

MEDICINAL PRODUCT DEFECT REPORTING FORM

Completed form to be returned to: Inspectorate and Enforcement Division, Medicines Authority, 198, Rue D'Argens, Gzira **or fax to:** 23439161.

| | | |
|---|-------------------|------------|
| <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 | | |

| | | |
|---|---|-------|
| 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 | |
| Date | | |
| Reference Number | EL | |
| 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 | | |