

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.

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

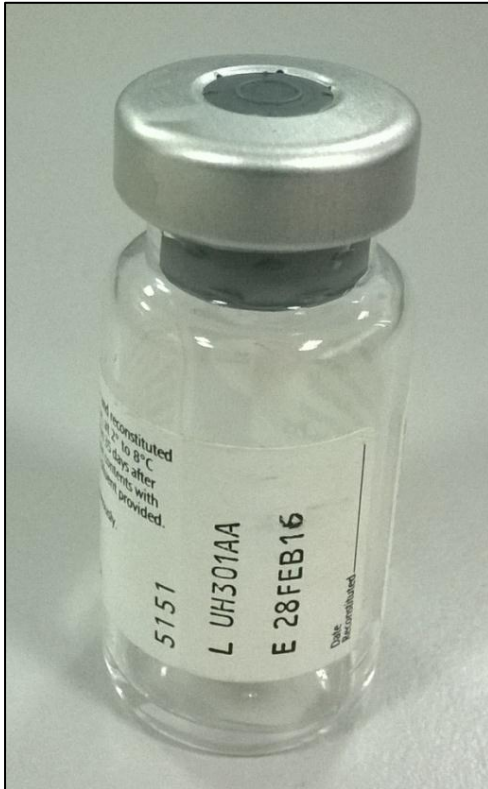


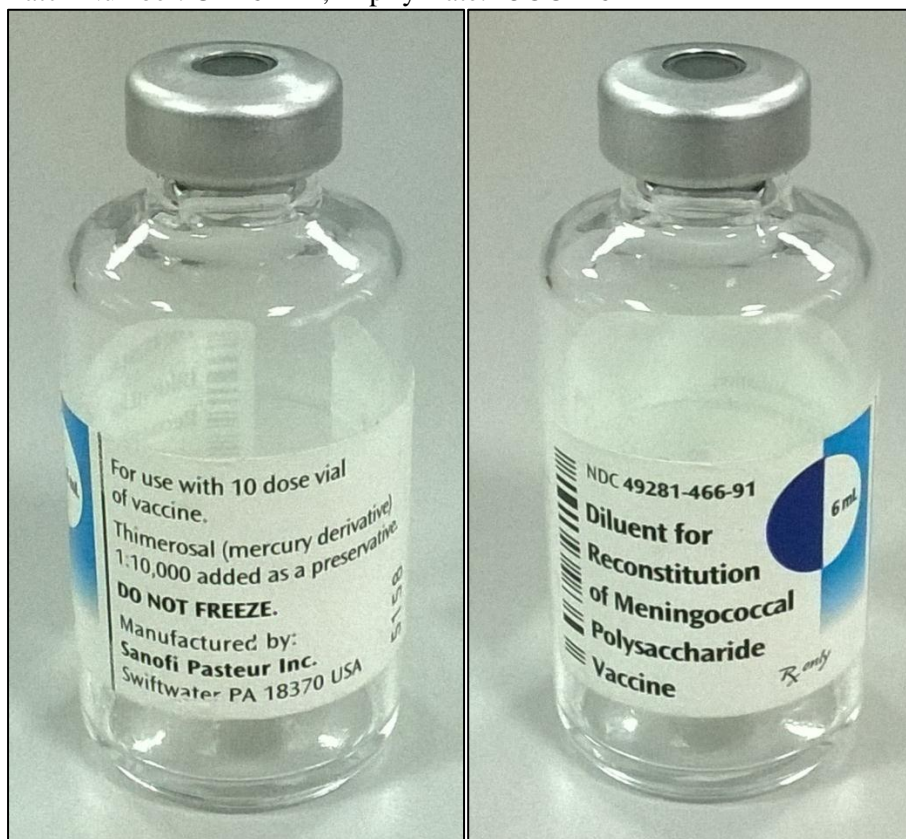
Fig. 2: Menomune ACYW-135 ;

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

