Veterinary Medicines Directorate

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

Reference Number: QD22/005
RapidAlert: QDefect,Class I; Recall, UK/I/027/001

1. To: All on rapid alert notification list	
2. Product Recall Class of Defect: **I** (circle one)	3. Counterfeit / Fraud (specify)* Counterfeit
4. Product: Micotil 300 mg/ml Solution for Injection	5. Marketing Authorisation Number: Vm 00879/4203 For use in animals
6. Brand/Trade Name: Micotil Solution for Injection	7. INN or Generic Name: Tilmicosin Injection
8. Dosage Form: Solution for Injection	9. Strength: 300mg/ml
10. Batch number (and bulk, if different): N/A	11. Expiry Date: N/A
12. Pack size and Presentation: 300mg/ml	13. Date Manufactured: N/A
14. Marketing Authorisation Holder: Elanco Europe Ltd Contact Person: Delphine Laurent Telephone: +44-01256-353 131 Email: DELPHINE.LAURENT@elancoah.com	
15. Manufacturers† Norbrook Laboratories Limited 105 Armagh Road Newry County Down Northern Ireland BT35 6PU Norbrook Laboratories Limited Station Works Camlough Road Newry Northern Ireland BT35 6JP	16. Recalling Firm (if different): Contact Person: Telephone:

17. Recall Number Assigned (if available):		
18. Details of Defect/Reason for Recall: The MAH has been made aware of something claiming to be this product being sold at local markets in the UK. No samples have been returned to the MAH for examination, but it is stated that the company logo wasn't correct and the print quality and lay out was also noticeably different. The reporter was unable to give more information (batch number or photographs) but based on the information above Elanco is confident that this product is a counterfeit.		
19. Information on distribution including exports (type of customer, e.g. hospitals): The authorised product is marketed and distributed in the UK only by wholesale dealers to veterinary clinics or directly to the vet.		
20. Action taken by Issuing Authority: Notifying of the network.		
21. Proposed Action: -		
22. From (Issuing Authority): United Kingdom, Veterinary Medicines Directorate (VMD)	23. Contact Person: rapidalert@vmd.gov.uk	
24. Signed: 	25. Date: 19/04/2022	26. Time: 14:45

* *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.