

正本

105B-0159
檔 號：
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1日

發文字號：新北衛食字第1050310171號

速別：普通件

密等及解密條件或保密期限：

附件：仿冒藥品訊息相關資料1份

主旨：檢送案內所陳「AMARIL stabilised yellow fever vaccine」之仿冒品於東南亞流通相關資料1份，為維護國民之健康與安全，請轉知所屬會員勿販售供應與使用，請查照。

說明：

- 一、依據衛生福利部食品藥物管理署105年2月22日FDA企字第1051200613號函辦理。
- 二、檢附仿冒藥品訊息相關資料1份。

正本：新北市藥師公會、新北市藥劑生公會、新北市醫師公會、新北市西藥商業同

業公會、新北市商業會

副本：新北市政府衛生局衛生稽查科

局長 林奇宏

本案依分層負責規定授權業務主管決行

世界林業

Ref. RHT/SAV/Alert 2.2016

11 February 2016

Medical Product Alert N° 2/2016

Falsified AMARIL yellow fever vaccines circulating in South East Asia

This Medical Product Alert relates to the confirmed circulation of falsified versions of “AMARIL stabilised vaccine” in South East Asia.

This vaccine is used to immunise against yellow fever and is a WHO prequalified product. Yellow fever vaccine is on the WHO list of Essential Medicines.

On the 9th of February 2016, the Pasteur Institute in Dakar, Senegal, informed WHO that they had identified a falsified version of their “AMARIL stabilised vaccine” circulating in Bangladesh.

Genuine AMARIL vaccines and solvents are manufactured by the Pasteur Institute in Dakar, Senegal

The Pasteur Institute in Dakar has confirmed there are a number of falsified elements on the packaging, including a falsified expiry date, as well as other inconsistencies that were identified through visual inspection of photographs of the falsified products, as compared to the genuine products. Laboratory analysis is pending.

Product Name: AMARIL stabilised yellow fever vaccine

Batch Number: 2265

Expiry Date: June 2017

Manufacturer: Pasteur Institute in Dakar

Photographs of the falsified versions available in annex.

It is necessary to ensure that all vaccines and 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 this falsified vaccine have been reported at this stage. However, if you have been immunized with this falsified product, or if you suffer an adverse event following an immunisation with this falsified product, 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 the same products as above, please do not use, 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 vendors of medical products.

Authorities are asked to immediately notify WHO if this falsified product is discovered. If you have any information on the supply and/or distribution of the falsified product 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

Falsified “AMARIL stabilised vaccine” discovered in 2016 in Bangladesh:



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