

OUR REF. AFMPS/DGI/205958

DATE 28.10.2010

Communication n° 572

To whom it may concern

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subject : Transmission to the "Contact point" at FAMHP of information regarding the application of the regulation relating to the struggle against excessive promotion of medicines and medical devices.

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

Dear Madam, dear Sir,

Following the publication in the Belgian Monitor of 8 February 2010 of the Royal Decree of 19 January 2010 amending the Royal Decree of 10 June 2006 establishing the contact point referred to in article 10, §5 of the Law of 25 March 1964 on medicines, my departments have been repeatedly asked about the practical methods that need to be respected to pass on information to the "contact point". It seems therefore useful to remind readers of some essential elements about these methods of communication of information to the "contact point" and how this works.

1. Creation and role of point-contact "

Creating a "contact point" at the FAMHP is provided for in article 10, §5 of the Law of 25 March 1964 on medicines, as amended by the Law of 16 December 2004 modifying the regulation on the struggle against excessive promotion of medicines.

The enforcement provisions are included in the Royal Decree of 10 June 2006 establishing the contact-point referred to in article 10, §5 of the Law of 25 March 1964 on medicines, modified by the Royal Decree of 19 January 2010.

The "contact point" is in charge of the centralizing and the reception of information concerning facts that may constitute infringements of the provisions relating to the struggle against excessive promotion of medicines, medical devices and accessories.

The "contact point" is one of the key organs for the enforcement of this regulation since the information which is communicated to it enables the control departments of the FAMHP to identify the more problematic situations.

2. Communication of information

2.1 In accordance with the Royal Decree of 10 June 2006 cited above, anyone who has information concerning facts that may constitute infringements of the law of 16 December 2004 can communicate this information to the "contact point" established by the Directorate-General Inspection (DG Inspection) of the Federal Agency for Medicines and Health Products (FAMHP).

- 2.2 The information must be written and submitted in the following way:
- or by registered mail sent to the “Contact-point” of the FAMHP - DG Inspection, Eurostation II, Place Victor Horta 40 box 40, 1060 Brussels;
 - or hand delivered to a staff member of DG Inspection.
- 2.3 The submitted information will include:
- if possible, convincing material elements behind the suspicion of infringement to the cited above regulation;
 - full details about the person sending this information so that the inspectors of the FAMHP handling the case file could, if necessary, easily contact him/her for any additional information.

I emphasize that in accordance with article 5 of the Royal Decree of 10 June 2006, the anonymity of the person submitting the information is preserved.
The information submitted anonymously to the “contact-point” are considered only if accompanied by convincing material elements.

3. Working of the “contact-point”

The information received by the “contact-point” is transmitted to the inspectors of the DG Inspection of the FAMHP. They examine these data and give the needed follow-up within their competences.

4. Additional information

As stated above, the “contact-point” deals with subjects relating to the struggle against excessive promotion of medicines, medical devices and accessories. As such, I remember the various circulars already issued by the FAMHP in this matter and in particular:

- Circular 465 of 16/01/2006: *Provisions relating to the struggle against the excessive promotion of medicines.*
- Circular 487 of 26/02/2007: *Relationships between health professionals and the pharmaceutical industry and medical devices industry.*
- Circular 489 of 19/03/2007: *Scientific event including at least one night. Mdeon visa.*
- Circular 513 of 27/02/2008: *Scientific event including at least one night. Reminder of the obligation of the Mdeon visa.*
- Communication 518 of 21/04/2008: *Scientific event including at least one night. Reminder of the obligation of visa granted by Mdeon.*

These circulars are available on the website www.afmps.be, section “circulars”.

I hope these points will be useful for you.
Yours faithfully,



Xavier De Cuyper
Chief Executive Officer