LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Guideline for follow-up via DKMAnet

The pharmaceutical company's rationale for requesting a follow-up on a case should be described in the first text field in the DKMAnet form. Unfortunately, there is no limit on the number of characters available in the DKMAnet form. However, please note that our back-end system can only handle up to 1,000 characters, including spaces.

When you submit a follow-up request via DKMAnet, the request will be added to a task list and it may be rejected if we disagree with the relevance. RMP forms should still be submitted via Eudralink to ADR@dkma.dk. In case there is only a few follow-up questions to a case and a table is not required for the sake of clarity, the questions can still be submitted directly via DKMAnet. Alternatively, the questions can be submitted in a Word document via Eudralink to ADR@dkma.dk

In the next text field, you should ask the recipient of the request to fill in the RMP form/answer the questions: 'Please fill in the enclosed RMP form/answer the questions.

Questions to citizens **must** be in Danish and should not contain any medical terminology. Many doctors prefer to have the questions in Danish, however, this is not a requirement. Please remember to submit RMP forms and other forms in Word format and completed with any known information.

To the extent possible, we will send out the questions electronically. Consequently, we need to send out a Word file in which the answers can be entered directly. To streamline the process of sending out the questions, the questions should be delivered in a format that is compatible with the letters, which our system can generate. The document 'Table templates', see Related content, contains tables formatted to our letters; they may provide inspiration for how to ask questions if the follow-up request is not based on an RMP requirement.

Please note that it should be possible to code the reply in structured fields, since pharmaceutical companies do generally not have access to case narratives after the transition to Centralised Reporting.

It may be a good idea to describe the rationale for the questions asked, so we encourage you to specify the reason for each individual question.

Note that citizens should be able to identify their own description of the adverse reactions, so you should not refer to the MedDRA term, but rather to their own wording as displayed in the primarysourcereaction field, if there is a need for requesting follow-up information about an adverse reaction from citizens.

Summary:

- Follow-up requests should be created via DKMAnet – the rationale for the follow-up request (to the Danish Medicines Agency) should be described in the first text field.
- Please send RMP forms in Word format via Eudralink to ADR@dkma.dk. Please do not enter the case number in the subject field as this field is not encrypted.
- Follow-up questions that do not originate from RMP forms may be sent via Eudralink in Word format to ADR@dkma.dk. Preferably in the format shown in the document Table templates. Please do not enter the case number in the subject field as this field is not encrypted.

As an alternative to Eudralink, you can send personal data by using the secure and encrypted form that you can find on our website. Use of this form requires a digital employee certificate and may only be relevant to persons working in Denmark.

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