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：姜俞臣
電話：(02)22577155 分機1310
傳真：(02)22572761
電子信箱：ak9458@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7月8日
發文字號：新北衛食字第1041214223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「VIAGRA」（批號B714830238）」及「Norditriopin Simplex 10 mg/1,5 ml（批號SC11255及CL70711）」不良品暨回收警訊相關資料，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6月30日FDA企字第1041202864號函及104年6月30日FDA企字第1041202867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

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：莊東憬
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6月30日
發文字號：FDA企字第1041202864號
速別：普通件
密等及解密條件或保密期限：
附件：資料2份(104120286400-1.PDF、104120286400-2.pdf)

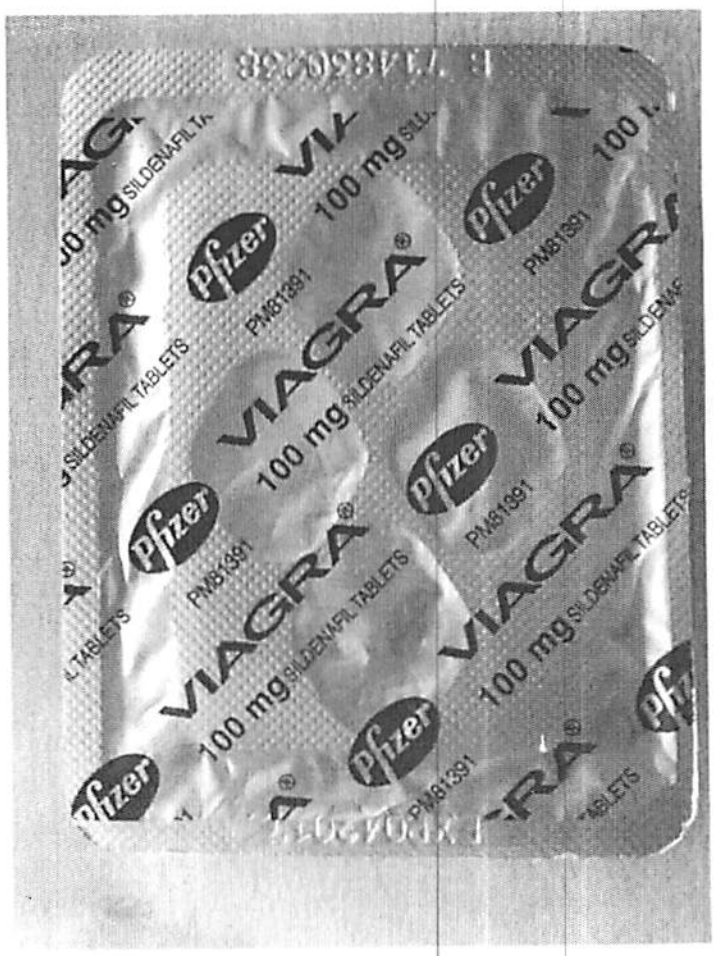
主旨：檢送案內所陳藥品「VIAGRA」（批號B714830238）」不良品暨回收警訊相關資料2份，為維護國民之健康與安全，請將該產品於市面可能販售及網路刊售之情事列入稽查工作重點，查明依法處辦，請 查照。

說明：依據本署104年6月25日接獲美義大利AIFA - Product Quality and Counterfeiting Office經PIC/S Rapid Alert System通報藥品不良品暨回收警訊相關資料辦理。

正本：各縣市衛生局
副本：

1041202864


Pfizer


VIAGRA®
100 mg SILDENAFIL TABLETS
Pfizer
PM81391

AIFA/PQ&C/65182/P del 25/06/2015

RAPID ALERT NOTIFICATION OF A QUALITY DEFECT/RECALL		
IMPORTANT - DELIVER IMMEDIATELY		Ref. IT/I/1/01
1.To: (see list attached, if more than one)		
2.Product Recall Class of Defect:	**3.Counterfeit / Fraud (specify)*: Counterfeit**	
4.Product: VIAGRA	**5.Marketing Authorisation Number:*** For use in Humans/ ~~animal~~	
6.Brand/Trade Name: VIAGRA	**7.INN or Generic Name: SILDENAFIL**	
8. Dosage Form: Tablets	**9. Strength: 100 mg**	
10.Batch/Lot Number: B714830238	**11.Expiry Date: 04/2017**	
12. Pack size and Presentation: 4 tablets	**13. Date Manufactured:**	
14. Marketing Authorisation Holder: Illegal Product		
15. Manufacturer: **Contact point:**	**16. Recalling Firm (if different):**	
17. Recall Number Assigned (if available): Ref. **IT/I/1/01**		
18. Details of Defect/Reason for Recall: Falsified blister of Viagra 100 mg 4 tablets (without the secondary packaging and patient information leaflet) have been seized by the local branch Italian Custom located in Bari during the Operation Pangea VIII. The blisters showed the batch number B714830238 and the expiry date 04/2017. The marketing authorization holder of the original medicine has reported that the batch number do not correspond to a genuine batch manufactured by Pfizer. Samples of the falsified product are about to be sent to the Italian OMCL/MAH laboratories for further investigation and testing.		
19.Information on distribution including exports (type of customer, e.g. hospitals): possible distribution through **illegal channels** (EG sex shops, Internet).		
20. Action taken by Issuing Authority: communication to the general public through the official website.		
21.Proposed Action: Operators (EG non pharmaceutical shops owners)/customers in possession of packs of Viagra 100mg 4 tabs, batch number B714830238, expiry 04-2017 are requested to not distribute the product and to report immediately to AIFA.		
22.From (Issuing Authority): **AIFA – Product Quality and Counterfeiting Office**	**23.Contact Person:** Domenico Di Giorgio, Ph D. d.digiorgio@aifa.gov.it medicrime@aifa.gov.it	
24.Signed: Domenico Di Giorgio	**25.Date:** June 25, 2015	**26.Time:***

