RAN-Formular (Rapid-Alert-Notification) zur Mitteilung über den RAS-Verteiler

DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Medicinal Product Falsification

☐ ASSUMED ☐ REASONABLY SUSPECTED ☒ VERIFIED

Landesamt für soziale Dienste Schleswig-Holstein
Abteilung Gesundheits- und Verbraucherschutz
Dezernat 31 Arzneimittelüberwachung

Gartenstraße 24
24534 Neumünster

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
☒ Ministerium für Soziales, Gesundheit, Jugend, Familie und Senioren des Landes Schleswig-Holstein	

2. Classification: 1	3. Falsification: verified
4. Product: MENOGON® 75 IU	5. Marketing Authorisation Number: * 236209/98 (Lebanon/Middle East) For use in humans
6. Brand/Trade Name: MENOGON® 75 IU	7. INN or Generic Name: Menotrophin
8. Dosage Form: Powder and solvent for solution for injection	9. Strength: 75 IU
10. Batch number (and bulk, if different): 78432	11. Expiry Date: 30-01-2024
12. Pack size and Presentation: 5 ampoules of powder and 5 ampoules of solvent	13. Date Manufactured:* 30-01-2021
14. Marketing Authorisation Holder: Ferring GmbH, Wittland 11, 24109 Kiel, Germany	
15. Manufacturer†: Ferring GmbH, Wittland 11, 24109 Kiel, Germany Contact Person: Claudia Binnewies Telephone: +49 431 5852 268	16. ~~Recalling Firm~~
17. Rapid Alert Notification Reference Number: not assigned	

18. Details: The Lebanon Health Authority informed Ferring that the aboved mentioned batch and other expired batches (648742, 648953) were noticed during a pharmacy inspection. The presentation is in English and Arabic language. Ferring was asked to evaluate if the batches are genuine or not. Batch numbers/data are not known for this product and do not follow the coding system of Ferring. Furthermore, the packaging layout of the batches does not comply with the original artwork. The falsification was classified as verified.		
19. Information on distribution including exports (e. g. type of customer, e.g. hospitals):* The above-mentioned batches were not imported into Lebanon by the legal supply chain. General information about the product: Germany: currently no batch of the product in the market (last batch expired on 30th of June 2021) Other European countries: marketing authorisations were de-registered. Other Arabic countries holding marketing authorisation with English/Arabic artwork: Bahrain, **Egypt**, Iran, **Iraq**, Jordan, Kuwait, **Libya**, **Oman**, Qatar, **Saudi Arabia**, **Sudan**, Syria, United Arabic Emirates, Yemen, Turkey (bold printed countries are those with the main supply)		
20. Action taken by Issuing Authority: Issuance of RAN		
21. Proposed Action: It is proposed that the BfArM forwards this notification to the Arabic Health Authorities.		
22. From (Issuing Authority): Landesamt für soziale Dienste Schleswig-Holstein mail to: post.arzneimittelueberwachung@lasd.landsh.de	23. Contact Person: Dr. Carsten Bode Telephone: +49 4321 913 958	
24. Electronically signed in internal file	25. Date: 09th of August 2021	26. ~~Time: *~~

* *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.*