

B&Mc Department

Address

Fax: 02/528.40.00

email: [VHBverpakk@fagg-afmps.be](mailto:VHBverpakk@fagg-afmps.be)

**our reference**

annual fee packages MAH

**attachments**

1

**date**

18/04/2019

## **Obligation to declare the number of packages of medicines put on the Belgian market (FAMHP Financing act – article 17, section 4)**

Dear sir or madam

Article 17, section 4 of the Act of March 11, 2018 (financing of the FAMHP), published in the Belgian Official Journal of March 26, 2018, provides for the **annual fees on packages of medicines**, in order to finance the duties of the Federal Agency for Medicines and Health Products.

For the year 2019, every marketing authorisation holder (MAH) of medicinal products, with the exception of homeopathic medicinal products, must submit a **declaration**, not later than **April 30, 2019**, of the number of packages put on the Belgian market in the year 2018 (including free samples).

Please send us the statement below, preferably by **email** ([VHBverpakk@fagg-afmps.be](mailto:VHBverpakk@fagg-afmps.be)), or optionally by **postal service** (FAMHP, for the attention of VHB-verpakkingen, Victor Hortaplein 40/40, 1060 Brussels, Belgium).

" *I, the undersigned, ....., authorised to represent the company ....., with company registration number ....., domiciled at the following address, ....., hereby declare as follows:*

*The aforementioned company placed the following numbers of packaging units on the Belgian market (against payment or for free) in the year 2018:*

*..... packaging units of medicines subject to medical prescription*

**AND**

*..... packaging units of medicines **NOT** subject to medical prescription.*

*Herewith, in addition, the total number split over the following categories:*

*A: Distributed through public pharmacies (accessible to all): ..... packaging units.*

*B: Distributed through hospital pharmacies: ..... packaging units.*

*C: Distributed through persons authorized to procure medicines to people responsible for animals:  
..... packaging units.*

*D: Samples for medical doctors: ..... packaging units.”*

Notifications by **email** must be sent from an email address belonging to the concerned company and must mention the subject “Declaration packaging units MAH 2018”.

Notifications by **postal service** must be dated and signed.

Afterwards, the FAMHP will communicate fee and **payment** procedure.

If you do not submit a declaration by April 30, 2019, the FAMHP has the **official capacity** to determine the fee. Additional sanctions are possible. This is provided for by the FAMHP Financing act of March 11, 2018, article 17 and article 41.

Please find **attached** to this letter answers to frequently asked questions.

Thank you for your kind attention to this letter.

Yours sincerely,

Department of Budget & Management Control

## Frequently asked questions about the annual fees on packages of medicinal products

### 1. There are two types of annual declaration. Which declaration do I have to submit?

#### You are a MAH, but not a wholesaler (in Belgium)

- You only have to submit the **annual declaration of packages by MAHs** for the medicinal products that you have put on the Belgian market.

You are a wholesaler, but not a MAH (in Belgium) (This case also applies when you distribute medicinal products of a MAH who is related to your company but who is a different legal entity.)

- You only have to submit the **annual declaration on packages by wholesalers(-distributors)**.

#### You are a MAH, and a wholesaler (in Belgium) (whether you are MAH of the products or not)

- You have to submit the **annual declaration of packages by MAHs** for the medicinal products that you have put on the Belgian market.
- In addition, you have to submit the **annual declaration on packages by wholesalers(-distributors)**. Here, you only declare the number of packages of other medicinal products you distribute on the Belgian market (i.e., for which you as a legal entity are not the MAH). In case you do not distribute any other medicinal product on the Belgian market, this second declaration is a zero declaration (see also question 2).

### 2. I have no packages to declare in a certain period. Do I have to submit a declaration anyway?

Yes. If you are a **MAH** or a **wholesaler**, you must submit a declaration. This can be a declaration with zero packages, a so-called “**zero declaration**”. Without a declaration, the FAMHP has the official capacity to determine the fee.

