**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.

|  |  |
| --- | --- |
|  | **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