Council Regulation (EC) No 1905/2005 of 14 November 2005 amending Regulation (EC) No 297/95 on fees payable to the European Medicines Agency

COUNCIL REGULATION (EC) No 1905/2005

of 14 November 2005

amending Regulation (EC) No 297/95 on fees payable to the European Medicines Agency

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products[(1)], and in particular Article 12 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament[(2)],

Whereas:

(1) Article 67(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation, supervision and surveillance of medicinal products for human and veterinary use and establishing a European Medicines Agency[(3)], stipulates that the revenue of the European Medicines Agency (hereinafter referred to as the Agency) shall consist of a contribution from the Community and fees paid by undertakings for obtaining and maintaining Community marketing authorisations and for other services provided by the Agency.

(2) Regulation (EC) No 726/2004 also provides for new tasks for the Agency. Furthermore, the existing tasks have also been changed following amendments to Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[(4)] and to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[(5)].

(3) In view of the experience gained since 1995, it is appropriate to maintain the general principles and overall structure of the fees, as well as the main operational and procedural provisions established by Regulation (EC) No 297/95. In particular, the calculation of the level of fees charged by the Agency should be based on the principle of the service actually provided and should be related to specific medicinal products. The proportionality between the fees and the assessment related costs of each application, as well as the provision of the service requested, should also be ensured.

(4) Regulation (EC) No 726/2004 lays down provisions for new post-authorisation activities to be carried out by the Agency. These tasks include the recording of the

actual marketing of medicinal products authorised in accordance with Community procedures, the maintenance of marketing authorisation dossiers and of the various databases managed by the Agency, as well as the continuous follow-up of the risk-benefit balance of authorised medicinal products. In addition, it is necessary to reduce the Agency's dependence on fees related to new applications. The annual fee should therefore be increased by 10 % to accommodate those changes.

(5) New categories of fees have to be created to cover new, specific tasks now provided by the Agency, such as new types of scientific opinions related to a medicinal product.

(6) The Management Board of the Agency should be competent to specify provisions necessary for the application of this Regulation, on a proposal from the Executive Director and following a favourable opinion from the Commission. In particular, since the levels of fees laid down in this Regulation are set as maximum fees, the Management Board should establish, for certain services for which this is laid down in the Regulation, detailed classifications and lists of reduced fees.

(7) The Executive Director should also keep the competence to decide, in exceptional circumstances, on reductions of the fees, in particular as regards certain cases related to specific medicinal products and where a reduction is necessary for imperative reasons of public or animal health. Likewise, the Executive Director should have the possibility to decide on exemptions from the obligation to pay a fee in the case of medicinal products for the treatment of rare diseases, for the treatment of diseases affecting minor animal species and for the addition of animal species in the case of the determination of maximum residue limits in accordance with the procedure laid down in Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin[(6)].

(8) In accordance with Article 70(2) of Regulation (EC) No 726/2004, the circumstances under which small and medium-sized enterprises may pay reduced fees, defer payment of the fee or receive administrative assistance are not to be covered by this Regulation.

(9) In order to allow an immediate budgetisation, the fees should be due on the date of validation but should be payable within a certain number of days.

(10) Provisions should be laid down to report on the implementation of this Regulation after experience has been gained and to review, if necessary, the level of the fees.

(11) It is appropriate to include an indexation mechanism for automatically adjusting the fees in relation to official inflation rates indices.

(12) For the sake of consistency, this Regulation should apply at the same time as the full entering into force of Regulation (EC) No 726/2004. It should not apply to valid applications pending at the time of its application.

(13) Regulation (EC) No 297/95 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 297/95 shall be amended as follows:

1. the second paragraph of Article 1 shall be replaced by the following:

   The amounts of these fees shall be laid down in euro.;

2. Article 3 is amended as follows:

   (a) the title shall be replaced by the following:

   Medicinal products for human use covered by the procedures laid down in Regulation (EC) No 726/2004;

   (b) paragraph 1 is amended as follows:

   (i) in point (a) the first and second subparagraph shall be replaced by the following:

   A full fee of EUR 232 000 shall apply for an application for a marketing authorisation supported by a full dossier. That fee shall cover a single strength associated with one pharmaceutical form and one presentation.

