

 PHARMA ROAD	PR-OP-004_M2 v1 Recall form	SOP címe: Nagykereskedelmi értékesítés Hatálybalépés dátuma: 2017.09.07.
---	--	---

Reference Number:

From: PharmaRoad Kft.		
1. To: Company, name, address, email.		
2. Product Recall Class of Defect: I II III (circle one)		3. Falsification / Fraud (specify)*
4. Product:		5. Marketing Authorisation Number:/For use in humans
6. Brand/Trade Name:		7. INN or Generic Name:-
8. Dosage Form: oral/tablets		9. Strength:
10. Batch number (and bulk, if different):		11. Expiry Date:
12. Pack size and Presentation:		13. Quantity:
14. Marketing Authorisation Holder: *		
15. Manufacturer*: Contact Person:- Telephone/Email:-		16. Recalling Firm (if different): Contact Person: Telephone/Email
17. Recall Number Assigned (if available):		
18. Details of Defect/Reason for Recall:		
19. Action taken by Issuing Authority:		
20. Proposed Action:		
22. From (Issuing Authority):-		
24. Signed:	25. Date:	26. Time: -

* 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.

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
