Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

30 JUL 2015

FDA ADVISORY
No. 2015-053

SUBJECT: **Public Health Advisory on World Health Organization's Medical Product Alert No. 4/2015 Re: Adverse Reactions caused by Falsified Diazepam in Central Africa**

The Food and Drug Administration (FDA) hereby informs the public that the World Health Organization (WHO) has recently issued Medical Product Alert No. 4/2015 regarding adverse reactions caused by the following falsified Diazepam Tablets in Central Africa:

Product	Batch No.	Mfg. Date	Exp. Date
Diazepam BP 5 mg Tablet (Solina)	SBG038	Sep 2014	Aug 2017
Diazepam BP 5 mg Tablet (Diazpam Tablets)	2332	Nov 2013	Oct 2016

(Attached is a copy of the WHO Medical Product Alert)

The said products have caused acute dystonic reaction affecting the muscles of the face, neck and tongue to over 400 patients in the north east region of the Democratic Republic of Congo. The reaction usually lasts, without treatment, for between 3 to 4 days, sometimes re-occurs, and has resulted in up to 40 hospital admissions per week.

All health care professionals and the general public are hereby warned to be vigilant of the mentioned falsified products that may reach the Philippine market. The presence of these products poses 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, and the Republic Act 8203 or the Special Law on Counterfeit Drugs.

In the interest of protecting public health and safety, and pursuant to Section 12 of R.A. No. 9711, the Field Regulatory Operations Office (FROO) officers are hereby ordered to seize the aforementioned falsified drug products found in the market.

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

Likewise, all local government units and law enforcement agencies are requested to ensure that these products are 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. Please look for the FDA Registration number on the product label. 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 email us at info@fda.gov.ph. To report continuous sale or distribution of falsified health products, kindly email us via report@fda.gov.ph or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), please report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

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Secretary of Health
Acting Director General[1]

DTN: 20150710094637

[1] Pursuant to DPO 2015-1845

World Health Organization

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Ref. RHT/SAV/MD/4/2015

2nd July 2015

Medical Product Alert No. 4/2015

Adverse reactions caused by Falsified Diazepam in Central Africa

This Medical Product Alert relates to the confirmed circulation of falsified versions of Diazepam tablets circulating in Central Africa.

Since December 2014, over 400 patients in the north east region of the Democratic Republic of Congo (DRC) have suffered from an acute dystonic reaction affecting the muscles of the face, neck and tongue. This reaction usually lasts, without treatment, for between 3 to 4 days, sometimes re-occurs, and has resulted in up to 40 hospital admissions per week. A detailed investigation carried out in DRC has revealed that patients had been taking Diazepam to treat a wide range of illnesses.

PRODUCT ONE

Laboratory analysis of a product labelled as Diazepam has shown that it does not contain Diazepam, but contains between 10mg to 20mg of Haloperidol per tablet.

Haloperidol is an antipsychotic and is used primarily for the treatment of schizophrenia, and one of the known side effects is acute dystonic reactions affecting the face and neck. So far, all known patients suffering a reaction have recovered. However the levels of Haloperidol present in the tablets represent a serious risk particularly to the young.

The details of this product are as follows:

The tablets are light yellow in colour and are scored across the centre of the tablet on one side and bear the letters AGOG on the other side (see figure 1):

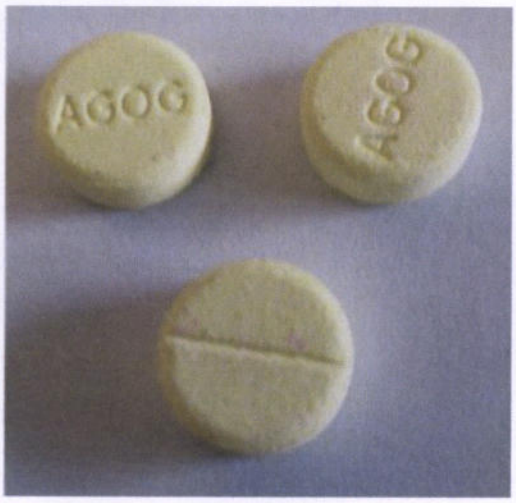

Figure 1

AGOG is a pharmaceutical manufacturer. They have stated that they manufacture Haloperidol tablets which are yellow in colour and bear the letters AGOG, but it is supplied in blisters of 10 tablets and boxes of 10 blisters under the trade name *AGOHAL, Haloperidol tablet BP 10mg*. AGOG Pharma Ltd have stated that they do not manufacture Diazepam.

The tablets that tested positive for Haloperidol were contained in white plastic bottles of 1000 tablets and marked with the trade name *SOLINA* and '*Diazepam Tablets BP 5 mg*' manufactured by CENTAUR Pharmaceuticals Ltd. (See figure 2).

Trade Name:	**SOLINA**
Product:	**Diazepam BP 5 mg**
Batch Number:	**SBG038**
Manufacturing Date:	**Sep 2014**
Expiry Date:	**Aug 2017**

CENTAUR pharmaceuticals have confirmed that they manufacture Diazepam and that the batch number, and dates of manufacturing and expiry are correct as shown on the packaging.

CENTAUR pharmaceuticals have stated that they do not manufacture Haloperidol. The tablets contained in the plastic bottles were not manufactured by CENTAUR pharmaceuticals and do not contain diazepam The plastic bottle is stamped in red ink *'Government of Uganda. For public use only, not for sale'*.

