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/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):

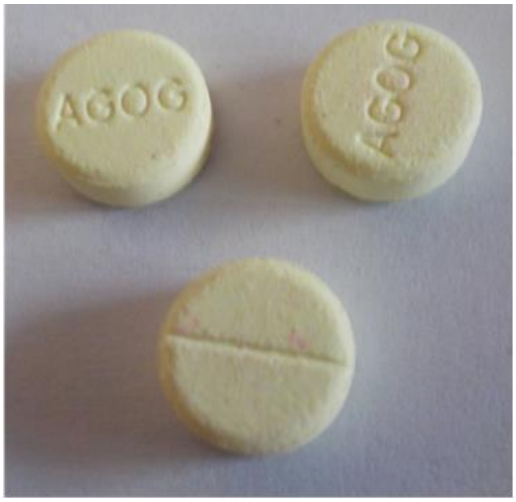

Figure 1

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'*.

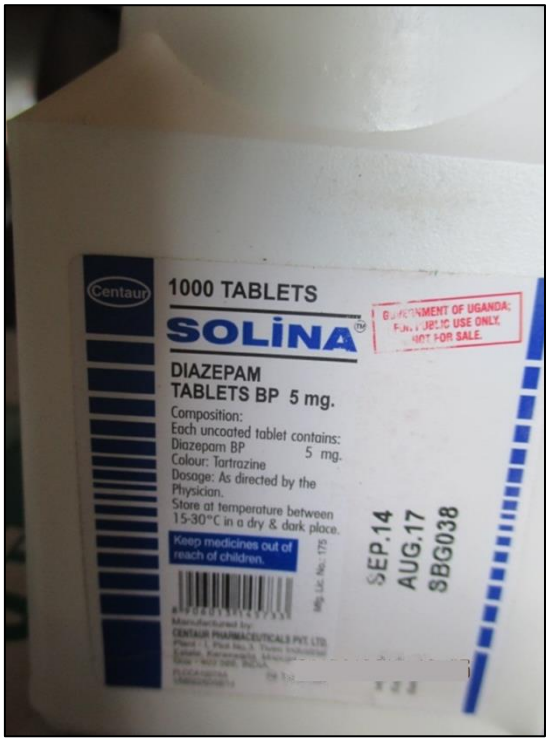

Figure 2

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