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

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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:

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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.

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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:

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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

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: