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Your message dated	Your reference	Our reference	Appendices	Date
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Amendments as a result of the new financing law of 2019

Dear Sir/Madam,

On 20 May 2019, the law changing provisions regarding providing scientific and technical advice by the Federal Agency for Medicines and Health Products and regarding the financing of the Federal Agency for Medicines and Health Products (financing law of 2019) has been published in the Belgian Official Gazette.

The new law changes a number of aspects of the function and financing of the Federal Agency for Medicines and Health Products (FAMHP).

This letter will update you on the most significant consequences of this change in the law.

Firstly, I'll refer you to the law dated 11 March 2018 regarding the financing of the Federal Agency for Medicines and Health Products (financing law of 2018). This law brought most of the provisions for the financing of the FAMHP together in one law. It also brought a great deal of changes to the provisions with it.

The financing law of 2019 revises the financing law of 2018 on various points, namely:

1. linguistic and technical corrections;
2. revision of the fees or percentages of a number of fees and contributions;
3. introduction of a number of new fees.

This letter is limited to the two latter categories.

1. Revised fees or percentages of a number of fees and contributions

The FAMHP is always closely calculating the costs of its activities to assign them to the associated sectors of which it has oversight in function of the services provided. These revisions are the result of this exercise.

Note, the fees according to the "old law" in this section are the unindexed fees for the year 2018.

Revised fees on packaging (art. 15):

- Old law:
  - Quarterly fee for pharmacies and veterinary depositories: €0.00587
  - Annual fee for wholesalers: €0.00032

- New law:
  - Quarterly fee for pharmacies and veterinary depositories: €0.00902
  - Annual fee for wholesalers: €0.0006

Revised annual fees (art. 16):

a. GMP/GDP

These are the annual fees that fund these inspections. In 2018, these lump-sum fees replaced the fee on the inspection performed which was applicable up to 2017. This means that the FAMHP no longer sends inspected companies an invoice for a GMP/GDP inspection, but that all companies involved pay a set annual fee to finance these inspections.

The financing law of 2019 revises the annual fees and removes the costs for re-inspections. From now, the FAMHP invoices these re-inspections via a new fee (fee for service). Thus, it is not the entire sector that pays for the costs generated by few.

- Old law:
  - GMP Sterile: €10,488.00
  - GMP non-sterile: €6,992.00
  - GDP: €3,337.00
- New law:
  - GMP (sterile and non-sterile) €3,029.95
  - GDP: €3,679.93

b. Specially regulated substances

These annual fees finance the inspections of marketing authorisation holders for specially regulated substances.

- Old law:
  - Manufacturer activity authorisations: €451.64
  - Distributor, wholesaler activity authorisations: €259.57
  - "Other" activity authorisations (no indication of sale, stock or fabrication register to the FAMHP): €37.38
- New law:
  - Manufacturer activity authorisations: €895.81
  - Distributor, wholesaler activity authorisations: €451.89
  - "Other" activity authorisations (no indication of sale, stock or fabrication register to the FAMHP): €32.41

Revised distribution key for the theoretic surplus of variable taxes (art. 17, annex III)

This is the way in which the FAMHP calculates the amounts it can refund if there is an surplus in income received. The new law makes a sixth tax variable, namely that for the exploitation licenses for pharmacies open to the public. This means that when the FAMHP has a financial surplus, it will refund part of the surplus income to the pharmacies open to the public.

- Old law:
  - Charge on the revenue from medical devices: 32.17%
  - Charge on the revenue from homeopathy: 0.26%
  - Charge on packing for wholesalers (wholesale distributors): 0.48%
  - Charge on the number of marketing authorisations (MAs) for human use: 43.13%
  - Charge on the number of MAs for veterinary use; 4.05%

- New law:
  - Charge on the revenue from medical devices: 35.62%
  - Charge on the revenue from homeopathy: 0.20%
  - Charge on packing for wholesalers (wholesale distributors): 0.36%
  - Charge on the number of MAs for veterinary use; 33.13%
  - Charge on the number of MAs for veterinary use; 3.11%
  - Charge on the exploitation license for pharmacies open to the public: 7.58%

Fee for service

a. National Scientific and Technical-Regulatory Advice (WTA) (art. 18 and 20.1°/1-2; annex III/1 and III/2)

The financing law of 2019 introduces a reduces fee and exemption from fee for requests for national scientific-regulatory advise (STA) for medicines:

