DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY!

Rapid Alert Notification of a Medicinal Product Falsification

☐ **ASSUMED** ☐ **REASONABLY SUSPECTED** ☒ **VERIFIED**

Regierungspräsidium Darmstadt, 64278 Darmstadt

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
☒ Hessisches Ministerium für Soziales und Integration, Referat V3	0611-32719 3611

2. Classification (not mandatory)	3. **Falsification**
4. Product: Pascorbin Solution for injection, 50 mL injection bottle, 150 mg ascorbic acid/ mL	5. Marketing Authorisation Number: * 6727989.00.00 For use in humans
6. Brand/Trade Name: Pascorbin	7. INN or Generic Name: ascorbic acid
8. Dosage Form: solution for injection	9. Strength: 150 mg/mL
10. Batch number (and bulk, if different): 0190 0058	11. Expiry Date: 12/2022 09/2022
12. Pack size and Presentation: 50 mL	13. Date Manufactured: unknown

14. Marketing Authorisation Holder (for Germany only):
Pascoe pharmazeutische Präparate GmbH
Schiffenberger Weg 55
35394 Giessen

15. Manufacturer†: Genuine: Pascoe Pharmazeutische Präparate GmbH Europastraße 2 35394 Giessen Contact Person: Holger Michels, QPPV Telephone: +49 641 7960-958	16. Recalling Firm

17. Rapid Alert Notification Reference Number: **DE_HE_2021_317**

18. Details:

Details of discovery:

1. The MAH was contacted via a Turkish business partner and was informed about a Turkish private clinic storing considerable amounts of Pascorbin. The MAH neither possesses a marketing authorisation in Turkey nor distributes the product to/ within the country. The MAH later was informed about a raid in a building adjacent to the clinic by the Turkish authorities. Photographs as well as a video were provided. The video was also broadcasted on Turkish TV. The Turkish authorities found Pascorbin, which is most likely falsified product. According to the MAH the seized medicinal product has a general genuine appearance but batch number and expiry date (batch no: 0190) are unknown. Other medicinal products as well as printed secondary packaging material, labels, a labelling machine and empty vials were seized by Turkish authorities.

2. In a second case (batch no 0058) the MAH was contacted by a person situated in Turkey who wanted to know whether the product bought was genuine. The person provided photographs and the counterfeit can be visually detected by misspellings (e.g.: Wirkstoof instead of Wirkstoff, Injecktionslösung instead of Injektionslösung, Kinde instead of Kinder) within the primary and the secondary labelling, as well as the blue flip off cap. The genuine product comes with a flip off cap in brown colour.

The labelling in both cases is in German language.

19. Information on distribution including exports (e. g. type of customer, e.g. hospitals):
At the moment, there is no knowledge whether product of batch no 0190 has been distributed. There is no knowledge were product of batch no 0058 was supplied from.

20. Action taken by Issuing Authority: FOR YOUR INFORMATION

21. Proposed Action: To date there is no action required in Germany.

22. From (Issuing Authority):	23. Contact Person:
Regierungspräsidium Darmstadt mail to: pharmazie@rpda.hessen.de	Svenja Braner Telephone: +49 06151-12 - 5345

24. Signed: gez. S. Braner	25. Date: 15.09.2021	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.*