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：蔡念桂
電話：(02)22577155 分機1307
傳真：(02)22572761
電子信箱：ad2164@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5月19日
發文字號：新北衛食字第1040886734號
速別：普通件
密等及解密條件或保密期限：
附件：案內相關資料影本1份

主旨：檢送有關「BOTOX（批號C3498 C3）」產品涉違反衛生法令相關資料，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5月14日FDA企字第1041202043號函辦理。

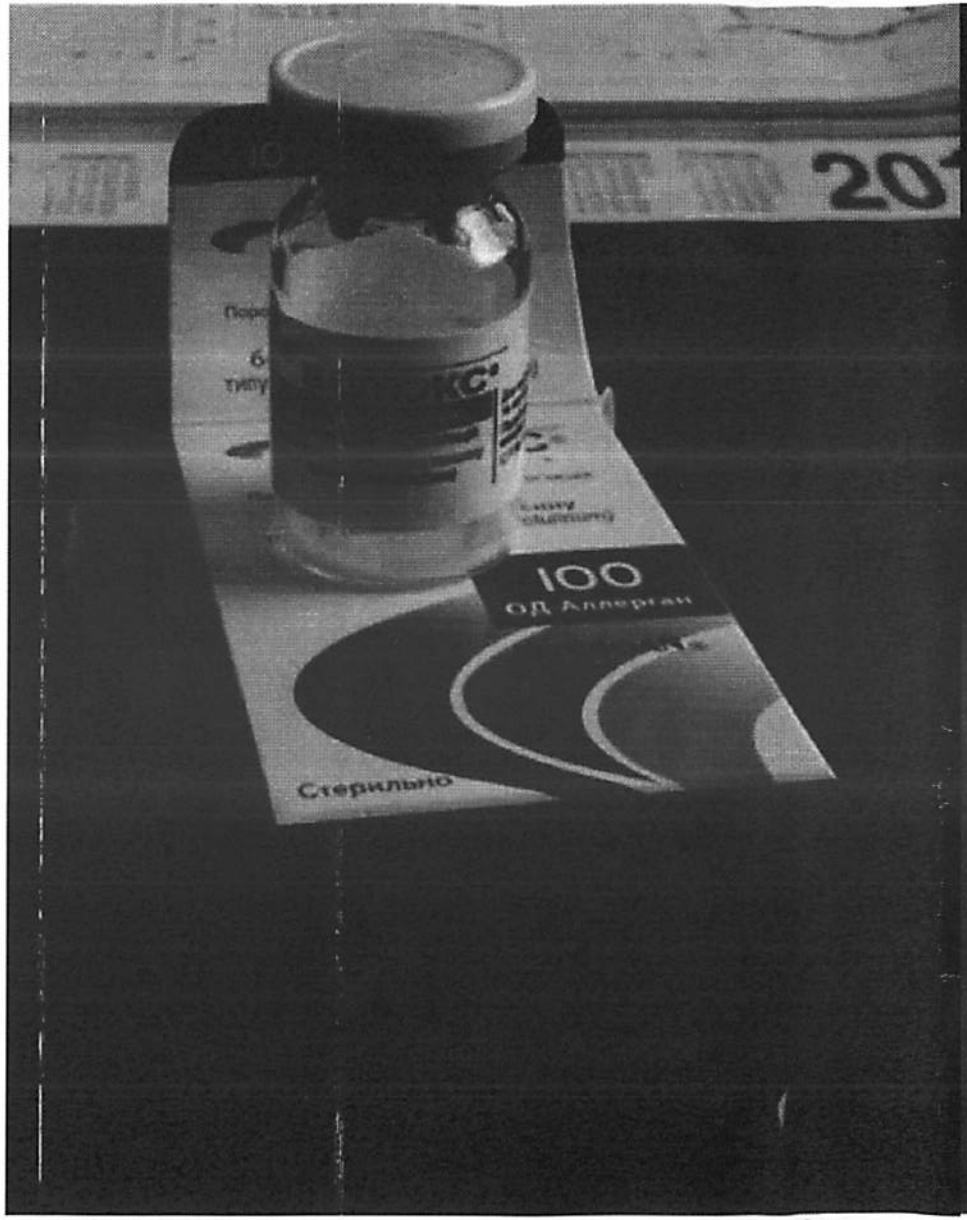
正本：新北市藥師公會
副本：

局長 林奇宏

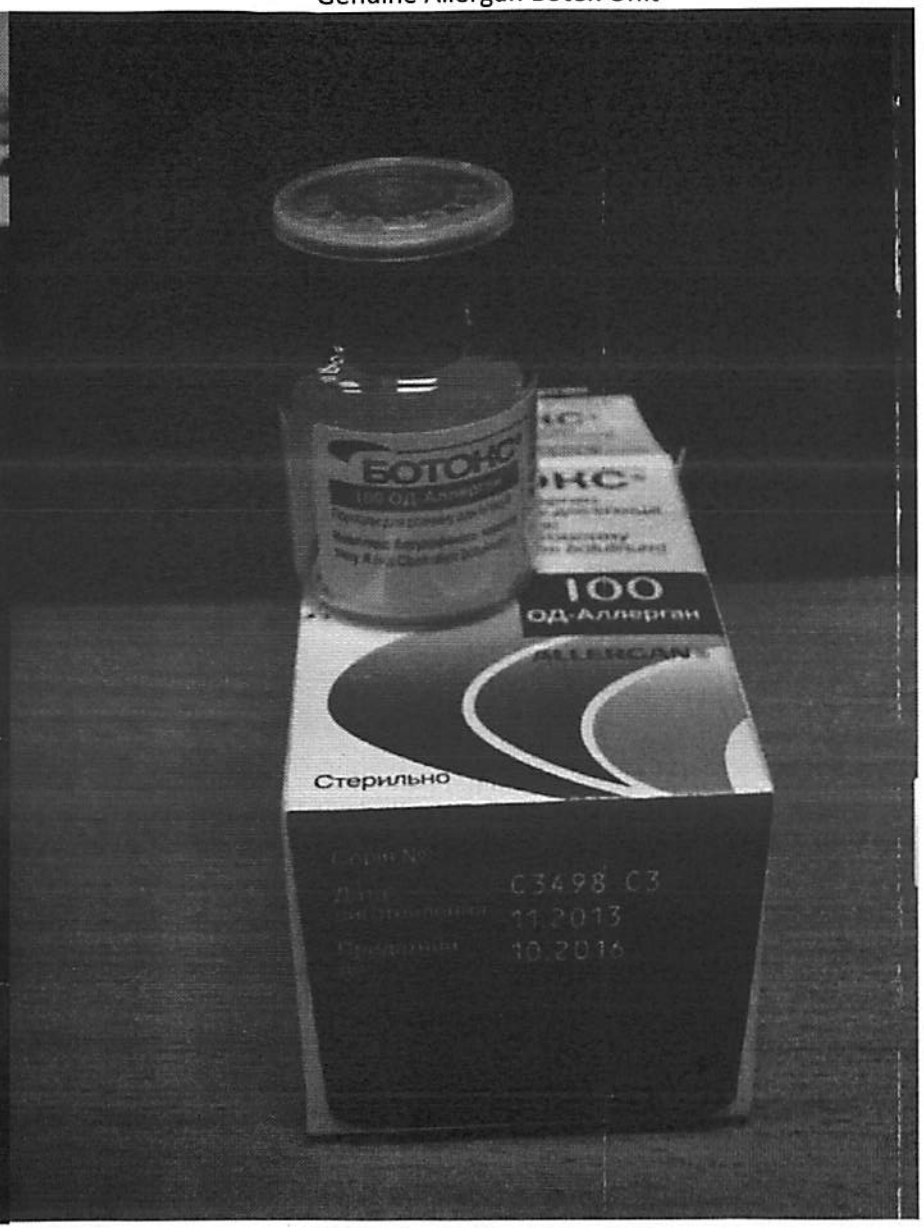
本案依分層負責規定授權業務主管決行

Attachment 1

Falsified Botox Unit



Genuine Allergan Botox Unit



Attachment 1

Falsified Botox Unit

Genuine Allergan Botox Unit

IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall

	Reference Number **IE/I/50/01**

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

1. To: see list attached	
2. Product Recall Class of Defect: I	3. **Confirmed Falsified**
4. Product: Botox 100U	5. Marketing Authorisation Number: 805/10-300200000 This is the genuine MA number on the Ukraine market. Genuine product is for use in humans
6. Brand/Trade Name: BOTOX	7. INN or Generic Name: The genuine product contains Botulinum toxin type A
8. Dosage Form: Vacuum dried Powder for Injection	9. Strength: The genuine product contains 100 Units per 10ml vial
10. Batch number: The following genuine Allergan batch number was applied to the falsified units: C3498 C3	11. Expiry Date: The genuine batch has an expiry date of: 10/2016 The falsified batch has an expiry date of: 12/2017
