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**

Regierung von Oberbayern
Sachgebiet 53.2 - Pharmazie
Maximilianstraße 39
D-80538 München

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
☐ Staatsministerium für Gesundheit und Pflege (StMGP)	pharmazie@ stmgp.bayern.de

2. *Classification (not mandatory)*	3. Falsification
4. Product: Tasigna 150 mg Hartkapseln	5. Marketing Authorisation Number: * EU/1/07/422/005 For use in humans
6. Brand/Trade Name: Tasigna	7. INN or Generic Name: Nilotinib
8. Dosage Form: Hard Capsules	9. Strength: 150 mg
10. Batch number (and bulk, if different): KJ3457	11. Expiry Date: 30.09.2022
12. Pack size and Presentation: 28 (7x4) Hard Capsules	13. Date Manufactured:* unknown

14. Marketing Authorisation Holder (potentially affected original product):
Vista Building
Elm Park, Merrion Road
Dublin 4
Ireland

15. Manufacturer†:	16. Recalling Firm
Manufacturer of original product unknown. Manufacturer of parallel imported medicinal product: EurimPharm Produktions GmbH 83416 Saaldorf-Surheim Contact Person: Eva-Maria Fögen Telephone: 08654-7707-314	

17. Rapid Alert Notification Reference Number: DE_

18. Details:
We were informed by EurimPharm Produktions GmbH (83416 Saaldorf-Surheim, Germany) on 9th of September 2020 that the serial numbers of two sourced original packages Tasigna 150 mg 28 (7x4) hard capsules (Authorisation No.: EU/1/07/422/005) were reported as "Supplied" during verification on 27th of July 2020 and 20th of August 2020. Further obtained packages of the batch were not affected.

Name	Serial No.	Batch No.
Tasigna 150 mg; 28 Hard Capsules	10313452619782	KJ3457
Tasigna 150 mg; 28 Hard Capsules	10239276997834	KJ3457

EurimPharm Produktions GmbH GER is a contract manufacturer of parallel imported medicinal products (repackaging, batch release), who received both affected original packages on 1st July 2020 from S.C. PI PHARMA M&D SRL (Intrarea Filmului no. 45; District 6; 062394 Bucharest; Romania; Licence No.: 432D) on behalf of Alphamed Arzneimittel GmbH (Michael-Walz-Gasse 17d, 5020 Salzburg, Austria). Alphamed Arzneimittel GmbH AT is still the owner of the packages. The packages are physically blocked at the site of EurimPharm Produktions GmbH GER.

So far known supply chain of the affected packages:

Verification by Romanian distributor S.C. PI PHARMA M&D SRL:	On 24th of June 2020: both serial numbers „active"
Pick up from S.C. PI PHARMA M&D SRL Delivery to EurimPharm Produktions GmbH GER	On 26th of June 2020 On 1st July 2020
Verification by EurimPharm Produktions GmbH GER	On 27th of July 2020: status „Supplied" for both serial numbers On 20th of August 2020: status „Supplied" for both seral numbers

Currently there are no hints for technical issues during verification. Unauthorized or manipulative access to the goods during transportation to EurimPharm Produktions GmbH GER by the transport service provider FRIGO TRANS GmbH were excluded. The investigation of both affected packages (design, layout, color, printing, braille, tamper evident seal) showed no obvious counterfeit features.

The complete verification of the supply chain by EurimPharm Produktions GmbH GER is not possible at the moment, because the Romanian distributor told that the documents were delivered to the responsible Romanian authority (National Agency for Medicines and Medical Devices, Bucharest) for further investigation. EurimPharm Produktions GmbH GER reported us, that the Romanian authority already started the investigation and found out that the status "supplied" in the Romanian system was set by an unknown "end user" on 15th of July 2020. At that date both packages were already physically at the EurimPharm Produktions GmbH GER site (see above).

The affected packages are requested by the Romanian authority for further investigation.

19. Information on distribution including exports (e. g. type of customer, e.g. hospitals):*
Both affected packages were blocked by EurimPharm Produktions GmbH GER and not distributed.

20. Action taken by Issuing Authority: FOR YOUR INFORMATION

21. Proposed Action: Further investigation

22. Regierung von Oberbayern Sachgebiet 53.2 - Pharmazie Maximilianstraße 39 D-80538 München mail to: xenia.dimont@reg-ob.bayern.de	23. Contact Person: Xenia Dimont Telephone: +49 89 2176 3093

24. Signed: i.V. M. Weidenhöfer	25. Date: 10.09.2020	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.*