e-form

Medicinal Product Quality Defect 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.

Shared 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
	Home
Email address:	

2. Product details:

Product name:	
Supplier (from label):	
Manufacturing Site:	
Marketing Authorisation No:	
Legal Status:	
POM/ OTC:	
Dosage forms:	
Strength:	
Container type/ size:	
Batch/ Lot No:	
Expiry date (if known):	
First distributed (if known):	

Is sample available for Medicines Authority arranged testing?

3. Reported defect and details of any associated clinical incident.

Do you consider the suspected defect to be:

4. Contact that can give further information of any clinical incident:

Name:

Position/ Status:

Organisation:

Address:

Telephone No: Work

Home

Email address:

5. Has manufacturer/ supplier been informed?

6. Other action taken by reporter:

7. Company Contact:

Name:

Position/ Status:

Company:

Address:

Telephone No: Work

Home

Email 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 Medicine Inspector:

Initials:	
Date:	
Time:	

10. Comments of Duty Medicinal Assessor (where applicable):

11. The following details should completed when available:

Cross ref. to other file(s):	
Ref no:	
Defect confirmed?	
Recall required?	
Drug alert to be issued?	

12. Drug Alert/ Recall Details:

Class:	
Date:	
Reference Number:	EL
Level:	
Distribution (In addition to miscellaneous list):	
Rapid alert issued?	

13. Company Reports:

Initial report received:		Date:	
Interim report received (if required):		Date:	
Closing report received:		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:

PRINT SAVE SUBMIT