Federal Agency for Medicines
and Health Products

Belgian Centre for Pharmacovigilance for
medicines for Human use

YOUR LETTER OF

YOUR REF.

OUR REF. FAMHP/MG/270899

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ANNEXE(S)

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To the holders of a marketing authorisation of a medicinal product
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To the sponsors of a clinical trial

RE **Modified procedure for the electronic reporting of adverse reactions of medicines to the Federal Agency for Medicines and Health Products (FAMHP)**

Until now, the FAMHP was receiving the reports of adverse reactions of medicinal products from the holders of a marketing authorisation of a medicinal product and from the sponsors of a clinical trial electronically (in E2B format) with as ReceiverID "**AFIGP**" within the production environment of EudraVigilance.

As of **22 April 2011**, the electronic reports that must be addressed to the FAMHP in accordance with the legislation below, must be sent in compliance with the procedure below. This procedure applies to the current partners who already report electronically to the FAMHP as well as to the new candidates.

I. For SUSARs (Suspected Unexpected Serious Adverse Reactions) from interventional clinical trials:

The reports from *interventional* clinical trials, which need to be sent according to the legal framework below, must be sent to the ReceiverID "**EVCTMPROD**" within the production environment of EudraVigilance.

1. **Law of 7 May 2004** concerning experiments on the human person.
2. **Royal Decree of 30 June 2004** determining the measures for carrying out the law of 7 May 2004 relating to the experiments on the human person concerning clinical trials with medicines for human use.

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II. <u>For spontaneous reports and those from non interventional clinical studies and others:</u>

The *spontaneous* reports and those from *non-interventional* clinical studies and others (e.g. "registries", "compassionate use"), which need to be sent according to the legal framework below, must be sent to the ReceiverID "**EVHUMAN**" within the production environment of EudraVigilance.

1. **Law of 25 March 1964** on medicines.
2. **Royal Decree of 14 December 2006** concerning medicines for human or veterinary use.
3. **REGULATION (EC) N° 726/2004** OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicines for human and veterinary use and establishing a European Medicines Agency.

This new procedure only includes a modification of the electronic addresses to which a report must be sent.

The FAMHP plans a transition period until 31 May 2011, during which it will continue to send acknowledgements to reports that have been sent to the ReceiverID "**AFIGP**" within the production environment in EudraVigilance.
The FAMHP requests for an engagement from the partners for whom, by that date, it will not be possible to report following the new procedure. If you are in that case, we ask you to submit, by the 1st of June, an implementation plan with timetable via icsr@fagg-afmps.be.

Yours faithfully,

Xavier De Cuyper
Chief Executive Officer