   The fee shall be increased by EUR 23 200 for each additional strength and/or pharmaceutical form submitted at the same time as the initial application for authorisation. That increase shall cover one additional strength or pharmaceutical form and one presentation.;

   (ii) points (b) and (c) shall be replaced by the following:

   (b) *Reduced fee*

   A reduced fee of EUR 90 000 shall apply to applications for a marketing authorisation pursuant to Article 10(1) and (3), and Article 10c of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[7]. That fee shall cover a single strength associated with one pharmaceutical form and one presentation.

   A specific reduced fee of EUR 150 000 shall apply to applications for a marketing authorisation pursuant to Article 10(4) of Directive 2001/83/EC. That fee shall cover a single strength associated with one pharmaceutical form and one presentation.

   The reduced fees referred to in the first and second subparagraph shall be increased by EUR 9 000 for each additional strength or pharmaceutical form submitted at the same time as the initial application for authorisation. That increase shall cover one additional strength or pharmaceutical form and one presentation.

The reduced fees referred to in the first and second subparagraph shall be increased by EUR 5 800 for each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.

(c) *Extension fee*

An extension fee of EUR 69 600 shall apply for each extension of a marketing authorisation within the meaning of Annex II to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[(8)], which has already been granted.

By derogation from the first subparagraph, a reduced extension fee falling within the range of EUR 17 400 to EUR 52 200 shall apply for certain extensions. Those extensions shall be included in a list, which shall be drawn up in accordance with Article 11(2) of this Regulation.

The extension fee and the reduced extension fee shall be increased by EUR 5 800 for each additional presentation of the same extension submitted at the time of the extension application.;

(c) paragraph 2 is amended as follows:

(i) in point (a) the first subparagraph shall be replaced by the following:

A Type I variation fee shall apply for a minor variation to a marketing authorisation, as defined in Article 3(2) of Regulation (EC) No 1085/2003. For Type IA variations, the fee shall be EUR 2 500. For Type IB variations, the fee shall be EUR 5 800.;

(ii) in point (b) the first subparagraph shall be replaced by the following:

A Type II variation fee of EUR 69 600 shall apply for a major variation to a marketing authorisation, as defined in Article 3(3) of Regulation (EC) No 1085/2003.

By derogation from the first subparagraph, a reduced Type II variation fee falling within the range of EUR 17 400 to EUR 52 200 shall apply for certain variations. Those variations shall be included in a list, which shall be drawn up in accordance with Article 11(2) of this Regulation.;

(d) paragraph 4 is amended as follows:

(i) the sole subparagraph shall be replaced by the following:

A fee of EUR 17 400 shall apply for any inspection within or outside the Community. For inspections outside the Community, travel expenses shall be charged extra on the basis of actual cost.;

(ii) the following subparagraph shall be added:

By derogation from the first subparagraph, a reduced inspection fee shall apply for certain inspections, according to the extent and nature of the inspection and on the basis of the conditions laid down in accordance with Article 11(2).;

(e) paragraph 6 shall be replaced by the following:

6. *Annual fee*

An annual fee of EUR 83 200 shall apply for each marketing authorisation of a medicinal product. That fee shall cover all authorised presentations of a given medicinal product.

By derogation from the first subparagraph, a reduced annual fee falling within the range of EUR 20 800 to EUR 62 400 shall apply for certain types of medicinal products. Those medicinal products shall be included in a list, which shall be drawn up in accordance with Article 11(2).;

3. Article 4 shall be replaced by the following:

Article 4

Medicinal products for human use covered by the procedures laid down in Directive 2001/83/EC

Referral fee

A referral fee of EUR 58 000 shall apply where the procedures laid down in Article 30(1) and Article 31 of Directive 2001/83/EC are initiated by the applicant of a marketing authorisation or the holder of an existing marketing authorisation.

