



YOUR LETTER OF
YOUR REF.

OUR REF. FAGG/nes
DATE 16.11.2009

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Circular no. 544

To the applicants for a registration on the
Belgian list of persons responsible for
pharmacovigilance of medicinal products for
human or veterinary use

**BETREFT Application to be registered as the person responsible for pharmacovigilance
of medicinal products for human or veterinary use**

Dear Madam or Sir

The Federal Agency for Medicines and Health Products (FAMHP) is in its new form operational since the first trimester of 2009. As a consequence, the files about applications to be registered as the person responsible for pharmacovigilance of medicinal products for human and veterinary use are now managed by the Directorate-General Inspection, Industry Division, of the FAMHP and not by the Belgian Centre for Pharmacovigilance (BCPH) anymore.

The purpose of this circular letter is to clarify the new terms for obtaining a registration as the person responsible for pharmacovigilance of medicinal products for human and veterinary use¹.

This circular letter applies to all applications for registration submitted as of December 1st, 2009.

1. Person responsible for medicinal products for human use

Article 68, §2, of the Royal Decree of 14 December 2006 concerning medicinal products for human and veterinary use defines the conditions which have to be fulfilled in order to be registered as the person responsible for pharmacovigilance of medicinal products for human use.

- Only those persons who hold a diploma in either pharmacy or of master in pharmaceutical sciences or in either medicine or of master in medicine, or in either veterinary medicine or of master in veterinary medicine, obtained in accordance with the legislation concerning the award of academic degrees and the program of university exams, or those persons being legally exempt therefrom, can be registered as person responsible for pharmacovigilance.

Citizens of another member state or another state which is a contracting party to the Agreement on the European Economic Area, who hold an equivalent diploma and meet the requirements referred to above, can be registered as well.

- These persons have to provide evidence that they have at least one year experience in the field of pharmacovigilance by submitting a certificate containing the description of the tasks they performed. This certificate has to be delivered by the person or institution where the experience was gained.
- Article 67 of the same Decree states that the person responsible for pharmacovigilance must reside in the Community.

2. Person responsible for medicinal products for veterinary use

Article 195 of the Royal Decree of 14 December 2006 concerning medicinal products for human and veterinary use defines the conditions which have to be fulfilled in order to be registered as the person responsible for pharmacovigilance of medicinal products for veterinary use.

- Only those persons who hold a diploma in either pharmacy or of master in pharmaceutical sciences or in either veterinary medicine or of master in veterinary medicine, or in either medicine or of master in medicine, obtained in accordance with the legislation concerning the award of academic degrees and the program of university exams, or those persons being legally exempt therefrom, can be registered as person responsible for pharmacovigilance.

Citizens of another member state or another state which is a contracting party to the Agreement on the European Economic Area, who hold an equivalent diploma and meet the requirements referred to above, can be registered as well.

- These persons have to provide evidence that they have at least one year experience in the field of pharmacovigilance by submitting a certificate containing the description of the tasks they performed. This certificate has to be delivered by the person or institution where the experience was gained.
- Article 193 of the same Decree states that the person responsible for pharmacovigilance must reside in the Community.



Federal Agency for Medicines
and Health Products

If you meet the conditions listed in point 1 or 2 and if you like to be registered as the person responsible for pharmacovigilance of medicinal products for human and/or veterinary use, and in accordance with Art. 68, §1, and Art. 194 of the Royal Decree of 14 December 2006, please provide the documents mentioned below to the Minister or his representative, Eurostation II, DG Inspection – Industry Division, Place Victor Horta 40/40, 1060 Brussels:

- the application form no. 001 (Appendix circular 544) to be registered as the person responsible for pharmacovigilance, properly filled in, dated and signed;
- a copy of the diploma or certificate of EC/EU/EEA recognized professional qualification for citizens of another EU member state or another state which is a contracting party to the Agreement on the European Economic Area.

The certificate of recognized professional qualification can be obtained from the following competent authority:

- o *Recognition of a diploma in pharmacy or medicine:* FPS Public Health, Cell 'International mobility of health professionals', Place Victor Horta 40/10, 1060 Brussels. E-mail: internationalmobility@health.fgov.be ;
 - o *Recognition of a diploma in veterinary medicine:* FPS Public Health, Directorate- General Animal Health and Animal Products, Place Victor Horta 40/10, 7th floor, 1060 Brussels. E-mail: chantal.dubois@health.fgov.be ;
- a statement, signed and dated by the applicant with the description of the performed tasks, to proof he has gained at least one year² experience in the field of pharmacovigilance and clearly mentioning start and end date with regard to the acquisition of the required experience.
This solemn statement has to be co-signed and dated by:
 - * either a person responsible for pharmacovigilance registered in Belgium with whom the experience was gained;
 - * either the CEO of the company where the experience was gained (in another EU member state or another state which is a contracting party to the Agreement on the European Economic Area);

The confirmation of your registration and the registration number will be sent to your place of residence by post.

The list of persons and their recognized professional qualification, registered throughout the year, is published each year in the Belgisch Staatsblad/Moniteur Belge.

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

Yours sincerely

Xavier De Cuyper

Chief Executive Officer

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1. Pursuant to Article 278 of the Royal Decree of 14 December 2006 concerning medicinal products for human and veterinary use, the persons who were recognized as persons responsible for pharmacovigilance of medicinal products based on Articles 28sexies, §3, and 28septies, §3, of the Royal Decree of 3 July 1969 concerning the registration of medicinal products, will still be recognized as person responsible for pharmacovigilance of medicinal products in accordance with the provisions of Title V of Part I and of Title V of Part II.
 2. The experience may be gained in several companies having a system for pharmacovigilance in conformity with the actual legislation and may be cumulated.