You receive this letter because, at the FAMHP, you are registered as active in the concerned domain. If this is incorrect, please send us an email:

- MAHs: [database@fagg.be](mailto:database@fagg.be) and in cc [VHBverpakk@fagg.be](mailto:VHBverpakk@fagg.be)
- Wholesalers: [certificates@fagg.be](mailto:certificates@fagg.be)

### 3. Do separate quarterly declarations and fees on packages still exist?

Yes. Besides these annual declarations, there still exist some quarterly declarations and fees. You can find them in **appendix II** to the Financing act. Those fees must be paid by pharmacists and depots of medicinal products for veterinary use.

The **template** for quarterly declarations is available on our website, though not in English.

In Dutch: <https://www.fagg.be/nl/items-HOME/bijdragen>

[Toezicht en controle op de grondstoffen](#)

[Controle op de geneesmiddelen](#) en template kwartaalaangifte (2018, 2019)

[Vergunningen - declaraties - certificaten - inspectie](#)

In French: <https://www.afmps.be/fr/items-HOME/Redevances>

[Surveillance et contrôle des matières premières](#)

[Contrôle des médicaments](#) et template déclaration trimestrielle (2018, 2019)

[Autorisation - déclarations - certificats - inspection](#)

### 4. I store or transport on behalf of third parties. Do I have to submit a declaration?

No. If you have a distribution licence, but only store or transport packages of medicinal products **for the account of third parties**, you do not have to submit a wholesaler declaration. If you were invited to submit such a declaration, please let us know by email to [certificates@fagg.be](mailto:certificates@fagg.be).

### 5. I am a wholesaler(-distributor) who exclusively distributes to other wholesalers(-distributors). Do I have to submit a declaration? Do these other wholesalers(-distributors) have to submit a declaration?

Twice yes. You must declare **all distributed packages**, whatever the capacity of the receiver. Since each link in the distribution chain is within the FAMHP supervision scope, **every wholesaler(-distributor)** must pay a fee.

### 6. Which products are considered as put on the market?

You must declare **all packages** of non-homeopathic medicinal products, including samples and products you make available for an *Unmet Medical Need* programme.

## 7. What is the difference between “putting on the market” and “distributing” packages?

“Putting on the market” packages is the activity of **MAHs**.

“Distributing” packages is the activity of **wholesalers(-distributors)**.

## 8. Are packages distributed to Belgium from abroad to be declared?

The scope of the declaration is packages distributed by a wholesaler(-distributor) licenced in Belgium. **Who** has shipped the packages to the wholesaler(-distributor), and whether the packages come from abroad, **does not matter**.

## 9. Are packages distributed from Belgium to abroad to be declared?

The scope of the declaration is packages distributed by a wholesaler(-distributor) licenced in Belgium. **To whom** the wholesaler(-distributor) ships them, and whether they are sent abroad, **does not matter**. So, it is possible that the declaration includes packages of medicinal products not authorised for sale in Belgium.

## 10. In 2018 I was MAH (or wholesaler), but not anymore now. Do I have to submit a declaration?

No. Although the calculations are based on 2018 numbers, this letter is about contributions on **activities in 2019**. If, on January 1, 2019, you are no longer MAH (or wholesaler), you do not need to submit a declaration or pay a fee, irrespective of the volume of your activities in 2018.

If you received this letter by mistake, please send us an email:

- MAHs: [database@fagg.be](mailto:database@fagg.be) and in cc [VHBverpakk@fagg.be](mailto:VHBverpakk@fagg.be)
- Wholesalers: [certificates@fagg.be](mailto:certificates@fagg.be)

## 11. Why are there two different divisions in the declaration?

The split between medicinal products **with** and **without medical prescription** is necessary to calculate the fee. Each category has its own tariff.

The split based on the type of the **final distribution channel** (A, B, C & D) was asked by the FAMHP Transparency committee, where the different sectors are represented.

12. I am a MAH who ships to wholesalers. Do I have to provide a split between categories A, B, C & D?

Yes. The MAH must indicate via which channel (A, B, C or D) the packages **reach the end user**.