COMMISSION REGULATION (EC) No 2049/2005

of 15 December 2005

laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to European Parliament and Council Regulation (EC) No 726/2004 of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [1], and in particular Article 70(2) thereof,

Whereas:

(1) Regulation (EC) No 726/2004, which replaces Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [2], provides that the revenue of the European Medicines Agency (hereinafter referred to as the Agency) must consist of a contribution from the Community and fees paid by companies.

(2) In the context of the system established by Regulation (EEC) No 2309/93, Council Regulation (EC) No 297/95 [3] provides for fees payable to the Agency.

(3) Pursuant to Regulation (EC) No 726/2004, the situation of micro, small and medium-sized enterprises (SMEs) has to be considered separately. In order to reduce the cost for SMEs of marketing medicinal products authorised via the centralised procedure, that Regulation therefore foresees the adoption of specific provisions allowing a reduction of fees, deferring the payment of fees, and providing administrative assistance. Such provisions should apply equally to the human and veterinary sectors and should aim at promoting innovation and the development of new medicinal products by SMEs.

(4) The definition of micro, small and medium-sized enterprises provided in Commission Recommendation 2003/361/EC [4] should apply, for reasons of coherence and transparency.

(5) Experience gained since the adoption of Regulation (EEC) No 2309/93 shows that the main financial and administrative entry hurdles for SMEs are the various steps involved in pre-marketing authorisation procedures, such as the seeking of scientific advice, the submission of the marketing authorisation application, and the undergoing of inspections. Provisions laid down in this Regulation should therefore be focused on these aspects.

(6) The fees for the marketing authorisation application and the related inspections conducted for the purpose of assessing the application could constitute a significant financial constraint for SMEs. Consequently, in order to avoid a weakening of the financial situation of undertakings during the assessment of the marketing authorisation application, it is appropriate to defer the payment of these fees until the end of the procedure.

(7) SMEs operating in the pharmaceutical sector are often innovative companies, such as those active in the fields of gene or somatic cell therapy, which can notably benefit from the pooling of scientific expertise at a Community level. Furthermore, the scientific evaluation of a marketing authorisation application is more likely to be favourable in the case of medicinal products which have obtained scientific advice. Therefore, access to the Agency's scientific advice for SMEs seeking marketing authorisation should be facilitated through fee reductions. As an additional incentive, a conditional fee exemption should be given to applicants who have requested such advice and who have actually taken it into account for the development of their medicinal product.

(8) Another incentive should also be provided, in the form of a fee reduction, for the establishment of maximum residue limits (MRL) for veterinary medicinal products in order to further support the establishment of such limits.

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 214, 24.8.1993, p. 1.
[3] OJ L 35, 15.2.1995, p. 1. Regulation as last amended by Regulation (EC) No 1905/2005 (OJ L 304, 23.11.2005, p. 1).
[4] OJ L 124, 20.5.2003, p. 36.

(9) Translations can constitute a significant administrative burden for SMEs. The Agency should therefore make appropriate arrangements to provide for the translations of certain documents required for the granting of marketing authorisation, in particular the draft summary of the product characteristics and the draft text of the labelling and package leaflet.

(10) A lack of experience with the centralised procedure and the Agency as an administrative organisation should not impair the development and marketing of new medicinal products. Consequently, it is appropriate to create an SME office, with the sole remit of offering administrative assistance to SMEs. The SME office should provide a single interface between the applicant SME and the Agency, so as to facilitate communication and to answer practical or procedural enquiries.

(11) In order to provide practical guidance to applicant SMEs, the Agency should publish a user guide on the administrative and procedural aspects linked to the centralised procedure which are of particular relevance for SMEs.

(12) The Agency should report annually on the operation of the provisions laid down in this Regulation, so that feedback on their practical application is available.

(13) In order to ensure that SMEs benefit, to the largest extent possible, from the derogation provided for in this Regulation it should enter into force immediately.

(14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for Medicinal Products for Human Use and of the Standing Committee for Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation establishes the circumstances in which, by derogation from the relevant provisions of Regulation (EC) No 297/95, micro, small and medium-sized enterprises (SMEs) may pay reduced fees, defer payment of fees, or receive administrative assistance when submitting applications under Regulation (EC) No 726/2004 to the European Medicines Agency, hereinafter 'the Agency'.

Article 2

Scope

1. This Regulation shall apply to SMEs within the meaning of Recommendation 2003/361/EC in the version of 6 May 2003 which are established in the Community.

2. Unless otherwise specified, this Regulation shall apply both to applications concerning medicinal products for human use and to applications concerning veterinary medicinal products, within the meaning of Directives 2001/83/EC [1] and 2001/82/EC [2] of the European Parliament and of the Council respectively.

Article 3

Definition

For the purposes of this Regulation, applicant means an undertaking seeking to benefit from the application of the provisions laid down in Chapters II and III.

