

臺北市政府衛生局 函

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發文字號：北市衛食藥字第10646343600號
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密等及解密條件或保密期限：
附件：相關資料1份(46343600A00_ATTCH1.pdf)

主旨：轉知案內所陳偽藥「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，惠請轉知所屬會員，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號函暨衛生福利部食品藥物管理署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、案係旨揭偽藥「Avastin(主成分bevacizumab)400mg tablets」及「Sutent(主成分sunitinib malate)12.5mg tablets」標示由AstraZeneca公司製造之產品發現在烏干達流通。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



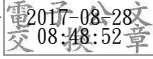
字第024593號)，製造廠為PFIZER公司。

三、為維護民眾用藥安全及權益，請轉知所屬會員案內之情事

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正本：臺北市藥師公會、台北市藥劑生公會、台北市西藥商業同業公會、台北市西藥代理商業同業公會、台北市牙醫師公會、台北市醫師公會

副本：衛生福利部食品藥物管理署



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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/AstraZeneca

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/>