正本

檔　　號：
保存年限：

# 新北市政府衛生局　函

地址：22006新北市板橋區英士路192-1號
承辦人：江佳穎
電話：(02)22577155 分機2353
傳真：(02)22536548
電子信箱：AQ5750@ntpc.gov.tw

24158
新北市三重區重新路5段646號8樓
受文者：新北市藥師公會

發文日期：中華民國106年6月13日
發文字號：新北衛食字第1061079903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1份

裝

主旨：檢送案內所陳「腦膜炎疫苗」及「Harvoni」（Bulk批號16SFC021，二級包裝批號16SFC021D）」警訊相關資料1份，為維護國民之健康與安全，請轉知所屬會員勿販售供應與使用，請查照。

說明：

一、依據衛生福利部食品藥物管理署105年6月5日FDA企字第1061201932號函及106年6月6日FDA企字第1061201934號函辦理。

訂

二、檢附案內相關資料1份。

正本：社團法人新北市醫師公會、新北市藥師公會、新北市藥劑生公會、新北市西藥商業同業公會、新北市商業會
副本：新北市政府衛生局衛生稽查科(含附件)

局長 林奇宏

線

本案依分層負責規定授權業務主管決行

檔　　號：
保存年限：

# 衛生福利部食品藥物管理署　函

地址：11561 臺北市南港區昆陽街161-2號
聯絡人：莊東憬
聯絡電話：02-27877243
傳真：02-26532055
電子信箱：dpqbdpqb@fda.gov.tw

受文者：新北市政府衛生局

發文日期：中華民國106年6月5日
發文字號：FDA企字第1061201932號
速別：普通件
密等及解密條件或保密期限：
附件：資料1份(A21020000I106120193200-1.pdf)

主旨：檢送案內所陳「腦膜炎疫苗」警訊相關資料1份，依通報資料所示，該產品在奈及利亞發現偽品流通，為維護國民之健康與安全，請將該產品於市面可能販售及網路刊售之情事列入稽查工作重點，查明依法處辦，請 查照。

說明：依據本署106年6月3日接獲轉知WHO通報藥品警訊相關資料辦理。

正本：地方政府衛生局
副本：



*1061201932*

World Health Organization

20 Avenue Appia – CH-1211 Geneva 27 – Switzerland – Tel central +41 22 791 2111 – Fax central +41 22 791 3111 – www.who.int

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.

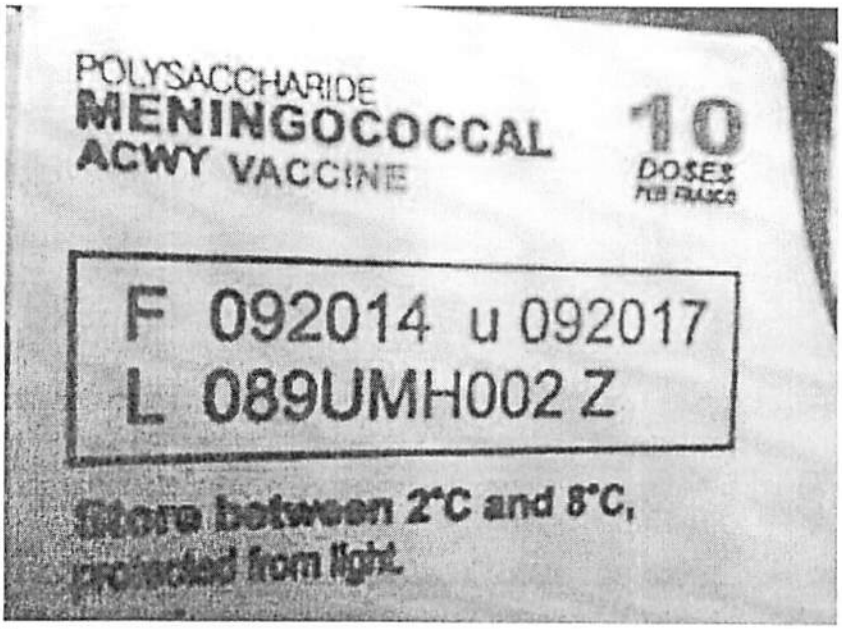
**WHO Global Surveillance and Monitoring System**
**Substandard and Falsified Medical Products**
**All WHO Medical Product Alerts are available at the following link:**
**http://www.who.int/medicines/publications/drugalerts/en/**

