Federal Agency for Medicines
and Health Products

Directorate general POST
Proper Use of Medicines Division

YOUR LETTER OF
YOUR REF.

OUR REF. AFMPS/MLB/
DATE NOVEMBER 3rd

ANNEX

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Circular n° 561
to the marketing authorisation or
registration holders for medicines

RE: Publication on the website of the FAMHP of the SPC's and the PIL's of the medicines authorised and marketed in Belgium

Dear Madam, Dear Sir,

The summary of product characteristics (SPC) and the patient information leaflet (PIL) approved by the marketing authorisation (MAA) or registration of a medicine are the basic information and reference for the prescription, the dispensing and the proper and secure use of this medicine. It is therefore essential that these documents are easily available, in their complete and up to date version, to all those who need it. That is why the Federal Agency for Medicines and Health Products (FAMHP) will make these documents freely available on its website. It is anyway a legal obligation for the Agency in application of articles 139 and 261 of the royal decree of 14 December 2006.

The FAMHP is currently developing a project to ensure this publication and its updating on the basis of an internal process for data processing. The implementation of this project is planned for the beginning of 2012.

Until this project has been implemented, it is essential that the FAMHP publishes this information as soon as possible. The Agency has been able to count on the effective collaboration of the Belgian associations that represent the medicinal products industry: pharma.be, FeBelGen and Bachi. An agreement has therefore been concluded according to which these associations will take care of the collection and of the supplying to the FAMHP of the SPC's/PIL's of the medicines of which their respective members are MA or registration holders, or are local representatives in Belgium of MA or registration holders located abroad.

In the first instance the publication on the website of the FAMHP will concern medicines that are authorised and marketed in Belgium.

For the publication planned for the beginning of January 2010, the associations have agreed to collect and supply the SPC's and PIL's of the medicines of which their members are MA or registration holders or are local representatives in Belgium of MA or registration holders located abroad to the FAMHP before 15 November 2009.

The MA or registration holders of medicines authorised and marketed in Belgium, that are established in our country or in another country of the European Union, that are not members of one of these three associations mentioned above are requested to introduce the SPC's/PIL's of their medicines authorised and commercialised in Belgium, in electronic format, by e-mail, to the address: spc-pil@fagg-afmps.be. So that these SPC's/PIL's are published as soon as the publication is launched in the beginning of January 2010, they must be introduced if possible before 15 November 2009 and at the latest by 1 December 2009.

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The SPC's must be introduced in French and in Dutch.
The PIL's must be introduced in French, Dutch, and German.

These documents can be supplied in the following electronic formats:
.PDF (Adobe format)
.DOC (Word format)

There is no required standard structure for the denomination of the documents added to the mail. If a SPC or a PIL concerns several presentations of a medicine (for example, under a same name, several dosages and/or pharmaceutical forms), this SPC or PIL only needs to be introduced once.

The database of SPC's and PIL's has to be regularly **updated**, especially in case of marketing of new medicines and in case of approval of variations.

This update, that can be continuous, must at least take place every three months and at the latest at the date of marketing of medicines with the new PIL.
In case of variations of clinical data of the SPC and/or the PIL (indications, posology, undesirable effects, contraindications, precautions, use in case of pregnancy and lactation,…) that entail new information for a safe and rational use of the medicine, the updated documents should be introduced to the FAMHP, whenever possible, within maximum 10 working days after their implementation.
The new documents should be sent to the e-mail address mentioned above.

May I remind you that the verification of the conformity of the SPC's and PIL's transmitted to the FAMHP to the most recently approved texts within the framework of the marketing authorisation or registration is the responsibility of the person responsible for the information appointed by the MA or registration holder in application of article 13 of the royal decree of 7 April 1995 relating to information and advertising concerning medicines for human use or, for medicines for veterinary use, in application of article 19 of the royal decree of 9 July 1984 relating to information and advertising concerning medicines.

I want to make clear that the content of the SPC's and the PIL's introduced that way will not be subjected to any modification or manipulation before their publication and that these documents will not be used for other ends than the one of their publication on the website of the FAMHP.

Thank you in advance for your collaboration in creating this new tool that is essential for the proper use of medicines.

Yours sincerely,

Xavier De Cuyper,
Chief Executive Officer