正本

檔　　號：
保存年限：

新北市政府衛生局　函

地址：22006新北市板橋區英士路192-1號
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24158
新北市三重區重新路5段646號8樓
受文者：新北市藥師公會

發文日期：中華民國106年8月31日
發文字號：新北衛食字第1061683854號
速別：普通件
密等及解密條件或保密期限：
附件：案內相關資料1份

主旨：檢送案內所陳偽藥「Avastin(主成分bevacizumab)400mg tablets」及「Sutent(主成分sunitinib malate)12.5mg tablets」標示由AstraZeneca公司製造之警訊相關資料1份，為維護國民之健康與安全，請轉知所屬會員勿販售供應與使用，請查照。

說明：

一、依據衛生福利部食品藥物管理署106年8月24日FDA企字第1061203046號函辦理。

二、檢附案內相關資料1份。

正本：新北市藥師公會、新北市藥劑生公會、社團法人新北市醫師公會、新北市西藥商業同業公會、新北市商業會
副本：新北市政府衛生局衛生稽查科(含附件)

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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電子信箱：mcj@fda.gov.tw

受文者：新北市政府衛生局

發文日期：中華民國106年8月24日
發文字號：FDA企字第1061203046號
速別：普通件
密等及解密條件或保密期限：
附件：相關資料1份(A21020000I106120304600-1.pdf)

主旨：檢送案內所陳偽藥「Avastin(主成分bevacizumab)400mg tablets」及「Sutent(主成分sunitinib malate)12.5mg tablets」標示由AstraZeneca公司製造之警訊相關資料1份，發現在烏干達流通，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，並週知轄區醫療院所、藥局知悉，請查照。

說明：

一、依據本署106年8月20日接獲疾管署轉WHO公布偽藥警訊及相關資料電子郵件辦理。

二、經查旨揭2項主成分，本署核准之藥品許可證資料簡述如下：

(一)Avastin(bevacizumab)25mg/ml Injection(衛署菌疫輸字第000807號)，製造廠為ROCHE公司。

(二)Sutent(sunitinib malate)12.5mg Capsules(衛署藥輸字第024593號)，製造廠為PFIZER公司。

正本：地方政府衛生局
副本：本署風險管理組、本署藥品組 電20170824 交15:35:35章

1061203046

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/Alert 3.2017 18 August 2017

Medical Product Alert N° 3/2017

Falsified Avastin (bevacizumab) and Sutent (sunitinib malate) circulating in East Africa

This Medical Product Alert relates to two falsified medicines discovered by the National Drug Authority, Uganda and reported to WHO.

In July 2017 falsified versions of Avastin (bevacizumab) and Sutent (sunitinib malate) were seized by the National Drug Authority, Uganda. Both products were being distributed in the vicinity of various cancer treatment centres in Kampala, Uganda.

The genuine manufacturers of both products have confirmed that they did not manufacture these products.

Details and photographs of both falsified products are shown below:

1: Avastin (Bevacizumab) 400 mg	
Product Name	**Avastin**
Batch Number	NC 1060
Expiry Date	02 - 2019
Stated Active Pharmaceutical ingredient	Bevacizumab
Stated Manufacturer	Astrazeneca/AstraZenaca

Avastin is the trade name of a medicine manufactured by Roche/Genentech for the treatment of various cancers. It is not manufactured by AstraZeneca as stated on the falsified versions.

This falsified version of Avastin is being presented in plastic bottles containing blue/grey tablets. The genuine version of Avastin is supplied only as an injection for intravenous use.

Fig 1. Falsified Avastin

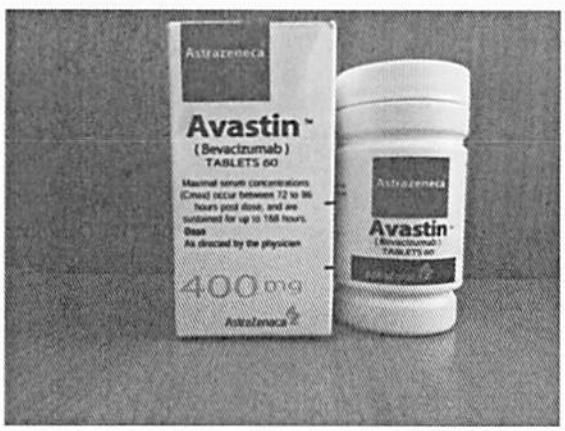
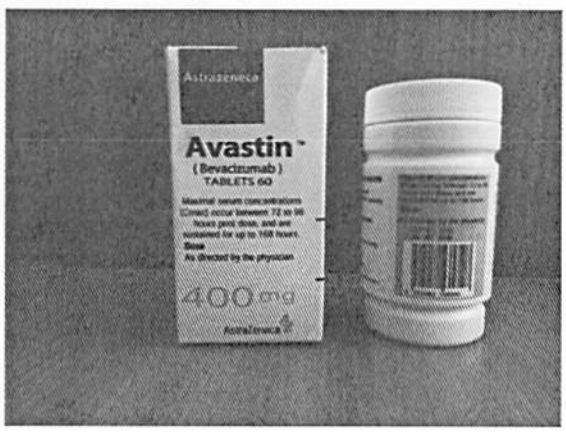


