General Directorate POST
Division Proper Use of Medicine

Federal Agency for Medicines and Health Products

YOUR LETTER FROM
YOUR REF.

OUR REF. AFMPS/MLB
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ANNEX

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Circular nr 568 for marketing authorization holders or registration holders

SUBJECT Publication on the FAMHP website of the PIL and the SPC of the medicines approved and marketed in Belgium - **Following the circular nr 561 of November 3rd 2009**.

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

Dear Madam,
Dear Sir,

On 11th January the Federal Agency for Medicines and Health Products published free access on its website www.afmps.be the patient information leaflets (PIL) and the summaries of product characteristics (SPC) of medicines approved and marketed in Belgium, both for human and veterinary use. This initiative has been widely appreciated and received very positive feedback.

Such a tool for the proper use of medicines was developed in a relatively short time, thanks to the effective and on-going collaboration of the pharmaceutical companies and their representative professional associations, to whom we are most grateful.

The pharmaceutical firms that have not yet sent (all) PIL's in French, Dutch or German or all SPC's in Dutch and French for the marketed medicines of which they are MA holders, are invited to do so as soon as possible, in electronic format .doc or .PDF, by e-mail to the address spc-pil@fagg-afmps.be or via the Belgian representative association of the pharmaceutical industry of which they are members.

Of course, the reliability of this tool is linked to its bringing up to date when new medicines are marketed or when variations are approved that have an impact on these documents. I remind you the details of this update.

The update may be continuous.

For new medicines, it must in any case take place not later than three months after the date of the effective placing on the market, communicated to FAMHP, under Article 6 § 1sexies of the Law of 25 March 1964 on medicines.

For the variations affecting the PIL and / or SPC, the update should occur at least every 3 months or, in any case, not later than 3 months after the marketing of the medicine with the new PIL.

Federal Agency for Medicines and Health Products

In case of variation of the clinical data of the PIL and / or SPC (indications, posology, undesirable effects, contraindications, precautions, use during pregnancy and lactation, ...) that represent new information for the safe and effective use of the medicine, the updated documents must be provided to the FAMHP, as far as possible within a maximum of 10 working days after the date on which the variation can be applied.

The new documents should be sent to the e-mail address given above or to the Belgian representative association of the pharmaceutical industry of which the firm is a member.

I remind you that the verification of the conformity of PILs and SPCs transmitted to the FAMHP and published on its website, with the most recently approved texts at time of marketing authorisation or registration of these medicines, is the responsibility of the person responsible for information designated by the marketing authorisation or registration holder in accordance with the Article 13 of Royal Decree of 7 April 1995 concerning information and advertising for medicines for human use or in accordance with Article 19 of Royal Decree of July 9th 1984 concerning information and advertising for medicines for veterinary use.

I thank you for your cooperation.

Sincerely yours,

Xavier De Cuyper
Chief Executive Office

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