World Health Organization

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Ref. RHT/SAV/Alert n°1/2017 02 June 2017

Medical Product Alert N° 1/2017

Falsified Meningococcal ACWY Vaccine circulating in West Africa

This Medical Product Alert relates to the circulation of a confirmed falsified *Meningococcal ACWY Vaccine* discovered in Niger.

PRODUCT DETAILS

This product is used to immunise against Meningococcal disease serogroups A, C, W, and Y. Meningococcal meningitis vaccine is listed as a WHO Essential Medicine.

On 31 May 2017, the manufacturer "Bio-Manguinhos/Fiocruz" informed WHO that a falsified version of the following product was available in Niger:

Product Name	**Polysaccharide Meningococcal ACWY Vaccine**
Batch Number	089UMH002 Z
Expiry Date	092017
Date of Manufacture	092014

The label on the product claims that it is manufactured by Bio-Manguinhos/Fiocruz and is presented in vials of 10 doses each.
Photographs of the falsified vaccine are available in annex. This falsified product has not yet been subject to laboratory analysis.

The manufacturer Bio-Manguinhos/Fiocruz has stated that:

- They do not manufacture Polysaccharide Meningococcal ACWY Vaccine
- Based on examination of the photographs they can confirm that this packaging is falsified

No adverse events following immunisation attributed to this falsified vaccine are known to have been reported at this stage.

On the basis of the above information, any **Meningococcal ACWY** Vaccine claiming to be manufactured by "Bio-Manguinhos/Fiocruz", should be considered falsified and reported.

ADVICE TO HEALTH CARE PROFESSIONALS, PATIENTS AND NATIONAL AUTHORITIES

If you are in possession of this vaccine, please do not use, contact a healthcare professional as soon as possible for advice and report the incident to your local Ministry of Public Health / National Medicines Regulatory Authorities/ National Pharmacovigilance Centre.

Please seek immediate advice from a qualified healthcare professional if you have been immunised with this falsified vaccine, or if you suffer an adverse event following its immunisation, and report the incident as indicated above.

Members of the public who are aware of falsified medical products sold by various retailers should report to their national health authorities.

It is necessary to ensure that all medical products are obtained from authentic and reliable sources. Their authenticity and origin should be carefully checked and verified with manufacturers before use.
WHO requests increased vigilance for the supply chains of countries likely to be affected by these falsified products. Vigilance should include hospitals, clinics, pharmacies and any other suppliers of medical products.

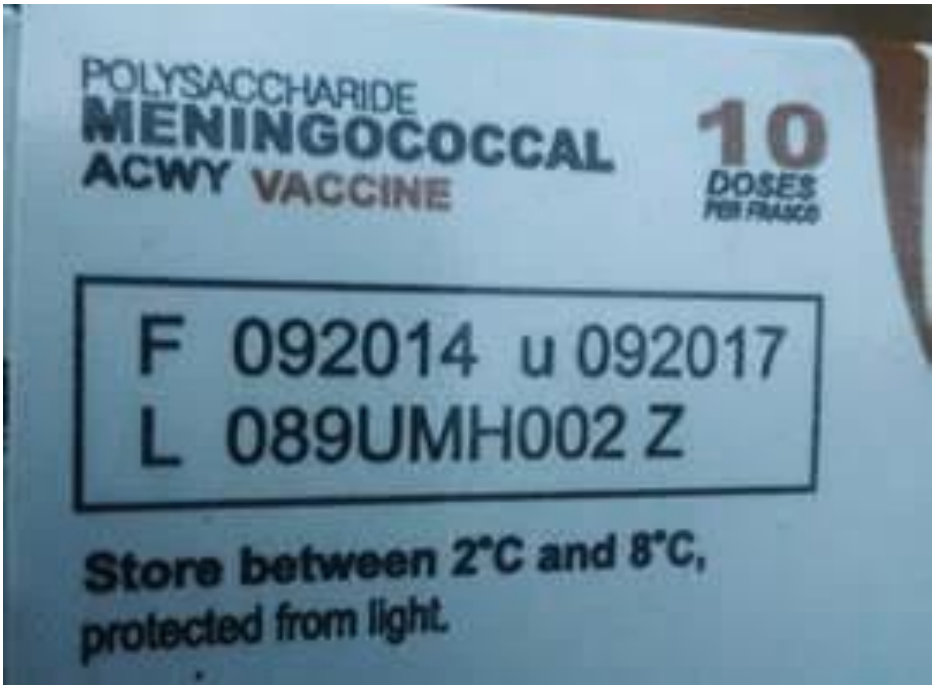
Authorities are asked to immediately notify WHO if these falsified products are discovered in their country. If you have any information on their supply and/or distribution please contact rapidalert@who.int

