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：江佳穎
電話：(02)22577155 分機2353
傳真：(02)22536548
電子信箱：AQ5750@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7月27日
發文字號：新北衛食字第1051370014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1份

主旨：檢送案內所陳藥品「Viread 245 mg(批號SPMGD)」警訊相關資料1份，該產品在德國發現仿冒品流通，為維護國民之健康與安全，請轉知所屬會員勿販售供應與使用，請查照。

說明：

一、依據衛生福利部食品藥物管理署105年7月20日FDA企字第1051203023號函辦理。

二、檢附案內相關資料1份。

正本：新北市藥師公會、新北市藥劑生公會、新北市醫師公會、新北市西藥商業同業公會、新北市商業會
副本：新北市政府衛生局衛生稽查科(含附件)

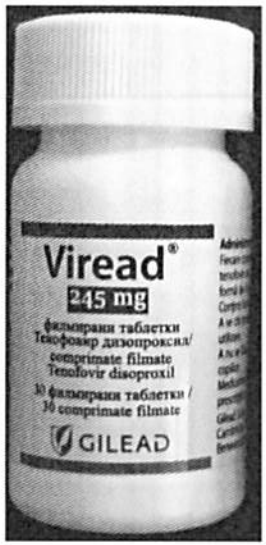
局長 林奇宏

本案依分層負責規定授權業務主管決行

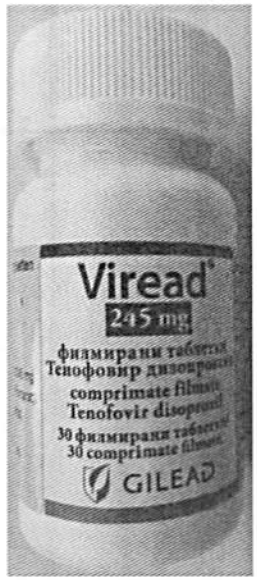
Viread 245 mg: Batch SPMGD Exp. 01/2020 - Romania

Labelling of primary packaging:

Deviation of the confirmed counterfeit related to former supplies of the same batch of Viread 245 mg



counterfeit



original

Indication of the strength:

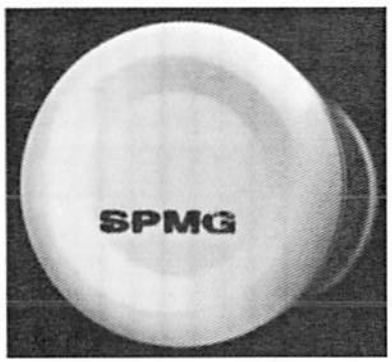
- The number „2“ is smaller in comparison with the other numbers.
- The number „4“is closed in the counterfeit, and open on the labelling of former supplies.

The fonts are different.

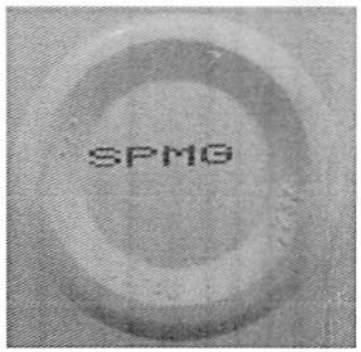
Text underneath the indication of the strength: The font is smaller on the labelling of the counterfeit related to the supplied original, from previous deliveries.

Viread 245 mg: Batch SPMGD Exp. 01/2020 - Romania

Indication of labelling on the bottom of the bottle:

