



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2016-036**

17 MAY 2016

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Advisory on World Health Organization's Medical Product Alert No. 2/2016 Re: Falsified Amaril Yellow Fever Vaccines 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. 2/2016 regarding falsified Amaril Yellow Fever Vaccines circulating in South East Asia:

PRODUCT	MANUFACTURER	BATCH NUMBER	EXPIRY DATE
STABILISED YELLOW FEVER VACCINE (AMARIL)	PASTEUR INSTITUTE – DAKAR	2265	JUNE 2017

(Attached is a copy of the WHO Alert)

The aforementioned vaccine is an unregistered drug product. Further, as stated in the WHO Alert, the genuine Stabilised Yellow Vaccine (Amaril) and its solvent are manufactured by Pasteur Institute – Dakar, Senegal. The said manufacturer has confirmed that the abovementioned product is falsified due to the observed inconsistencies in its packaging, including the expiry date.

All healthcare professionals and the general public are hereby warned to be vigilant of the falsified Stabilised Yellow Vaccine (Amaril) that may reach the Philippine market. The presence of this identified product poses 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 product. Anyone found selling the said product will be penalized.


Likewise, all local government units and law enforcement agencies are requested to ensure that this product is 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 vaccines 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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OIC, Director General

DTN: 20160226140353

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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