Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

01 June 2015

FDA ADVISORY
No. 2015-030

SUBJECT: **Public Health Advisory on World Health Organization's Medical Product Alert No. 3/2015 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. 3/2015 regarding falsified Meningitis Vaccines circulating in West Africa with the following batches:

PRODUCT	BATCH NUMBER	EXPIRY DATE
MENOMUNE ACY-W135 (10 DOSES/ VIAL)	**UH 301AA**	**29 APR 17**
MENOMUNE ACY-W135 (10 DOSES/ VIAL)	**UH 301AA**	**28 FEB 16**
MENOMUNE ACY-W135 (10 DOSES/ VIAL)	**UH299AA**	**28 FEB 16**
DILUENT FOR MENOMUNE	**UH 262 AA**	**25 OCT 16**
DILUENT FOR MENOMUNE	**D0953-1**	**20-2017**

(Attached is a copy of the WHO Alert.)

These product batches were not imported by the Marketing Authorization Holder (MAH), Sanofi Pasteur, Inc. – Makati City Philippines.

Based on FDA records, the registered Meningococcal Polysaccharide Vaccine, Group A, C, Y and W-135 (Menomune-A/C/Y/W-135) Powder for Injection (SC) 10 mL vial (10 doses) has Registration Number: BR-623. The MAH reported that the last importation was in September 2011.

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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Acting Director General[1]

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[1] Pursuant to DPO 2015-1845

World Health Organization

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Ref. RHT/SAV/MD/3/2015

27th May 2015

Medical Product Alert No. 3/2015

Falsified Meningitis Vaccines circulating in West Africa UPDATE

This Medical Product Alert relates to the confirmed circulation of falsified versions of Meningitis Vaccines in Niger and follows Medical Product Alert 2/2015 issued on the 22nd May 2015

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 falsified lots/batches of vaccines and diluants.

Product: **Menomune ACY-W135**
Batch Number: **UH 301AA**
Expiry Date: **29 APR 17**

The batch number is genuine but the expiry date is false. The genuine version of this batch of vaccine expired in 2014. This falsified product contains 10 doses per vial.

Product: **Menomune ACYW-135**
Batch Number: **UH 301AA**
Expiry Date: **28 FEB 16**

The batch number is genuine but the expiry date is false. The genuine version of this batch of vaccine expired in 2014. This falsified product contains 10 doses per vial.

Product: **Menomune ACYW-135**
Batch Number: **UH299AA**
Expiry Date: **28 FEB 16**

The batch number is genuine but the expiry date false. The genuine version of this batch of vaccine expired in 2014. This falsified product contains 10 doses per vial.

Product: **Diluant for Menomune**
Batch Number: **UH 262 AA**
Expiry Date: **25 OCT 16**

The batch number is genuine but the expiry date false. The genuine version of this batch of diluant expires on 25 OCT 15. This falsified product contains sufficient solvent to reconstitute 10 doses of vaccine.

Product:	**Diluant for Menomune**
Batch Number:	**D0953-1**
Expiry Date:	**20-2017**

This is not a genuine batch number for a diluent for Menomune Vaccine. This falsified product contains sufficient solvent to reconstitute 10 doses of vaccine.

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Genuine Menomune vaccines and their diluents are manufactured by Sanofi Pasteur.

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 Sanofi Pasteur that some of the batch numbers, and all of the expiry dates are inconsistent with their genuine products.

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 all vaccines and diluants are obtained from authentic and reliable sources. The authenticity and origin of vaccines should be carefully checked and verified with manufacturers before use.

No serious adverse reactions linked to these batches of falsified vaccines and diluants have been reported at this stage. However, should you suffer an adverse event following an immunisation 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 have any information concerning these batches and/or diluents please report the matter to your Ministry of Public Health / National medicines regulatory authorities.

