

正本

檔 號：  
保存年限：

592

## 新北市政府衛生局 函

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受文者：新北市藥師公會

發文日期：中華民國104年6月3日  
發文字號：新北衛食字第1040981691號  
速別：普通件  
密等及解密條件或保密期限：  
附件：案內相關資料影本1份

主旨：檢送有關「偽造之腦炎疫苗產品」涉違反衛生法令相關資料，  
為維護國民之健康與安全，惠請轉知所屬會員，如有案內違  
規產品應立即下架勿販售，請查照。

說明：依據衛生福利部食品藥物管理署104年5月27日FDA企字第  
1041202266號函及104年6月1日FDA企字第1041202366號函  
辦理。

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



Ref. RHT/SAVMD/2/2015

22<sup>ND</sup> 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

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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](mailto:rapidalert@who.int)

*Annex with photographs on next pages*

## Photographs of falsified "Mencevax" products

Fig. 1.: Falsified Mencevax, batch number AMEHA020AA

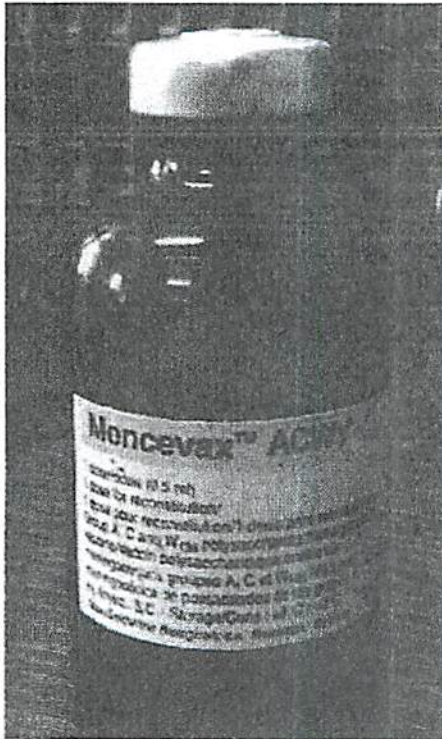


Fig. 2. : Falsified Mencevax, batch number AMENA020AA

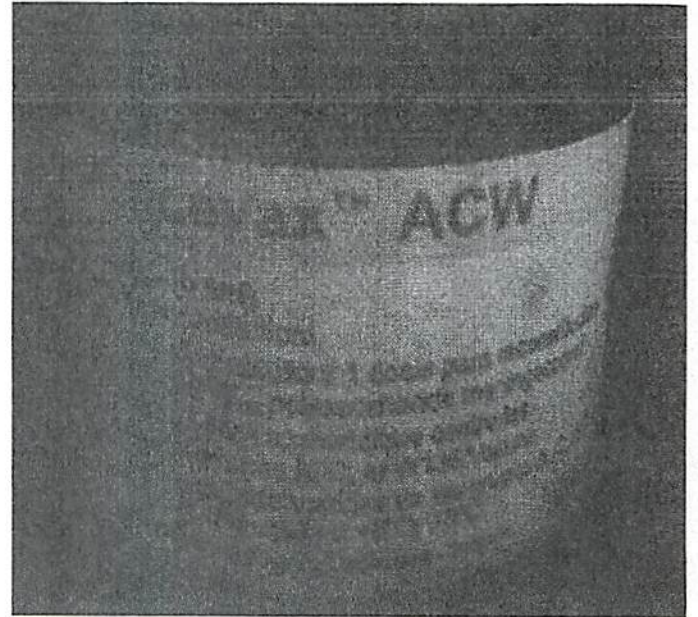
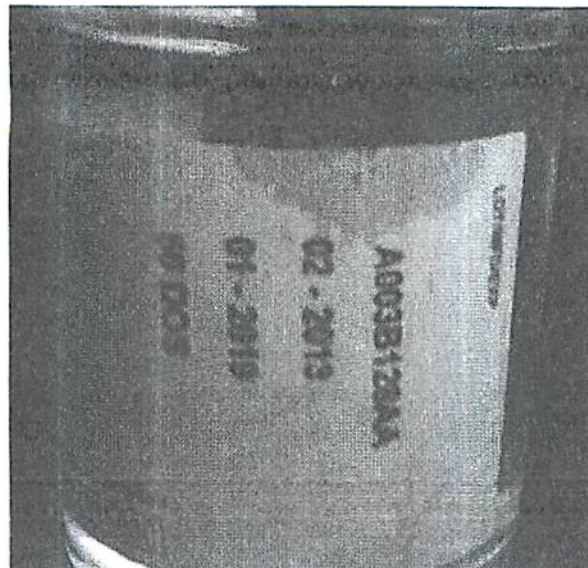


Fig. 3.: Falsified diluent for Mencevax, batch number A003B128AA





Ref. RHT/SAV/MD/3/2015

27<sup>th</sup> 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 22<sup>nd</sup> 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.

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.

