

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：王峙懿
電話：(02)22577155 分機1307
傳真：(02)22536548
電子信箱：AP6125@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104年8月14日
發文字號：新北衛食字第1041495698號
速別：普通件
密等及解密條件或保密期限：
附件：原函及相關資料影本各1份

主旨：檢送有關「EXJADE 500 MG (批號S0178A)」警訊相關資料
1份，該產品在境外發現仿冒品流通，為維護國民之健康與
安全，惠請轉知所屬會員，如有案內違規產品應立即下架勿
販售，請查照。

說明：依據衛生福利部食品藥物管理署104年8月7日FDA企字第
1041203499號函辦理。

正本：新北市藥師公會
副本：

局長 林奇宏

本案依分層負責規定授權業務主管決行

张林林

檔 號：
保存年限：

衛生福利部食品藥物管理署 函

地址：11561 臺北市南港區昆陽街161-2號
聯絡人：莊東傑
聯絡電話：02-27877243
傳真：02-26532055
電子信箱：dpqbdpqb@fda.gov.tw

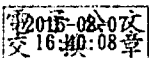
受文者：新北市政府衛生局

發文日期：中華民國104年8月7日
發文字號：FDA企字第1041203499號
速別：普通件
密等及解密條件或保密期限：
附件：資料1份(A210200001104120349900-1.pdf)

主旨：檢送案內所陳藥品「EXJADE 500 MG (批號S0178A)」警訊相關資料1份，該產品在境外發現仿冒品流通，為維護國民之健康與安全，請將該產品於市面可能販售及網路刊售之情事列入稽查工作重點，查明依法處辦，請查照。

說明：依據本署104年8月4日接獲捷克State Institute for Drug Control, Prague, Czech Republic經PIC/S Rapid Alert System通報藥品警訊相關資料辦理。

正本：各縣市衛生局

副本：



Appendix 2

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

		Reference Number CZ/I/06/01	
State Institute for Drug Control, Prague, Czech Republic			
1. To: see list attached			
2. Product Recall Class of Defect:		I	11
		3. Falsification /-Fraud-(specify)?:	
4. Product: EXJADE 500 mg 28x500 mg		5. Marketing Authorisation Number: * For use in humans EU/1/06/356/005	
6. Brand/Trade Name: EXJADE 500 MG		7. INN or Generic Name: DEFERASIROXUM	
8. Dosage Form: dispersible oral tablets		9. Strength: 500 MG	
10. Batch number (and bulk, if different): S0178A		11. Expiry Date: 03/2017	
12. Pack size and Presentation: 28 x 500 mg		13. Date Manufactured: not known	
14. Marketing Authorisation Holder: Novartis Europharm Limited, Camberley, Frimley Business Park, Great Britain			
15. Manufacturer†:		16. Recalling Firm (if different):	
Contact Person: E-mail:		Contact Person: Telephone:	
17. Recall Number Assigned (if available):*			
18. Details of Defect/Reason for Recall:			
<p>The suspected counterfeited packages (25 in total) of Exjade 500 MG were detected by AxiCorp Pharma GmbH, Germany, during check of incoming goods. AxiCorp Pharma informed its supplier - the wholesaler GlucoPharma, Prague, Czech Republic - that the content of the packages was completely different from the original: blisters or parts of other medicinal drugs and food (broth Knorr of Slovak origin) were inside. The medicinal product is marketed in bilingual packaging (CZ/SK). In documents gained from GlucoPharma CZ is declared that suspected counterfeited packages of Exjade were purchased from the wholesaler D-Pharm, Male namestie 2873/18, Malacky 901 01, Slovakia.</p> <p>In the same delivery from D-Pharm, Slovakia, there were also 17 packages of Zyvoxid 600mg tablets, the batch H94148 (the same batch in RAS from 8.7.2015), contained different blisters from other medicinal products and dietary supplements.</p> <p>The source of 7 packages of Zyvoxid (the above said batch following RAS from 8.7.2015) was according to our current information the wholesaler D-pharm, Slovakia, too.</p>			
19. Information on distribution including exports (type of customer, e.g. hospitals): * Not known			
20. Action taken by Issuing Authority: Suspension of distribution and dispensing of the respective batch of Exjade in CZ.			
21. Proposed Action: Warning information to parallel importers in other states. Inspection of the wholesaler D-Pharm Slovakia by authority to check supply chain and scope of distribution of the affected medicinal products.			

22. From (Issuing Authority): State Institute for Drug Control, Prague, Czech Republic		23. Contact Person: Eva Komrsková E-mail: eva.komrskova@sukl.cz	
24. Signed: <i>MeeEva</i>	25. Date: 3.8.2015	26. Time: <i>19:00</i>	

* 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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8/27	收發文	專員	專員	秘書	總幹事
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公告	網站連結			常務理事	常務監事
					理事長