

正本

檔 號：  
保存年限：

105B-0182

## 新北市政府衛生局 函

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24158

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受文者：新北市藥師公會

發文日期：中華民國105年3月11日  
發文字號：新北衛食字第1050418074號  
速別：普通件  
密等及解密條件或保密期限：  
附件：相關資料影本1份

主旨：有關案內藥品「Combigan(批號E74469及E73028)」在埃及發現仿冒品流通，惠請轉知所屬會員，如有案內批號產品請立即下架勿再販售，並儘速配合回收事宜，請查照辦理。

說明：

- 一、依據衛生福利部食品藥物管理署105年3月9日FDA企字第1051200860號函辦理。
- 二、為保障民眾用藥安全，惠請轉知所屬會員，如有案內批號產品請立即下架勿再販售，並儘速配合回收事宜。
- 三、檢附相關資料影本1份。

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

林業公司

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105年3月9日

發文字號：FDA企字第1051200860號

速別：普通件

密等及解密條件或保密期限：

附件：資料1份(A210200001105120086000-1.pdf)

主旨：檢送案內所陳藥品「Combigan(批號E74469及E73028)」

警訊相關資料1份，該產品在埃及發現仿冒品流通，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105年3月5日接愛爾蘭Health Products Regulatory Authority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：

交換戳記 105/03/09 12:37
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王峙懿

衛生局




1050418074

(2015/03/09)

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

Reference Number  
**IE/I/51/01**

		
1. To: see list attached		
2. Product Recall Class of Defect:	1	3. <b><u>Confirmed Falsified</u></b>
4. Product: Combigan 2mg/ml + 5mg/ml Eye Drops, Solution		5. Marketing Authorisation Number: 25750/2008  This is the genuine MA number on the Egyptian market.  Genuine product is for use in humans
6. Brand/Trade Name: Combigan		7. INN or Generic Name:  The genuine product contains Brimonidine tartrate and Timolol maleate
8. Dosage Form: Eye drops, solution		9. Strength:  The genuine product contains 2mg brimonidine tartrate and 5mg timolol maleate per ml
10. Batch number:  Batch numbers E74469 & E73028 were printed on the label and outer carton of the falsified product. The batch numbers correspond to genuine batches of <u>other</u> Allergan products. See description and attachment below		11. Expiry Date:  Various, see attachment
12. Pack size and Presentation:  The genuine product is contained in a 5ml LDPE bottle		13. Date Manufactured:  Various, see attachment
14. Marketing Authorisation Holder:  The MAH for the genuine product in Egypt is Allergan Pharmaceuticals Ireland		
15. Manufacturer†:  <b><u>Falsified product:</u></b> Unknown  <b><u>Genuine product:</u></b> Allergan Pharmaceuticals Ireland, Westport, Co. Mayo, Ireland		16. Recalling Firm: Allergan Pharmaceuticals Ireland, Dublin Office  Contact Person: Sarah Graham  Tel: +353 1 6445271

17. Recall Number Assigned: No recall on Irish market. Investigation number is QDR-H-16-109		
18. Details of Defect/Reason for Recall: <p>Allergan Pharmaceuticals Ireland became aware of cases of falsified Combigan on the Egyptian market. Users noticed that the eye drops were a different colour than expected and that batch numbers on the carton and label did not match. In addition, adverse reaction reports have been received, of increased intraocular pressure in patients with open-angle glaucoma or ocular hypertension.</p> <p>The investigation confirmed that authentic product manufactured by Allergan had been relabelled and repackaged as Combigan product. The batch numbers printed on the base of the suspect units corresponded to genuine batches of <u>other</u> Allergan products which had not been supplied to Egypt. The cartons, leaflets and labels of falsified packs were examined and showed only minor variances from the approved artwork (incorrect drawing number on the leaflet and different DOM and expiry of the batch numbers). The investigation confirms the falsified Combigan packs are limited to those with lot numbers E74469 &amp; E73028 printed on the label and carton.</p>		
19. Information on distribution including exports: <p>The <u>falsified</u> packs have been detected in Egypt only.</p> <p>The <u>genuine</u> batches of the other Allergan products, batch details of which were coded on the falsified product bottles have been distributed to various markets, see appendix. There is no action required with these products.</p> <p>At this time, there is no evidence that falsified packs of Combigan are in circulation outside of Egypt.</p>		
20. Action taken by Issuing Authority: <p>None. Falsified packs have not been identified on the Irish market.</p>		
21. Proposed Action: <p>Class I recall on the Egyptian market, to patient level.</p>		
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: <b>Rob Smyth</b> <small>Digitaly signed by Rob Smyth  The content length, attributes, integrity, authority, timestamp compliance, and other information is correct  Date: 2016.03.04 16:15:30 Z</small>	25. Date: 4 <sup>th</sup> March, 2016	26. Time: 16.15 GMT

Appendix 1. Details of Components Used in Falsified Combigan Bottles

Counterfeit	Lot Number on unit Bottles	lot number printed on Carton label	Product Name/Formulation Number	Material Number	Market Distribution	Active Substance Name	Product Strength	Manufacture date	Quantity manufactured	Expiry Date	Egyptian Wholesaler	MA Number Egypt
2D coded bottle	E7607	Carton E7449	Olan, 761X	4003D	Egypt	Olanam	0.7%	11-Mar-15	76,044	11-Apr-17	Sciopharm Pharmaceutical Care	1903406
		Label E7449		4003G	Australia							
	E7544	Carton E7449	Prod Fortz, 762X	3720G	Egypt	Prednisone Acetate	Suspension 1%	08-Apr-15	83,680	08-Mar-17	Sciopharm Pharmaceutical Care	2545404
		Label E7449										
	E7592	Carton E7449	Prod Fortz, 762X	3720G	Egypt	Prednisone Acetate	Suspension 1%	05-Mar-15	83,320	15-Apr-17	Sciopharm Pharmaceutical Care	2545404
		Label E7449										
	E7582	Carton E7449	Prod Fortz, 762X	3720G	Egypt	Prednisone Acetate	Suspension 1%	22-Apr-15	84,024	22-Mar-17	Sciopharm Pharmaceutical Care	2545404
Label E7449												
E7595	Carton E7449	Prod Fortz, 762X	3720G	Egypt	Prednisone Acetate	Suspension 1%	06-Mar-15	86,424	06-Apr-17	Sciopharm Pharmaceutical Care	2545404	
	Label E7449											
E7586	Carton E7328	Prod Fortz, 762X	3720G	Egypt	Prednisone Acetate	Suspension 1%	08-Jan-15	81,264	08-Dec-16	Sciopharm Pharmaceutical Care	2545404	
	Label E7328											
Counterfeit	Lot Number Printed on Carton label	N/A	Product Name	Material Number	Market Distribution	Active Substance Name	Product Strength	Manufacture date	Quantity manufactured	Expiry Date	Wholesaler Shipped to	MA Number
Combigan carton and label	E7528	N/A	Evoxen, 761X	4070E	Italy San Marino Vatican City	Olanam	0.7%	15-Mar-14	68,832	13-Feb-16	No units shipped to Egypt	1903406
									10,476			1903406
	E7449	N/A	Ginfert, 937X	9250E1 9250E3 9250E8 9250E1	Italy San Marino Vatican City Malta Turkey Greece	Binatiprost, Tirokid, Makate	6.03% + 0.5%	08-Oct-14	40,000	08-Sep-16	No units shipped to Egypt	25279207
									4,404			25279207
									32,400			25279207
22,224									25279207			