

De : dvs defauts-qualite
À : Rapid Alert 2019EU
CC : Anne-Cecile PONS; Florent ROBIC
Date : 30/03/2021 17:49
Objet : RapidAlert; Fraud, Class I; DASATINIB SANDOZ 50 mg, film-coated tablet, Follow-up, FR/I/04/02
Pièces jointes : Followup RA vol Dasatinib Sandoz 50mg.pdf

Dear RA network,

Please find attached a follow-up of RA notification, following the theft of 159 units of Dasatinib Sandoz 50mg, comprimé pelliculé, in France.

Kind regards

Défauts Qualité médicaments
Pôle DQRS
Direction de l'Inspection
ANSM - France

IMPORTANT – DELIVER IMMEDIATELY
Rapid Alert Notification of a Quality Defect / Recall

		Reference Number FR/I/04/02 (follow-up FR/I/04/01)	
From: ANSM			
1. To: RA Network			
2. Product Recall Class of Defect: NA		3. Falsification / Fraud (specify)* Product theft	
4. Product: DASATINIB SANDOZ 50 mg, film-coated tablet		5. Marketing Authorisation Number: * For use in humans	
6. Brand/Trade Name: DASATINIB SANDOZ 50 mg, comprimé pelliculé		7. INN or Generic Name: dasatinib	
8. Dosage Form: film-coated tablet		9. Strength: 50mg	
10. Batch number: 89594		11. Expiry Date: 05/2023	
12. Pack size and Presentation: 60 tablets per pack		13. Date Manufactured: *	
14. Marketing Authorisation Holder: SANDOZ			
15. Manufacturer†: /		16. Recalling Firm (if different): NA	
Contact Person:		Contact Person:	
Telephone:		Telephone:	
17. Recall Number Assigned (if available): NA			
18. Details of Defect: Two cartons of 159 units of DASATINIB SANDOZ 50 mg (packaging in French), were stolen during the transport between the manufacturer (Slovenia) and the wholesaler which is located in France. Follow-up : the units concerned were found by the police near the place of the theft. They have been recovered by the MAH, who will not put them back into circulation. The MAH confirms that they were decommissioned last November.			
19. Information on distribution including exports: NA.			
20. Action taken by Issuing Authority: No recall of the batch. This information has been transferred to Customs and circulated in the Working Group of Enforcement Officers (WGEO). Serial numbers of the units stolen were decommissioned in the EU database on the 09th of November by the MAH. The carrier lodged a complaint.			
21. Proposed Action: Novartis plans to release on the French market, the remaining 140 unit of this batch after having checked their conformity.			
22. From (Issuing Authority): ANSM Inspectorate Division		23. Contact Person: Mrs Mélanie CACHET Telephone: +33(0)1 55 87 40 95	
24. Signed: Mélanie Cachet – La Directrice adjointe de la Direction de l'inspection	25. Date: 30/03/2021		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.

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