

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

