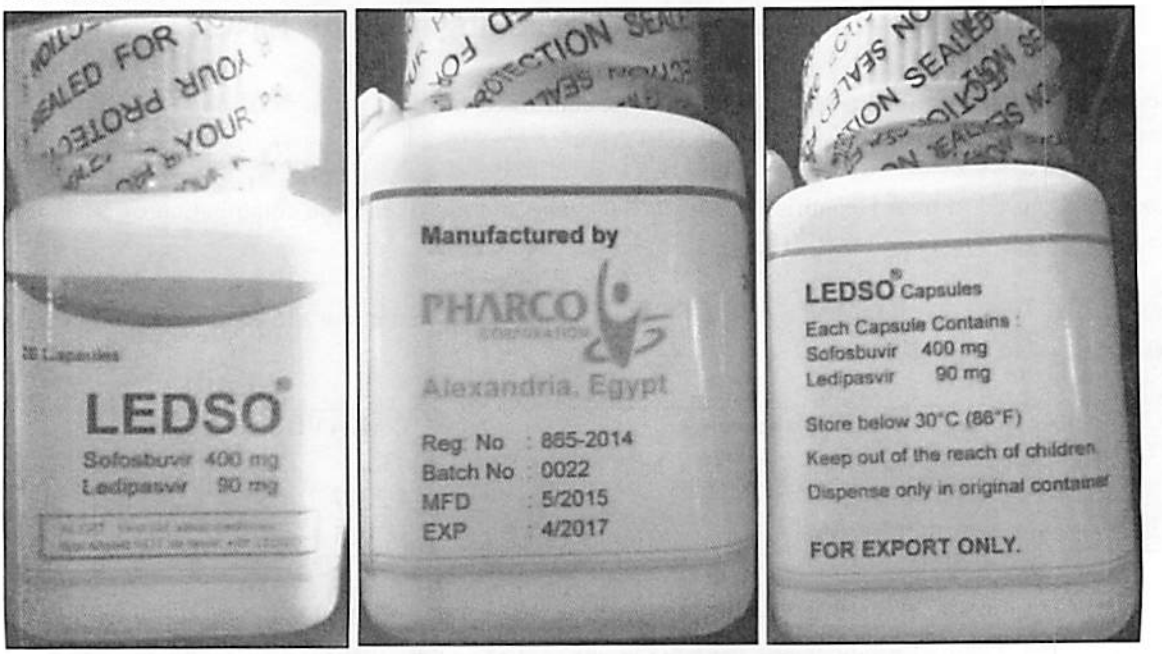
Health authorities are asked to immediately notify WHO if these falsified products are discovered in their country. If you have any information on their supply and/or distribution please contact rapidalert@who.int

WHO Surveillance and Monitoring – Rapid Alert

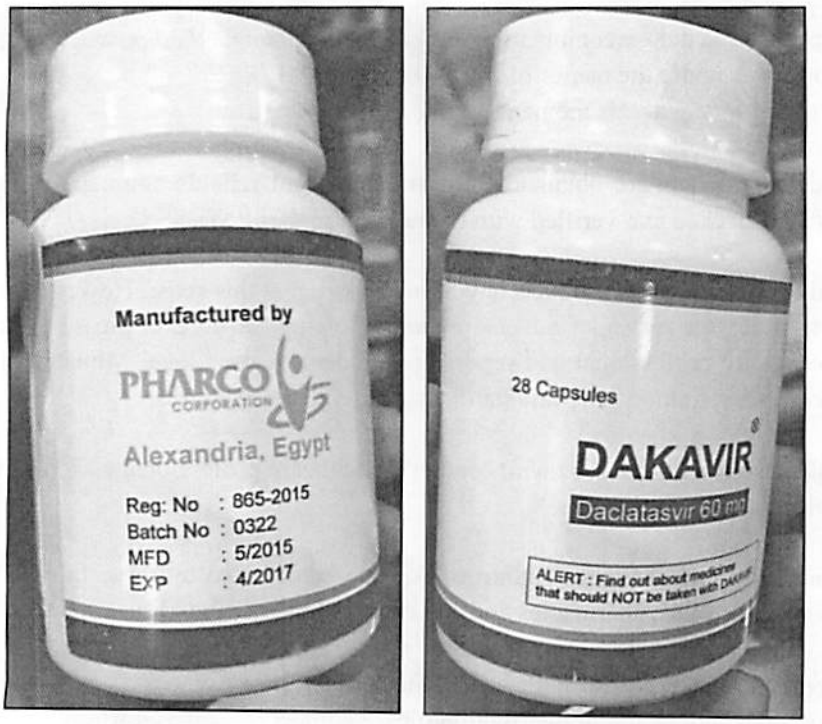
Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) Medical Products
All WHO Drug Alerts are available at the following link: http://www.who.int/medicines/publications/drugalerts/en/

ANNEX WITH PHOTOGRAPHS

1. Falsified LEDSO



2. Falsified DAKAVIR



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