

Department of Budget & Management Control

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Your message dated	Your reference	Our reference	Appendices	Date
				12.12.2019

Payment method: fees for applications regarding marketing authorisations for medicines for human and veterinary use (new applications, amendments and renewals) and clinical trials for medicines for veterinary use

Dear sir,
dear madam

You may have inferred or noticed that the FAMHP has switched to a payment system after invoicing for a large part of its fees, instead of prepayments or using an allowance account.

Over time, we want to implement this transition for (nearly) all fees.

We have noticed that for the fees of some procedures that have not yet undergone this step, there is ambiguity for a number of fee-payers.

Therefore, in this memorandum we want to clarify that to date, the **fees for applications regarding marketing authorisations for medicines for human and veterinary use (new applications, amendments and renewals) and clinical trials for medicines for veterinary use** still follow the old manner of prepayment or the use of an allowance account.

This includes the fees for the following procedures:

DG POST Authorisations

→ department of marketing authorisation / variations & renewals

- Variation (administrative, type IA, type IB, type II) for MA for medicines for human use
- Notification (article 61.3 and article 34§4) for MA for medicines for human use
- Renewal of MA for medicines for human use
- New application for Parallel Import (PI) authorisation for medicines for human use
- Renewal of PI authorisation for medicines for human use
- Amendment to PI authorisation for medicines for human use

DG PRE Authorisations

→ department of medicines for veterinary use

- New applications for an MA for medicines for veterinary use
- Variations (administrative, type IA, type IB, type II) for MA for medicines for veterinary use
- Renewal of MA for medicines for veterinary use
- New application for PI authorisation for medicines for human use
- Renewal of PI authorisation for medicines for human use
- Renewal of PI authorisation for medicines for human use
- Applications for clinical trials for medicines for veterinary use

→ department of marketing authorisation/new authorisations

- New applications for MA for medicines for human use and registrations for herbal remedies and homeopathic medicines
- Variation (administrative, type IA, type IB, type II) for herbal remedies
- Notification (article 61.3 and article 34§4) for herbal remedies
- Renewal for herbal remedies

These are not the only incomes that will temporarily still follow this rule, but we find that there is much confusion among the aforementioned files.

For an exhaustive list of the fees that **have made the transition**, we refer you to the following communication on our website:

https://www.famhp.be/sites/default/files/content/famhp_-_invoice_replaces_advance_payment_-_update_28.08.2019.pdf

Please implement these instructions carefully to prevent delays in the processing of your files.

The additional step for the principle of payment after invoicing will be announced prior to its implementation.

Kind regards,

Department of Budget & Management Control