

## **Guidelines on follow-up on adverse reaction reports**

Marketing authorisation holders have the opportunity of submitting follow-up questions to adverse reactions reported by consumers, doctors or other healthcare professionals.

### **The Danish Medicines Agency passes on your questions**

We forward your questions to the person who reported the adverse reaction, unless it has been specifically stated that the questions should be sent elsewhere.

When the person who reported the adverse reaction has submitted his or her answers to the Danish Medicines Agency, we update the report and return it to you electronically.

### **Questions:**

#### **When you submit a follow-up request, please make sure that:**

- the questions have not already been answered in the report,
- that you ask all your questions in the first request to avoid having to contact the same report submitter more than once,
- the questions are relevant in relation to the adverse reaction report,
- the questions asked when requesting follow-up information from consumers are written in an easily understandable style,
- questions for consumers are written in Danish,
- it is clearly indicated if you request a medical reply to questions in connection with a report submitted by a consumer.

#### **Time allowed to submit a follow-up request**

Please note that you have maximum three weeks to submit your follow-up request to the Danish Medicines Agency from the day you received the adverse reaction report.

#### **Be specific**

Always be specific when you formulate your follow-up questions. Experience has shown that too open questions often result in doctors sending a copy of the patient file or discharge summary, in which case you do not get the doctor's medical opinion.

Examples of specific questions:

- What reactions has the patient experienced from prior exposures?
- Has the patient experienced similar reactions?
- What was the batch number of the product?
- What was the strength of the product?
- How long after exposure did the patient experience the first symptoms?
- When did the adverse reaction stop?

**You do not need to request the Danish Medicines Agency to obtain a medical confirmation<sup>1</sup>**

The Danish Medicines Agency seeks a medical confirmation whenever it involves reports of **serious** adverse reactions from consumers, and therefore, you do not need to request the Danish Medicines Agency to obtain such confirmation.

Please note that you cannot request a medical confirmation to reports of non-serious adverse reactions from consumers since we do not seek to obtain such confirmation when it concerns non-serious adverse reactions, unless they fall under special focus areas.

**You do not need to ask about causal relationship when it concerns reports from doctors**

When reports are submitted by doctors, the Danish Medicines Agency takes it for granted that it is suspected that there is a causal relationship between the suspected adverse reactions and the medicine. For this reason, there will be no need to ask whether a causal relationship exists.

**The Danish Medicines Agency sends reminders to doctors for follow-up replies at appropriate intervals.**

Therefore, there is no reason for you to send a reminder.

**Using DKMANet for follow-up on adverse reaction reports**

On our extranet, DKMANet, you can find a form to submit follow-up questions to reported adverse reactions. We prefer to receive follow-up questions via DKMANet, as the solution offers many advantages, e.g. a secure connection for submission of personal details, integration with the Danish Medicines Agency's adverse reaction database and easy access for companies.

**Can I attach files with my follow-up questions?**

No, it is not possible to attach files, but you can pose as many questions as you please.

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<sup>1</sup> A medical confirmation only implies that the doctor considers it possible that there might be a causal relationship between the suspected side effects and the medicine. A medical confirmation does not validate the patient data, etc.