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：莊東悰
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6月30日
發文字號：FDA企字第1041202867號
速別：普通件
密等及解密條件或保密期限：
附件：資料1份(104120286700-1.pdf)

主旨：檢送案內所陳藥品「Norditriopin Simplex 10 mg/1,5 ml（批號SC11255及CL70711）」不良品暨回收警訊相關資料1份，該等產品在波士尼亞與赫塞哥維納發現仿冒品流通，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6月27日接獲克羅埃西亞HALMED-Agency for Medicinal Products and Medical Devices of Croatia經PIC/S Rapid Alert System通報藥品不良品暨回收警訊相關資料辦理。

正本：各縣市衛生局
副本：電2015-06-30 交17:49:53章

1041202867

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

	Reference Number HR/I/01/01

HALMED
Agency for Medicinal Products and Medical Devices of Croatia

1. To: (see list attached, if more than one)		
2. Product Recall Class of Defect: (circle one) I II III		3. **Falsification***
4. Product: Norditriopin Simplex 10 mg/1,5 ml	5. Marketing Authorisation Number: * For use in humans	
6. Brand/Trade Name: Norditriopin Simplex	7. INN or Generic Name: somatropin	
8. Dosage Form: solution for injection	9. Strength: 10 mg/1,5 ml	
10. Batch number (and bulk, if different): **SC11255** **CL70711**	11. Expiry Date: 11/2016 (SC 11255) 08/2017 (CL 70711)	
12. Pack size and Presentation: unknown	13. Date Manufactured: *	
14. Marketing Authorisation Holder: * Of original medicine Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd, Danmark		
15. Manufacturer#: Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd, Danmark Contact Person: Telephone:	16. Recalling Firm (if different): *Reporting representative* Novo Nordisk Hrvatska d.o.o. Damira Tomljanovića Gavrana 17a 10020 Zagreb Croatia Contact Person: Martina Kaić, MPharm Telephone: 0997022033	
17. Recall Number Assigned (if available): not applicable (internal case number 530-09/15-01/60)		

18. Details of Defect/Reason for Recall:

The Croatian affiliate has received a phonbe call about two suspected Norditropin SimpleXx 10 mg/1,5 ml counterfeit products (photo attached). The products are labelled as Norditropin SimpleXx from Novo Nordisk with batch number SC11255, expiry date 11/ 2016 and CL70711, expiry date 08/2017. A cartridge with batch number CL70711 was received for investigation by MAH. The complainant claimed that he got the product from a private pharmacy in the city of Banja Luka, Bosnia and Herzegovina. However the complainant was not willing to reveal the name and the address of the location. The text on the boxes is printed in Romanian language and boxes are concluded to be fake. The batch numbers and expiry dates are not valid production data used by Novo Nordisk.

There have been three earlier cases on batch number SC11255, two in Germany, one in Spain. Only the pictures were received for investigation for this case so Novo Nordisk was not able to perform an investigation.

There has been one earlier batch nuber on batch number CL70711 in UK. One sample was receieved for an investigation for the present case. Macroscopically and microscopically examinations were performed. The content in the sample was clear. One dark hair fibre appeared in solution approximately 1,5 ml was left in the cartridge. The rubber membrane did not originate from Novo Nordisk and there was no penetration mark in the rubber membrane. Furthermore the code cap is not from Novo Nordisk and the plunger is without silicone. There is a weak smell of phenol. It is not possible to detect somatropin in the cartridge. Based on the results of the investigation sample with batch number CL70711 is considered to be counterfeit.

19. Information on distribution including exports (type of customer, e.g. hospitals): *

No precise information is available.

20. Action taken by Issuing Authority:

Classification as Class I defect, information of RAS
Inform Regulatory authority in Bosnia and Herzegovina

21. Proposed Action:
market action as needed

22. From (Issuing Authority):	23. Contact Person:
Agency for Medicinal Products and Medical Devices (HALMED) Ksaverska cesta 4, Zagreb Croatia	Ana Boban, MPharm rapidalert.hr@halmed.hr Telephone: +385 99 263 7898

24. Signed:	25. Date: 26.06.2015.	26. Time: 21:05*
Ana Boban 26.06.2015 21:05		

* 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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