Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

27 May 2015

FDA ADVISORY
No. 2015-029

SUBJECT: **Public Health Advisory on World Health Organization's Medical Product Alert No. 2/2015 Re: Falsified Meningitis Vaccines Circulating in West Africa**

The Food and Drug Administration (FDA) hereby informs the public that the World Health Organization (WHO) has recently issued Medical Product Alert No. 2/2015 regarding falsified Meningitis Vaccines circulating in West Africa with the following lots/ batches:

PRODUCT	BATCH NUMBER	MANUFACTURING DATE	EXPIRY DATE
MENCEVAX ACW (50 DOSES/ VIAL)	**AMENA020AA**	**12-2014**	**11-2017**
MENCEVAX ACWY (50 DOSES/ VIAL)	**AMEHA020AA**	**12-2013**	**11-2016**
DILUENT	**A003B128AA**	**02-2013**	**01-2019**

(Attached is a copy of the WHO Alert.)

Based on FDA records, Mencevax ACW 50 doses vial and Mencevax ACWY 50 doses vial are unregistered drug products. The Marketing Authorization Holder (MAH), GlaxoSmithKline Philippines, Inc., has confirmed that Mencevax vial with the specified batch numbers (including that of the diluent mentioned) are not included in their importation. Further, the registered Meningococcal Polysaccharide Vaccine, Group A, C, W135 and Y (Mencevax ACWY) Powder for Injection (SC) with Registration Numbers: BR-519 and BR-643 are available in 10 doses/ vial and monodose vial, respectively.

All health care professionals and the general public are hereby warned to be vigilant of the falsified lots/ batches of the Meningitis Vaccines 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, and the Republic Act 8203 or the Special Law on Counterfeit Drugs.

In the interest of protecting public health and safety, and pursuant to Section 12 of R.A. No. 9711, the Field Regulatory Operations Office (FROO) Officers of this Office are hereby ordered to seize the aforementioned falsified drug products found in the market.

All establishments and outlets are hereby warned against selling and/or dispensing the above 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 email us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly email 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.

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Secretary of Health
Acting Director General[1]

DTN:20150525164043

[1] Pursuant to DPO 2015-1845

World Health Organization

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Ref. RHT/SAV/MD/2/2015

22ND May 2015

Medical Product Alert No. 2/2015

Falsified Meningitis Vaccines circulating in West Africa

This Medical Product Alert relates to the confirmed circulation of falsified versions of Meningitis Vaccines in Niger.

Following a report submitted to the WHO Surveillance and monitoring system for substandard and falsified medical products by the focal point within the Niger Regulatory Authority, increased vigilance is requested for the following lots/batches of vaccines and solvents.

Product: **Mencevax ACW**
Batch Number: **AMENA020AA**
Manufacturing date: **12-2014**
Expiry Date: **11-2017**

The batch number is genuine but the manufacturing and expiry dates are false. The genuine version of this batch expired in 2011. The product contains 50 doses per vial.

Product: **Mencevax ACWY**
Batch Number: **AMEHA020AA**
Manufacturing date: **12-2013**
Expiry Date: **11-2016**

The batch number, manufacturing date and expiry date for this product are false. This falsified product contained 50 doses per vial.

Product: **Diluent**
Batch Number: **A003B128AA**
Manufacturing date: **02-2013**
Expiry Date: **01-2019**

The batch number, manufacturing date and expiry date for this diluent are false. This falsified product contained 50 doses of diluent.

No serious adverse reactions linked to these batches of falsified vaccines have been reported at this stage

Genuine Mencevax is manufactured by GlaxoSmithKline (GSK). These falsified products have not yet been subject to Laboratory analysis. This alert is issued on the basis of inconsistencies in the

packaging material and confirmation from GSK that the batch numbers, manufacturing dates and expiry dates are inconsistent with the genuine product.

WHO recognises the seriousness of the current meningitis outbreak in West Africa and the additional demand for meningitis vaccines. Further information concerning this outbreak is available through the following link

http://www.who.int/mediacentre/news/situation-assessments/meningitis-niger/en/

WHO advises increased vigilance within the supply chains of countries likely to be affected by these falsified products.

It is necessary to ensure that vaccines are obtained from authentic and reliable sources.

If you have any information concerning these batches and/or diluents please report the matter to your Ministry of Public Health / National Medicines Regulatory Authorities.

Ministry of Public Health / National medicines regulatory authorities are asked to immediately notify WHO if these batches are discovered in your country via rapidalert@who.int

Annex with photographs on next pages

Photographs of falsified "Mencevax" products

Fig. 1.: Falsified Mencevax, batch number AMEHA020AA

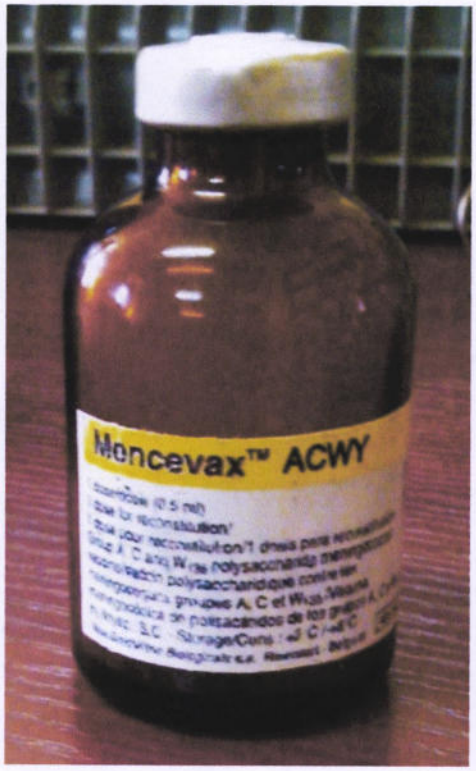

Fig. 2. : Falsified Mencevax, batch number AMENA020AA

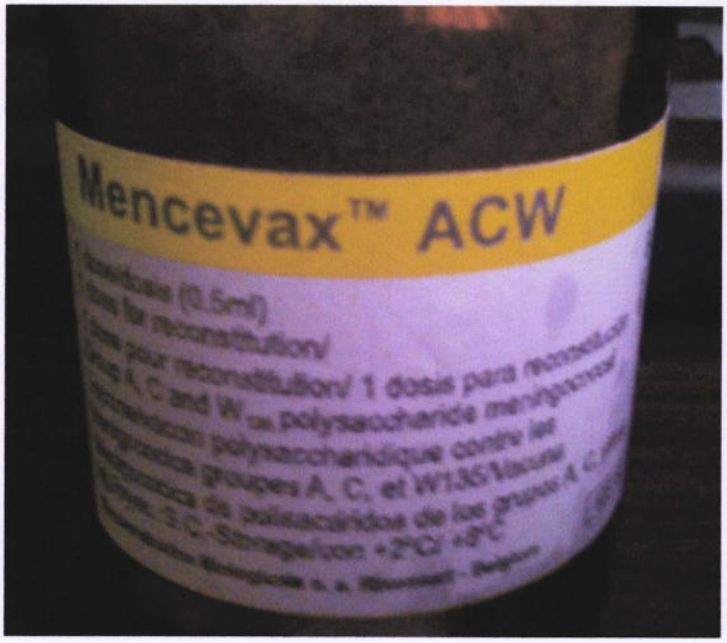

Fig. 3.: Falsified diluent for Mencevax, batch number A003B128AA