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federal agency for medicines and health products

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Circular no. 600
For the attention of holders of a marketing authorisation or registration for medicines for human use[1]

Your letter of	Your reference	Our reference	Annex	Date
		568896	2	15 JUNI 2013

Subject : authorization and registration holders notifying FAMHP about the local contact person and current information concerning (human) pharmacovigilance

Dear Sir,
Dear Madam,

This circular refers to the application of the new legislation about pharmacovigilance, and particularly the changes in pharmacovigilance, as in the royal decree of 14th December 2006 concerning medicines for human use, by means of the royal decree of 28th May 2013, published in Belgisch Staatsblad/Moniteur belge on the 10th of June 2013, in order to adapt directive 2010/84/EU.

The purpose of this circular is to explain the main changes in terms of the requirements for local persons responsible for pharmacovigilance.

Following article 23 of the revised royal decree of 14th December 2006, these points come into effect the first day of the third month after the publication of the decree.

This circular, together with circular no. 601 (veterinary), replace circular no. 520 and 545. Circular no. 544 about the need to register as the person responsible for pharmacovigilance is cancelled.

1. Notification of the local contact person for pharmacovigilance (appendix I)

Following the revision of article 66 §2 in the royal decree of 14th December 2006, the function of the local contact person has been introduced and replaces the function of the local person responsible for pharmacovigilance.

The local contact person is linked to the qualified person responsible for pharmacovigilance at the European level and is responsible for carrying out local tasks concerning pharmacovigilance.

The local contact person does not have to be registered on a list set up by the minister or his representative. Nor does he/she have to meet the demands in terms of diplomas or submit a certificate proving at least one year's experience in pharmacovigilance.

However, following the revised article 66 §2 of the royal decree of 14th December 2006, the local contact person must meet the following requirements:

- He/she must be contactable 24 hours a day, 7 days a week ;
- He/she must carry out activities in pharmacovigilance in Belgium ;
- He/she must have adequate qualifications to carry out his/her activities in pharmacovigilance, particularly the necessary language skills to be able to receive correspondents in the national language they choose and to be able to communicate with the qualified person responsible for pharmacovigilance.

Since the function of the local person responsible for pharmacovigilance is replaced by the function of the local contact person, the outstanding files requesting registration for local persons responsible for pharmacovigilance will no longer be handled by FAMHP.

We would draw your attention to the fact that the persons who are currently approved as local persons responsible for pharmacovigilance (with a "P number") do not automatically assume the function of local contact person but they must meet the new demands for local contact persons as mentioned above in case they are designated as local contact person.

Marketing authorisation or registration holders must submit to FAMHP a declaration indicating the name and contact details of the designated local contact person and indicating that the local contact person meets the above demands and has the qualifications and means necessary for carrying out his tasks in matters of pharmacovigilance. Please complete in full the form in the appendix (Appendix I) and send an electronic version (PDF) of this form to the following e-mail address: PhVInsp@fagg-afmps.be

If the qualified person responsible for pharmacovigilance at the European level is carrying out his activities in Belgium, he/she can combine the function of qualified person responsible for pharmacovigilance with the function of local contact person, provided the requirements for the local contact person are met. In this case the marketing authorization or registration holder must advise FAMHP that this person has been designated as the local contact person by means of the form in the appendix (Appendix I)

Concerning the currently designated local persons responsible for pharmacovigilance who have already been registered with FAMHP by means of a declaration and who now meet the new above-mentioned requirements to be able to act as local contact persons, we would also ask the marketing authorisation or registration holder to submit a new declaration to FAMHP by means of the form in the appendix (Appendix I), thus confirming the designation of this person as local contact person.

2. Notification of additional data about pharmacovigilance (Appendix II)

In order to have correct and up-to-date data about the pharmacovigilance system, every marketing authorisation or registration holder is required to advise FAMHP as soon as possible about any changes in the data. Please complete in full the appendix (Appendix II) and send an electronic version (PDF) of this table to the following e-mail address: PhVInsp@fagg-afmps.be.

The following data must be filled in by the marketing authorisation or registration holder:

1. name, address and website of the marketing authorisation or registration holder ;
2. family name, first name, professional address, telephone number, mobile phone number, 24 / 7 duty number, fax and e-mail address of the local contact person ;
3. family name, first name, professional address, telephone number, mobile phone number, 24 / 7 duty number, fax and e-mail address of the person responsible for pharmacovigilance at the European level (EEA QPPV) ;
4. if appropriate, address where the Master File is located ;
5. if appropriate, the names, addresses, telephone numbers, mobile phone numbers, e-mail addresses and websites of firms subcontracted by the marketing authorisation or registration holder for pharmacovigilance activities at the local level, with an indication of the type of activity subcontracted
6. name, address (server) and telephone number of the company where the relevant electronic data is collected and accessible concerning all suspicious undesirable effects that occurred in the European Community or in a third country

For each change relating to the data about the local contact person, apart from the table mentioned above, the form mentioned in point 1 should also be sent by e-mail to: PhVInsp@fagg-afmps.be

3. Transition period

All marketing authorisation or registration holders are requested to advise FAMHP, within three months following publication of this circular, by means of the form in the appendix (Appendix I) and the table in the appendix (Appendix II), the required information about pharmacovigilance.

Yours faithfully

Xavier De Cuyper,
CEO

[1] Pursuant to Article 42 of the Royal Decree of 14 December 2006 concerning medicinal products for human and veterinary use, the provisions of Title V of Part I do not apply, with exception to article 68 § 2, to homeopathic medicinal products as meant in Article 38.
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 21 and 22 of regulation 1235/2010.