- A **reduced fee** for small and medium enterprises, universities, certified hospitals, foundations for the public good and statutory administrations for requests for national scientific and technical-regulatory advice (STA) on research into and the development of a medicine with the intention of possible application for marketing authorisation or registration of a drug or a request for a change of such. This fee is reduced by 75% (compared to the standard fees for STA requests of type I, II and III) to make this FAMHP service more accessible for these companies and organizations and thus support and accelerate the development and access to innovative medicines in Belgium.
- An **exemption from the fee** for STA requests type I, II and III regarding clinical trials originating from all types of enterprises and non-commercial organizations if the applicant for the exemption commits to submitting an admissible request for approval of a clinical trial, within two years after the granting of the national STA related to this planned clinical trial, based on the law dated 7 May 2017 regarding clinical trials with medicines for human use (including the pilot files pursuant to the law dated 7 May 2004 regarding experiments using human subjects). This unilateral declaration of intent must be attached to the formal STA request. If the applicant does not fulfil this commitment, he will owe the fee to the FAMHP. The fee is the indexed amount of the standard STA fee for the specific STA request of the applicant.

The revised fees according to the new law are:

- For SMEs, universities, certified hospitals, foundations for the public good and statutory administrations:
  - STA type I: €541.75
  - STA type II: €3,250.49
  - STA type III: €4,333.99
- For an applicant (request type STA I, II or III) who commits to requesting a clinical trial within two years: €0
  - If the applicant does not fulfil this commitment (fee to be indexed compared to 2019):
    - STA type I: €2,166.99
    - STA type II: €13,001.94
    - STA type III: €17,335.94

b. Specially regulated substances (art. 20.3°-18°, 21°, 23° and 25°)

Fact subject to fee	Fee obligor	Old amount	New amount
VII.2.1.1 Application for an activity authorisation according to article 1 of the Drugs Act	applicant	€175.47	€374.22
VII.2.1.2 Application for an activity authorisation that leads to an inspection, according to article 1 of the Drugs Act	applicant	€451.64	€710.31
VII.2.1.3 Applications for an activity authorisation if the location is not licensed at the time the application is submitted and the application is associated with a location for which a production authorisation is granted in accordance with article 12b (1), (1,5) of the law dated 25 March 1964 on medicines and according to article 1 of the Drugs Act.	applicant	€799.46	€1,231.257
-VII.2.1.4 Applications from end users and the application for renewal of the end user authorisation according to article 1 of the Drugs Act	applicant	€89.29	€184.86
VII.2.1.5	applicant	€89.29	€184.86

Applications for an individual authorisation and the request for renewal of an individual authorisation according to article 1 of the Drugs Act			
VII.2.1.6 Application for revision of data in the activity authorisation, end user authorisation, Individual authorisation according to article 1 of the Drugs Act	applicant	€69.89	€147.67
VII.2.1.7 Application for an import authorisation according to article 1 of the Drugs Act	applicant	€32.34	€33.01
VII.2.1.8 Application for an import/export authorisation submitted via the FAMHP website (NDSWeb) according to article 1 of the Drugs Act	applicant	€19.81	€31.81
VII.2.1.9 Applications for an import/export authorisation electronically submitted via a file according to the model set up by the FAMHP and published on the FAMHP website according to article 1 of the Drugs Act	applicant	€24.95	€22.58
VII.2.1.10 Applications for an import/export authorisation subject to an audit by the authorised official according to article 1 of the Drugs Act	applicant	€170.27	€83.42
VII.2.1.11 Applications for an import/export authorisation submitted via the FAMHP website (NDSWeb) and subject to audit by the authorised official according to article 1 of the Drugs Act	applicant	€157.74	€82.22
VII.2.1.12 Applications for an import/export authorisation electronically submitted via a file according to the model set up by the FAMHP and published on the FAMHP website if this request is subject to audit by the authorised official according to article 1 of the Drugs Act	applicant	€162.88	€72.99
VII.2.2.1 Application for a "declaration of no objection" according to article 1 of the Drugs Act	applicant	€43.61	€72.61
VII.2.2.2 Applications for a book of 100 coupons according to article 1 of the Drugs Act	applicant	€5.42	€17.41
VII.2.2.3 Inspections except for those intended in chapter 1 according to article 1 of the Drugs Act	applicant	€623.99	€170.19
VII.2.4.1 Applications for an authorisation or registration for the manufacture, sale, provision for sale, possession or delivery of registered substances by or according to Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors, article 3) and Council Regulation (EC) no. 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors, articles 6 and 7) according to article 1 of the Drugs Act	applicant	€132	€287.69
VII.2.4.2 Application for an import authorisation for registered substances by or according to Council Regulation (EC) no. 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors, article 20) according to article 1 of the Drugs Act	applicant	€71	€84.02
VII.2.4.3	applicant	€59	€84.02

