QD002/08 – Appendix 1 Version Number 01

Medicinal Product Defect Reporting Form

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.

Shaded areas to be completed by Medicines Authority Staff	Date:	Time:
	Reference: MDR	Initials:

Please complete sections 1 to 6 providing as much information as possible.

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	