



Health Directorate

Division of Pharmacy and Medicines (DPM)

# Declaration of a quality defect related to a medicinal product for human and veterinary use Healthcare professional / wholesaler-distributor / marketing authorisation holder – form

The data protection notice, which explains how personal data is processed in the context of reporting quality defects, can be consulted online on the dedicated page of the <u>Division de la pharmacie et médicament - Portail Santé - Luxembourg</u>

1 3		
Contact details of the reporter		
First name and surname		
Occupation or Name of wholesaler- distributor or Name of the MAH		
Telephone		
Email address		
Mailing address		
Medicinal product		
Brand name		
Dosage, pharmaceutical form		
Batch number		
Serial number (SN)		
Product number (PC)		
Expiry date (EXP)		
Is the affected medicinal product used in a clinical trial?	□ Yes □ No	



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Name of pharmaceutical company		
Has the company been notified?	□ Yes □ No	
If so, when and how (email, call, mail, etc.)?		
Did you receive any feedback from the company? Specify their response	☐ Yes ☐ No  If yes, please specify:	
Quality defect suspected		
Defect detection date		
Clear description of the defect		
Has the affected medicinal product been kept? If yes, keep it for any subsequent request from the DPM and/or the pharmaceutical company.	□ Yes □ No	
Has the medicinal product been administered?	☐ Yes ☐ No  If yes, please specify:	
Please attach a photo of the product with the quality defect.		



DPM-043-FO-001 v1.0

# Division of Pharmacy and Medicines (DPM)

# Contact details for reporting

Please send this completed form and any other potentially useful information to the following contact details:

# Division of Pharmacy and Medicines

E-mail: qualitydefects@ms.etat.lu for medicinal products for human use,

or <a href="mailto:luxvet@ms.etat.lu">luxvet@ms.etat.lu</a> for veterinary medicinal products

<u>Tel:</u> +352 247 85592

# Postal address:

Division of Pharmacy and Medicines Health Directorate - Market Surveillance 2a Thomas Edison Street L-1445 Strassen