正 本

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社團法人高雄市第一藥師公會
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高雄市政府衛生局　函

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受文者：社團法人高雄市第一藥師公會

一、文檢存查
二、擬PO文公告週知

發文日期：中華民國105年6月7日
發文字號：高市衛藥字第10534250900號
速別：普通件
密等及解密條件或保密期限：
附件：案內相關資料乙份

裝

主旨：有關衛生福利部食品藥物管理署函轉「Humira」警訊相關資料一份，詳如說明，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、本案「Humira」藥品（批號54092XH05及52077XH05）在保加利亞發現仿冒品流通，為維護國民之健康與安全，請貴公會轉知所屬會員。

三、副本抄送各區衛生所，將違規產品於市面可能販售、供應之情事列入稽查工作重點，查明依法處辦。

訂

正本：社團法人高雄市第一藥師公會、社團法人高雄市藥師公會、高雄市藥劑生公會、高雄市新高雄藥劑生公會、高雄市西藥商業同業公會、高雄縣西藥商業同業公會

副本：高雄市左營區衛生所、高雄市楠梓區衛生所、高雄市三民區衛生所、高雄市苓雅區衛生所、高雄市前鎮區衛生所、高雄市旗津區衛生所、高雄市小港區衛生所、高雄市三民區第二衛生所、高雄市鳳山區衛生所、高雄市岡山區衛生所、高雄市旗山區衛生所、高雄市美濃區衛生所、高雄市林園區衛生所、高雄市大寮區衛生所、高雄市大樹區衛生所、高雄市仁武區衛生所、高雄市大社區衛生所、高雄市鳥松區衛生所、高雄市橋頭區衛生所、高雄市燕巢區衛生所、高雄市田寮區衛生所、高雄市阿蓮區衛生所、高雄市路竹區衛生所、高雄市湖內區衛生所、高雄市茄萣區衛生所、高雄市永安區衛生所、高雄市彌陀區衛生所、高雄市梓官區衛生所、高雄市六龜區衛生所、高雄市甲仙區衛生所、高雄市杉林區衛生所、高雄市內門區衛生所、高雄市茂林區衛生所、高雄市桃源區衛生所、高雄市那瑪夏區衛生所、高雄市鼓山區衛生所、高雄市鳳山區第二衛生所、高雄市新興衛生所（均含附件）

線

局長 黃志中

本案依分層負責規定授權業務主管判發

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

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

Вх 22199 / 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.

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