DRINGEND - BITTE SOFORT AUSLIEFERN! IMPORTANT - DELIVER IMMEDIATELY

Rapid Alert Notification of a Quality Defect / Recall		
Meldende Stelle		
1. To / Empfänger:		FAX
☐	Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	0228-207-4630
☐	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	030-18444-30409
☐	Paul-Ehrlich-Institut - Bundesamt für Sera und Impfstoffe - (PEI)	06103/77-1263
☐	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†: Contact Person: Telephone:		16. Recalling Firm (if different): Contact Person: 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.