

DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall	
Meldende Stelle	
1. To / Empfänger:	FAX
<input type="checkbox"/> Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	0228-207-4636
<input type="checkbox"/> Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	030-18444-30409
<input type="checkbox"/> Paul-Ehrlich-Institut - Bundesamt für Sera und Impfstoffe - (PEI)	06103/77-1263
<input type="checkbox"/> Oberste Landesgesundheitsbehörde	
2. Product Recall Class of Defect: I II (circle one)	3. Counterfeit / Fraud (specify)*
4. Product:	5. Marketing Authorisation Number: * For use in humans/animals (delete as required)
6. Brand/Trade Name:	7. INN or Generic Name:
8. Dosage Form:	9. Strength:
10. Batch/Lot Number:	11. Expiry Date:
12. Pack size and Presentation:	13. Date Manufactured: *
14. Marketing Authorisation Holder: *	
15. Manufacturer†:	16. Recalling Firm (if different):
Contact Person:	Contact Person:
Telephone:	Telephone:
17. Recall Number Assigned (if available)	
18. Details of Defect/Reason for Recall:	
19. Information on distribution including exports (type of customer, e.g. hospitals): *	

20. Action taken by Issuing Authority:		
21. Proposed Action:		
22. From (Issuing Authority):		23. Contact Person: Telephone:
24. Signed:	25. Date:	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 released the batch in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC if different.

This is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us by telephone immediately and return it to us at the above address by mail. Thank you