World Health Organization

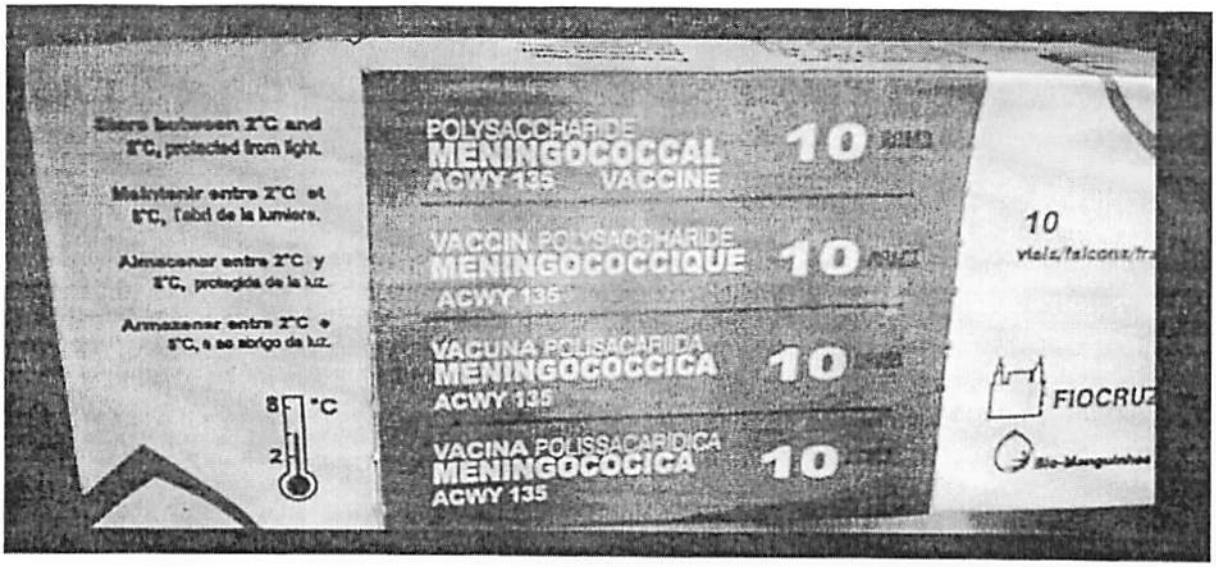
20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

## ANNEX WITH PHOTOGRAPHS

1.




2.

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速別：普通件
密等及解密條件或保密期限：
附件：資料1份(A21020000I106120193400-1.pdf)

主旨：檢送案內所陳藥品「Harvoni」（Bulk批號16SFC021，二級包裝批號16SFC021D）」警訊相關資料1份，該產品在德國發現疑似偽品流通，為維護國民之健康與安全，請將該產品於市面可能販售及網路刊售之情事列入稽查工作重點，查明依法處辦，請查照。

說明：依據本署106年6月3日接獲德國Federal Institute for Drugs and Medical Devices (BfArM)經PIC/S Rapid Alert System通報藥品警訊相關資料辦理。

正本：地方政府衛生局
副本：本署風險管理組、本署藥品組 電子公文交換章 2017-06-07 08:39:59



*1061201934*

RAS-Formular für Risikoklasse I oder II und für follow-up-Meldungen

**DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY**

## Rapid Alert Notification of a Quality Defect / Recall

Add Letter Head of Sender / Meldende Stelle

| 1. To / Empfänger: | | FAX |
|---|---|---|
| ☒ | Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) | 0228-207-4636 |
| ☐ | Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) | 030-18444-30409 |
| ☐ | Paul-Ehrlich-Institut - Bundesamt für Sera und Impfstoffe - (PEI) | 06103/77-1263 |
| ☐ | Oberste Landesgesundheitsbehörde | |
| ☐ | Oberste Landesveterinärbehörde | |

