Federal Agency for Medicines
and Health Products

DG Inspection –Industry Division

YOUR LETTER OF
YOUR REF.

OUR REF. FAGG/nes
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CONTACT MATTHIJS NELE
TEL. +32 (0)2/524.82.49
FAX +32 (0)2/524.80.01
E-MAIL PhVInsp@fagg-afmps.be

Circular no. 545

To the holders of a Belgian marketing authorisation (MA) or a Belgian registration for medicinal products for human and veterinary use

SUBJECT **Reporting to the FAMHP by the MA or registration[1] holders of the person responsible for human or veterinary pharmacovigilance**

Dear Madam or Sir

As the holder of a marketing authorisation (MA) or a registration[1] for medicinal products for human and veterinary use, you need to report the name of the person responsible for pharmacovigilance to the Federal Agency for Medicines and Health Products (FAMHP).

My staff notice unfortunately that all too often this obligation is not fulfilled.

I therefore hereby would like to remind you of this obligation and inform you about the way in which this information has to be reported to the FAMHP since its reorganisation.

1. Introduction

Pursuant to Articles 67, 192 and 193 of the Royal Decree of 14 December 2006 concerning medicinal products for human and veterinary use, the holder of a marketing authorisation (MA) and registration[1] must be assisted permanently and continuously by a qualified person responsible for pharmacovigilance who resides in the Community. The name of this person must be updated whenever it changes.

Pursuant to Articles 68, §1, and 194 of the same Decree, the person responsible for pharmacovigilance must be registered on a list drawn up and kept updated by the Minister or his representative[2].
The list of persons and their qualification, registered throughout the year, is published each year in the Belgisch Staatsblad/Moniteur Belge.

2. Reporting of the name of the person responsible for pharmacovigilance in your company

The new organisation of the FAMHP is operational since the first trimester of 2009. As a consequence, the name of the person responsible for pharmacovigilance must be reported from now on electronically by the holders of an MA or registration[1] for medicinal products to the Directorate-

General Inspection, Industry Division, of the FAMHP via the mailbox PhVInsp@fagg-afmps.be and not to the Belgian Centre for Pharmacovigilance (BCPH) anymore.

In order to have correct and up-to-date information, each MA or registration[1] holder is asked to report to the FAMHP within three months following publication of this circular letter the following data[2]:

- Last name, first name and registration number of the appointed person responsible of pharmacovigilance;
- Contact details of this person (address, mobile phone, fax and e-mail);
- Telephone number where the company can be reached 24/7.

The reporting has be to done by sending an electronic version (pdf) of the letter appointing the person responsible together with the required information, dated and signed by both parties, i.e. the CEO or his legitimate representative and the appointed person responsible for pharmacovigilance.

I remind you that

a) the appointed person responsible for pharmacovigilance for national authorisations according to the national procedure and authorisations granted in accordance with the decentralised or mutual recognition procedure has to be registered as such beforehand in Belgium[3];

b) the position of the person responsible for pharmacovigilance is incompatible with the position of director of a pharmaceutical company.

I would like to mention as well that the additional information provided by means of the annex to circular letter no. 520 (Word table) is archived at the FAMHP and that pursuant to Articles 5, §2, 16) and 146, §3, 15) of the Royal Decree of 14 December 2006 concerning medicinal products for human and veterinary use each change of the name or contact details of the person responsible for pharmacovigilance must be reported immediately to the DG Inspection, Industry Division, via the above-mentioned e-mail address.

I thank you in advance for your kind co-operation.

Yours sincerely

Xavier De Cuyper

Chief Executive Officer

1. Pursuant to Articles 42 and 178 of the Royal Decree of 14 December 2006 concerning medicinal products for human and veterinary use, the provisions of Title V of Parts I and II apply to homeopathic medicinal products, except for homeopathic medicinal products as meant in Articles 38 and 173 (special simplified registration procedure).

   Pursuant to Article 49 of the Royal Decree of 14 December 2006 concerning medicinal products for human and veterinary use, the provisions of Title V of Part I apply to traditional herbal medicinal products.

   For authorisations granted according to the centralised procedure you need to handle in accordance with the provisions of Articles 22 & 23, 48 & 49 respectively of Regulation 726/2004.

2. Holders of an MA or registration[1] having provided this information within the scope of circular letter no. 520 do not need to provide a new, electronic version.

3. Please also refer to circular letter no. 544 of 16.11.09