Article 4

Submission of information

An SME wishing to benefit from the provisions of this Regulation shall submit to the Agency the information necessary to demonstrate compliance with the criteria mentioned in Article 2(1).

CHAPTER II

FEE DEFERRALS AND REDUCTIONS

Article 5

Fee deferrals

1. The payment of the following fees shall be deferred until the notification of the final decision on the marketing authorisation is issued, or the application is withdrawn:

(a) the fee for an application for a marketing authorisation of a medicinal product, as referred to in points (a) and (b) of Article 3(1) and points (a) and (b) of Article 5(1) of Regulation (EC) No 297/95;

(b) the fee for inspections undertaken for the purpose of assessing a marketing authorisation application for a medicinal product, as referred to in Article 3(4) and Article 5(4) of Regulation (EC) No 297/95.

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 311, 28.11.2001, p. 1.

2. The fees referred to in paragraph 1 shall be payable within 45 days of the date of the notification of the final decision on the marketing authorisation, or within 45 days of the date of the notification of withdrawal of the application.

Article 6

Conditional fee exemption

Without prejudice to Article 5, where an application for marketing authorisation is submitted for a medicinal product on which scientific advice has already been given by the Agency, the fee payable to the Agency for the examination of that application shall be due only if a marketing authorisation is granted.

Article 7

Fee reductions

1. The following reductions shall apply:

(a) in the case of inspections a 90 % reduction to the inspection fee, as referred to in Article 3(4) and Article 5(4) of Regulation (EC) No 297/95;

(b) in the case of scientific advice a 90 % reduction to the scientific advice fee, as referred to in Article 8(1) of Regulation (EC) No 297/95;

(c) in the case of scientific services a 90 % reduction to the scientific service fee, as referred to in Article 8(2) of Regulation (EC) No 297/95.

2. The administrative services, as referred to in Article 8(3) of Regulation (EC) No 297/95, shall be provided free of charge, except where those services concern the parallel distribution of medicinal products, as referred to in Article 57(1)(o) of Regulation (EC) No 726/2004.

3. By derogation from points (b) and (c) of paragraph 1, scientific advice and scientific services for designated orphan medicinal products as referred to in Regulation (EC) No 141/2000 of the European Parliament and of the Council [1] shall be provided free of charge.

Article 8

Fee reduction for the establishment of maximum residue limits for veterinary medicinal products

1. A 90 % reduction shall apply to the full and additional maximum residue limits (MRL) fees, as referred to in Article 7 of Regulation (EC) No 297/95.

2. The reduction referred to in paragraph 1 shall not be taken into account when calculating the deduction of the MRL fees from the fee payable for an application for a marketing authorisation or an application to extend a marketing authorisation, for a medicinal product containing the substance for which the MRL concerned has been set, where such applications are submitted by the same applicant.

However, this deduction shall not exceed one half of the fee to which it applies.

Article 9

Multiple fee reductions

By derogation from Articles 7 and 8, where the applicant could, in respect of the same fee, also benefit from other reductions provided for in Community legislation, the provisions which are the most favourable to the applicant shall apply.

Cumulative fee reductions for a given fee and a given applicant shall not be allowed.

CHAPTER III

ADMINISTRATIVE ASSISTANCE

Article 10

Translations

The Agency shall provide for the translations of the documents referred to in points (a) to (d) of Article 9(4) and points (a) to (e) of Article 34(4) of Regulation (EC) No 726/2004 that are required for the purpose of granting a Community marketing authorisation.

Article 11

SME Office

1. The Executive Director of the Agency shall set up dedicated administrative structures and specific procedures for the establishment of an SME Office.

2. The SME Office shall have the following tasks:

(a) to give advice to applicants on the administrative and procedural steps necessary to comply with the requirements laid down in Regulation (EC) No 726/2004;

(b) to ensure the appropriate monitoring of all requests and applications submitted by the same applicant and related to a particular medicinal product;

[1] OJ L 18, 22.1.2000, p. 1.

(c) to organise workshops and training sessions for applicants on the administrative and procedural steps necessary to comply with the requirements laid down in Regulation (EC) No 726/2004.

Article 12

User Guide

The Agency shall, upon agreement of the Commission, publish a detailed User Guide on the administrative and procedural aspects of the provisions laid down in Regulation (EC) No 726/2004, which are of particular relevance for SMEs. The User Guide shall be kept updated.

The User Guide shall also contain references to existing national provisions for SMEs applicable to the pharmaceutical sector.

For the purposes of the second paragraph, the Member States shall communicate those references to the Agency.

CHAPTER IV

FINAL PROVISIONS

Article 13

Report

The Agency shall include in the Annual Report of its activities a section on the experience acquired as a result of the application of this Regulation.

Article 14

Transitional provision

This Regulation shall not apply to valid applications pending at the date of its entry into force.

Article 15

Entry into force

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

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

Done at Brussels, 15 December 2005.

For the Commission
Günter VERHEUGEN
Vice-President