

FAQ FINANCING LAW – GENERAL POINTS

1. [How must the annual fees be paid, given the most recent publication of the financing law?](#)
2. [Does the compensation relating to packaging also apply to medicinal products authorised via the centralised procedure?](#)
3. [As of when do annual subscriptions come into effect?](#)
4. [Will the FAMHP send notifications to its partners concerning annual Fees and annual subscriptions?](#)
5. [Is the annual fee referred to in Annex III to the financing law calculated per brand name or per authorisation number?](#)
6. [The tariffs will enter into force ten days after their publication in the Belgian Official Journal. When will this publication take place?](#)
7. [If we still have more follow-up questions, who should we contact?](#)
8. [Now that the fees have changed, have the number of people and the file processing times also changed? The interpretation is that since the money now goes directly to where it is needed, it should be better spent.](#)
9. [Why has no annual fee been proposed for the variations?](#)
10. [The proposed payments are considerable. How is it that these are different to those in the Netherlands?](#)
11. [If too high an amount has been paid in reimbursable taxes, the 'excess' will be deducted from the amount due the following year. Why is this excess not reimbursed during the current financial year?](#)
12. [Concerning the variable tax, the excess would be reimbursed, but what if there is a deficit?](#)
13. [What if an entity closes on 31 December in the year N?](#)
14. [Is it true that the turnover for medical devices must be submitted before the end of March or will it be the subject of consultation?](#)
15. [Why are we working with 'current accounts' or provisions in certain cases \(variations, for example\) and with individual payments in other cases \(new marketing authorisations, for example\)?](#)

Question: How must the annual fees be paid, given the most recent publication of the financing law?

Answer: The transitional provision is set forth in Article 68 (2) of the financing law.

1. Fees on the packaging of medicinal products destined for the *Service de Contrôle des Médicaments* (Medicine Control Service) (also known as '*taxe compte numéro 1*'): this fee is still due quarterly.
2. Fees on the packaging of medicinal products, which cover the Agency's activities (also known as '*impôt compte numéro 2*'): this fee is still due quarterly for dispensing pharmacies. For the pharmaceutical industry and distributors, the fee for the first quarter of 2018 will be cancelled and replaced, from the second quarter of 2018, with an annual fee. The fee for the first quarter will therefore not be due twice.

Question: Does the compensation relating to packaging also apply to medicinal products authorised via the centralised procedure?

Answer: Yes, this also applies to medicinal products authorised via the centralised procedure.

Question: As of when do annual subscriptions come into effect?

Answer: Annual subscriptions come into effect on 1 April 2018.

Question: Will the FAMHP send notifications to its partners concerning annual fees and annual subscriptions?

Answer: The answer to this question is in two parts.

1. If the unit to which the annual subscription or annual fee applies is known to the FAMHP, an invoice will be sent based on this '*snapshot*'. This is the case, for example, for the annual fee based on the number of GMP entities.
2. If the unit to which the annual subscription or annual fee applies is not known to the FAMHP, the '*snapshot*' of the year N-1 must be sent to the FAMHP by the company in question. The FAMHP will send the invoice based on this response. This is the case, for example, for fees on the packaging of medicinal products, which cover the Agency's activities (also known as '*impôt compte numéro 2*').

Question: Is the annual fee referred to in Annex III to the financing law calculated per brand name or per authorisation number?

Answer: The annual fee of economic operators is calculated per authorisation number. This currently corresponds to the number of marketing authorisations (MA).

Question: The tariffs will enter into force ten days after their publication in the Belgian Official Journal. When will this publication take place?

Answer: The financing law was signed by the King on 11 March 2018 and will shortly be published in the Belgian Official Journal. The FAMHP does not know the exact publication date but can confirm that the new tariffs will enter into force ten days after publication.

Question: If we still have more follow-up questions, who should we contact?

Answer: There is no specific contact person for questions relating to the new financing law. All information is available on our website via the following links (in FR and NL):

<https://www.afmps.be/fr/items-HOME/Redevances> and <https://www.fagg.be/nl/items-HOME/bijdragen>.

As is already the case, you may also contact the specific division by e-mail if you still have questions. You will find an overview of contacts on our website via the following link:

<https://www.famhp.be/en/contact>.

Question: Now that the fees have changed, have the number of people and the file processing times also changed? The interpretation is that since the money now goes directly to where it is needed, it should be better spent.

Answer: Adjustment of our payments does not mean an increase but rather a redistribution of revenues based on the fee-for-service principle. The fees have been changed to correspond more closely to the real cost of the service in question. If one now has to pay more for a service, this means that the price was not correct in the past.

The tariff increase therefore has no impact on the current resources employed on the current volumes. It is important that we know about any possible increase in volume at the time of the budget, in order to make any necessary recruitment in good time.

Question: Why has no annual fee been proposed for variations?

Answer: In fact this has been discussed, but after examining the advantages and disadvantages, it appeared that the best solution for variations was an individual fee.

Question: The proposed payments are considerable. How is it that these are different to those in the Netherlands?

Answer: The agencies of the various Member States are entirely independent in terms of their operational procedures and financing. The package of services offered also differs significantly from one country to another. In Belgium, payments are established according to the fee-for-service principle. The payments are adjusted to the workload per output.

Question: If too high an amount has been paid in reimbursable taxes, the 'excess' will be deducted from the amount due the following year. Why is this excess not reimbursed during the current financial year?

Answer: Yes, this is correct. Concerning fiscal issues, a document will indicate the real amount for the current year and will mention the fact that part of the money is available to the FAMHP and will not be used until the following year. This governs the issue from a fiscal perspective. Returning the money and then requesting a new payment would make things more complex.

Question: Concerning the variable tax, the excess would be reimbursed, but what if there is a deficit?

Answer: The law only provides for reimbursement and not for additional payment.

Question: What if an entity closes on 31 December in the year N?

Answer: In this case, no collective fee will be requested for the year N+1.

Question: Is it true that the turnover for medical devices must be submitted before the end of March or will it be the subject of consultation?

Answer: Submission of the turnover for medical devices is computerised and will be performed via the portal.

Question: Why are we working with 'current accounts' or provisions in certain cases (variations, for example) and with individual payments in other cases (new marketing authorisations, for example)?

Answer: Depending on whether the company is large or small, the payment preference will be different. A large company will prefer provisions, a small company will prefer an individual payment. We are currently examining which is more efficient: the use of invoices with structured communication or the use of provisions. Provisions make internal monitoring by the FAMHP more difficult because it is less easy to link the amounts to the files submitted, whereas this link is much clearer in the case of individual invoices.