

Formular Follow-up-Meldungen und Non urgent Informationen (NUI)

Follow-up and Non-urgent Information for Quality Defects

Add Letter Head of Sender / Meldende Stelle	
Landesamt für Arbeitsschutz, Verbraucherschutz und Gesundheit (LAVG) Abteilung Gesundheit Dezernat G3 - Apotheken und Arzneimittel Wünsdorfer Platz 3 15806 Zossen 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 Landesbehörde	0331 – 866 5161
2. Recall Number Assigned: n.a.	2a. National reference number (When applicable)
4. Product: Testoviron-Depot	5. Marketing Authorisation number: 6929279.00.00
6. Brand/Trade name: Testoviron-Depot 250mg	7. INN or Generic Name: Testosterone enantate
8. Dosage form: Ampoule	9. Strength: 250mg/1ml
10. Batch number (and bulk, if different): KT06P07	
14. Marketing Authorisation holder: Jenapharm GmbH & Co. KG Otto-Schott-Straße 15 07745 Jena, Germany Tel.: +49 – (0)3641 - 648888	
15. Manufacturer ¹ : Bayer AG 51368 Leverkusen	16. Contact Person: -

¹ The holder of an authorisation to under Article 40 of Directive 2001/83/EC and 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

17. Subject title The LAVG Brandenburg reported with the Rapid Alert Notification on 15th September 2020 about the loss / possible theft of 1440 packages Testoviron Depot 250mg in German labeling. The LAVG recently received the information from the manufacturer, that the batch entirely will not be marketed. The LAVG shared this disclosure of the manufacturer with the competent authority of Thuringia, that is responsible for the MAH.		
22. From (issuing Authority): Landesamt für Arbeitsschutz, Verbraucherschutz und Gesundheit (LAVG) Abteilung Gesundheit Dezernat G3 – Apotheken und Arzneimittel Wünsdorfer Platz 3 15806 Zossen Germany arzneimittel@lavg.brandenburg.de	23. Contact person: doreen.lehmann@lavg.brandenburg.de Tel: +49 – 331 - 8683-882 GMP Inspector: Dr. Steffen Rodewald	
24. Signed: Dr. Rodewald 	25. Date: 19.01.2021	26. Time: 