

正本

檔 號：
保存年限：

753

新北市政府衛生局 函

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24158

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受文者：新北市藥師公會

發文日期：中華民國104年7月14日
發文字號：新北衛食字第1041287468號
速別：普通件
密等及解密條件或保密期限：
附件：原函及相關資料影本各1份

主旨：檢送有關「DIAZPAM TABLETS」及「SOLINA」等2款含Diazepam西藥成分之仿冒品於中非地區流通及「Herceptin（批號H4361B02）」不良品暨回收警訊相關資料1份，為維護國民之健康與安全，惠請轉知所屬會員，如有案內違規產品應立即下架勿販售，請查照。

說明：依據衛生福利部食品藥物管理署104年7月9日FDA企字第1041203059號函及104年7月9日FDA企字第1041203063號函辦理。

正本：新北市藥師公會
副本：

局長 林奇宏

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
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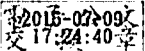
受文者：新北市政府衛生局

發文日期：中華民國104年7月9日
發文字號：FDA企字第1041203059號
速別：普通件
密等及解密條件或保密期限：
附件：資料1份(104120305900-1.pdf)

主旨：檢送案內所陳「DIAZPAM TABLETS」及「SOLINA」等2款含
Diazepam西藥成分之仿冒品，於中非地區流通相關資料1
份，為維護國民之健康與安全，請將該等產品於市面可能
販售及網路刊售之情事列入稽查，查明依法處辦，請 查照

說明：依據本署104年7月7日接獲WHO EIS公布中非地區現正流通
diazepam之仿冒藥品訊息相關資料辦理。

正本：各縣市衛生局

副本：



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):

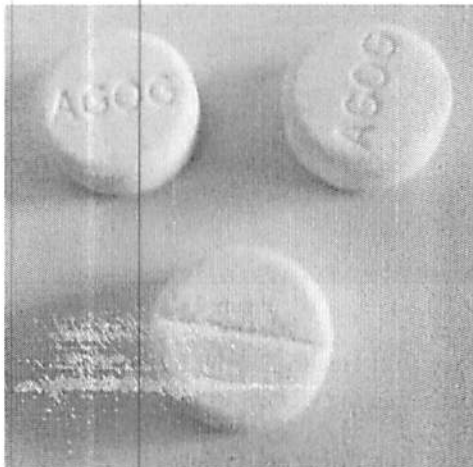


Figure 1

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).

<i>Trade Name:</i>	SOLINA
<i>Product:</i>	Diazepam BP 5 mg
<i>Batch Number:</i>	SBG038
<i>Manufacturing Date:</i>	Sep 2014
<i>Expiry Date:</i>	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:

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

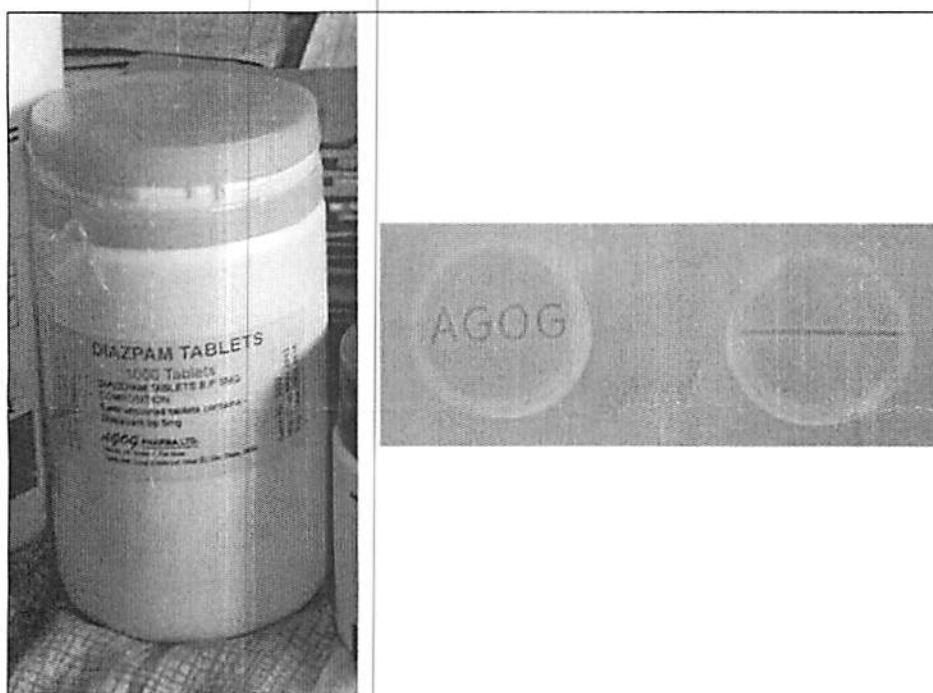


Figure 3

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/>

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受文者：新北市政府衛生局

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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(104120306300-1.pdf)

主旨：檢送案內所陳藥品「Herceptin (批號H4361B02)」不良
品暨回收警訊相關資料1份，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104年7月6日接獲克羅埃保加利亞Bulgarian Drug Agency經PIC/S Rapid Alert System通報藥品不良品暨
回收警訊相關資料辦理。

正本：各縣市衛生局

副本：