

## **PART I. Historical overview : For which reason the FAMHP has taken this decision regarding a new procedure for electronic reporting?**

The FAMHP informed the partners on 24 December 2010 about the problems it encountered with its local Eudravigilance system, the electronic system for exchanging reports of adverse reactions with medicinal products (ICSRs = Individual Case Safety Reports) between the partners and the FAMHP, namely:

**Eudravigilance: communication to the (future) partners in the framework of the electronic reporting of adverse reactions (authorization holders, sponsors of clinical studies...)**

Date: 24 December 2010

**The FAMHP wants to inform the partners and future partners in the framework of the electronic reporting of adverse reactions of medicinal products for human use of the current status of the problems related to the local Eudravigilance programme and the processing of electronic reportings in this programme during Christmas holiday (from 25 December 2010 to 2 January 2011).**

**Link: <http://www.fagg-afmps.be/nl/news/> - <http://www.fagg-afmps.be/fr/news/>**

First of all, the FAMHP wants to explain why this decision has been taken.

For this purpose, we will briefly describe how the electronic system for the electronic reporting is built up technically.

The main parts of the EMA's Eudravigilance system, but also of the Belgian local system, are the following:

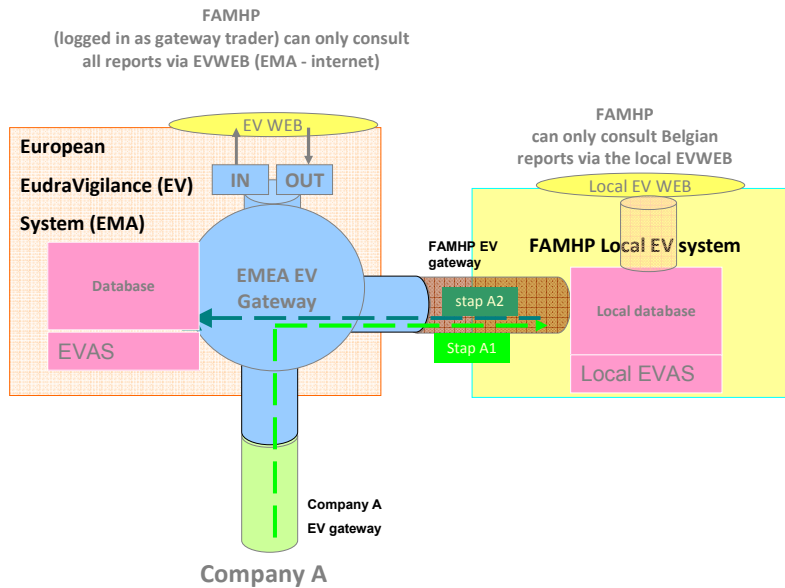
1. ORA server (= the database);
2. EVAS server (Eudravigilance analysis system): each report that comes in is first fully analysed according to the business rules before being entered in the database;
3. EV gateway : connection between the different partners who must send electronically to each other;
4. EVWEB : Eudravigilance internet application that allows to search, to create and to manage reports (receive and send) in the database, and to create and send acknowledgments,...

The Belgian local Eudravigilance system is a copy of the EMA system and consists therefore of the same parts.

The only difference is that the Local EVWEB application is only usable internally for the tasks on the Belgian reports that have been sent to the local system of the FAMHP. This is one of the reasons for which the FAMHP has opted for one OrganizationID, namely "AFIGP", within its Eudravigilance system.

All the partners, having the obligation to send/receive reports, should have their own system for electronic reporting available. The following colours are used for the different partners in the Eudravigilance system: blue parts for "EMA"; brown parts for "FAMHP"; green parts for "Company".

