Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. **2016-043**

18 MAY 2016

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Advisory on World Health Organization's Medical Product Alert No. 1/2016 Re: Falsified Phenobarbitone Tablets Circulating in West Africa**

The Food and Drug Administration (FDA) hereby informs the public that the World Health Organization (WHO) has recently issued Medical Product Alert No. 1/2016 regarding falsified Phenobarbitone circulating in West Africa with the following details:

PRODUCT	SOURCE	BATCH NUMBER	MANUFACTURING DATE	EXPIRY DATE
PHENOBARBITONE (PHENOBABBITONE) 100 mg TABLET	**Liberia**	**2081**	**7-2012**	**6-2016**
	Guinea Bissau		**7-2010**	**6-2014**

(Attached is a copy of the WHO Alert)

Based on FDA records, the aforementioned product is an unregistered drug product. Further, as stated in the WHO Alert, the manufacturer (Mejoc Pharm and Chemical - 28 Crosby Avenue, Swipzeland) is non-existent and the labeling contains misspelled words.

All healthcare professionals and the general public are hereby warned to be vigilant of the falsified Phenobarbitone (Phenobabbitone) 100 mg Tablet that may reach the Philippine market. The presence of this identified product poses potential danger or injury to the consuming public and the importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009.

In the interest of protecting public health and safety, the Officers of the Field Regulatory Operations Office (FROO) are hereby mandated to exercise their regulatory function pursuant to Section 14 of Republic Act No. 9711.

All establishments and outlets are hereby warned against selling and/or dispensing the identified product. Anyone found selling the said product will be penalized.

Likewise, all local government units and law enforcement agencies are requested to ensure that this product is not sold or offered for sale in their localities or area of jurisdiction.

All consumers are advised to purchase their medications only from FDA-licensed establishments. Please note that in addition to inspection of establishments, product evaluation, registration, and testing are measures that the government undertakes to ensure the quality, safety, and efficacy of health products. Moreover, please be reminded that drug products registered with FDA Philippines bear in their labels information in English and/or in Filipino for all consumers to understand.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly e-mail us via report@fda.gov.ph or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report immediately to FDA through our website: www.fda.gov.ph. Look for the ADR Report tab and fill out all the required fields.

Dissemination of the information to all concerned is requested.

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OIC, Director General

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World Health Organization

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Ref. RHT/SAV/Alert 1.2016 05 February 2016

Medical Product Alert N° 1/2016

Falsified phenobarbitone tablets circulating in West Africa

This Medical Product Alert relates to the circulation of falsified versions of phenobarbitone (also known as phenobarbital) in West Africa.

Phenobarbital is used as a treatment against epilepsy and is frequently dispensed free of charge in community-care health centres.

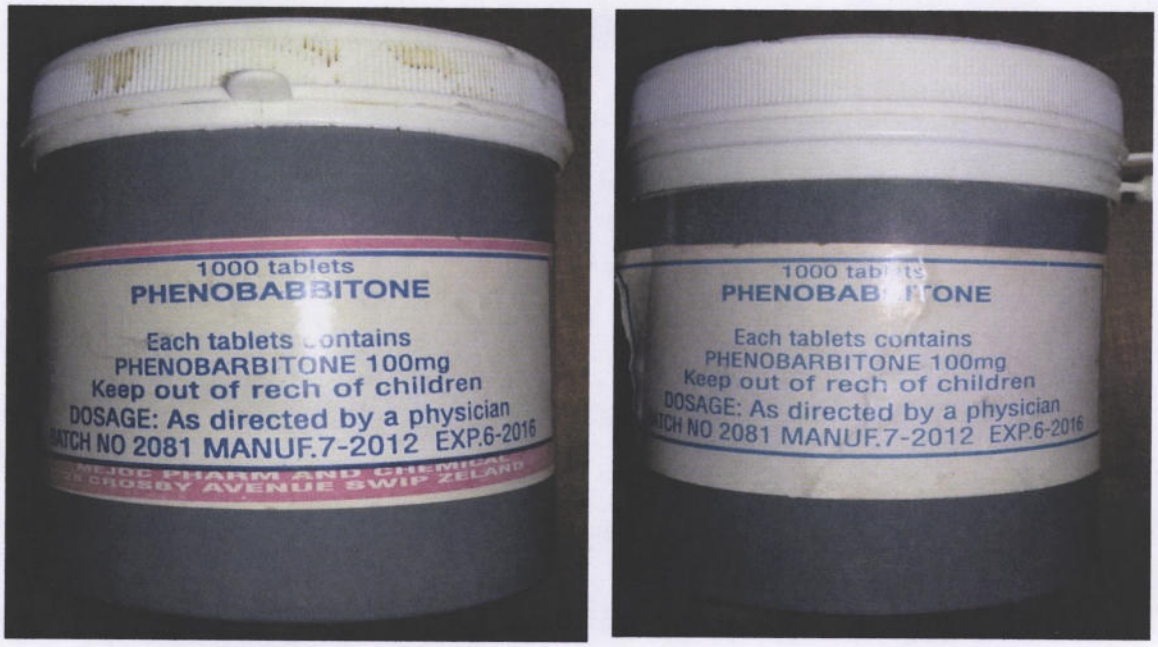
In December 2015, the Liberia Medicines and Health Products Regulatory Authority (LMHRA) notified WHO of two suspect products that supposedly contain tablets of 100 mg of phenobarbitone.