WHO will issue Medical Product Alerts to ensure a timely, proportionate, accurate and consistent response to health events arising from substandard and falsified medical products which represent a significant threat to international public health. Alerts will be published on the WHO website, and will remain on the website for a period of 5 years before archiving. Alerts may also be disseminated to the current known networks of National Medicines Regulatory Authorities dealing with defective medicines, International Health Regulation Focal Points, substandard and falsified surveillance and monitoring focal points and National pharmacovigilance and vaccine networks.

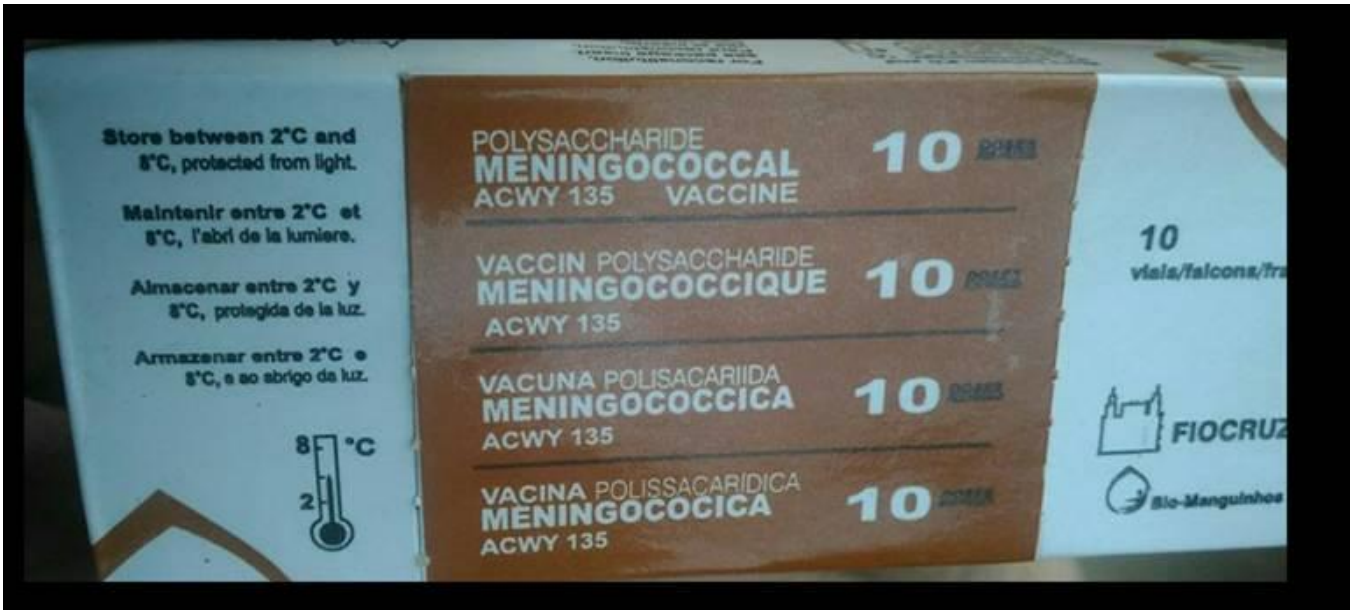
WHO Global Surveillance and Monitoring System
Substandard and Falsified Medical Products
All WHO Medical Product Alerts are available at the following link:
http://www.who.int/medicines/publications/drugalerts/en/

ANNEX WITH PHOTOGRAPHS

1.



2.



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