Where more than one applicant of marketing authorisations or holder of existing marketing authorisations are concerned by the procedures referred to in the first subparagraph, the applicants or holders may be grouped for the purpose of the payment of one single referral fee. If however, the same procedure concerns more than ten different applicants or holders, the fee shall be charged by the application of the abovementioned referral fee.;

4. Article 5 is amended as follows:

(a) the title shall be replaced by the following:

Medicinal products for veterinary use covered by the procedures laid down in Regulation (EC) No 726/2004;

(b) paragraph 1 is amended as follows:

(i) point (a) shall be amended as follows:

— the first and second subparagraph shall be replaced by the following:

> A full fee of EUR 116 000 shall apply for an application for a marketing authorisation supported by a full dossier. That fee shall cover a single strength associated with one pharmaceutical form and one presentation.
>
> The fee shall be increased by EUR 11 600 for each additional strength and/or pharmaceutical form submitted at the same time as the initial application for authorisation. That increase shall cover one additional strength or pharmaceutical form and one presentation.;

— the fourth subparagraph shall be replaced by the following:

> In the case of immunological veterinary medicinal products, the full fee shall be reduced to EUR 58 000, with each additional strength and/or pharmaceutical form and/or presentation entailing an increase of EUR 5 800.;

(ii) point (b) shall be replaced by the following:

(b) *Reduced fee*

A reduced fee of EUR 58 000 shall apply to applications for a marketing authorisation pursuant to Article 13(1) and (3), and Article 13c of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[(9)]. That fee shall cover a single strength associated with one pharmaceutical form and one presentation.

A specific reduced fee of EUR 98 000 shall apply to applications for a marketing authorisation pursuant to Article 13(4) of Directive 2001/82/EC. That fee shall cover a single strength associated with one pharmaceutical form and one presentation.

The reduced fees referred to in the first and second subparagraph shall be increased by EUR 11 600 for each additional strength or pharmaceutical form submitted at the same time as the initial application for authorisation. That increase shall cover one additional strength or pharmaceutical form and one presentation.

The reduced fees referred to in the first and second subparagraph shall be increased by EUR 5 800 for each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.

In the case of immunological veterinary medicinal products, the fee shall be reduced to EUR 29 000, with each additional strength and/or pharmaceutical form and/or presentation entailing an increase of EUR 5 800.

For the purposes of this point, the number of target species is irrelevant.;

(iii) point (c) shall be replaced by the following:

(c) *Extension fee*

An extension fee of EUR 29 000 shall apply for each extension of a marketing authorisation within the meaning of Annex II to Regulation (EC) No 1085/2003, which has already been granted.

By derogation from the first subparagraph, a reduced extension fee falling withn the range of EUR 7 200 to EUR 21 700 shall apply for certain extensions. Those extensions shall be included in a list, which shall be drawn up in accordance with Article 11(2) of this Regulation.

The extension fee and the reduced extension fee shall be increased by EUR 5 800 for each additional presentation of the same extension submitted at the time of the extension application.;

(c) paragraph 2 is amended as follows:

(i) in point (a) the first subparagraph shall be replaced by the following:

A Type I variation fee shall apply for a minor variation to a marketing authorisation, as defined in Article 3(2) of Regulation (EC) No 1085/2003. For Type IA variations, the fee shall be EUR 2 500. For Type IB variations, the fee shall be EUR 5 800.;

(ii) point (b) shall be replaced by the following:

Type II variation fee

A Type II variation fee of EUR 34 800 shall apply for a major variation to a marketing authorisation, as defined in Article 3(3) of Regulation (EC) No 1085/2003.

By derogation from the first subparagraph, a reduced Type II variation fee falling within the range of EUR 8 700 to EUR 26 100 shall apply for certain variations. Those variations shall be included in a list, which shall be drawn up in accordance with Article 11(2) of this Regulation.

In the case of immunological veterinary medicinal products, the fee shall be EUR 5 800.

In the event of the same variation being introduced, the fee referred to in the first, second and third subparagraph shall cover all authorised strengths, pharmaceutical forms and presentations.;

(d) paragraph 4 is amended as follows:

(i) the sole subparagraph shall be replaced by the following:

A fee of EUR 17 400 shall apply for any inspection within or outside the Community. For inspections outside the Community, travel expenses shall be charged extra on the basis of actual cost.;

(ii) the following subparagraph shall be added:

By derogation from the first subparagraph, a reduced inspection fee shall apply for certain inspections, according to the extent and nature of the inspection and on the basis of the conditions laid down in accordance with Article 11(2).;

(e) paragraph 6 shall be replaced by the following:

6. *Annual fee*

An annual fee of EUR 27 700 shall apply for each marketing authorisation of a medicinal product. That fee shall cover all authorised presentations of a given medicinal product.

