Federal Agency for Medicines and Health Products

Vigilance Division

YOUR LETTER FROM

YOUR REF.

OUR REF. AFMPS/VC-FK/TR/54717

DATE

ANNEX

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Circular n° 530
For the attention of the marketing authorisation holders for medicinal products for human use and veterinary use

SUBJECT Royal Decree of 21 January 2009 setting the fees for the submission of a periodic safety update report

Dear Madam, Dear Sir,

We want hereby to call your attention to the publication of the royal decree mentioned above that introduces a fee in case of submission of periodic safety update reports (PSURs). This fee comes into effect as soon as this royal decree comes into force, that is on 8 February 2009, for the medicinal products for human use and veterinary use, authorised by the national procedure, the mutual recognition procedure and the decentralised procedure.

The amount of the fee to pay to the Federal Agency for Medicines and Health Products (FAMHP) for each submission of a PSUR is fixed at 1150 €.
This amount is raised to 2300 € when Belgium is acting as RMS during a mutual recognition procedure of during a decentralised procedure.
These amounts are halved for the PSURs that are submitted during the period between the granting of the marketing authorisation (MA) and the effective marketing as well as during the first two years of the marketing.

The halved amount also applies to the PSURs that are submitted on immediate demand of the FAMHP.

We call your attention to the fact that this fee is due for each submitted PSUR[1].

[1] It is recommended that information on all indications, dosage forms, routes of administration and regimens for a given active substance for medicinal products authorised to one Marketing Authorisation Holder should be included in a single PSUR, see Eudralex vol. 9A, I.6.2.2
For the medicinal products for veterinary use: it is possible to handle in a single PSUR of the same MA(s) holder the information over a pharmaceutical form including the different dosings, the different target species, the routes of administration, the different indications,… of medicines containing one or several active substances. Volume 9 B has been adopted by the CVMP but it must still be adopted and published by the European commission DG Enterprise.

As regards the medicinal products for human use, the fee form must be submitted in the following file: m1/eu/12-form/be and with the name be-form-proofpayment[2].

As regards the medicinal products for veterinary use, the PSURs must be addressed to the FAMHP, Belgian Centre for Pharmacovigilance for the medicinal products for veterinary use, by postal mail or to the following address: Adversedrugreactions_vet@afmps.be, Adversedrugreactions_vet@fagg.be

The fee form to be submitted is the same than the one for the MAs fees, with clear indication of the subject: « PSURs ».

The payment of the fee, done by bank transaction, must be done on the account of the FAMHP:

Account n° 679-0021942-20
IBAN: BE28 6790 0219 4220
BIC: PCHQBEBB

I already want to inform you that a new circular concerning the compulsory notification to the FAMHP of the submission planning of the PSURs will soon be sent to you.

Yours faithfully,

Xavier De Cuyper,
CEO

[2] See Circular 476.