正本

檔　　號：
保存年限：

1102

新北市政府衛生局 函

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受文者：新北市藥師公會

發文日期：中華民國104年10月19日
發文字號：新北衛食字第1041985321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

裝

主旨：檢送有關「Humira 40 mg（批號50062XD09）」產品，於境外發現仿冒品流通相關資料，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10月15日FDA企字第1041204574號函辦理。

訂

正本：新北市藥師公會
副本：

局長 林奇宏

線

本案依分層負責規定授權業務主管決行

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
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受文者：新北市政府衛生局

發文日期：中華民國104年10月15日
發文字號：FDA企字第1041204574號
速別：普通件
密等及解密條件或保密期限：
附件：資料2份(A21020000I104120457400-1.pdf、A21020000I104120457400-2.pdf)

主旨：檢送案內所陳「Humira 40 mg（批號50062XD09）」產品，於境外發現仿冒品流通流通相關資料2份，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，查明依法處辦，請 查照。

說明：依據本署104年10月7日接獲德國landesamt für soziales, Jugend und Versorgung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：電2015-10-15文交16:50:05章

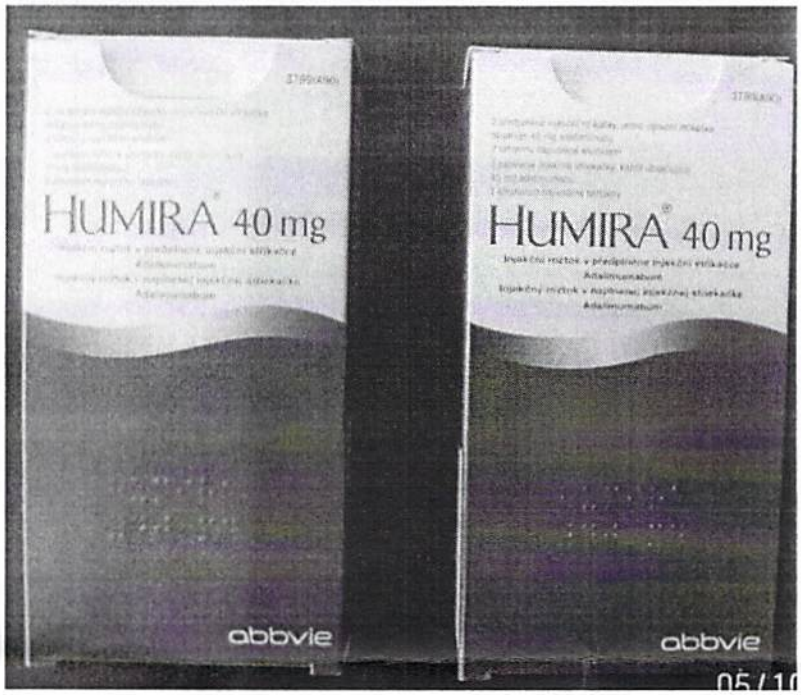
1041204574

Short Summary of differences between falsified and original secondary package.

Humira 40 mg Batch 50062XD09 Expiry: 01/2017 – Import from Slovakia

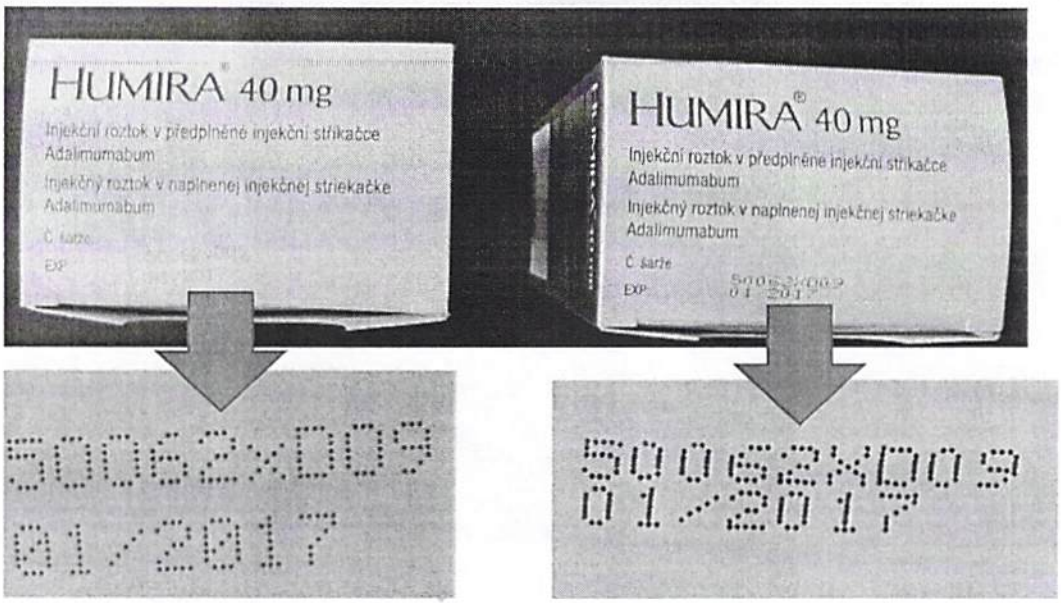
Two packages with the same batch were delivered together. One of the packages (package 1) is a falsification.

A) Package 1(falsified) Package 2



The shade of the red colour is slightly different. The cove of the braille is different too. The cove of the braille printing is smaller on the falsified package.

