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6月6日
發文字號：新北衛食字第1051026877號
速別：普通件
密等及解密條件或保密期限：
附件：案內相關資料1份

主旨：檢送案內所陳「Humira」（批號54092XH05及52077XH05）」藥品警訊相關資料1份，該產品在保加利亞發現仿冒品流通，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6月1日FDA企字第1051202253號函辦理。

二、檢附案內相關資料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(含附件)

局長 林奇宏

本案依分層負責規定授權業務主管決行

РЕПУБЛИКА БЪЛГАРИЯ
Изпълнителна агенция по лекарствата
REPUBLIC OF BULGARIA
Bulgarian Drug Agency

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

Ин 22099 / 20 -05- 2016

Reference Number BG/I/09/01

[add letter head of sender]		
1. To: (see list attached, if more than one)		
2. Product Recall Class of Defect: (circle one)	**I**	3. **Confirmed counterfeit**
4. Product: **Humira**	5. Marketing Authorisation Number: EU/1/03/256/003 For use in humans	
6. Brand/Trade Name: **Humira**	7. INN or Generic Name: **Adalimumab**	
8. Dosage Form: solution for injection in a pre-filled syringe	9. Strength: 40 mg	
10. Batch number (and bulk, if different): **54092XH05** on the primary packing **52077XH05** on the secondary packing	11. Expiry Date: 05/2017 on the primary packing 03/2017 on the secondary packing	
12. Pack size and Presentation: 2 pre-filled syringes + 2 alcohol pads	13. Date Manufactured: NA	
14. Marketing Authorisation Holder: AbbVie Ltd., Maidenhead SL6 4UB, UK		
15. Manufacturer†: NA Contact Person: Telephone:	16. Recalling Firm (if different): Contact Person: SOFIYA VELKOVA, AbbVie EOOD, Bulgaria Telephone: sofiya.velkova@abbvie.com	
17. Recall Number Assigned (if available): NA		
18. Details of Defect/Reason for Recall: AbbVie EOOD, Bulgaria informed the BDA that **one package** of HUMIRA 40 mg solution for injection in a pre-filled syringe EU/1/03/256/003, MAH: AbbVie Ltd, UK was with information on the primary packing on Turkish language with batch no. 54092XH05 and information on the secondary packing with batch no. 52077XH05 and the leaflet in Bulgarian language. The package was bought in a pharmacy "Pharma 1", No.17 "General Scobelev" str., Kazanlak, Bulgaria and was sent to AbbVie Germany by AbbVie EOOD, Bulgaria for clarification of the authenticity. The results of the AbbVie Germany were sent to the EMA and the BDA and can confirm that based upon the evaluation of the packaging components of the sample, the unit can be classified as falsified medicinal product. The carton and the leaflet are non-authentic material. Both sealed pre-filled syringes are authentic.		
19. Information on distribution including exports (type of customer, e.g. hospitals):		
20. Action taken by Issuing Authority: Currently the Bulgarian Drug Agency has been performing an inspection of the pharmacy for availability of other packages and tracing of the supply chain.		
21. Proposed Action: Increased vigilance in parallel import of batch (52077XH05).		
22. From (Issuing Authority): BULGARIAN DRUG AGENCY, BULGARIA		23. Contact Person: RUMIANA HUBCHEVA Telephone: +359 2 890 34 52
24. Signed: Assoc. Prof. Assena Stoimenova, PhD, MScPharm, MPH Executive Director	25. Date:	26. Time:

* 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.

****