Diagram A. Reporting to the FAMHP via a functioning local database (AFIGP if gateway user)

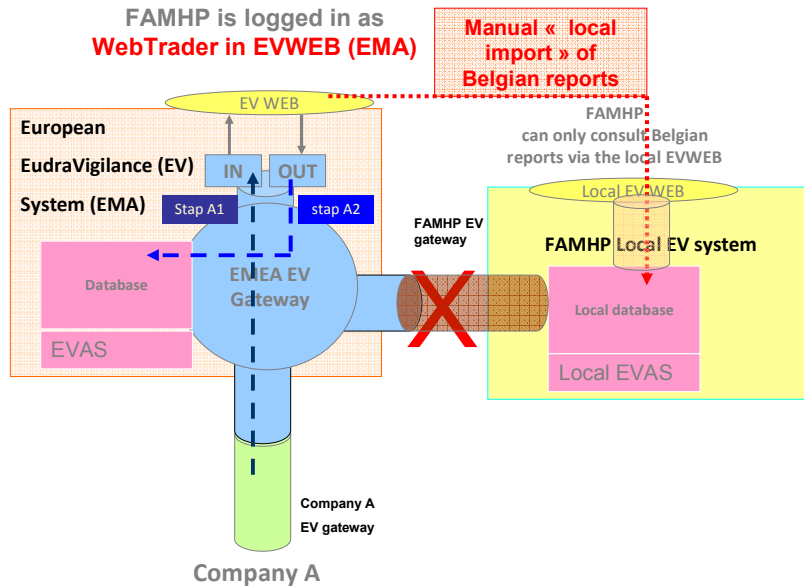


1

The FAMHP receives all the reports, included in a “message”, in its local system. Acknowledgements for these messages are automatically sent to the sender.

The transmission to the EMA is then performed starting from the local system. The distinction between a message (which includes spontaneous reports and reports from non interventional clinical studies and others) for the PM (post marketing) module and a message (which includes the clinical trial reports) for the CT (clinical trial) module is then made automatically by the local system.

Diagram B. Reporting to the FAMHP with a non-functioning local database (AFIGP if webtrader user)



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In this situation, as a result of the fact that the FAMHP EV gateway doesn't receive any messages anymore, it has been converted into webtrader. Therefore, the FAMHP receives all the messages on the EVWEB system of the EMA on its receiverID "AFIGP" whereas the EMA doesn't pick up these messages.

The acknowledgements for these messages (within the 2 days following the reception day of a report) need to be created and sent manually. The Belgian reports must also be sent to the EMA. To this end, more manipulations are necessary than via the local system, including the fact that the messages for the CT or the PM module are not automatically distinguished anymore.

Furthermore, all messages must be uploaded in the local system to be able to make a distinction between an initial and a follow-up report. The manual work linked to this upload is time-consuming to be done every day. That's why this task is performed every 2 weeks or every month.

**For these reasons, the FAMHP has decided to modify the reporting process, as proposed in the official communication of 22 April 2011.**

**The receiverID "AFIGP" is adapted as follows:**

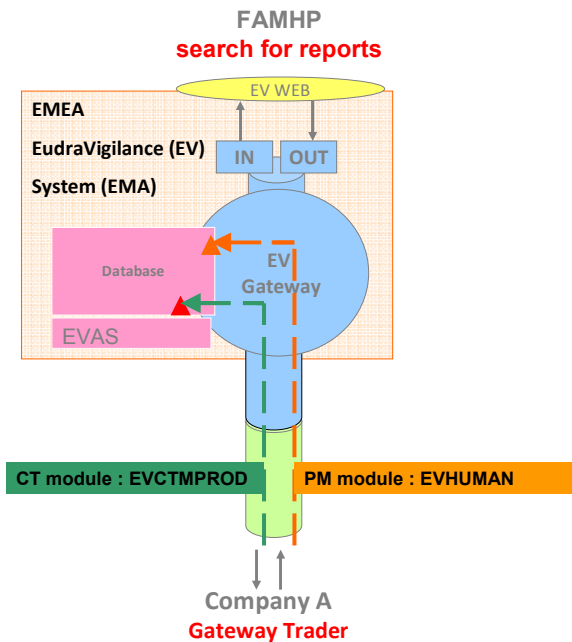
**SUSARs that result from interventional clinical trials must be sent to the CT module, using "EVCTMPROD" as receiverID.**

**Spontaneous reports and reports coming from non-interventional clinical studies and others (see official communication) must be sent to the PM module, using "EVHUMAN" as receiverID.**

**These IDs correspond to the respective modules in the Eudravigilance system of the EMA.**

The following schema shows how the sending according to the new procedure is performed.

Diagram C. Reporting to the FAMHP via EVHUM/EVCTMPROD



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The FAMHP will collect the Belgian reports from the European Eudravigilance system daily.  
The module (PM or CT) determines which business rules set must be applied to a message that is sent to the EMA.