

MEDICINAL PRODUCT DEFECT REPORTING FORM

Completed form to be returned to: Inspectorate and Enforcement Division, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN3000 or by e-mail at inspectorate.adm@gov.mt.

<i>Shaded areas to be completed by Medicines Authority Staff</i>	Date:	Time:
	Reference: MDR	Initials:
<i>Please complete sections 1 to 6 providing as much information as possible.</i>		
1. Report made by		
Name:	Position/Status:	
Organisation:		
Address:		
Telephone No:	Work:	Fax: Home:
E-mail address:		
2. Product details		
Product name:		
Supplier (from label):		
Manufacturing Site:		
Marketing Authorisation No:		
Legal status	POM / OTC	
Dosage form:		
Strength:		
Container type/size:		
Batch/Lot No:		
Expiry date (if known):		
First distributed (if known):		
Is sample available for Medicines Authority arranged testing?	YES/NO	
3. Reported defect and details of any associated clinical incident.		
Do you consider the suspected defect to be: MINOR / SERIOUS / LIFE THREATENING / DON'T KNOW		

4. Contact that can give further information of any clinical incident.			
Name:	Position/Status:		
Organisation:			
Address			
Telephone No:	Work:	Fax:	
E-mail address:			
5 Has manufacturer/supplier been informed?		YES/NO	
6. Other action taken by reporter:			
7. Company Contact			
Name:	Position/Status:		
Company:			
Address			
Telephone No:	Work	Ext	Fax:
e-mail address:			
8. The following details should be obtained/confirmed with the licence holder			
Site of manufacture			
Date of distribution			
Batch size			
Distribution (including other countries)			
Other similar defects			
Retained sample to be tested / examined.			
Name of QP(s) responsible for batch release			

9. Comments of Duty Medicines Inspector:		
Initials:	Date:	Time:
10. Comments of Duty Medical Assessor (where applicable)		

11. The following details should completed when available		
Cross ref. to other file(s)	Ref no:	
Defect confirmed?	Y/N	
Recall required?	Y/N	
Drug Alert to be issued?	Y/N	
12. Drug Alert/Recall Details		
Class	1 / 2 / 3 / 4	
Date		
Reference Number	MDR	
Level	Wholesaler /Hospital Pharmacy/Community Pharmacy / Patient	
Distribution (In addition to miscellaneous list)	Hospital Only / Hospitals & Pharmacies	
Rapid Alert issued	Y/N	
13. Company Reports		
Initial report received	Y/N	Date:
Interim report received (if required)	Y/N	Date:
Closing report received	Y/N	Date:
14. Administrative details		
Communication to Competent Authority in Country of Manufacture	Date	
File opened	Date:	
Acknowledgement sent to reporter	Date:	
Closing letter sent to:	Reporter	Date

	Company	Date
File closed		Date
Database updated		Date
15. Additional notes		