B) Package 1 (falsified) Package 2



Type face is not comparable. Package 1 (falsified) the letter "x" is small, number "0" printed with slash.

Short Summary of differences between falsified and original secondary package.

Humira 40 mg Batch 50062XD09 Expiry: 01/2017 – Import from Slovakia

C) Package 1 (falsified)

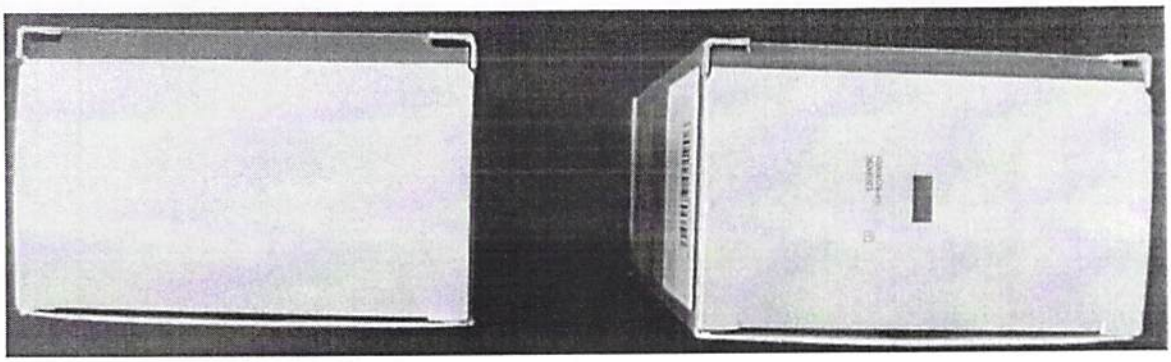
Package 2

On smaller package side: There are differences in printing the EU authorization number. It is remarkable by comparing the type of number "1". On the left side the short ascending line is straight, while on the right side the line is curved. Other numbers show also differences. The type faces are different.

Short Summary of differences between falsified and original secondary package.

Humira 40 mg Batch 50062XD09 Expiry: 01/2017 – Import from Slovakia

D) Package 1 (falsified) Package 2



On the bottom of package 1 a small label was missing.

Final Conclusion:
Especially the differences in the type face - compare example C) and D) - are typical for the falsified secondary package and are easily recognizable.

By Order
Markus Walther

DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / ~~Recall~~		
Meldende Stelle Landesamt für Soziales, Jugend und Versorgung Moltkestr. 19 54292 Trier		
1. To / Empfänger:		FAX
☒	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	0228-207-4636
☒	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	030-18444-30409
☒	Paul-Ehrlich-Institut - Bundesamt für Sera und Impfstoffe - (PEI)	06103/77-1263
☒	Oberste Landesgesundheitsbehörde	

2. Product ~~Recall~~ Class of Defect: (I) (circle one)	3. **Counterfeit** / ~~Fraud~~ (specify)* Report of suspected counterfeit product
4. Product: **Humira 40mg**	5. Marketing Authorisation Number: * For use in humans/~~animals~~ (delete as required)
6. Brand/Trade Name: Humira 40mg	7. INN or Generic Name: Adalimumab
8. Dosage Form: pre-filled syringe	9. Strength: 40mg
10. Batch/Lot Number: 50062XD09	11. Expiry Date: 01/2017
12. Pack size and Presentation: 1 vial	13. Date Manufactured: not known
14. Marketing Authorisation Holder: * AbbVie Ltd, Maidenhead, SL6 4XE, United Kingdom	
15. Manufacturer†: Contact Person:	16. Recalling Firm (if different): *Not applicable!* The suspected counterfeited package was detected by parallel importer CC-Pharma, D-54570 Densborn during the check of incoming goods. No packages of the concerned Humira shipment from Slovakia were released by CC-Pharma!
17. Recall Number Assigned (if available)	

18. Details of Defect/~~Reason for Recall~~: Parallel importer CC-Pharma GmbH, Densborn received a delivery of 2 packages Humira 40mg pre-filled syringe witch Batch No. 50062XD09 from the wholesaler Pharma Comp s.r.o, Zarnovica (Slovakia). The packages showed remarkable differences in some details, when they were compared to each other. (compare Appendix) Therefore it was assumed that one of the packages is suspected counterfeit. After contact with the original manufacturer it was confirmed that the secondary package of No. 1 (compare pictures in the appendix, the "x" in the batch number is written smaller than the other letter and numbers) is a falsification. The attached leaflets to this package showed differences and were falsified too. Although the primary package didn't show any hints of manipulation or falsification, it has to be assumed, that this product, which has to be stored at a cool temperature, was out of the regular chain of distribution and therefore the quality of the product in this falsified package is uncertain.
19. Information on distribution including exports (type of customer, e.g. hospitals): * CC-Pharma did not sell the package to any customer.
20. Action taken by Issuing Authority: Information of the Competent Authorities in Germany by RAS, Information of the Marketing Authorisation Holder
21. Proposed Action: Warning information to parallel importers in other federal states by their competent authority Inspection of the delivering wholesaler by competent authority in Slovakia to check supply chain.

22. From (Issuing Authority):	23. Contact Person:
Landesamt für Soziales, Jugend und Versorgung Moltkestraße 19 54292 Trier	Markus Walther walther.markus@lsjv.rlp.de Telephone: 0651 / 1447 208

24. Signed:	25. Date: 07.10.2015	26. Time: *11:00

* 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 released the batch in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.