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受文者：新竹市藥師公會

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附件：

收文日期	104年 6月 10日		
批閱	理事長	常務理事	常務理事
	理事長 高偉權(印)		

批閱  
總幹事 陳來元

主旨：檢送案內所陳腦炎疫苗之偽造產品，「Menomune ACY-W135、Menomune ACYW-135」及其Diluent(稀釋液)等3品項5批次，於西非地區流通相關資料1份，為維護國民之健康與安全，本局將列入稽查，倘查獲違規情事依法處辦，請查照。

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

正本：新竹市醫師公會、新竹市藥師公會、新竹市藥劑生公會、新竹市西藥商公會  
副本：本局食品藥物管理科

## 局長何秉聖

本案依分層負責規定授權業務主管決行



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 diluents 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 diluents 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

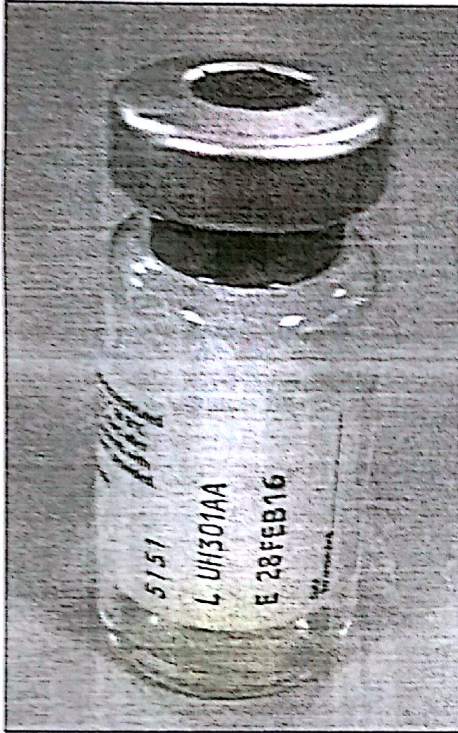
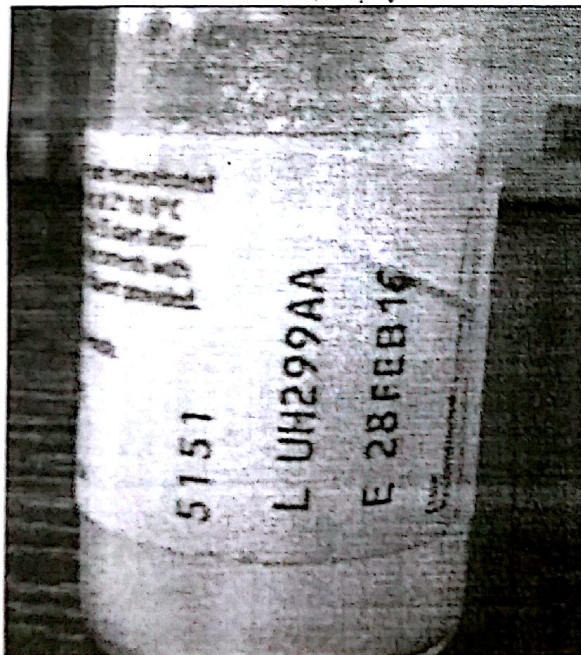


Fig. 2: Menomune ACYW-135 ;  
Batch Number: UH299AA ; Expiry Date: 28FEB16



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Fig. 4: Diluent for MenomuneACYW-135;

Batch Number: UH262AA; Expiry Date: 25OCT16

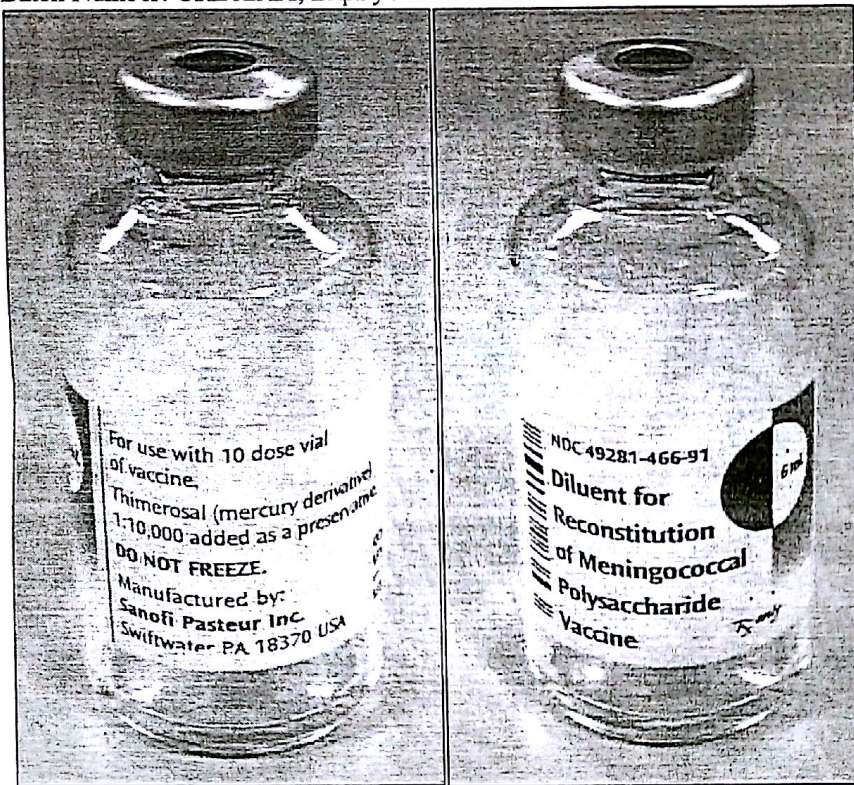
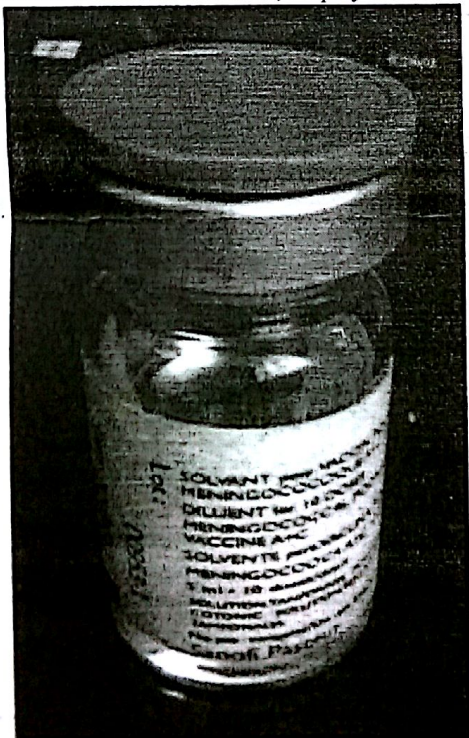


Fig. 5: Diluent for Menomune ACYW-135;

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



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