

Transversal Support/Budget and Management Control Division

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	Your letter fromYour referenceOur referenceAnnexDate28.08.2019
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New payment method: invoice replaces advance payment

Dear sir or madam,

To date, the Federal Agency for Medicines and Health Products (FAMHP) has collected most of its income through **advance payments**. It did this in two ways:

- 1. Via an **exact advance payment**: a company pays the amount owed in advance and adds proof of payment when it submits its file.
- 2. Via an **allowance account**: a company has an allowance account with the FAMHP and indicates when submitting its file that the FAMHP may use this to pay the amount owed.

The advance payments have **problems**, however:

- General problems:
 - Making a payment without a supporting document can be problematic for some companies.
 - Manually linking payments to invoices is a heavy workload for the FAMHP accounting department.
 The service that manages a file for the FAMHP must check the payment. This delays the
 - processing of the file.
- Problems with exact advance payments:
 - A company cannot immediately submit its request. It must always wait for proof of payment to add to the request.
 - The FAMHP cannot link some payments to the correct file based on the message with the transfer.
 - Companies sometimes pay the wrong amounts because they misinterpret the type of file or because they take a non-indexed amount from a payment from the previous year. This can lead to the file being blocked.
- Problems with payments via allowance accounts:
 - If various entities of the same legal person are working with different budgets, it is difficult to keep an overview and avoid errors.
 - If legal persons with a commercial relationship submit each other's files and/or make their payments, it is harder for the FAMHP to determine which allowance account is the correct one. This can cause errors.
 - There is a great deal of ambiguity about the allowance account, so the FAMHP receives many questions about them.

The FAMHP strives for a dynamic, efficient and customer-friendly management of its incomes. To prevent problems with advance payments, we are moving step-by-step to **payment via invoice** with structured messages. This will be the payment method for the major share of the services and contributions to the FAMHP.

This means that companies will submit their services for the services and contributions without advance payment. The FAMHP sends the invoice with structured message when the competent service processes the file.

The new method is currently applicable to the following services and contributions:

Directorate-General PRE authorisation: 0

- Pharmacopoeia/Raw Materials: unit
- Initial authorisations
- · Pharmacopoeia
- Monographs

0

0

0

- Annual contributions (distribution, manufacturing)
- Marketing authorisation Division (human use)
- Annual contribution to the sale of homoeopathic medicines (variable tax)

Research and Development Division (human use): 0

- Clinical trial phase I accreditation
- Unmet medical need
- Clinical trials
- Clinical investigations medical devices (MDD, AIMD)
- DSURs
- Medicines for Veterinary Use Division:
- Quarterly fees for packaging units

Directorate-General POST authorisation:

- Vigilance Division (pharmaco, materio, haemo, bio):
- Annual contributions per MA Human (variable tax)
- Annual contributions per MA Veterinary (variable tax)
- DHCPs
- PSURs

Health Products Division:

- Annual contributions for sales of Medical Devices (variable tax)
- Export certificates health products
- IVD contribution

Proper Use Division: 0

- Publicity
- RMAs

Directorate-General Inspection:

- Certificates
- Brokers
- Declarations (export, contract manufacturing)
- API registrations
- Precursors (import/export, registration)
- Hormones (registration, modification, LONO)
- Narcotics authorisations import/export
- Narcotics LONO import/export
- Narcotics annual contributions (production, distribution, other)
- Annual contribution GMP inspections
- Certified lab inspections
- GCP inspections
- Annual contribution GDP inspections
- Responsible information (RIP) (authorisation, modification)
- Annual contributions for pharmacies

Fees on packaging:

- Annual fees for wholesalers and the wholesale distributors (variable tax)
- Annual fees for MA holders

The FAMHP requests that advance payments be made for these services and contributions, but to wait for the invoice (or invitation to pay) with a structured message for payment.

Currently we are in a transition period. So you may receive an invoice for a contribution that you have already (partially) paid via an advance payment. Is that the case? Send the invoice number and proof of your advance payment in an e-mail to <u>fin@famhp.be</u>. Thus the service handling your file can link the advance payment to the right invoice.

Does your advance payment only cover part of the amount on the invoice? Then just transfer the remaining balance. Don't forget to include the structured message you see on the invoice.

Are you currently working with an **allowance account**? Send an e-mail to <u>fin@famhp.be</u>, and the FAMHP will refund your allowance upon simple request. The FAMHP no longer uses the credit in your allowance account to pay your fees, even if it is enough to pay it. We kindly request to now pay your fees after receiving an invoice with a structured message.

Over the year, the FAMHP will also start collecting **other fees** via invoice with structured message. The services within the FAMHP that manage your files will inform you of this. The FAMHP will also communicate this on its website (<u>https://www.famhp.be/en/items-HOME/fees</u>).

We are convinced that this new procedure will be to the advantage of both the FAMHP and the companies using our services. Do you still have questions about the new invoicing process after reading this letter? Ask them in an e-mail to <u>fin@famhp.be</u>. For information about the content of the invoice (amount, items charged...), it is best to contact the file manager who processed your request.

Yours sincerely,

Budget and Management Control Division