**Template for shortage notification**

This form is only intended for notification of shortages. It is not intended to notify DKMA of the withdrawal of a marketing authorisation or a change in the marketing status of any particular product.

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|  | **Template for shortage notification** | |
| **Product details** | Product name1,2 | Klik eller tryk her for at skrive tekst. |
| Procedure Type (NAP, MRP/DCP, CP) | Klik eller tryk her for at skrive tekst. |
| National Authorisation code/EMA Authorisation number1 | Klik eller tryk her for at skrive tekst. |
| Human medicine1 |  |
| Veterinary medicine1 |  |
| If veterinary, species authorised in MA | Klik eller tryk her for at skrive tekst. |
| ATC code | Klik eller tryk her for at skrive tekst. |
| Active substance(s) | Klik eller tryk her for at skrive tekst. |
| Pharmaceutical form1,2 | Klik eller tryk her for at skrive tekst. |
| Strength1,2 | Klik eller tryk her for at skrive tekst. |
| Route(s) of administration2 | Klik eller tryk her for at skrive tekst. |
| Pack size(s)2 | Klik eller tryk her for at skrive tekst. |
| **Details on shortage** | Date of the beginning of shortage (may be anticipated date)1,2 | Klik eller tryk her for at skrive tekst. |
| Expected end date of the shortage, if applicable1,2 | Klik eller tryk her for at skrive tekst. |
| Reason for shortage1,2 | Klik eller tryk her for at skrive tekst. |
| Impacted countries (if known) | Klik eller tryk her for at skrive tekst. |
| Reference number of any Rapid Alert (quality/safety) related to the issue | Klik eller tryk her for at skrive tekst. |
| Other authorities notified (e.g. other NCAs, EMA), including reference to Quality Defect report if relevant | Klik eller tryk her for at skrive tekst. |
| Reference to related pending regulatory action, if relevant | Klik eller tryk her for at skrive tekst. |
| Risk assessment of impact of shortage1 | Klik eller tryk her for at skrive tekst. |
| Proposed mitigation plan to deal with the shortage | Klik eller tryk her for at skrive tekst. |
| Are any actions from NCA required? If yes, what actions? | Klik eller tryk her for at skrive tekst. |
| **Details of notifying person** | Company name and address (MAH, duly authorised representative or wholesale distributor, if applicable)2 | Klik eller tryk her for at skrive tekst. |
| Name of the person completing the form and date | Klik eller tryk her for at skrive tekst. |
| E-mail of contact person1 | Klik eller tryk her for at skrive tekst. |
| Telephone number contact person | Klik eller tryk her for at skrive tekst. |
| **Contact information for details regarding the shortage** | Company E-mail and Telephone number1,2 | Klik eller tryk her for at skrive tekst. |
| **Impact assessment** | Potential alternative medicinal products1,2   * Same medicine in different packaging   size/strength/pharmaceutical form   * Other medicinal product with the same active substance:   o the same strength  o the same pharmaceutical form  o the same route of administration   * Authorised and marketed products in the same class   (therapeutic/pharmacological subgroup) with the same indications   * Authorised and marketed products in other class with the same approved indications | Klik eller tryk her for at skrive tekst. |
| Estimated size of population affected by the shortage of this product:   * Market share of the product1   (hospital and ambulatory markets)   * Market sales volume (monthly/six monthly) and volume of   prescriptions   * Proportion market sales affected by shortage * Estimated stock in the current supply chain * Stock that will be made available at the expected end date of the shortage and at the following supplies | Klik eller tryk her for at skrive tekst. |
| Considering:   * Patient/animal safety * Will patients/animals have no access to a treatment? | Klik eller tryk her for at skrive tekst. |

1 Minimum information to be provided to competent authority to proceed with the assessment of the case.

2 This information may be shared on the DKMA web page