



Federal Agency for Medicines and Health Products

Obtaining “follow-up” information on yellow cards

To request additional information on the yellow card, the FAMHP wishes to change the current procedure as it encounters problems in obtaining this information. Under the current procedure, the reporter who reports an adverse drug reaction with the yellow card is requested to send additional information either to the MAH or the FAMHP.

The FAMHP requested the MAH to send a reminder to the reporter if he did not receive a follow-up.

The traceability in such a system is difficult for the FAMHP.

For the new procedure, the FAMHP made the following proposal:

- The MAH needs to initialize the process for obtaining follow-up information concerning the yellow card. Therefore, he needs to use the form as presented below. Consequently, the completed form needs to be sent to the FAMHP.
- The FAMHP will send this request for additional information to the reporter of the yellow card (via e-mail, phone, post).
- In case there is no answer, the FAMHP will repeat the request for information to the reporter and if needed, up to 2 reminders will be sent. This process should be finalized within 3 months.
- The MAH will in any case be informed by the FAMHP of the outcome (irrespective of whether the reporter has answered or not).

An ‘info’ document should be added to this request, containing the following information :

Request of follow-up information on yellow cards :

MAH requesting information :

Contact person :

Medicinal Product (tradenname) :

FAMHP Reference number :

Reason for this request :

- Risk management plan
- New product
- New indication
- Investigation of a possible signal
- Casus not complete
- Others :
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Other additional information/requests :

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Comments

1. The MAH should not send reminders to the FAMHP but can still ask a question about the status of the dossier.

2. The FAMHP receives the requests preferably by e-mail; these requests may be sent to the following e-mail address adrs-mah@fagg-afmps.be. A response to this e-mail will be sent.