

Entity/Division/Unit/Cell

M-L. Bouffioux  
Tel. : 00 32 2 524 83 56  
Fax : 00 32 2 524 80 01  
e-mail : [marie-louise.bouffioux@afmps.be](mailto:marie-louise.bouffioux@afmps.be)

Circular n° 592 for the attention of holders of marketing authorisation and/or registration for medicines

Your letter from	Your reference	Our reference	Annex	Date
				30.10.2012

**Subject: Publication on the famhp website of the SmPCs and patient information leaflets of the authorised medicines marketed in Belgium: following on from circulars 561 and 568**

Dear Madam,  
Dear Sir,

Since 11th January 2010 the Federal Agency for Medicines and Health Products (famhp) has been publishing, freely available on its [www.famhp.be](http://www.famhp.be) website, the patient information leaflets (PILs) and the summaries of product characteristics (SmPCs) of the approved medicines marketed in Belgium, both for human and veterinary use.

This tool, which has become an indispensable source of information for proper use of the medicines, has been developed thanks to the effective and continued collaboration of the pharmaceutical companies and their professional associations that we would like to thank once again.

To begin with it was announced that the system put in place would allow the FAMHP to publish the SmPCs/ PILs, whilst they developed an internal procedure to process and publish the PILs / SmPCs from its own sources made at the end of the marketing authorisation procedure of the medicines. We are pleased to announce that the new system has been put into operation.

For the user there is no change. Searching for SmPCs / PILs from the homepage of the famhp site and the results are similar.

On the other hand, it will not be necessary for the marketing authorization (MA) holders or their associations to transmit to us the SmPCs / PILs of their medicines or the medicines for which their members are MA holders. The provisions of circulars 561 and 568 are no longer applicable from 1st November 2012. The [spc-pil@fagg.afmps.be](mailto:spc-pil@fagg.afmps.be) mail box will be closed.

However I want to emphasize that only SmPCs / PILs of the marketed medicines are published on our site. It is therefore imperative, as provided in Article 6 § 1e of the law of 25th March 1964, to inform the famhp of the marketing status of medicines for which you are the MA holder. This requirement also applies to medicinal products authorised via the centralised European procedure. The implementation rules of this communication were defined in Circular no. 577 of 15th February 2011, which is available on the famhp website (click "circulars" in the right column on the home page and then click "circulars issued in 2011").

The publication of the SmPCs / PILs of the medicines marketed by your firm will be directly related to how you fulfill this legal obligation.

Thank you again for your cooperation.

Yours sincerely,

Xavier De Cuyper,

CEO