World Health Organization

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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.

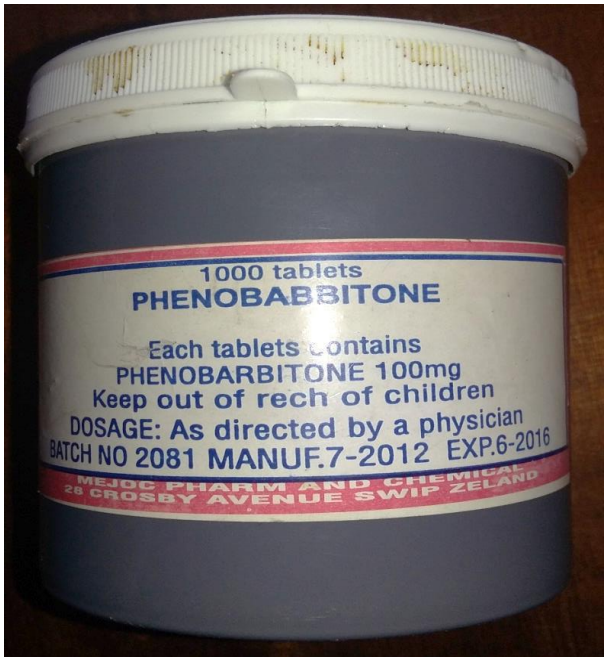
In December 2015, the Liberia Medicines and Health Products Regulatory Authority (LMHRA) notified WHO of two suspect products that supposedly contain tablets of 100 mg of phenobarbitone.

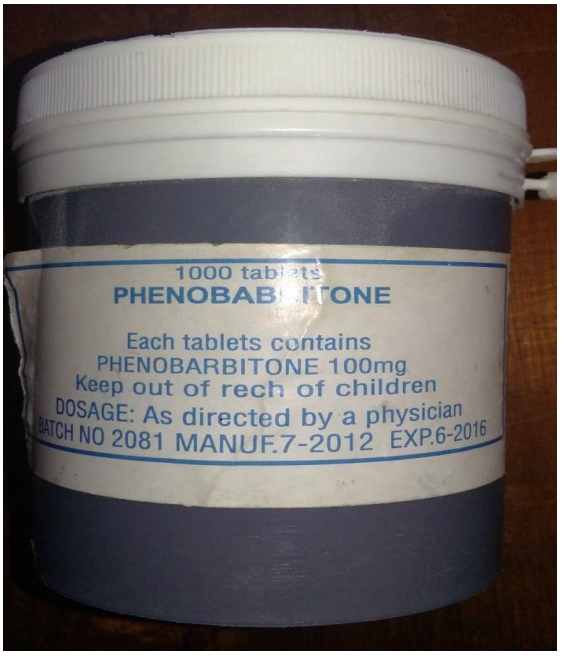
These products were detected through a lack of efficacy (patients treated for epilepsy had an increased recurrence of seizures during the course of their treatment with these products).

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:



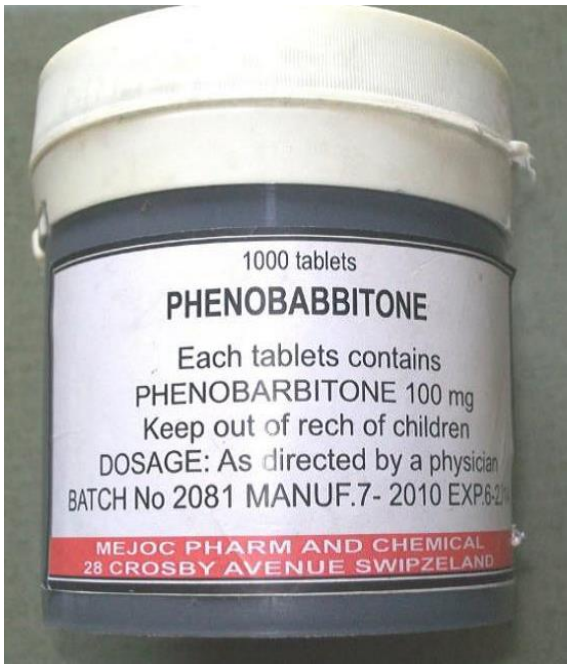


Investigation of the WHO SSFFC Medical Products database identified that a similar product was found in Guinea Bissau in 2013, with almost identical packaging and labelling and bearing the same batch number. The product found in Guinea Bissau was tested by an independent laboratory and analysis indicated 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/