

Division B & Cg

Fax : 02/524.50.53
e-mail : fin@afmps.be

Circular n° 589

For the attention of those persons entitled to deliver and/or supply medicines, to those authorised to sell medicines by wholesale and to wholesale – distributors

Your letter dated	Your references	Our references	Appendices	Date
			1	08.06.2012

Collection of fees per pack as laid down in the new framework law of 29th March 2012

THIS DOCUMENT IS A TRANSLATION OF THE OFFICIAL AND SIGNED VERSIONS IN DUTCH AND FRENCH.

Dear Sirs,

The framework law of 29th March 2012 (in the Moniteur Belge of 6th April 2012) reviews the adaptation of the tax system to finance the activities of the AFMPS – l'Agence fédérale des médicaments et des produits de santé (the Federal Agency for Medicines and Health Products). These changes have been made following the new requirements concerning pharmacovigilance on the European level.

This law modifies article 225 of the law dated 12th August 2000 covering social, budgetary and other provisions on which the system of fees per pack is based.

A) Fees for persons entitled to deliver medicines

1. The framework law of 29th March 2012 stipulates that :

- all persons entitled to deliver medicines to the general public (e.g. through public or hospital pharmacies) and

- all persons entitled to deliver medicines to people responsible for animals,

are required to pay € 0.00596 for each pack obtained both by payment and free-of-charge.

The payment is made by the wholesaler – distributor or by the person authorised to act as wholesaler in the case of direct delivery. These persons must pay during the second 10-day period of each quarter the total amount of « € 0.00596 » fees that are due for the previous quarter.

This payment should be made to « compte spécial n°2 » (special account no. 2) as follows:

IBAN : BE46 1106 0013 1136

BIC : BKCPBEBB

2. We would point out that the framework law of 29th March 2012 does not change the fees foreseen in article 228/1 of the framework law dated 12th August 2000 aimed at financing the re-control of the medicine.

As a reminder:

Article 225/1 foresees a fee to be paid by persons entitled to deliver medicines (through public and hospital pharmacies and through veterinary warehouses): the fee of € 0.0157 (the amount being indexed in 2012) for each pack obtained both by payment and free-of-charge.

The payment is made by the wholesaler – distributor or by the person authorised to make the wholesale transaction in the case of direct delivery. These persons must pay during the second 10-day period of each quarter the total amount of « € 0.0157 » fees that are due for the previous quarter.

This payment should be made to « compte spécial n° 1 » (special account no. 1) as follows:

IBAN: BE57 1106 0013 1035

BIC: BKCPBEBB

B) Wholesalers', wholesale-distributors' and authorisation holders' fees

The framework law of 29th March 2012 stipulates that the following fees should be paid:

1. The holders of marketing authorisations pay € 0.01118 per pack of medicine that they sell in the market; the exception is holders of marketing authorisation on the European level¹ who are exempt from paying this fee.
2. All wholesalers or wholesaler – distributors have to pay € 0.00014 per pack of medicines that they have distributed with the exception of those people that have to pay the fees mentioned above.

Authorisation holders, wholesalers and wholesaler - distributors must pay during the second 10-day period of each quarter the total amount of « € 0.01118 or € 0.00014 » fees that are due for the previous quarter

This payment should be made to « compte spécial n° 2 » (special account no. 2) as follows:

IBAN: BE46 1106 0013 1136

BIC: BKCPBEBB

C) Practical application

The framework law of 29th March 2012 is intended to have effect during the quarter and to simplify the application of the changes, so these conditions will apply from 1st July 2012 and the new payments are expected in the second 10-week period of October 2012

¹ in line with article 3 of (CE) Regulation n°726/2004 of the European Parliament and Council dated 31st March 2004 setting out the procedures of the community for the authorisation and surveillance of medicines for human and veterinary use and for setting up a European medicines agency.

Furthermore it is requested that payment is accompanied by an e-mail sent to the following address: fin@afmps.be.

This mail should include a table with the information about the relevant quarter, the number of packs taken into account and the amount paid in line with the attached appendix.

Thanking you for taking note of the above I remain

Yours faithfully

Xavier De Cuyper,

CEO

Appendix to circular n° XXX

Number of packs marketed, both those paid for and those free-of-charge	Total amount owed by those persons entitled to deliver medicines and transferred to Special Account no. 2 – c.f.A)1	Total amount owed by those persons entitled to deliver medicines and transferred to Special Account no. 1 – c.f.A)2	Number of packs marketed, both those paid for and those free-of-charge	1. Total amount owed by holders of marketing authorisation - c.f.B)1	Number of packs distributed	Total amount owed by the wholesaler - c.f.B)2	Number of packs distributed	Total amount owed by the wholesale distributors c.f. B) 2.
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