

105B-0289

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
承辦人：江佳穎
電話：(02)22577155 分機2353
傳真：(02)22536548
電子信箱：AQ5750@ntpc.gov.tw



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105年4月21日
發文字號：新北衛食字第1050689180號
速別：普通件
密等及解密條件或保密期限：
附件：仿冒藥品訊息相關資料1份

主旨：檢送案內所陳「Soliris (Eculizumab)」之仿冒品於境外流通相關資料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105年4月15日FDA企字第1056021254號函辦理。
- 二、檢附仿冒藥品訊息相關資料1份。

正本：新北市藥師公會、新北市藥劑生公會、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

局長 林奇宏

本案依分層負責規定授權業務主管決行

浙 林 林 局

Attachment 1

Name(s) of product(s) affected by the problem.	SOLIRIS
Pharmaceutical form.	Concentrate for solution for infusion
Strength.	300mg
Pack size and type.	1 x 30ml labelled vial with patient information leaflet in carton. UK & Ireland livery.
Language on pack	English
Marketing Authorisation Holders name and address.	Alexion Europe SAS 1-15, avenue Edouard Belin 92500 Rueil-Malmaison France
Details of defect or problem.	<p>Suspected falsified medicinal product.</p> <ul style="list-style-type: none"> - The product received was in an amber glass vial (official vial is a clear glass vial). - The vial had no label but appeared as though a label had been removed from the vial. - The carton was missing the patient information leaflet. - Carton text error (bu instead of by); <p>The text should read "<i>Eculizumab is a humanised monoclonal IgG2/4 k antibody produced in NS0 cell line by recombinant DNA technology</i>", but the pack states "<i>Eculizumab is a humanised monoclonal IgG2/4 k antibody produced in NS0 cell line bu recombinant DNA technology</i>".</p>
Manufacturer/Distribution	<p>Alexion determined on 30 Mar 2016 that this material originated in Turkey and was sold to RCC Pharma, a wholesaler in Switzerland. The product was received by a UK Wholesaler Bionical Limited (Bionical Limited are not a customer of Alexion).</p> <p>3 vials of product from batch P0003601 were shipped from Bionical Limited to an R&D location in the USA on 21st March 2016, arriving on 25th March 2016. The 3 vials of product were supplied for R&D use, and not for human use. Refer to Pages 2-4: 'DISTRIBUTION DETAILS SOLIRIS 300MG BATCH P0003601'</p>

DISTRIBUTION DETAILS SOLIRIS 300MG BATCH P0003601:

Batch Number	Number of Vials Released for Distribution	Number of Vials Returned	Number of Vials Redistributed	Total
P0003601	15,999	122	52	16,173

Batch Number	Country	Date first Distributed	Date last Distributed	Quantity Distributed
P0003601	United Arab Emirates	03 Jul 2015	07 Aug 2015	192
P0003601	Argentina	21 Aug 2015	12 Oct 2015	1032
P0003601	Brazil	24 Aug 2015	09 Aug 2015	6407
P0003601	Chile	15 Sep 2015	02 Oct 2015	50
P0003601	Cyprus	14 Sep 2015	14 Sep 2015	20
P0003601	Czech Republic	21 Sep 2015	14 Oct 2015	234
P0003601	United Kingdom	21 Sep 2015	14 Oct 2015	4510
P0003601	Greece	16 Sep 2015	08 Oct 2015	85

P0003601	Croatia	02 Sep 2015	14 Oct 2015	21
P0003601	Ireland	25 Aug 2015	08 Oct 2015	145

Batch Number	Country	Date first Distributed	Date last Distributed	Quantity Distributed
P0003601	Iceland	15 Sep 2015	15 Sep 2015	24
P0003601	Lithuania	21 Sep 2015	21 Sep 2015	4
P0003601	Latvia	07 Sep 2015	30 Sep 2015	13
P0003601	Peru	21 Aug 2015	23 Nov 2015	36
P0003601	Portugal	25 Aug 2015	23 Nov 2015	153
P0003601	Romania	01 Sep 2015	14 Oct 2015	40
P0003601	Slovenia	02 Sep 2015	01 Oct 2015	67
P0003601	Slovakia	25 Aug 2015	07 Oct 2015	134
P0003601	Turkey	21 Aug 2015	09 Oct 2015	2770
P0003601	Taiwan, Providence of China	14 Sep 2015	14 Sep 2015	210
P0003601	South Africa	08 Sep 2015	12 Oct 2015	26

Total 16,173