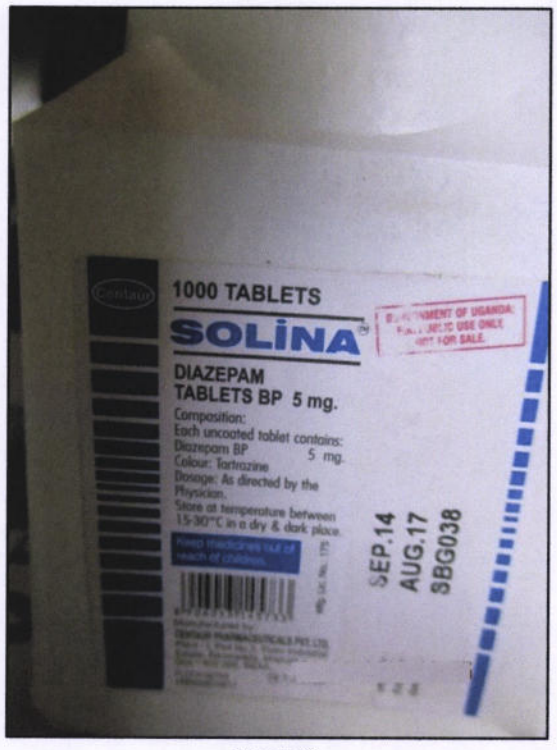

Figure 2

This product is circulating in the Ituri Health District of the Democratic Republic of Congo and the adverse reactions have been focused in the vicinity of Nono

WHO are requesting urgent vigilance for these tablets and careful examination of the contents of bottles marked *SOLINA, Diazepam 5mg*, as they should not contain tablets marked with the lettering AGOG.

PRODUCT TWO

The following version of falsified Diazepam is also circulating in the Democratic Republic of Congo in containers of 1000 tablets. They are labelled as manufactured by AGOG Pharma Ltd, and again contain yellow tablets bearing the lettering AGOG (See figure 3).

AGOG pharma have confirmed that this packaging and labelling is falsified, and that they do not manufacture Diazepam. The tablets have not yet undergone laboratory analysis, but on the basis of confirmation that the labelling is falsified WHO request increased vigilance for the following batch:

Trade Name:	**DIAZPAM TABLETS**
Product:	**Diazepam BP 5 mg**
Batch Number:	**2332**
Manufacturing Date:	**Nov 2013**
Expiry Date:	**Oct 2016**

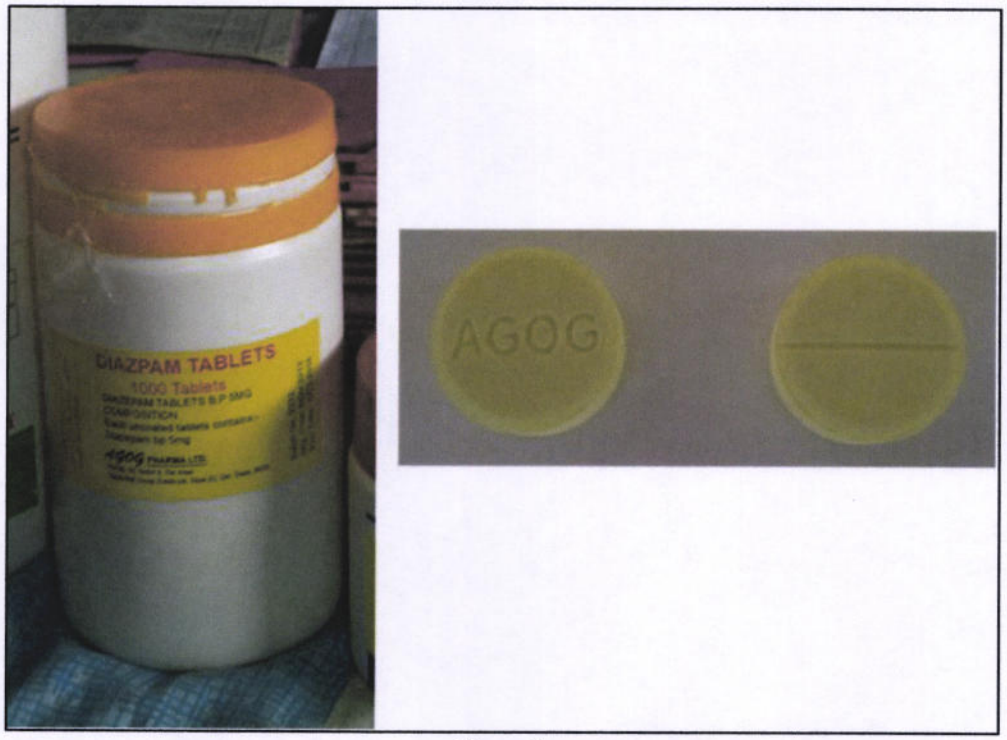

Figure 3

If you are in possession of the tablets shown in the photographs or containers bearing the batch number shown above please do not use them, contact a Pharmacist or Doctor as soon as possible for advice and report the incident to the National Medicines Regulatory Authority/ National Pharmacovigilance Centre. If you think you have taken this product please seek medical advice immediately.

If you have any information concerning the supply of these products 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/