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

	Reference Number **CZ/I/24/01**
State Institute for Drug Control, Prague, Czech Republic	
1. To: See list attached	
2. Product Recall Class of Defect: (I) II	3. Falsification / ~~Fraud (specify)~~* Confirmed Falsification
4. Product: Viread 245 mg	5. Marketing Authorisation Number: * EU/1/01/200/001 For use in humans
6. Brand/Trade Name: Viread 245 mg	7. INN or Generic Name: *tenofovirum disoproxilum*
8. Dosage Form: film-coated tablets	9. Strength: 245 mg
10. Batch number: SPMGD	11. Expiry Date: 01/2020
12. Pack size and Presentation: 30 film-coated tablets/pack	13. Date Manufactured: N/A
14. Marketing Authorisation Holder: Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	
15. Manufacturer†: Orifarm Supply s.r.o. Palouky 1366 Hostivice, 253 01 Czech Republic Contact Person: Ladislava Zikmundova Ladislava.Zikmundova@Orifarm.com	16. Recalling Firm (if different): Not applicable. The counterfeit packages were identified by authorised manufacturer Orifarm Supply, Czech Republic, during the check of incoming goods.
17. Recall Number Assigned (if available)*: N/A*	
18. Details of Defect: The counterfeit packages were identified by authorised manufacturer Orifarm Supply, Czech Republic, during the control of incoming goods. Orifarm Supply CZ purchased 56 packages of batch SPMGD from Bulgarian wholesaler: City Company OOD (2016-08-16). During the check of incoming goods they found unusual findings (see photos attached): 1) Blue colour on the carton has darker shade 2) Label on the bottle is from different material than usual (glossier than usual) 3) The leaflet is pallid and the thick layer of glue has been used The delivery was quarantined immediately. One package was sent to the MAH for further examination. The secondary package and the label of the bottle were in Bulgarian language version; the leaflet was in Bulgarian-Romanian language version. The MAH has actually confirmed the counterfeit.	
19. Information on distribution including exports (type of customer, e.g. hospitals): * Orifarm Supply did not sell the packages to any customer and save all packages (55 pcs) in quarantine. One package was sent to the MAH for further examination.	
20. Action taken by Issuing Authority: Notification, disclosure of this information on the web site	
21. Proposed Action: Warning information to parallel importers	
22. From (Issuing Authority): State Institute for Drug Control, Prague, Czech Republic	23. Contact Person: Ing. Radka Otawova, Ph.D. radka.otawova@sukl.cz

24. Signed: Mgr. Apolena Jonášová	25. Date: 24th January 2017	26. Time: * 17:00

* 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 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.

This is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us by telephone immediately and return it to us at the above address by mail. Thank you

****