**Reporting of defective medicinal product**

**Please note** that the completion of this form must never delay the reporting of critical product defects. In critical situations, please contact us as quickly as possible on telephone +45 44 88 95 95 or by email to rapidalert@dkma.dk and present the available information.

If the quality defect concerns several products, the reporting company decides whether the information should be submitted in a single form, whether several forms should be submitted, or whether an overview of products and batches should be provided as appendices.

Fields marked with an \* must be filled in.

Please send the completed form, including any relevant appendices, to the Danish Medicines Agency by email to rapidalert@dkma.dk.

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| --- | --- | --- | --- | --- |
| **1.** | **Origin of report** | | | |
| 1.1 | Contact person\* | | Name and title:  Email:  Telephone no. |  |
| 1.2 | Reporting company\* | | Company name:  Address: |  |
| 1.3 | Date of reporting | |  | Select date of reporting |
| **2.** | **Cause of reporting** | | | |
| 2.1 | The Danish Medicines Agency is informed due to\*  *Please tick all relevant options* | | The product is distributed to Denmark  The product is released in Denmark  One or more manufacturing steps take place in Denmark  Other reasons – please describe: | |
| 2.2 | Which other authorities have been/will be notified?\*  *Please state reasoning* | |  | |
| **3.** | **Product details** | | | |
| 3.1 | Name(s) of product(s) affected by the problem\* | |  | |
| 3.2 | Strength(s)\* | |  | |
| 3.3 | Pharmaceutical form(s)\* | |  | |
| 3.4 | Parallel imported or parallel distributed product? | | Parallel imported (PI)  Parallel distributed (PD) | |
| 3.5 | Domain of use  *Please state the relevant domain(s) of use of the product* | | Human  Veterinary | |
| 3.6 | Short description of (primary) use of the product\*  *E.g. indication, specific patient groups etc.* | |  | |
| 3.7 | Marketing authorisation number\* | |  | |
| 3.8 | Name and address of the company responsible for the product release\* | | Company name:  Address: |  |
| 3.9 | Name and address of the company manufacturing the product  *Please state all relevant manufacturing steps, incl. manufacturing of API. Please state the manufacturing step performed at each site. If there are more than two manufacturing steps, please provide the information in an appendix.* | | Manufacturing step 1:  Company name:  Address: |  |
| Manufacturing step 2:  Company name:  Address: |  |
| 3.10 | Marketing authorisation holder (MAH)\* | | Company name:  Address: |  |
| 3.11 | Danish MAH representative, if relevant | | Company name:  Address: |  |
| 3.12 | Pack size(s) and type(s) | |  | |
| 3.13 | Legal status  *Please state relevant legal status from the list* | | Select relevant legal status | |
| **4.** | **Nature of defect** | | | |
| 4.1 | Source of problem: Where, when, how and by whom was the product defect noticed?\* | |  | |
| 4.2 | Short description of the defect or problem\*  *A more detailed description may be attached as an appendix* | |  | |
| 4.3 | Extent of the problem\* *E.g. details about batch numbers and number of batches affected. If a large number of batches are affected, please provide the information in an appendix.* | |  | |
| 4.4 | Indication of the patient risk\*  *Risk assessment etc. may be attached as an appendix.* | |  | |
| 4.5 | Preliminary risk classification of the defect/problem\*  *Please select risk classification from the list* | | Select relevant risk classification | |
| Please state the reason for the selected risk class\*: | |
| 4.6 | Any adverse reactions/events that may be related to the defective product? | |  | |
| 4.7 | Details regarding the extent of distribution and recipient countries for the affected batch(es)\*  *Please provide details about e.g.*  *– whether the product was distributed to wholesalers, pharmacies, hospital pharmacies or retailers*  *– whether the product was distributed to other countries*  *The details may be included in the overview of batches as part of the appendix referred to in section 4.3.* | |  | |
| 4.8 | Corrective and preventive actions taken so far\*  *Please describe any actions taken or initiated before the report was sent to the Danish Medicines Agency.* | |  | |
| 4.9 | Corrective and preventive actions planned or proposed\*  *Please describe any planned or proposed actions. More detailed descriptions regarding corrective and preventive actions can be provided later on.* | |  | |
| **5.** | **Other relevant information** | | | |
|  | | | | |
| **6.** | **Appendices to this report (if relevant)** | | | |
|  | | Title/description | | |
| Appendix 1 | |  | | |
| Appendix 2 | |  | | |
| Appendix 3 | |  | | |
| Appendix 4 | |  | | |
| Appendix 5 | |  | | |