

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*:

16. Recalling Firm (if different):

Contact Person:-

Contact Person:

Telephone/Email:-

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.

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