正本

檔　　號：
保存年限：

新北市政府衛生局　函

1218

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受文者：新北市藥師公會

發文日期：中華民國104年11月26日
發文字號：新北衛食字第1042237483號
速別：普通件
密等及解密條件或保密期限：
附件：通報藥品警訊相關資料1份

主旨：檢送案內所陳「Mabthera 500mg（批號N7030B01）」產品，於境外發現仿冒品流通相關資料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104年11月19日FDA企字第1041205080號函辦理。

二、檢附通報藥品警訊相關資料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

Appendix 2

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

	Reference Number **CZ_I_08_01**
State Institute for Drug Control, Prague, Czech Republic	
1. To: see list attached (if more than one)	
2. Product Recall Class of Defect: (I)	3. Falsification ~~/ Fraud~~ Suspected falsification
4. Product: MabThera 500 mg	5. Marketing Authorisation Number: For use in humans~~/animals~~ EU/1/98/067/002
6. Brand/Trade Name: MabThera 500 mg	7. INN or Generic Name: *rituximab*
8. Dosage Form: Concentrate for solution for infusion	9. Strength: 500mg
10. Batch number (and bulk, if different): N7030B01	11. Expiry Date:02/2017
12. Pack size and Presentation: 1x50ML, vial	13. Date Manufactured: NA
14. Marketing Authorisation Holder: Roche Registration Ltd., Welwyn Garden City, Hertfordshire Falcon Way 6, AL7TW Welwyn Garden City - Shire Park United Kingdom	
15. Manufacturer†: Contact Person: Telephone:	16. Recalling Firm (if different): NA Contact Person: Telephone:
17. Recall Number Assigned (if available) NA	
18. Details of Defect/Reason for Recall: 47 suspected units of the respective Batch N7030B01 (exp. 02/2017) were detected by Axicorp Pharma GmbH, Germany during the check of incoming products. Axicorp Pharma GmbH informed its supplier – wholesaler "Lékárna na Údolní s.r.o." that all the packages are suspected falsification. Lékárna Na Údolní s.r.o. purchased all these packages from Bulgarian wholesaler BB Pharma Ltd., KIRCHIM STR 69, 1164 Sophia, Bulgary. The packages were intended for the Romanian market. 43 out of 47 packages contain vials batch N7030, exp. 02/2017 and four vials have a different batch N7023, exp. 12/2016, on the outer package was batch N7030B01 only. German wholesaler Axicorp returned all respective packages to the Czech wholesaler Lékárna Na Údolní s.r.o., Údolní 392/16, 602 00 Brno Czech republic. Affected units are now in quarantine in Lékárna Na Údolní s.r.o.	
19. Information on distribution including exports (type of customer, e.g. hospitals): Suspected packages haven't been sold to any customers. All packages are now in quarantine in Lékárna Na Údolní s.r.o.	
20. Action taken by Issuing Authority: Information of the competent authorities by RAS, information of MAH, publication of the warning information to pharmacies and wholesalers on the website. The inspection of the wholesaler Lékárna Na Údolní s.r.o. has been performed.	

21. Proposed Action: Warning information to wholesalers .		
22. From (Issuing Authority): State Institute for Drug Control, Prague, Czech Republic		23. Contact Person: Eva Komrskova Eva.Komrskova@sukl.cz Telephone:
24. Signed: Pupkl	25. Date: 16. 11. 2015	26. Time: * 15:00

* 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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