Application for an export authorisation for registered substances by or according to Council Regulation (EC) no. 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors, article 12) according to article 1 of the Drugs Act			

c. Medical Devices (art. 20.1° and 28; annex VIII)

Fact subject to fee	Fee obligor	Old amount	New amount
VII.9.1.1 Notification to the FAMHP of the intention to start a commercial clinical trial for a medical device, even if it is an active implantable medical device	manufacturer or its representative	€8,982	€10,436.42
VII.9.1.2 Granting of an export certificate for a medical device	applicant	€159	€117.23

2. New fees

These new fees are the result of a finer budgetary exercise through which existing activities subject to fee can be split up.

Fee for service

a. Registrations and authorisations (art. 20.3°; annex IV)

Fact subject to fee	Fee obligor	amount
VII.1.15.6 Validation of a document created by the applicant in connection with registrations and authorisations for medicines	applicant	€150.28

b. Specially regulated substances (art. 20.19°; annex V and art. 20.26°; annex VI)

Fact subject to fee	Fee obligor	amount
VII.2.2.4 Applications for a "declaration of no objection" (that indicates that the products involved are not subject to an import or export authorisation) according to article 1 of the Drugs Act for the import of small quantities of products for analytical purposes in the form of reference standards (max. 1 mg/ml and max. 1 ml).	applicant	€69.75
VII.2.4.4 Application for a "declaration of no objection" according to article 1 of the Drugs Act	applicant	€72.61

c. Re-inspections (art. 20.27°; annex VII)

The FAMHP invoices these re-inspections from now on directly to the affected party via a new fee (fee for service). Thus the entire sector does not have to pay costs generated by the shortcomings of few that come up during regular inspections.

Fact subject to fee	Fee obligor	amount
VII.8.1.1 Re-inspection of manufacturer of medical devices/devices for in-vitro diagnostics (IVD)	Re-inspected party	€9,779.36
VII.8.1.2 Re-inspection of hospital on the medical device	Re-inspected party	€2,124.84
VII.8.1.3 Re-inspection of human bodily material	Re-inspected party	€4,572.86
VII.8.1.4 Re-inspection of veterinary depository	Re-inspected party	€1,007.33
VII.8.1.5 Re-inspection of health care practitioner - depository (art. 20 of the coordinated law dated 10 May 2015 regarding the performance of health care occupations)	Re-inspected party	€ 1,495.18
Re-inspection of a (public) pharmacy	Re-inspected party	€1,160.01
VII.8.1.7 Re-inspection of hospital on the medicine	Re-inspected party	€1,983.03
VII.8.1.8 Re-inspection of distributor of medical devices	Re-inspected party	€3,634.96
VII.8.1.9 Re-inspection of detail distributor of medical devices	Re-inspected party	€1,495.18

d. Medical Devices (art. 20.28°; annex VIII)

Fact subject to fee	Fee obligor	amount
VII.9.1.3 Notification of mono-national clinical performance studies IVD (in-vitro diagnostics)	applicant	€393.85
VII.9.1.4 Granting of an export certificate for a medical device IVD (in-vitro diagnostics)	applicant	€155.41

Applicability of the new fees and percentages of contributions and fees in the financing law of 2019:

- The rates of the fees on packaging, the annual fees and the distribution key for the variable taxes are applicable from 1 January 2020. In 2019, the indexed rates from the financing law of 2018 are applicable.
- The rates for all other contributions and fees apply from the tenth day after the publication of this law. In the prior period, the indexed rates of the financing law of 2018 are applicable.
- The amounts and percentages described in this letter form the basis for the indexation from 1 January 2020. Retroactive indexing to 1 January 2019 is not applicable here.

The information in this letter is purely of an informative nature and is at all times subject to the provisions of the relevant legislation.

The official legal text can be found in the Belgian Official Gazette at http://www.ejustice.just.fgov.be/cgi/article_body.pl?language=fr&pub_date=2019-05-20&caller=list&numac=2019030478

With courteous regards

Xavier De Cuyper
Administrator-general of the FAMHP