12. Pack size and Presentation: 10ml glass vial in carton	13. Date Manufactured: The falsified unit has a date of manufacture of 01.2015 The date of manufacture of the genuine batch is 11.2013
14. Marketing Authorisation Holder: The MAH for the genuine product in the Ukraine is Allergan Pharmaceuticals Ireland.	
15. Manufacturer†: Falsified product: Unknown Genuine product: Allergan Pharmaceuticals Ireland, Westport, Co. Mayo, Ireland	16. Recalling Firm: Allergan Pharmaceuticals Ireland Contact Person: Mr. Finbar O'Neill Tel: +353-98-55929

17. Recall Number Assigned: No recall on Irish market. Investigation number is QDR-H-15-203

18. Details of Defect/Reason for Recall:

A falsified unit of Botox 100U/vial was detected on the Ukrainian market. Doctors in the Ukraine received email communication advising them of the availability of Botox at a lower price. Supply of these units led to the identification of falsified packs.

The following anomalies were identified by inspection of images of the falsified unit:

1. The batch number is a genuine Allergan batch number but the manufacturing and expiry dates printed on the outer carton do not correspond to the details for the genuine batch.
2. The font of the falsified unit differs from the approved label artwork. An image is shown in attachment 1.
3. The crimp is grey and appears not to have the batch number printed on it. The genuine crimp is purple and has the batch number printed on it.
4. The flip-off seal is white and appears not to have the batch number printed on it. The genuine flip-off seal is clear/colourless and has the product information printed on it in 2D code which is visible under UV light.
5. The vial is not the same size as the genuine vial. The falsified vial is taller and has a smaller diameter.
6. The product physical appearance is also different (see attachment 1). The falsified product has a large quantity of dried product present in the base of the vial, much more than what is present in the genuine product.

19. Information on distribution including exports:

The falsified packs were detected in the Ukraine by a doctor who notified Allergan's authorised distributor.

The genuine batch was distributed to: Morocco, Egypt, Greece, Thailand, Indonesia, Malaysia, Taiwan, Ukraine, Chile, Argentina, Croatia, Guatemala, Ecuador, Hungary, Peru, Serbia and Tunisia.

At this time, there is no evidence that falsified packs of batch C3498 C3 are in circulation outside of Ukraine.

20. Action taken by Issuing Authority:

None. Falsified packs have not been identified on the Irish market.

21. Proposed Action:

Local action as considered necessary.

22. From (Issuing Authority): Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.	23. Contact Person: Rob Smyth Telephone:+353 1 676 4971	
24. Signed: rob smyth	25. Date: 7th May, 2015	26. Time: 14.30 GMT