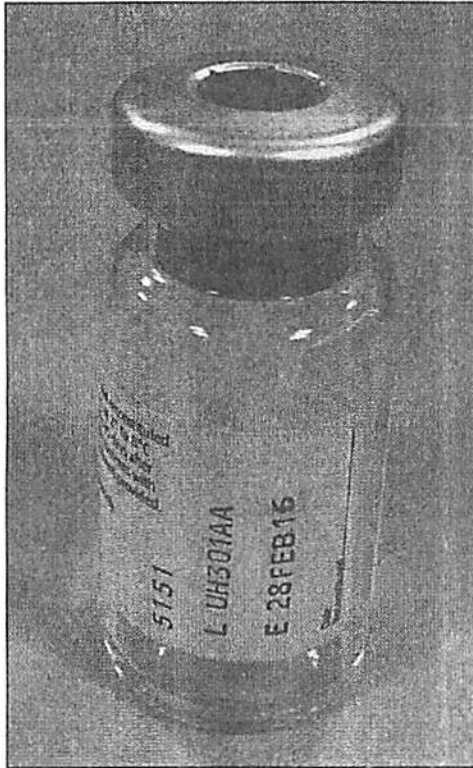
Authorities are asked to immediately notify WHO if these batches are discovered in your country via [rapidalert@who.int](mailto:rapidalert@who.int)

*Annex with photographs on next pages*

## Photographs of falsified “Menomune” Vaccines and Diluents

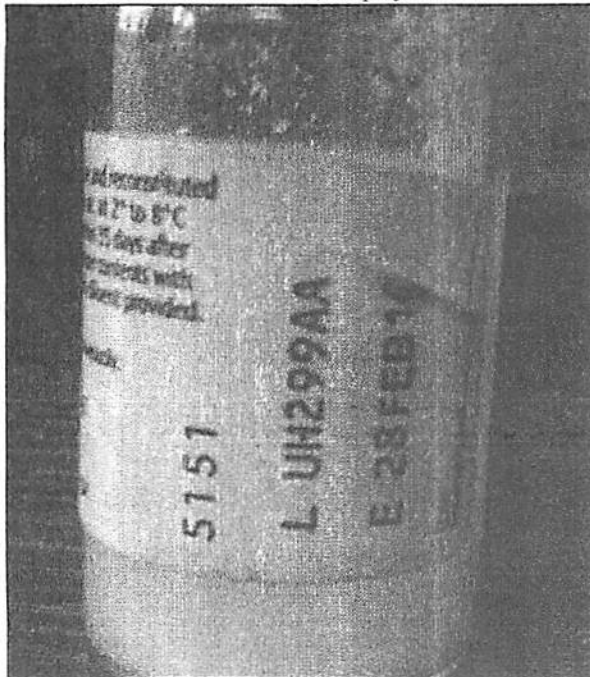
**Fig. 1: Menomune ACYW-135;**

Batch Number: UH301AA; Expiry Date: 28FEB16



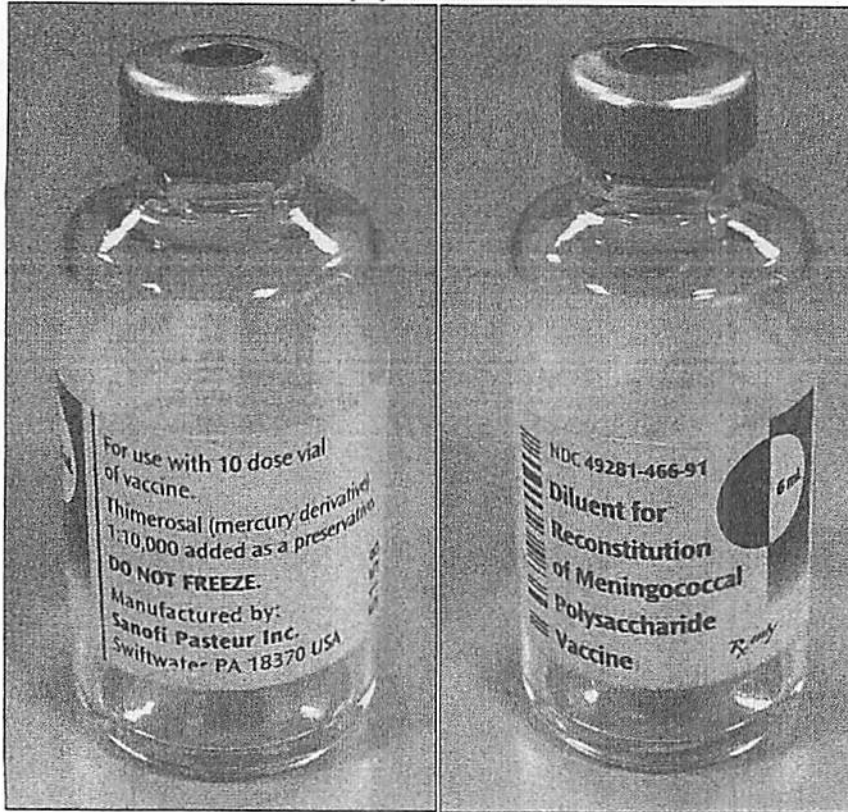
**Fig. 2: Menomune ACYW-135 ;**

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