| 2. Product Recall Class of Defect: I II (circle one) | 3. Falsification/Fraud (specify)* Suspected Falsification |
|---|---|
| 4. Product: Harvoni® 90 mg/400 mg | 5. Marketing Authorisation Number: * For use in humans/~~animals~~ (delete as required) |
| 6. Brand/Trade Name: Harvoni | 7. INN or Generic Name: Sofosbuvir, Ledipasvir |
| 8. Dosage Form: Solid Oral Dosage Form | 9. Strength: Sofosbuvir 400 mg / Ledipasvir 90mg |
| 10. Batch number (and bulk, if different): 16SFC021 (bulk) 16SFC021D (Secondary packaged product) | 11. Expiry Date: June 2018 |
| 12. Pack size and Presentation: A carton containing a High density polyethylene (HDPE) bottle with a polypropylene child-resistant closure with an induction seal, containing 28 film-coated tablets, polyester fibre and a silica gel desiccant | 13. Date Manufactured: 15 June 2016 |

14. Marketing Authorisation Holder:

Gilead Sciences Cambridge International Ltd

Cambridge

CB21 6GT

UK

15. Manufacturer†:

Gilead Sciences Ireland UC

IDA Industrial Estate

Carrigtohill

Co. Cork

Ireland

Contact Person: Ruth Gould

Telephone: + 353 (21) 4825506

16. Recalling Firm (if different):

Gilead Sciences GmbH, Martinsried

Contact Person: Tanja Rohkamm

Telephone: +49 (89) 89989028

17. Recall Number Assigned (if available): -

18. Details of Defect/Reason for Recall:

A suspected falsification of the medicinal product Harvoni® 90 mg / 400 mg film coated tablets from the company Gilead, which has reached the German market and was discovered in a pharmacy in North-Rhine-Westphalia.

The tablets are not orange as specified, but white. The packages bear the Lot number 16SFC021D (expiry date 06/2018), which is a real existing lot for the German market. The falsified tablets only differ from the original in the white colour. The package of the tablets as well as the form and embossing of the tablets match the original.

The origin of the suspected falsification as well as the content of the tablets are currently under investigation.

Currently the known supply chain is:

1. Lopstar Pharma Solutions Unipessoal LDA. Portugal
2. Pharma World 24 B.V. (Celesiusweg 32-38, 5928 PR Venlo, Netherlands)
3. Herz Apotheke Berlin, Bad Str. 57-58, 13357 Berlin, Germany (Pharmacy with WDA)
4. Haemato Pharm GmbH, Germany
5. Phoenix Pharma-Einkauf GmbH Mannheim, Germany
6. Phoenix Pharmahandel Vertriebszentrum Herne, Germany

The Supplier of Lopstar (Portugal) is unknown.

| | | |
|---|---|---|
| 19. Information on distribution including exports (type of customer, e.g. hospitals): *<br>The bulk-batch (16SFC021) was distributed to following countries:<br>Germany, Turkey, Ireland, Netherlands, Poland, France, Italy, Singapore, Slovakia, Czech Republic, Great Britain, Israel and Spain | | |
| 20. Action taken by Issuing Authority:<br>Information of BfArM and EMA<br>Initiation of Recall (Immediate information on the websites of AMK, PHAGRO-System, Publication in the pharmaceutical press (PZ/DAZ)<br>Initiation of sampling | | |
| 21. Proposed Action:<br>Surveillance of Recall | | |
| 22. From (Issuing Authority):<br>Government of Upper Bavaria<br>Maximilianstraße 39<br>80538 Munich | | 23. Contact Person:<br>Dr. Gabriele Wanninger<br>Telephone:<br>+49 89 2176 2171 |
| 24. Signed: | 25. Date: 02.06.2017 | 26. Time: * |

* Information not required, when notified from outside EU.

† The holder of an authorisation referred to under Article 40 of Directive 2001/83/EC or Article 44 of Directive 2001/82/EC and the holder of the authorisation on behalf of whom the Qualified Person has certifiedthe batch for release in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.