**Reporting of medicinal product pack(s) suspected of being falsified and conclusion as to whether the medicinal product pack(s) are falsified**

**Note!** Filling in this form must never delay the reporting of a potential falsification to us. If you suspect a falsification, please contact us immediately on +45 44 88 95 95 or via email to rapidalert@dkma.dk to pass on the information you have.

**The first part of the form "SUSPICION"** is completed by the marketing authorisation holder/manufacturer to report packs if a dialogue with the verifying/decommissioning unit has taken place, and if the preliminary investigations of the pack suggest that the pack has been falsified, implying that the pack must be returned for further investigations.

**The second part of the form "CONCLUSION"** is also completed by the marketing authorisation holder/manufacturer to report the conclusion of the investigation of the suspected packs.
In case it is confirmed that a medicinal product pack is a falsification, possibly after a thorough investigation, it must be reported IMMEDIATELY to the Danish Medicines Agency.

If a falsification or a suspected falsification concerns several products/packs, you can choose to report them on one form or on several forms, if relevant, and you can also choose to enclose a list of the products/packs and batches involved in an appendix.

Fields marked with \* are mandatory.

Please send the form to the Danish Medicines Agency to rapidalert@dkma.dk enclosing relevant appendixes.

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| **1.** | **Information about the reporter** |
| 1.1 | Contact person for the report\* | Name and title:Email:Telephone: |                 |
| 1.2 | Reporting company\* | Company name:Address: |            |
| 1.3 | Date of the report |  | Click here to select date |
| **2.** | **Reason for the report** |
| 2.1 | The Danish Medicines Agency is informed because\**Please select all that applies* | [ ]  Alert[ ]  Broken anti-tampering device[ ]  Other – please describe:       |
| 2.2 | Can a technical/procedural error be ruled out?\* | [ ]  Yes  |
| 2.3 | What other authorities have been/will be informed?*Please state reason if relevant* |       |
| **3.** | **Information about the product** |
| 3.1 | GTIN\* |       |
| 3.2 | Unique Package Return Code |       |
| 3.3 | Product Code\* |       |
| 3.4 | Serial number\* |       |
| 3.5 | Medicinal product name(s)\* |       |
| 3.6 | Product number\* |       |
| 3.7 | Batch number\* |       |
| 3.8 | Pharmaceutical form(s)\* |       |
| 3.9 | Strength(s)\* |       |
| 3.10 | Pack size\* |       |
| 3.11 | Expiry date\* |       |
| 3.12 | Is the product a parallel import/distributed product? \* | [ ]  Parallel import (PI)[ ]  Parallel distributed (PD) |
| 3.13 | Has the product been quarantined? \* | [ ]  Yes[ ]  No |
| **4.** | **Information about the error** |
| 4.1 | Alert ID, incl. text\* |       |
| 4.2 | Where and when was the suspected falsification discovered? | Where      When       |
| 4.3 | Description of why a falsification is suspected |       |
| **5.** | **Other relevant information** |
|       |

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| **6** | **Conclusion of falsification investigation** |
| 6.1 | Is the pack a falsification? | [ ]  Yes (go to points 6.3 and 6.4)[ ]  No (go to point 6.2)[ ]  Other – please describe:       |
| 6.2 | Reason for the alert – please describe |       |
| 6.3 | Please describe the characteristics of the falsification as detailed as possible |       |
| 6.4 | Distribution level and recipients of the affected pack\*CONCLUSION*For example, information about whether the products have been distributed to wholesalers, pharmacies, hospital pharmacies, retailers and other countries.*  |       |

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| **7** | **Appendixes to the report (image material, if relevant)** |
|  |  | Title/description |
|  | Appendix 1 |       |
|  | Appendix 2 |       |
|  | Appendix 3 |       |
|  | Appendix 4 |       |
|  | Appendix 5 |       |