These products were detected through a lack of efficacy (patients treated for epilepsy had an increased recurrence of seizures during the course of their treatment with these products).

Product Name:	Phenobabbitone
Batch Number:	2081
Manufacturing Date:	7-2012
Expiry Date:	6-2016
Manufacturer:	Mejoc Pharm and Chemical

Note that the manufacturer name only appears on one of the two containers (see photographs below). The name and address of the Manufacturer does not exist and the labelling contains spelling errors.

"Phenobabbitone" discovered in 2015 in Liberia:

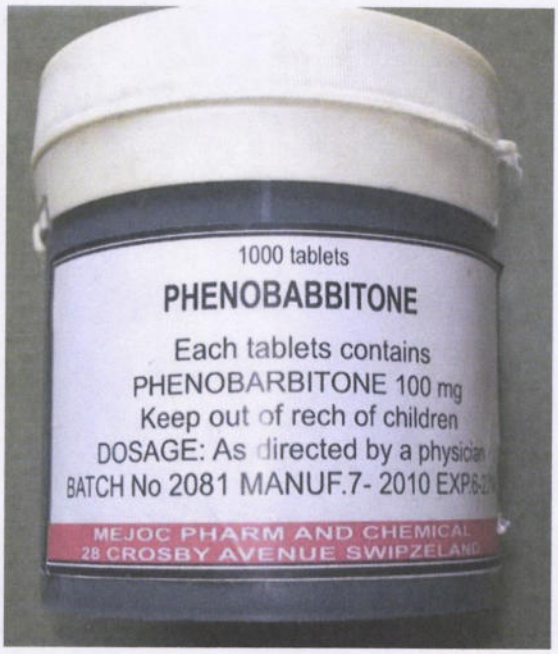


Investigation of the WHO SSFFC Medical Products database identified that a similar product was found in Guinea Bissau in 2013, with almost identical packaging and labelling and bearing the same batch number. The product found in Guinea Bissau was tested by an independent laboratory and analysis indicated that the product contained no active pharmaceutical ingredient. Authorities in Guinea Bissau had been notified.

This product was also detected through a lack of efficacy (patients treated for epilepsy had an increased recurrence of seizures during the course of their treatment with these products).

Product Name: Phenobabbitone
Batch Number: 2081
Manufacturing Date: 7-2010
Expiry Date: 6-2014
Manufacturer: Mejoc Pharm and Chemical
The packaging also contains spelling mistakes.

"Phenobabbitone" discovered in Guinea Bissau in 2013:



WHO requests increased vigilance within the supply chains of countries likely to be affected by these falsified products. That vigilance should include hospitals, clinics and pharmacies in addition to drug stores, street markets and roadside vendors.

If you are in possession of the same products as shown above, please do not use, contact a Pharmacist or a Doctor as soon as possible for advice and report the incident to your National Medicines Regulatory Authority.

If you think you have taken this product, please seek medical advice immediately.

If you have any information concerning the supply of this product please contact rapidalert@who.int

WHO Surveillance and Monitoring – Rapid Alert

Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) Medical Products

All WHO Drug Alerts are available at the following link:
http://www.who.int/medicines/publications/drugalerts/en/