

正本

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277

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受文者：新竹市藥師公會

發文日期：中華民國106年8月25日

發文字號：衛食藥字第1060017896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

收文日期	106.年8.30日		
批閱	常務理事	常務理事	常務理事

公告局員 理事長壽偉瑾

主旨：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，發現在烏干達流通，為維護國民之健康與安全，請貴會轉知所屬會員知悉，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、經查旨揭2項主成分，衛生福利部食品藥物管理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。
- 三、檢附相關資料1份。

正本：新竹市醫師公會、新竹市藥師公會、新竹市藥劑生公會、新竹市西藥商公會
 副本：本局食品藥物管理科

代理局長楊清媚

本案依分層負責規定授權業務主管決行

裝訂線

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

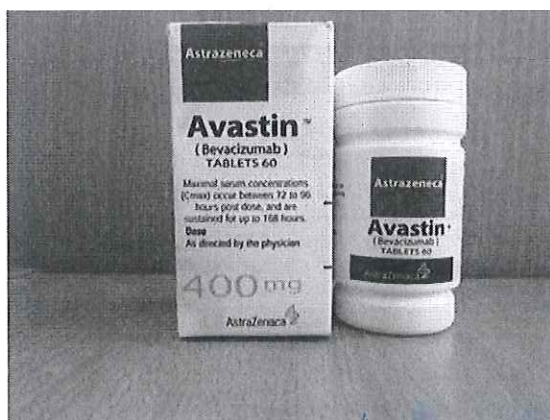
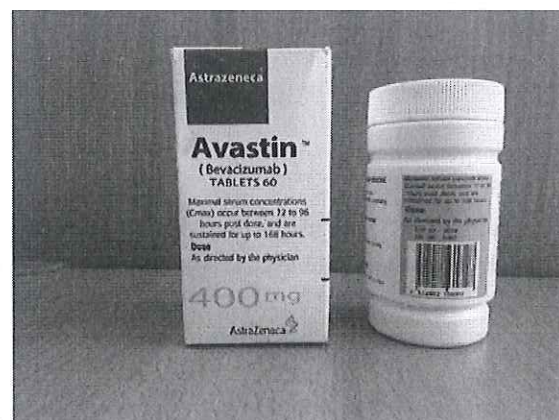


Fig 2. Falsified Avastin



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/AstraZeneca

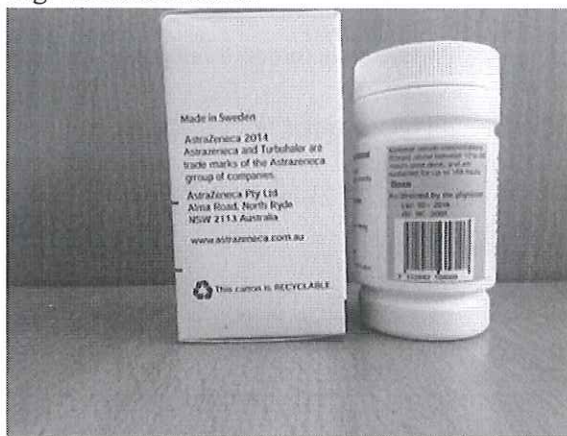
Sutent is the trade name of a medicine for the treatment of pancreatic cancer manufactured by Pfizer. It is not manufactured by AstraZeneca as shown on the falsified versions.

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/>