By derogation from the first subparagraph, a reduced annual fee falling within the range of EUR 6 900 to EUR 20 800 shall apply for certain types of medicinal products. Those medicinal products shall be included in a list, which shall be drawn up in accordance with Article 11(2).;

5. Article 6 shall be replaced by the following:

Article 6

Veterinary medicinal products covered by the procedures laid down in Directive 2001/82/EC

Referral fee

A referral fee of EUR 34 800 shall apply where the procedures laid down in Article 34(1) and Article 35 of Directive 2001/82/EC are initiated by the applicant of a marketing authorisation or the holder of an existing marketing authorisation.

Where more than one applicant of marketing authorisations or holder of existing marketing authorisations are concerned by the procedures referred to in the first subparagraph, the applicants or holders may be grouped for the purpose of the payment of one single referral fee. If however, the same procedure concerns more than ten different applicants or holders, the fee shall be charged by the application of the abovementioned referral fee.;

6. Article 7 is amended as follows:

(a) the title shall be replaced by:

Establishment of maximum residue limits (MRL) for veterinary medicinal products in accordance with the procedures laid down in Regulation (EEC) No 2377/90;

(b) in paragraph 1 the second subparagraph shall be replaced by the following:

An additional fee of EUR 17 400 shall apply for each application to modify an existing MRL, as included in one of the Annexes to Regulation (EEC) No 2377/90.;

(c) paragraph 2 shall be deleted and the numbering of paragraph 1 shall be deleted;

7. Article 8 shall be replaced by the following:

Article 8

Various Fees

1.
Fee for scientific advice

The scientific advice fee shall apply where an application is made for scientific advice concerning the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products.

When it concerns medicinal products for human use, the fee shall be EUR 69 600.

When it concerns veterinary medicinal products, the fee shall be EUR 34 800.

By derogation from the second subparagraph, a reduced scientific advice fee falling within the range of EUR 17 400 to EUR 52 200 shall apply for certain scientific advice concerning medicinal products for human use.

By derogation from the third subparagraph, a reduced scientific advice fee falling within the range of EUR 8 700 to EUR 26 100 shall apply for certain scientific advice concerning veterinary medicinal products.

The scientific advice referred to in the fourth and fifth subparagraph shall be included in a list, which shall be drawn up in accordance with Article 11(2).
2.
Fee for scientific services not covered by Articles 3 to 7 or by Article 8(1)

A scientific service fee shall apply where an application is made for any scientific advice or opinion by a scientific Committee, which is not covered by Articles 3 to 7 or by Article 8(1). This includes any evaluation of traditional herbal medicinal products, any opinion on medicinal products for compassionate use, any consultation on ancillary substances, including blood derivatives, incorporated in medical devices, and any evaluation of plasma master files and vaccine antigen master files.

When it concerns medicinal products for human use, the fee shall be EUR 232 000.

When it concerns veterinary medicinal products, the fee shall be EUR 116 000.

Article 3 of this Regulation shall apply to any scientific opinion for the evaluation of medicinal products for human use intended exclusively for markets outside the Community pursuant to Article 58 of Regulation (EC) No 726/2004.

By derogation from the second subparagraph, a reduced scientific service fee falling within the range of EUR 2 500 to EUR 200 000 shall apply for certain scientific opinions or services concerning medicinal products for human use.

By derogation from the third subparagraph, a reduced scientific service fee falling within the range of EUR 2 500 to EUR 100 000 shall apply for certain scientific opinions or services concerning veterinary medicinal products.

The scientific opinions or services referred to in the fifth and sixth subparagraph shall be included in a list, which shall be drawn up in accordance with Article 11(2).

3.

Fee for administrative services

A fee falling within the range of EUR 100 to EUR 5 800 shall apply for administrative services where documents or certificates are issued outside the framework of services covered by another fee provided for in this Regulation or where an application is rejected following the conclusion of the administrative validation of the related dossier or where the information required in the case of parallel distribution has to be checked.

