Federal Agency for Medicines and Health Products

Transmission by the FAMHP to the MAH of the notifications of adverse drug reactions by healthcare professionals ("paper" yellow cards)

According to VOLUME 9A of The Rules Governing Medicinal Products in the European Union - Guidelines on Pharmacovigilance for Medicinal Products for Human Use - the FAMHP is obliged to send notifications of serious adverse reactions with medicinal products to the holder of the concerned MA.

For some products authorized in Belgium, the MAH may be established abroad. So far, the FAMHP sent by post one copy of the yellow card only to the MAH, whether he is situated in Belgium or abroad. In the latter case the yellow card often traveled a long way before finally reaching the local person responsible for pharmacovigilance.
More and more MAHs ask whether the yellow cards can be sent directly to the person responsible for pharmacovigilance in Belgium.

The FAMHP wishes to offer the possibility to MAHs to send a copie of the yellow card directly to the local person responsible for pharmacovigilance.

If the MAH wishes to have this procedure in place, the following information should be provided :

A. The MAH provides a "declaration of power" in which he allows the yellow cards to be sent directly to the local person responsible for pharmacovigilance. A copy (signed by the MAH and scanned) is sent to the FAMHP.

B. The MAH also provides a list (.xls) with the following data on all the medicinal products under his responsibility :

1. Name (under which the medicine is authorized in Belgium) **(MP)***
2. Person responsible for pharmacovigilance (or the person to whom the yellow card should be sent) **(QP)***
3. **(company name)***
4. street and number **(address)***
5. **(postal code)***
6. **(city)***
7. **(country)***
8. fax (if problems occur when sending by e-mail, the report will be faxed) **(fax)***
9. e-mail address of the QP (of the person (see point 2) to whom the scanned version (pdf) of the yellow card may be sent) **(e-mail QP)***
10. e-mail address of the MAH (if the MAH wishes to receive an electronic copy (pdf) **(e-mail MAH)***
11. Additional information (if necessary) **(comments)***

*The words printed in bold and brackets should be used as column names in the Excel file.

The Excel list should be set up as follows:

In this Excel list, other columns or rows above the column names may not be added and no changes can be made to the column names. There is no limit to the number of characters in a cell.
The FAMHP can establish a database with all of this data from any company, enabling it to easily retrieve the required information.

C. The MAH/the person responsible for pharmacovigilance transmits to the FAMHP the data required for any new drug approved. Please create a new Excel spreadsheet with only the new data.
If the FAMHP does not have this data, it will send the yellow card by post to the MAH (as is the case now in accordance with the law).

All the information contained in paragraphs A and B must be sent in one e-mail to: adrs-mah@fagg-afmps.be.

The information contained in section C may also be sent to adrs-mah@fagg-afmps.be. If necessary, a new version of the Excel file can be sent using this e-mail address.

If the complete information is not available, the FAMHP will continue to send the yellow cards, as foreseen in Vol. 9A.