Quality defect report reporting form for MAHs, manufacturers and wholesalers

Note: Healthcare professionals and patients should use a separate [online reporting portal](https://www.hpra.ie/homepage/about-us/report-an-issue/suspected-medicinal-product-defect).

* Guidance on reporting of quality defects, which will support completion of this form, is available in the HPRA’s [Guide to Reporting and Initial Investigation of Quality Defects in Medicinal Products for Human and Veterinary Use](https://www.hpra.ie/homepage/about-us/publications-forms/guidance-documents/item?id=b860f925-9782-6eee-9b55-ff00008c97d0&t=/docs/default-source/publications-forms/guidance-documents/sur-g0023-guide-to-reporting-and-investigation-of-quality-defects-in-medicinal-products-for-human-and-veterinary-use-v8).
* Please complete all sections and ensure details have been independently checked before submission. When complete, submit the form to qualitydefects@hpra.ie.
* If the defect relates to a centrally authorised product (CAP) where the HPRA is the supervisory authority, there is no need to complete this form. Instead, the Defective Product Report which has been submitted to the EMA may be submitted to the HPRA.
* A privacy notice in relation to personal data collected is available on the HPRA website: [Privacy and Data Protection](https://www.hpra.ie/privacy---data-protection/privacy-notice---quality-defects-reporting)

**Section 1: Reporter details**

|  |  |
| --- | --- |
| Date reported:  |       |
| Reporter’s name and position: |       |
| Company name and address: |       |
| Telephone no.: |       |
| Email address: |       |

**Section 2: Details of impacted product(s)**

|  |  |
| --- | --- |
| Company reference no.: |       |
| Product name(s):(exact product name, as labelled) |       |
| Dosage form and strength:  |       |
| Active substance(s):  |       |
| Registered shelf life:  |       |
| Where the product(s), or equivalent product(s) is authorised in Ireland, provide the PA/VPA/EU/CT number(s):  |       |
| For product(s), or equivalent product(s) authorised in Ireland, provide details of marketing authorisation / clinical trial authorisation holder(s): |       |
| Is the product supplied in Ireland as an **Exempt Medicinal Product (EMP)?**  | [ ]  Yes [ ]  No |
| Have any **other competent authorities/EMA** been informed of the defect?  | [ ]  Yes [ ]  No  |
| If yes, provide details: |       |

**Section 3: Details of impacted batch(es)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Batch no.(s)** | **Date of manuf.** | **Expiry date** | **No. of units**  | **Market(s) to which the batch was distributed** | **Date first distributed**  | **Date last distributed**  | **No. of units at IE primary wholesaler**  |
|  **by IE primary wholesaler** |
|       |       |       |       |       |       |       |       |
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**Section 4: Manufacturer(s) details**

|  |  |
| --- | --- |
| Site(s) where defect occurred: |       |
| Name and address of Irish manufacturer(s) involved, if relevant, and details of the activities performed at the site(s): |       |
| MIA number:  |       |
| Name and address of manufacturer responsible for batch release: |       |
| MIA number (if batch release site is in Ireland):  |       |

**Section 5: Details of the quality defect**

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| --- | --- |
| **Date on which the defect was first identified:** |       |
| **Defect initially identified by:** | [ ]  Patient/carer[ ]  Pharmacy/prescriber/HCP[ ]  Manufacturer/MAH[ ]  Wholesaler |
| **Full description of the defect** (photographs may also be included here):       |
| **Outcome of examination/testing** of the defective sample and/or retained sample, where appropriate:       |
| **Summary of the main findings to date of the investigation:**      |

**Section 6: Interim assessment of extent, risk and potential market impact**

|  |  |
| --- | --- |
| Have any **similar reports** been received for the batch(es), or for the product (in the previous 24 months)?  | [ ]  Yes [ ]  No |
| 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: |       |
| Have **adverse drug reactions** been reported which may be related to the defect? | [ ]  Yes [ ]  No |
| Has an **impact assessment** been carried out to determine if other batches, or other products may be within scope? | [ ]  Yes [ ]  No |
| Please provide details: |       |
| **Extent** – Has the issue been ring-fenced to the above listed products/batches? | [ ]  Yes [ ]  No |
| If not, please justify: |       |
| **Risk** – Has a risk assessment been performed? | [ ]  Yes [ ]  No |
| If not, please justify:(If a risk assessment has been performed, please include the assessment as an appendix to the form) |       |
| **Preliminary risk-based classification** of the defect:(considering extent, risk, market impact etc.) | [ ]  High[ ]  Moderate[ ]  Low |
| Has any **remedial action** been taken to date? (e.g., quarantine at primary wholesale level) | [ ]  Yes [ ]  No |
| Please provide details: |       |
| Is **market action** proposed? (e.g. recall, Caution In Use notification) | [ ]  Yes [ ]  No |
| Please justify:If market action is proposed, please comment on whether other unimpacted batches/products are available or whether there is potential for **shortage.** |       |
| Other relevant information: |       |