A classification of the services and fees shall be included in a list, which shall be drawn up in accordance with Article 11(2).;

8. in Article 9 the second paragraph shall be replaced by the following:

> A total or partial exemption from payment of the fees laid down in this Regulation may be granted, in particular for medicinal products for treating rare diseases or diseases affecting minor animal species or for extension of existing MRL to additional animal species or for medicinal products available for compassionate use.
>
> The detailed conditions for the application of the total or partial exemption shall be determined in accordance with Article 11(2).
>
> The fee payable for an opinion on a medicinal product for compassionate use shall be deducted from the fee payable for an application for a marketing authorisation of the same medicinal product, where such application is submitted by the same applicant.;

9. Article 10 shall be replaced by the following:

Article 10

Due date and deferral of the payment

1 Fees shall be due on the date of the administrative validation of the relevant application unless specific provisions stipulate otherwise. They shall be payable within 45 days of the date of the notification of the administrative validation to the applicant. They shall be paid in euro.

The annual fee shall be due on the first and each subsequent anniversary of the notification of the marketing authorisation decision. It shall be payable within 45 days of the due date. The annual fee shall relate to the preceding year.

The inspection fee shall be payable within 45 days from the date on which the inspection is carried out.

2 The payment of the fee for an application for a marketing authorisation of a medicinal product to be used in a human pandemic situation shall be deferred until the pandemic situation is duly recognised, either by the World Health Organisation or by the Community in the framework of Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community[10]. Such deferral shall not exceed five years.

3 Where any fee payable under this Regulation remains unpaid at its due date and without prejudice to the Agency's capacity to institute legal proceedings conferred on it by Article 71 of Regulation (EC) No 726/2004, the Executive Director may decide not to provide the requested services or to suspend all the services and procedures under way until the fee has been paid, including the relevant interest as provided for in Article 86 of Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities[11].;

10. Article 11(2) shall be replaced by the following:

2. Without prejudice to the provisions of Regulation (EC) No 726/2004, the Management Board of the Agency may, on a proposal from the Executive Director and following a favourable opinion from the Commission, specify any provision necessary for the application of this Regulation. Those provisions shall be made publicly available.;

11. Article 12 is amended as follows:

(a) the second paragraph shall be replaced by the following:

> However, amendments to the amounts of the fees established by this Regulation shall be adopted in accordance with the procedure laid down in Article 87(2) of Regulation (EC) No 726/2004, with exception of the updating provided for in the fifth paragraph of this Article.;

(b) the third and fourth paragraphs shall be replaced by the following:

> By 24 November 2010, the Commission shall present a report on its implementation to the Council, this report shall contain an analysis of the need for including a dispute settlement procedure into this Regulation.
>
> Any review of the fees shall be based on an evaluation of the Agency's costs and on the basis of the related costs of the services provided for by the Member States. Those costs shall be calculated in accordance with generally accepted international costing methods, which shall be adopted in accordance with Article 11(2).;

(c) the following paragraph shall be added:

With effect from 1 April of each year, the Commission shall review the fees by reference to the inflation rate as published in the *Official Journal of the European Union* and update them.

Article 2

Transitional period

This Regulation shall not apply to valid applications pending at 20 November 2005.

Article 3

Entry into force

This Regulation shall enter into force on the day following its publication in the *Official Journal of the European Union*.

It shall apply from 20 November 2005.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 November 2005.

For the Council

The President

T. JOWELL

(**1**) OJ L 35, 15.2.1995, p. 1. Regulation as last amended by Commission Regulation (EC) No 494/2003 (OJ L 73, 19.3.2003, p. 6).

(**2**) Not yet published in the Official Journal.

(**3**) OJ L 136, 30.4.2004, p. 1.

(**4**) OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

(**5**) OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

(**6**) OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1518/2005 (OJ L 244, 20.9.2005, p. 11).

(**7**) OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

(**8**) OJ L 159, 27.6.2003, p. 24.’;

(**9**) OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).’;

(**10**) OJ L 268, 3.10.1998, p. 1. Decision as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

(**11**) OJ L 357, 31.12.2002, p. 1. Regulation as amended by Regulation (EC, Euratom) No 1261/2005 (OJ L 201, 2.8.2005, p. 3).’;

Changes to legislation:
There are outstanding changes not yet made to Council Regulation (EC) No 1905/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

– Regulation revoked in part by S.I. 2019/775 Sch. 9 para. 1(i)