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 "Menomune" Vaccines and Diluents

Fig. 1: Menomune ACYW-135;
Batch Number: UH301AA; Expiry Date: 28FEB16

Fig. 2: Menomune ACYW-135 ;
Batch Number: UH299AA ; Expiry Date: 28FEB16

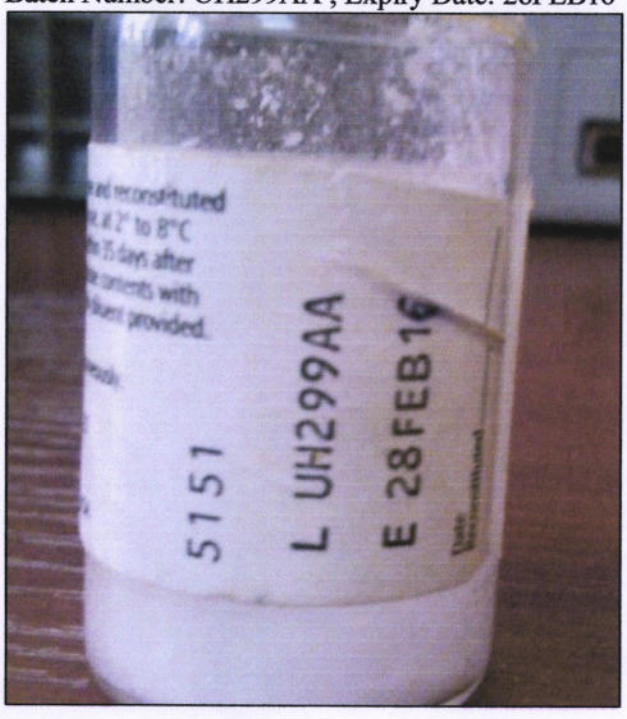

Fig. 4: Diluent for MenomuneACYW-135;

Batch Number: UH262AA; Expiry Date: 25OCT16

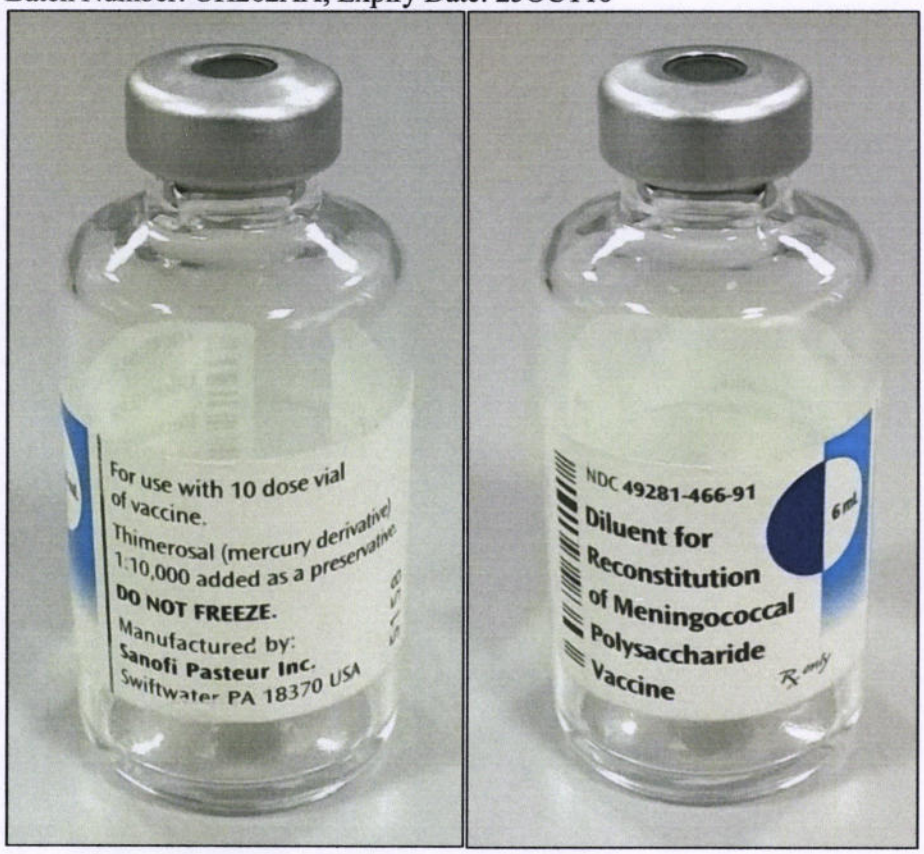

Fig. 5: Diluent for Menomune ACYW-135;

Batch Number: D0953-1; Expiry Date: 20-2017