Federal Agency for Medicines and Health Products

Electronic sending of ICSRs reported in Belgium since 01/01/1995 in the Eudravigilance system ("Retrospective population")

According to VOLUME 9A of The Rules Governing Medicinal Products in the European Union - Guidelines on Pharmacovigilance for Medicinal Products for Human Use - section iii 'retrospective population of EudraVigilance post-authorisation module', the MAH and the competent national authorities must send all reports of adverse reactions observed with drugs that have been reported since 1995, to the EudraVigilance system of the European Medicines Agency (EMEA).

Following the recommendations of the EMEA, the FAMHP would like to propose the following to the MAH :

Belgian reports, issued during the "backlog" period from 01/01/1995 until the MAH has made an electronic report in the production system of FAMHP, can be sent directly to the EudraVigilance system of the EMEA and do **not** need to be sent to the FAMHP.

Therefore the FAMHP will perform the following procedure :

1) The FAMHP will ask the EMEA which MAHs have already sent Belgian "backlog" cases before 01/01/2010.

2) MAHs who wish to send their backlog to the EMEA after 01/01/2010, should inform the FAMHP, in which period they will do it or have done it. The FAMHP will be able to find them back if this process has been performed over a small period.

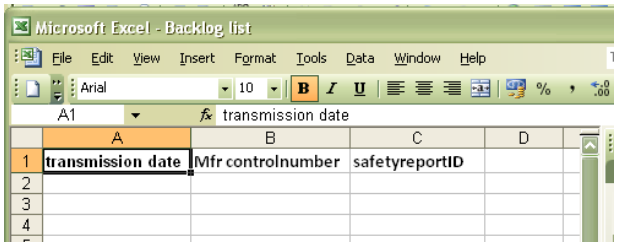
For both previous cases, the FAMHP will verify whether all reports, received since 01/01/1995, were sent to the EMEA's EudraVigilance system.

If the FAMHP is not able to link the electronic reports to the paper reports, the following request will be made to the MAH :

1) If the FAMHP is not able to make the link between the paper report and the electronic report for some of the paper reports, the MAH will be informed about these paper reports (mfr. control number on the CIOMS paper form). The MAH will be requested to send the respective Safety report ID for each report *(the safety report ID is reference number of a report in EudraVigilance, structured as follows : BE-COMPANY REFERENCE- NUMBER OF REPORT exp. BE-FAMHP-Case 1)*.

2) If the FAMHP is not able for all reports to make the link between the paper report and the electronic report, the MAH will be requested to make an overview with the following information: A list of all the reports with their SafetyreportID e.g. BE-companyX-12345 (safetyreportID), as is mentioned in the electronic version (E2B) of your report that was sent to the EMEA and

the controlnumber of the manufacturer (Mfr controlnumber), as is mentioned on the CIOMS form that the FAMHP (formerly IGP and DGM) received in the past and the date on which this report has been sent to the FAMHP (transmission date).
Such information must be transmitted in an Excel list in accordance with the structure established below:



Remark : For both procedures, the MAH will be contacted personally by FAMHP.

Any information or questions regarding this procedure should be directed to the FAMHP e-mail address: adrs-mah@fagg-afmps.be.