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| --- |
| **Form** |
| **Quality defect report** |
| **Identification number:** | MU102\_10\_001 |
| **Version:** | 2.0 |
| **Valid from:** | 27.02.2024 |

Template for dynamic documents like forms and checklists for external use.

|  |  |
| --- | --- |
| Recipient at Swissmedic | Division Market Control of Medicines |

# Origin of Report

|  |  |
| --- | --- |
| Information required | Information obtained |
| 1. Name of person reporting problem
 | …… |
| 1. Organisation (e.g. name of company, pharmacy, individual, etc.)
 | …… |
| 1. Address
 | …… |
| 1. Telephone number
 | …… |
| 1. Facsimile number
 | …… |
| 1. E-mail address
 | …… |
| 1. Time of report
 | …… |
| 1. Date of report
 | ……  |

# Product Details / Extent of the Problem

Note: for each product a separate form should be submitted

|  |  |
| --- | --- |
| Information required | Information obtained |
| 1. Name of product affected by the problem
 | …… |
| 1. Authorisation number or other reference number
 | …… |
| 1. Marketing Authorisation Holders or importers[[1]](#footnote-1) name and address (see package)
 | …… |
| 1. Pharmaceutical form
 | …… |
| 1. Active ingredient(s) (INN)
 | …… |
| 1. Manufacturer’s name and address (final product)
 | …… |
| 1. a) Process step that caused the quality problem (e.g. production of the active ingredient, packaging, quality control)b) Name and address of the company in question
 |  |
| 1. Lot number(s) concerned (manufacturing date(s) / expiry date(s) / strength / batch size(s) / type(s) of packs / number of packs)
 | If needed please attach separate list…… |
| 1. Distribution of the lots concerned (countries / clients delivered e.g. wholesale distributors, hospitals, pharmacies, doctors [lot number(s), number of pack(s), date of delivery])
 | If needed please attach separate list…… |
| 1. Other products involved(name / authorisation number or reference number)
 | …… |

# Nature of defect(s)

|  |  |
| --- | --- |
| Information required | Information obtained |
| * 1. Where was the product defect noticed
 | [ ]  Patient[ ]  Hospital[ ]  Pharmacy[ ]  Manufacturer[ ]  Inspectors[ ]  …… |
| * 1. Details of defect or problem
 | …… |
| * 1. Is the problem associated with any adverse event?

If so please specify | [ ]  yes / [ ]  no…… |
| * 1. Is there any evidence or suspicion of a risk to public health (adverse effects or inefficacy)?
 | [ ]  yes / [ ]  no |
| * 1. Classification of defect (I, II or III)[[2]](#footnote-2), please justify
 | …… |
| * 1. Quality defect reported due to inspection

If yes, please provide the following information | [ ]  Yes / [ ]  NoInspection performed by [ ]  Swissmedic [ ]  RHI [ ]  RFS-OZ [ ]  ISOPTH [ ]  IRM-S [ ]  foreign authority ……Date ...... |

# Action taken and proposed

|  |  |
| --- | --- |
| Information required | Information obtained |
| * 1. Name and address of any regulatory authority notified of the problem
 | …… |
| * 1. Action taken so far (if any)
 | …… |
| * 1. Batch or product recall proposed?

If so please attach drafts for recall letter to clients and for publication in Schweizerische Apotheker Zeitung, Schweizerische Ärzte Zeitung, Schweizerische Drogisten Zeitung | [ ]  yes / [ ]  no…… |
| * 1. Please indicate what happens to the pack(s) withdrawn
 | …… |
| * 1. Further action planned or proposed
 | …… |
| * 1. Other relevant information
 | …… |

**List of attachments to this report**

……

Place and date: ……

Signature and typed name: ……

**To be submitted via:**

fax +41 58 462 07 22

or

e-mail market.surveillance@swissmedic.ch

or

post Swissmedic, Swiss Agency for therapeutic products
Medicinal product licences and surveillance
Market Monitoring of Medicines
Hallerstrasse 7
3012 Berne

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 2.0 | Contact details adjusted | com |
| 1.4 | Added to point 3.1 "Inspectors" and added a new point 3.6. | nuf |
| 1.3 | Precisions and changes under points 1.2 and 2.8. Content unchanged. | prf |
| 1.2 | Revision. No adjustment was required | prf |
| 1.1 | Position 2.7. added to document.References to PIC/S and EMA documents updated.Postal code updated | prf |
| 01 | New QM ident: MU102\_10\_001Old QM ident: MU102\_00\_004The remaining content of the document was not reviewed and stays unchanged. | dms |
| 05 | "and" replaced by "or" under Submission of the notification form | ris |
| 04 | Telephone and fax numbers within the document updated, telephone and fax number in the footer updated, link(s) revised, new change history inserted in the document, document name modified in the header | sel |

1. for medicinal products distributed in parallel [↑](#footnote-ref-1)
2. refer to Swissmedic Journal 3/2006 and document PI 010-5 "Procedure for handling rapid alerts and recalls arising from quality defects" of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) [↑](#footnote-ref-2)