

正本

檔 號：
保存年限：

105B-0181

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：王峙懿
電話：(02)22577155 分機2355
傳真：(02)22536548
電子信箱：AP6125@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105年3月11日
發文字號：新北衛食字第1050412996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：有關衛生福利部食品藥物管理署查獲「Harvoni」（批號004702）」產品在以色列發現仿冒品流通，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8日FDA企字第1051200838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

游林泉

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105年3月8日

發文字號：FDA企字第1051200838號

速別：普通件

密等及解密條件或保密期限：

附件：資料1份(A210200001105120083800-1.pdf)

主旨：檢送案內所陳藥品「Harvoni」（批號004702）」警訊相關資料1份，該產品在以色列發現仿冒品流通，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2日接以色列Israeli Ministry of Health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
105/03/08 17:09

王峙懿

衛生局

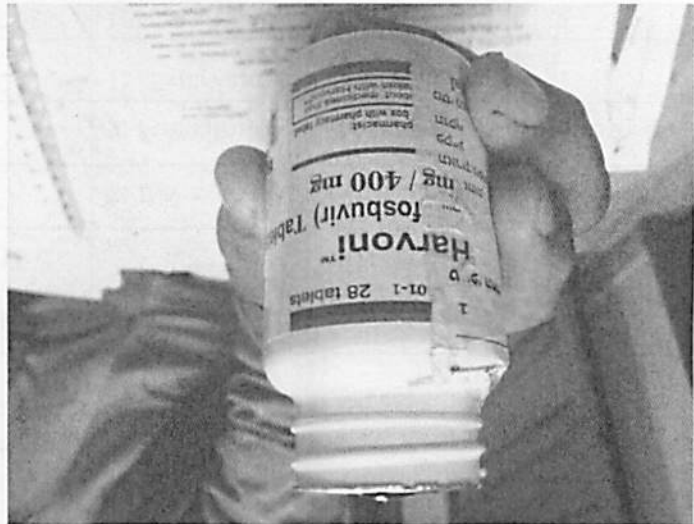
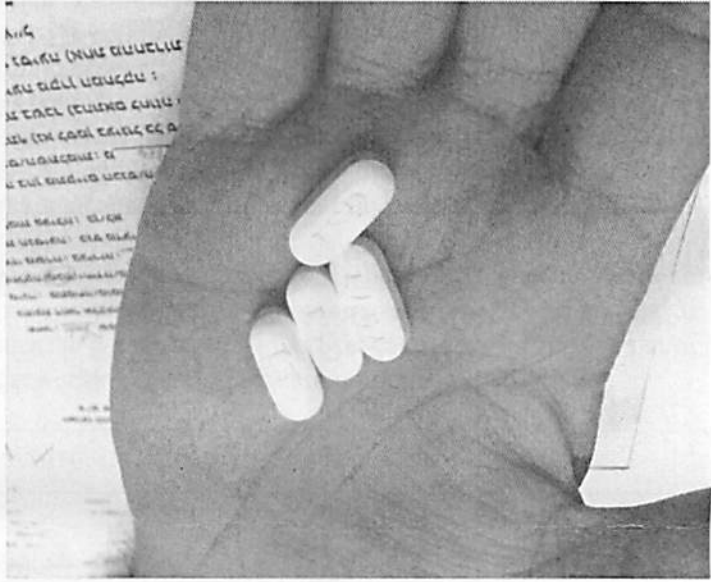




IMPORTANT - DELIVER IMMEDIATELY
Rapid Alert Notification of a Quality Defect / Recall

Reference Number 2/2016

Institute for Standardization and Control of Pharmaceuticals (ISCP)		
1. To: See list attached		
2. Product Recall Class of Defect: I		3. Falsification / Fraud (specify)
4. Product: Harvoni (ledipasvir and sofosbuvir)		5. Marketing Authorisation Number: NA
6. Brand/Trade Name: Harvoni		7. INN or Generic Name : ledipasvir and sofosbuvir
8. Dosage Form: Tablets		9. Strength: 90 mg ledipasvir /400 mg sofosbuvir
10. Batch number (and bulk, if different): 004702		11. Expiry Date: 03 2017
12. Pack size and Presentation: 28 tablets in a HDPE bottle		13. Date Manufactured: Unknown
14. Marketing Authorisation Holder: Not applicable, unlicensed product.		
15. Manufacturer : As stated on the HDPE bottle: "Manufactured for Gilead Sciences, Inc. foster city, ca 94404, Made in Ireland " Contact Person: NA Telephone:		16. Recalling Firm (if different): Genmedix via Promedico Contact Person: Tali Dreifinger Shimoni <res.rx@Genmedix.co.il> Telephone: +972-54 -6645977
17. Recall Number Assigned (if available): 2/2016		
18. Details of Defect/Reason for Recall: Based on the visual evaluation conducted Gilead sciences inconsistencies are noted; 1. The bottle label is not authentic due to differences in barcode, label font/size, color used for the top bar of the brand color, and out of proportion graphic elements (Rx, Gilead logo) when compared to the label retain for this lot 2. The lot number on the bottom of the bottle TWTW is inconsistent with that which would have occurred at GSIUC (TWTWD). 3. The tablets found in the bottle (Sovaldi Access) are inconsistent with the bottle label (Harvoni tablets) Harvoni tablets are orange, diamond-shaped, film-coated, debossed with "GSI" on one side and "7985" on the other side of the tablet. The suspect tablet was white, capsule shaped, debossed with "GSI" on one side and "7977" on the other instead of the patient's normal Harvoni tablets. Based on the photographs provided, the tablets found in the bottle labeled lot 004702 are consistent with Sovaldi Access product. The bottom of the bottle is printed with lot number TWTW which corresponds to a lot of Sovaldi Access product manufactured at a contract manufacturing operation.		
19. Information on distribution including exports (type of customer, e.g. hospitals): from the information gained till know 3 packages of the product was imported from RCC Pharma Switzerland and distributed to 3 patients in Israel. The packages were recalled by the distributor once they learnt from one of the patients about a different color and shape of the tablets inside the package.		
20. Action taken by Issuing Authority: Recall of all items from patients for further investigation.		
21. Proposed Action: Investigate the source for the product at RCC Pharma Switzerland and verify that this product was not distributed elsewhere.		
22. From (Issuing Authority): Israel, ISCP		23. Contact Person: Rachel Shimonovitz Telephone:972-506243564
24. Signed: Rachel Shimonovitz	25. Date:02/03/2016	26. Time: 16:00



Falsified products: photos:

* Information not required, when notified from outside EU.