Fig 2. Falsified Avastin



2: Sutent (sunitinib malate) 12.5 mg

Product Name	**Sutent**
Batch Number	NC 2001
Expiry Date	02 - 2019
Stated Active Pharmaceutical Ingredient	sunitinib malate
Stated Manufacturer	Astrazeneca/AstraZenaca

Sutent is the trade name of a medicine for the treatment of pancreatic cancer manufactured by Pfizer. It is not manufactured by AstraZeneca as shown on the falsified versions.

This falsified version of Sutent is presented in plastic bottles containing blue/grey tablets. Genuine Sutent is only available as gelatin capsules.

Fig 3. Falsified Sutent

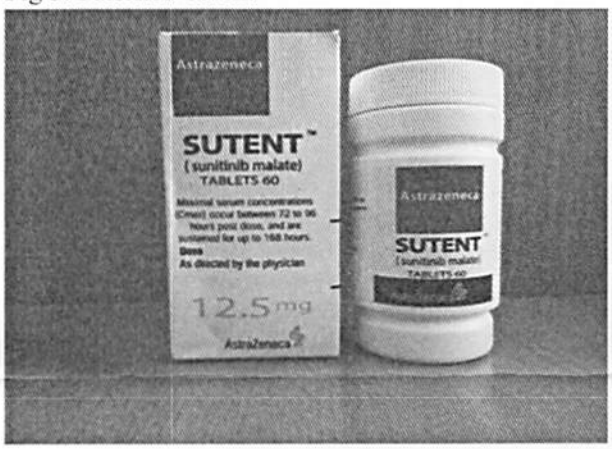
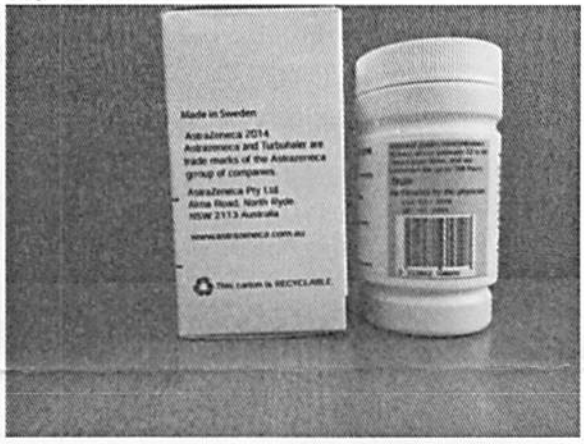


Fig 4. Falsified Sutent



WHO requests increased vigilance within the supply chains of countries likely to be affected by these falsified products. Increased vigilance should include hospitals, clinics, health centres, wholesalers, distributors, pharmacies and any other suppliers of medical products.

If you are in possession of these products, please do not use them. If you have taken this falsified product, or if you suffer an adverse event having taken these products, please seek immediate advice from a qualified healthcare professional, and report the incident to your local Ministry of Health/National Medicines Regulatory Authorities/National Pharmacovigilance Centre.

It is necessary to ensure that all medical products are obtained from authentic and reliable sources. Their authenticity and condition should be carefully checked. Seek advice from a healthcare professional if there is any doubt.

National health authorities are asked to immediately notify WHO if these falsified products are discovered in their country. If you have any information concerning the manufacture, distribution, or supply of these products, please contact rapidalert@who.int

WHO Global Surveillance and Monitoring System on Substandard and Falsified Medical Products

For further information, please visit our website: http://www.who.int/medicines/regulation/ssffc/en/
To sign up for WHO Medical Product Alerts, please visit: http://www.who.int/about/licensing/rss/en/