

QD002/10 – 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 5 providing as much information as possible.

Section 1: Reporter details

Date reported:	
Reporter's name and position:	
Company name and address	
Telephone no.:	
E-mail address:	

Section 2: Product details

Product name:	
Supplier:	
Dosage form and strength:	
Active substance:	
Container type/size:	
If the product is licenced in Malta provide the MA/AA/PI/EU/CT number:	
If the product is licenced in Malta provide details of the product licence holder/clinical trial authorisation holder:	

Is the product supplied in Malta as an Article 20 product?	YES/NO
Have any other competent authorities/EMA been informed of the defect? If yes, provide details:	YES/NO

Section 3: Details of impacted batch(es)

Batch no.	Date of manuf.	Expiry date	No. of units	Market(s) to which batch was distributed	Date first distributed (if known)

Is sample available for Medicines Authority arranged testing?	YES/NO

Section 4: Details of the quality defect

Date on which defect was first identified:	
Defect identified by:	□ Patient/Carer □ Pharmacy/Prescriber/HCP □ Manufacturer/MAH □ Wholesaler
Description of the defect (photographs may also be included):	

Outcome of examination/testing of the defective sample and/or retained sample where appropriate:
Summary of the main findings to date of the investigation (if applicable):

Section 5: Additional information

Have adverse drug reactions been reported which may be related to the defect?	YES/NO
Contact that can give further information related to the adverse drug reaction:	
Preliminary risk-based classification of the defect: (considering extent, risk, market impact etc	□ HIGH □ MODERATE □ LOW □ DON'T KNOW
Has manufacturer/MAH/supplier been informed?	YES/NO
Other action taken by the reporter:	

Section 6: Company contact details

Name and position:	
Company name and address	
Telephone no.:	
E-mail address:	

Section 7: Details to be obtained/confirmed with manufacturer/product licence holder and/or local representative

Site of manufacture:	
Date of first and last distribution of impacted batch(es):	
Batch size(s):	
Distribution (including other countries):	
QP responsible for batch certification:	
Other similar defects for the batch(es) or for the product (in the previous 24 months) If so, provide details of previous reports, including the number of previous reports and confirm if an increased trend been detected for reports of this type:	YES/NO
Has an impact assessment been carried out to determine if other batches or other products may be within scope? Please provide details:	YES/NO
Extent – Has the issue been ring-fenced to the listed products/batches? If not please justify:	YES/NO

Risk – Has a risk assessment been performed? If not, please justify: (If a risk assessment has been performed a copy is required)	YES/NO
Has any remedial action been taken to date? (eg quarantine at primary wholesale level) Please provide details:	YES/NO
Is market action proposed? (eg recall, Caution In Use notification) Please justify: If market action is proposed, provide details on whether unimpacted batches/products are available or whether there is potential for shortage.	YES/NO
Other relevant information:	

Section 8: Comments of Duty Medicines Inspector

Initials:	**Date:**	**Time:**

Section 9: The following details should be 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

Section 10: 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

Section 11: Company reports

Initial report received	Y/N Date:
Interim report received (if required)	Y/N Date:
Closing report received	Y/N Date:

Section 12: 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:

Section 13: Additional notes