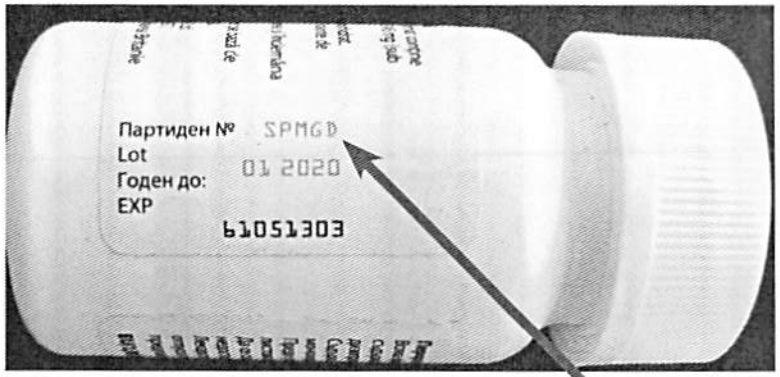


counterfeit:
heavy print of labelling

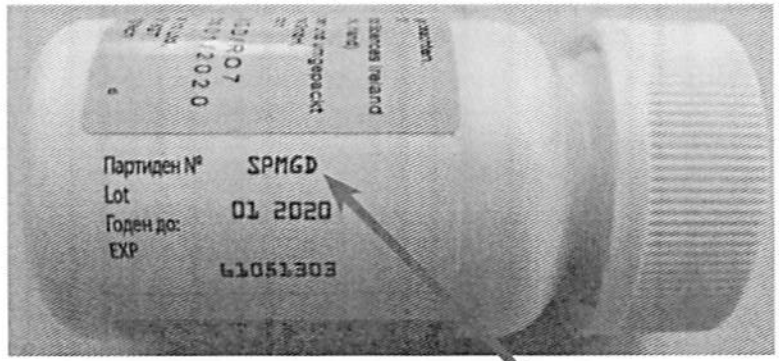


original:
light pixelated print of labelling

Viread 245 mg: Batch SPMGD Exp. 01/2020 - Romania



counterfeit:
light print of batch number



original:
heavy print of batch number

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: (1) (circle one)		3. **Counterfeit** / ~~Fraud~~ (specify)*
4. Product: Viread 245 mg		5. Marketing Authorisation Number: * EU/1/97/055/008; EU/1/97/055/009 For use in humans/~~animals~~ (delete as required)
6. Brand/Trade Name: Viread 245 mg		7. INN or Generic Name: Tenofovirdisoproxilfumarat
8. Dosage Form: film-coated tablets		9. Strength: 245 mg
10. Batch/Lot Number: SPMGD		11. Expiry Date: 01/2020
12. Pack size and Presentation: 30 film-coated tablets/pack		13. Date Manufactured: *
14. Marketing Authorisation Holder: * Gilead Sciences International Limited, Cambridge, CB21 6GT, United Kingdom (Originator)		
15. Manufacturer†: CC-Pharma GmbH, In den Feldern 2, D-54570 Densborn [parallel import/- distribution] Contact Person: Peter Koch (Pharmakovigilance) Telephone: +49 (0)6594-9219-248		16. Recalling Firm (if different): Not applicable! The counterfeit packages were identified by parallel importer CC-Pharma, D-54570 Densborn during the check of incoming goods. No packages of the concerned Viread 245mg shipment from Romania were released by CC-Pharma!:
17. Recall Number Assigned (if available)		

18. Details of Defect/: Confirmed counterfeit (see pictures). An incoming delivery (2016-07-06) of Viread 245mg (Batch SPMGD) from Romania was identified to be probably counterfeit by parallel importer CC Pharma. The delivery was quarantined immediately. The originator has actually confirmed the counterfeit and informed that the company will be notifying the HPRA, Irish regulatory authority, in a defect report. CC Pharma received the delivery from the Bulgarian wholesaler: Perfect Care Distribution SRL, Bucharest.
19. Information on distribution including exports (type of customer, e.g. hospitals): * CC-Pharma did not sell the packages to any customer. The packages are now in quarantine. One package was send to the originator for further examination.
20. Action taken by Issuing Authority: Information of the competent authorities in Germany by RAS
21. Proposed Action: Warning information to parallel importers in other federal states by their competent authority.

22. From (Issuing Authority):	23. Contact Person:
Landesamt für Soziales, Jugend und Versorgung Moltkestraße 19 54292 Trier	Telephone: +49-261-4041-209 or +49-651-1447-208

24. Signed:	25. Date: 15.07.2016	26. Time: *10:00

* 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.