Federal Agency for Medicines
and Health Products

Directorate general POST
Division Proper use of medicines

YOUR LETTER OF

YOUR REF.

OUR REF. FAMHP/GYD/

DATE 15/02/2011

ANNEXE(S)

CONTACT M.L. Bouffioux
TEL 00 32 2 524 83 56
FAX 00 32 2 524 80 01
E-MAIL marie-louise.bouffioux@afmps.be

Circular n° 577 to the holders of marketing authorisation or registration of medicines for human use or medicines for veterinary use

RE : LEGAL OBLIGATIONS AND PRACTICAL MEASURES AS REGARDS INFORMATION ON THE MARKETING STATUS OF THE AUTHORISED MEDICINES

Dear Madam,
Dear Sir,

Circulars n° 481 of 5 March 2007 and n° 547 of 28 July 2009 dealt with the communication of data with reference to the actual presence on the Belgian market of medicines. As for circular n° 571 of 28 July 2010, it concerned the problem of regularly unavailable medicines.

Hereby, it seems useful to me to take stock of all the legal obligations as regards communication to the FAMHP by the marketing authorisation or registration holders of the information concerning the marketing status of their medicines as well as of the different mailboxes put at their disposal to communicate this information to us.
These provisions apply as well for the MA granted by the European Commission as for the MA and registrations granted by the Belgian authorities.

Marketing

Law of 25 March 1964 on medicines, article 6, §1st sexies, 1st subparagraph:

After granting a marketing authorisation or a registration, its holder informs the minister or his/her delegate of the date of effective marketing of the medicine, taking the different authorised or registered presentations into account.

By « presentation », one should understand « package size ».

This information must be sent to the mailbox: commercialisation@fagg-afmps.be, and the following data must be clearly indicated:

- the name of the medicinal product,
- the MA or registration holder,
- the MA or registration number,
- the marketed package size(s),
- the marketing date.

Federal Agency for Medicines
and Health Products

Temporary or permanent cessation of marketing

Law of 25 March 1964 on medicines, article 6, §1st sexies, 2nd subparagraph:

The marketing authorisation or registration holder also informs the minister or his/her delegate if the medicinal product is not marketed anymore, temporarily or permanently. This notification must occur, save for exceptional circumstances, at least two months before the cessation of marketing of the medicinal product.

RD of 14 December 2006 on medicines for human and veterinary use, article 113, §3 concerning the medicinal products for human use:

If the MA holder does not market - temporarily or permanently - the concerned medicinal product anymore, he communicates the reasons for this with the notification provided for in article 6, § 1sexies, of the law on medicines. If this withdrawal may cause a problem for public health, the FAMHP releases this information on its website.

RD of 14 December 2006 on medicines for human and veterinary use, article 238, §3 concerning the medicinal products for veterinary use:

If the MA holder does not market - temporarily or permanently - the concerned medicinal product anymore, he communicates the reasons for this with the notification provided for in article 6, § 1sexies, of the law on medicines. If this withdrawal may cause a problem for human or animal health, the FAMHP releases this information on its website.

We therefore insistently remind you of your legal obligation to communicate to the FAMHP any information concerning a temporary cessation of marketing of a medicine, including the reasons for it.

For the enforcement of this obligation, the FAMHP aligns itself with the rules of the INAMI as regards unavailability, which means that the marketing authorisation or registration holder who expects that the unavailability of the medicinal product may last for 14 days at least, informs the FAMHP about it at the latest within the 7 days after the start date of the unavailability.

In order to communicate this temporary unavailability, the FAMHP puts a new box at your disposal: supply-problems@fagg-afmps.be.
It goes without saying that you also have to inform us to the same address of the date of the effective return of the medicine on the market.

A template to notify us of any temporary unavailability of a medicine is available on the website www.afmps.be (*homepage → right column → list of circulars → circulars published in English since 2010 → circular 577 + template*).

In case of a permanent cessation of marketing, this information must be communicated to the mailbox: commercialisation@fagg-afmps.be, and the following data must be clearly indicated:

- the name of the medicinal product,
- the MA or registration holder,
- the MA or registration number,
- the package size(s) withdrawn from the market,
- the marketing end date,
- the package size(s) that is/are still marketed.

As for the MA granted by the Belgian authorities, this information is also taken into account for the enforcement of article 6 §1st of the law of 25 March 1964 (sunset clause).

Federal Agency for Medicines
and Health Products

Radiation of MA or registration of a medicine for human use

Requests for radiation of the MA or registration can be sent to the mailbox: revocation@fagg-afmps.be.

If the company prefers to send a request for radiation by post, it has to be send to this address:

FAMHP
DG Post Authorisation
Division Marketing Authorisation: Variations & Renewal
Radiations (8th floor)
Place Victor Horta 40 box 40
1060 Brussels

In both cases, the original MA or registration must be sent back to this address.

Radiation of MA or registration of a medicine for veterinary use

Requests for radiation of the MA or registration can be communicated to the manager of the concerned medicine.

If the company prefers to send a request for radiation by post, it has to be sent to this address:

FAMHP
DG Pre authorisation
Division of medicines for veterinary use
Place Victor Horta 40 box 40
1060 Brussels

In both cases, the original MA or registration must be sent back to this address.

Thank you for your collaboration.

Yours faithfully,

Xavier De Cuyper
Chief Executive Officer