

Division B & Cg

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Circular n° 588

For the attention of holders of marketing authorisations and/or authorisation for parallel imports

Your letter dated	Your references	Our references	Appendices	Date
				08.06.2012

Collection of the annual fees as laid down in the new framework law of 29th March 2012

THIS DOCUMENT IS A TRANSLATION OF THE OFFICIAL AND SIGNED VERSIONS IN DUTCH AND FRENCH.

Dear Sirs,

The framework law of 29th March 2012 (in the Moniteur Belge of 6th April 2012) reviews the adaptation of the tax system to finance the activities of the AFMPS – l'Agence fédérale des médicaments et des produits de santé (the Federal Agency for Medicines and Health Products). These changes have been made following the new requirements concerning pharmacovigilance on the European level.

From now on an annual fee of € 58.00 for each marketing authorisation will be charged to the authorisation holder. This relates to medicines for human use concerning:

- marketing authorisations granted by the minister
- marketing authorisations granted by the European Commission for which a price was fixed
- authorisations for parallel imports

Each authorisation holder will receive a letter from the AFMPS (Agence fédérale des médicaments et des produits de santé) indicating the sum of the € 58 's due for the current year.

A transfer should be made to « compte spécial n°2 » (special account no. 2) as follows:

IBAN : BE46 1106 0013 1136

BIC : BKCPBEBB

Thanking you in advance for complying with the above I remain

Yours faithfully

Xavier De Cuyper,

CEO