正本

檔　　號：
保存年限：

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106年10月31日
發文字號：新北衛食字第1062130305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：檢送案內所陳在保加利亞發現藥品「RoActemra」（批號：B3014H08）疑似偽品流通警訊相關資料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10月26日FDA企字第1061203946號函辦理。

二、檢附仿冒藥品訊息相關資料1份。

正本：社團法人新北市醫師公會、新北市藥師公會、新北市藥劑生公會、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

Inspectie voor de Gezondheidszorg
Ministerie van Volksgezondheid, Welzijn en Sport

IMPORTANT – DELIVER IMMEDIATELY
Rapid Alert Notification of a Quality Defect / Recall

		Reference Number NL/I/17/01
Dutch Healthcare Inspectorate		
1. To: rapid alert list		
2. Product Recall Class of Defect: (circle one)	I ~~II~~	3. Falsification ~~/ Fraud (specify)~~*
4. Product: RoActemra 20 mg/mL (400 mg)	5. Marketing Authorisation Number: * EU/1/08/492/005 For use in humans~~/animals~~ (delete as required)	
6. Brand/Trade Name: RoActemra	7. INN or Generic Name: TOCILIZUMAB	
8. Dosage Form: concentrate for solution for infusion	9. Strength: 20 mg/mL (400 mg)	
10. Batch number (and bulk, if different): B3014H08	11. Expiry Date: 02/19	
12. Pack size and Presentation: 1 vial	13. Date Manufactured: 17/8/2016	
14. Marketing Authorisation Holder: Roche Registration Limited, UK		
15. Manufacturer**: Roche Contact Person: Mr. T. Schortinghuis (The Netherlands) tijmen.schortinghuis@roche.com Telephone: +31 348 438 205	16. Recalling Firm (if different): Not (yet) applicable. Contact Person: Telephone:	
17. Recall Number Assigned (if available):		
18. Details of Defect/Reason for Recall: 200 suspected packages of batch B3014H08 were discovered by PD Abacus Medicine Hungary. Abacus have not distributed the suspected packages. Roche Basel confirmed the counterfeit: all secondary packaging is falsified; the content of the investigated vials is real. All packages contain the same serial number S/N 100010066279965. Language of the package is Bulgarian. Packages may be identified by slightly different colour, slight differences in font style, different kind of gluing, different colour, paper thickness and way of folding of leaflet, different perforation in label and different positioning of text at label.		
19. Information on distribution including exports (type of customer, e.g. hospitals): Only distributed to Bulgaria (629 packages). Abacus got packages from PD DEKA Pharmaceuticals Ltd, Bulgaria. Abacus Hungary did not distribute suspected packages. Dutch PD BModesto also received the suspected packages from supplier Nipex Pharma, Bulgaria, but already blocked the supply.		
20. Action taken by Issuing Authority: not applicable (non of the identified packages were placed on the market)		
21. Proposed Action: inform PD, map supply chain. For our Bulgarian colleagues: investigate role DEKA Pharmaceuticals and Nipex Pharma.		
22. From (Issuing Authority): IGZ		23. Contact Person: P. Nagtegaal igz-qdefect@igz.nl Telephone: +31 6 11733482

24. Signed: 	25. Date: 15 september 2017	26. Time: 13:32

* Information not required, when notified from outside EU.

** The holder of an authorisation referred to under Article 40 of Directive 2001/83/EC or Article 44 of Directive 2001/82/EC and the holder of the authorisation on behalf of whom the Qualified Person has certified the batch for release in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.

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