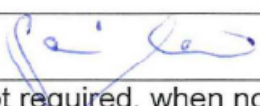


RAS-Formular für Risikoklasse I oder II und für follow-up-Meldungen

DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / <u>Recall</u>		
Add Letter Head of Sender / Meldende Stelle Landesverwaltungsamt Referat 504 - Gesundheitswesen, Pharmazie Referatsbereich 504.c - Pharmazie Ernst-Kamieth-Straße 2 06112 Halle (Saale) Germany		
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		
☐ Oberste Landesveterinärbehörde		
2. Product Recall Class of Defect: I II (circle one)	3. Falsification/Fraud (specify)* Theft of Testoviron Depot ampoules	
4. Product: Testoviron Depot	5. Marketing Authorisation Number: 8888222 (Portugal) For use in humans	
6. Brand/Trade Name: Testoviron Depot	7. INN or Generic Name: Testosterone enanthate	
8. Dosage Form: Ampoules	9. Strength: 250 mg/ml	
10. Batch number (and bulk, if different): KT02S51	11. Expiry Date: 12/2023	
12. Pack size and Presentation: 1 ampoule per package	13. Date Manufactured:	
14. Marketing Authorisation Holder: Bayer Portugal, Lda.		

15. Manufacturer†: Bayer Portugal, Lda. Rua da Quinta do Pinheiro, 5 2794-003 Carnaxide Portugal Contact Person: Telephone:		16. Recalling Firm (if different): MPA Pharma GmbH Betriebsstätte: Stendaler Chaussee 28 D-39606 Osterburg Contact Person: Dr. Carsten Holst Telephone: +49 4154 806 156	
17. Recall Number Assigned (if available):			
18. Details of Defect/ <u>Reason for Recall</u> : Theft			
19. Information on distribution including exports (type of customer, e.g. hospitals): * The manufacturer MPA Pharma GmbH informed the responsible authority, that 582 packages of Testoviron Depot have been stolen on 15 th of May 2019. All packages have been marked with serial numbers. The serial numbers will be presented in a separate file. Originally, Bayer Portugal, Lda. produced the packages for the Portuguese market. Thus, the packages are labelled in Portuguese language.			
20. Action taken by Issuing Authority: MPA Pharma GmbH submitted charge against unknown at the police. The serial numbers have been registered as stolen by MPA Pharma GmbH at the hub. This form is considered to inform other authorities.			
21. Proposed Action:			
22. From (Issuing Authority): Landesverwaltungsamt Referat 504 - Gesundheitswesen, Pharmazie Referatsbereich 504.c - Pharmazie Ernst-Kamieth-Straße 2 D-06112 Halle (Saale) Germany		23. Contact Person: Dirk Seiler Telephone: +49 345 514 1222 E-mail: pharmazie@lvwa.sachsen-anhalt.de	
24. Signed: 	25. Date: 22.05.2019	26. Time: 13:03 h	

* 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.

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