Federal Agency for Medicines and Health Products

Department
Vigilance

YOUR LETTER FROM

YOUR REF.

OUR REF. AFMPS/nes
DATE 12/12/2008

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Circular n° 520

- To the marketing authorisation holders for medicinal products for human and veterinary use.

- To the Qualified Persons for Pharmacovigilance (QPPVs).

SUBJECT **Pharmacovigilance inspections.**

Updating of the information relating to pharmacovigilance (human and veterinary).

This document is a translation of the official and signed versions in Dutch and French

Dear Madam, Dear Sir,

Pursuant to articles 112 & 237, §1 and 115 & 240 of the Royal Decree of December 14, 2006 relating to medicinal products for human and veterinary use, the Federal Agency for Medicines and Health Products (FAMHP) informs you hereby of the planning of Pharmacovigilance inspections since May 2008.

In accordance with the detailed guidelines published by the European Commission in "The rules governing medicinal products in the European Community", the inspection of the conformity of the pharmacovigilance system of the marketing authorisation holders is the responsibility of the Competent Authority of the Member State in whose territory the QPPV is located (point 2.4.1).

In order to ensure that the pharmacovigilance inspections are properly conducted, it is essential that we may have correct and updated information available. That's the reason why we found it appropriate to underline some of the legal obligations that are to be respected by the marketing authorisation holders:

- *In accordance with articles 68 and 194 of the RD of December 14, 2006, each QPPV must be registered on a list that is drawn up and updated by the Minister or his/her delegate*.

In order to be registered on this list and receive then an approval number, the following documents must be submitted to the Belgian Centre for Pharmacovigilance (CBPH), for the attention of Mr. Thierry Roisin, Place Victor Horta 40 Box 40, 1060 Brussels:

- A letter of personal request for recognition as a QPPV, with mention of the home address;
- A copy of the diploma[1];
- A certificate, with a detailed description of the accomplished tasks, justifying an experience of at least one year in the field of pharmacovigilance. This certificate is issued by the person or the institution by which the experience has been gained.

  The accuracy of this certificate can be checked by the members of the staff of the FAMHP.

- *Moreover, articles 67, 192 and 193 of the same decree mention that a MA holder must permanently and continuously have at his/her disposal a person with the appropriate qualifications, QPPV, and that this person must be located in the Community*.

Each MA holder must therefore notify to the Belgian Centre for Pharmacovigilance, at the following address *PhVInsp@fagg-afmps*.be, the person appointed as QPPV (among those who have received an approval number) within the firm. This communication must be performed by dated letter [electronic version (pdf)], signed by both parties and clearly indicating the contact data of the appointed QPPV (surname, first name, address of the company, phone number, GSM, e-mail).

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[1] HUM Only the holders of the legal diploma either of pharmacist or of master of pharmaceutical sciences, either of physician or of master of medicine, obtained in accordance with the legislation on the awarding of academic degrees and with the programme of university examinations, or the persons who are legally exempted from this, can be accepted as QPPVs. The foreign nationals who hold an equivalent diploma and who meet the requirements mentioned before can also be accepted.

VET Only the holders of the legal diploma, either of master of pharmacy or of master of pharmaceutical sciences, either of veterinary surgeon or of master of veterinary medicine, obtained in accordance with the legislation on the awarding of academic degrees and with the programme of university examinations, or the persons who are legally exempted from this, can be accepted as QPPVs. The foreign nationals who hold an equivalent diploma and who meet the requirements mentioned before can also be accepted.

In order to organise at best the inspection of the companies, we would be grateful if you would kindly submit, for March 1, 2009 at the latest, an electronic version (pdf) of the above-mentioned letter, as well as the following additional information via a Word version of the annexed form (to be uploaded on www.afmps.be), to the following address: *PhVInsp@fagg-afmps*.be

1. Name, address, website of the marketing authorisations holder.
2. Surname, first name, corporate address, phone number, GSM, number of 24h/24 contactability, fax, e-mail of the QPPV at the local level (local QPPV).
3. Surname, first name, corporate address, phone, GSM, number of 24h/24 contactability, fax, e-mail of his/her replacement for this function (deputy).
4. If appropriate, name, address and website of the company that concentrates the pharmacovigilance activities at European level.
5. Surname, first name, corporate address, phone, GSM, number of 24h/24 contactability, fax, e-mail of the QPPV at European level (EEA QPPV).
6. Surname, first name, corporate address, phone, GSM, number of 24h/24 contactability, fax, e-mail of his/her replacement for this function (deputy).
7. If appropriate, name, address, phone number, GSM, fax, e-mail and website of the companies by which the authorisations holder subcontracts the pharmacovigilance activities at the local level, as well as the nature of the subcontracted activity.
8. Name, address and phone number of the company where the computerized data relating to all suspected adverse reactions that occurred in the Community or in a third-country are concentrated and available.

We want to call your attention to the following information :

- The request for approval, as well as the appointment of the QPPV by the MAH, will always be done in accordance with the procedure described on pages 1 and 2;

- Any modification brought to the data relating to the pharmacovigilance system that are known by the FAMHP ⌈change of the QPPV, appointment of a new replacement (back-up), subcontracting of the pharmacovigilance obligations, …⌋ will have to be reported to the CBPH as soon as possible, in accordance with *articles 5, §2, 16) and 146, §3, 15) of the above-mentioned decree*, to the following address: *PhVInsp@fagg-afmps*.be.

Thank you in advance for your cooperation.

Yours faithfully,

The CEO

Xavier De Cuyper

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