afmps
agence fédérale des médicaments et des produits de santé

DG Inspection / Division Distribution

Federal Agency for Medicines and Health Products
Eurostation II - Place Victor Horta 40/40
1060 Bruxelles
www.afmps.be

Hyacintha Fiers
Tel: +3225284501
Email: publicity@afmps.be

For the attention of MAH holders and registration of medicinal products for human use, located in Belgium and abroad

Your letter dated	Your references	Our references	Annex(es)	Date
		AFMPS/DGI/DIS/VHY	1	16/10/2017

Re: Reminder of the legislation relating to:

- the obligation to designate an approved responsible for information, communicate their designation to FAMHP and data update request;
- the obligation to send the list of medical samples issued to prescribers during the course of the previous calendar year to FAMHP on an annual basis.

Dear Madam,

Dear Sir,

This circular is to remind both Belgian and foreign holders of medicinal product marketing authorisations (MA) or registrations in Belgium of their legal obligations concerning the **Responsible Person for Information and Publicity (RIP).**

1. Obligation to designate an approved responsible for information and communicate their designation to FAMHP

Article 13(1) of the Royal Decree of 7 April 1995 about information and advertising concerning medicinal products for human use provides that each MA or registration holder, whether situated in Belgium or abroad, shall provide the services of a responsible for information approved by the Minister, on a permanent basis[1].

The responsible for information shall ideally be designated by the CEO of the MA or registration holder. Their designation must always be communicated to FAMHP, giving mention of the following information: the complete contact details at which the responsible for information may be reached if necessary (email, tel., mobile, etc.), their responsible for information approval number and their starting date in the position. Furthermore, the designated responsible for information must also sign this communication, thereby confirming their assumption of the position and responsibilities.

[1] Article 13*(1). 'The holder (of the marketing authorisation or) of the registration must ensure the collaboration of a responsible for information approved by the Minister and establish a permanent connection with a scientific service responsible for providing information relating to the medicinal products that they place on the market.*
The responsible for information must be added to a list drawn up and kept up to date by the Minister. Their name must be communicated to FAMHP by registered letter.'.

If the MA or registration holder is situated abroad, I would invite the local Belgian branch to pay particular attention to this obligation to designate a responsible person and communicate the details to the foreign company holding the MA or registration, in an appropriate way, in order to comply with the legal provisions.

Please note that this obligation to designate a responsible for information for MA or registration holders applies as soon as the medicinal product(s) has/have been authorised or registered, even if it/they has/have not yet been marketed in Belgium.

- **Other obligations and recommendations for communications to FAMHP**

I would also like to remind holders of MAs and registrations of medicinal products for human use that, in addition to the above-mentioned compulsory official designation of their responsible for information,

- they must communicate any unavailability of their responsible for information (leave, illness, etc.) to FAMHP if the responsible person is unreachable (start and end date), as well as the identity of their approved replacement, their complete contact details (email, tel., GSM, etc.) and their approval number;

- they must inform FAMHP when their designated responsible for information is no longer exercising their function (the date on which their responsibility ends must be specified) and must communicate the complete identity (contact details and approval number) of the new responsible for information and the date on which they started in the position.

- It is also recommended that the responsible persons for information themselves inform FAMHP on their own account when they are no longer exercising their responsibility for an MA or registration holder, in order to ensure that the FAMHP database is kept as up to date as possible.

- **Updating of the FAMHP list of responsible persons for information of MA or registration holders**

In order to update and supplement the list drawn up by FAMHP, I would ask all MA or registration holders, without exception, to confirm that the last communication made to FAMHP is still up to date and, if this is not the case, to communicate the fact that it has been updated, or any designation of a new approved responsible for information, by 15 November 2017 at the latest. I would ask that you do this using the standard form attached herewith to standardise the way in which this information is communicated to us.

- **Approval as a responsible for information**

The practical procedures for approval of a responsible for information are described in Articles 13(2) and 14 of the aforementioned royal decree. Additional information is also available on the following FAMHP web page:

https://www.fagg-afmps.be/en/human_use/medicines/medicines/proper_use/responsible_information

- **Contact**

For all questions and communications concerning the responsible for information (approval application, designations, absences and replacements, etc.) the point of contact at FAMHP is the Publicity unit of DG Inspection - Division Distribution:

Email: publicity@afmps.be

Address: FAMHP
DG Inspection-Division Distribution
Publicity unit
Eurostation II
Place Victor Horta, 40 boîte 40
B - 1060 Brussels

2. Obligation to send the list of medical samples issued to prescribers during the course of the previous calendar year to FAMHP on an annual basis

I will also take this opportunity to remind holders of MAs or registrations of medical products for human use about one of the obligations incumbent on their responsible for information, which is described in Article 8*bis* of the Royal Decree of 11 January 1993 establishing the conditions under which the delivery of medicinal products for human use as samples can be performed[2].

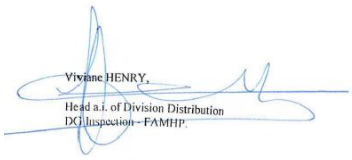
The responsible person for information designated by the marketing authorisation or registration holder, shall communicate the following data to FAMHP, before 1 March of each year and for the previous calendar year:

- the name, dosage, pharmaceutical form and packaging size of the medicinal product dispensed in the form of samples;
- the number of samples distributed for each medicinal product;
- the ATC code allocated by the WHO, if there is one.

This data must be submitted to FAMHP in the form of an Excel file corresponding to the template provided in the annex to circular 503. This file must be sent to FAMHP before 1 March of each year, by electronic means, to the address ech_staal@fagg-afmps.be. If you have not yet sent FAMHP the file relating to the dispensing of medical samples during the course of the 2016 year, I would invite you to do so as swiftly as possible.

Thank you for giving this document your attention and I count on your collaboration in ensuring that these obligations are rigorously applied.

Please accept the assurance of my highest consideration



Viviane Henry
Chief of Division Distribution a.i.
DG Inspection FAMHP

[2] See circular 503 and the FAMHP website: https://www.fagg-afmps.be/en/human_use/medicines/medicines/proper_use/Advertising-premiums-advantages-samples