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COUNCIL REGULATION (EC) No 297/95

of 10 February 1995

on fees payable to the European Agency for the Evaluation of Medicinal Products

(OJ L 35, 15.2.1995, p. 1)

Amended by:

		Official Journal		
		No	page	date
►M1	Council Regulation (EC) No 2743/98 of 14 December 1998	L 345	3	19.12.1998
►M2	Commission Regulation (EC) No 494/2003 of 18 March 2003	L 73	6	19.3.2003
►M3	Council Regulation (EC) No 1905/2005 of 14 November 2005	L 304	1	23.11.2005
►M4	Commission Regulation (EC) No 312/2008 of 3 April 2008	L 93	8	4.4.2008
►M5	Commission Regulation (EC) No 249/2009 of 23 March 2009	L 79	34	25.3.2009
►M6	Commission Regulation (EU) No 261/2010 of 25 March 2010	L 80	36	26.3.2010
►M7	Commission Regulation (EU) No 301/2011 of 28 March 2011	L 81	5	29.3.2011
►M8	Commission Regulation (EU) No 273/2012 of 27 March 2012	L 90	11	28.3.2012
►M9	Commission Regulation (EU) No 220/2013 of 13 March 2013	L 70	1	14.3.2013
►M10	Commission Regulation (EU) No 272/2014 of 17 March 2014	L 79	37	18.3.2014
►M11	Commission Regulation (EU) 2015/490 of 23 March 2015	L 78	9	24.3.2015
►M12	Commission Regulation (EU) 2016/461 of 30 March 2016	L 80	25	31.3.2016

Corrected by:

►C1	Corrigendum, OJ L 75, 4.4.1995, p. 29 (297/95)

NB: This consolidated version contains references to the European unit of account and/or the ecu, which from 1 January 1999 should be understood as references to the euro — Council Regulation (EEC) No 3308/80 (OJ L 345, 20.12.1980, p. 1) and Council Regulation (EC) No 1103/97 (OJ L 162, 19.6.1997, p. 1).

▼B

COUNCIL REGULATION (EC) No 297/95

of 10 February 1995

on fees payable to the European Agency for the Evaluation of Medicinal Products

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, in particular Article 235 thereof,

Having regard to the proposal from the Commission,

►C1 Having regard to the European Parliament [1] ◄,

Whereas Article 58 of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [2], hereinafter referred to as 'the Agency', requires the Council to establish the structure and the amount of fees referred to in Article 57 (1);

Whereas Article 57 (1) of the Regulation establishes that the revenues of the Agency shall consist of a contribution from the Community, and the fees paid by undertakings for obtaining and maintaining a Community marketing authorization and for other services provided by the Agency;

Whereas Articles 6 (3) and 28 (3) respectively of Regulation (EEC) No 2309/93 require that any application for authorization for a medicinal product or any application for a variation be accompanied by the fee payable to the Agency for the examination of the application;

Whereas the calculation of the amount of the fees charged by the Agency must be based on the principle of the service actually provided;

Whereas the amount of the fees laid down in this Regulation should not be a determining factor for the applicant for an authorization where there is a choice between a centralized procedure and a national procedure;

Whereas the basic fee should be defined as the fee charged for the initial application for an authorization for a medicinal product plus a fee for each different strength and/or pharmaceutical form; whereas, however, a ceiling should be established;

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[1] Opinion delivered on 19 January 1995 (not yet published in the Official Journal).

[2] OJ No L 214, 24.8.1993, p. 1.

▼B

Whereas to the same end, an extension fee should be laid down for subsequent applications regarding a medicinal product which has already been authorized in order to take account of the additional work and expenditure where an applicant chooses to submit the applications gradually and subsequently;

Whereas provision should be made for a reduced fee for applications which may be sustained by a less detailed dossier pursuant to point 8 of the second paragraph of Article 4 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products [1] and point 8 of the second paragraph of Article 5 of Council Directive 81/851/EEC of 28 September 1981 on approximation of the laws of the Member States relating analytical, pharmaco-toxicological and clinical standards protocols in respect of the testing of veterinary medicinal products [2] respectively and for applications concerning a medicinal product for use in non-food producing animals;

Whereas the examination of variations to the terms of existing authorizations not requiring full evaluation of the product's quality, safety and efficacy should be charged according to the complexity of the variations and the real workload linked to them, and therefore at a rate far lower than for a standard application;

Whereas the work involved in the mandatory five-yearly renewal of a Community marketing authorization justified the charging of a fee;

Whereas a fee should be laid down for arbitration services in the event of disagreement between Member States on applications for authorizations submitted under the decentralized procedure;

Whereas a fee should be levied on a flat-rate basis for any inspection made successively to a marketing authorization at the request or in the interest of its holder;

Whereas the market for a veterinary medicinal product differs from that of a medicinal product for human use and therefore justifies a general reduction of the fee; whereas it should furthermore be possible to take account of the particular situation linked to the marketing of certain veterinary medicinal products on an individual basis; whereas this aim can best be achieved by means of special provisions such as a clause for reductions and waivers;

Whereas, as regards the evaluation of applications to establish maximum residue limits (MRLs), it is up to the applicant to decide whether to apply separately for the establishment of MRLs or to do so together with his application for a Community marketing authorization in which case the fee incurred for the evaluation of the application for authorization should cover the one for the establishment of MRLs; whereas, however, if the applicant deliberately chooses to apply separately for the establishment of MRLs, the additional work and expenditure should be recouped by means of an isolated MRL fee;

[1] OJ No 22, 9.2.1965, p. 369/65. Directive as last amended by Directive 93/39/EEC (OJ No L 214, 24.8.1993, p. 22).

[2] OJ No L 317, 6.11.1981, p. 1. Directive as last amended by Directive 93/40/EEC (OJ No L 214, 24.8.1993, p. 31).

▼B

Whereas all other fees for the evaluation of veterinary medicinal products should follow the principles described above;

Whereas provision should be made for waivers or reductions of the fees stated above under exceptional circumstances for essential public health or animal health reasons; whereas any decision upon those cases should be taken by the Director after hearing the competent committee and on the basis of general criteria laid down by the Agency's Management Board;

Whereas a provisional period of three years should be laid down after which the experience gained will enable the financial needs of the Agency to be re-assessed; whereas for practical reasons provision should also be made for machinery to permit rates to be updated over shorter periods;

Whereas the Treaty does not provide the necessary powers for fixing fees at Community level, within the framework of a Community system; whereas it is therefore appropriate to have recourse to Article 235 of the Treaty,

HAS ADOPTED THIS REGULATION:

▼M1

Article 1

Scope

Fees for obtaining and maintaining a Community authorisation to market medicinal products for human and veterinary use and for other services supplied by the Agency shall be levied in accordance with this Regulation.

▼M3

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

▼B

Article 2

The Agency shall indicate in its annual estimate intended for the establishment of the preliminary draft budget of the Commission the estimates concerning the fees for the following financial year, and this shall be done separately from the estimating of the overall expenditure and the possible contribution by the Community.

▼M1

Article 3

▼M3

Medicinal products for human use covered by the procedures laid down in Regulation (EC) No 726/2004 [1]

▼M1

1. *Authorisation to market a medicinal product*

(a) Full fee

▼M3

A full fee of ►M12 EUR 278 800 ◄ 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 ►M12 EUR 28 000 ◄ 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.

▼M1

The fee shall be increased by ►M10 EUR 7 000 ◄ for each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.

▼M3

(b) Reduced fee

A reduced fee of ►M12 EUR 108 200 ◄ 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 [2]. That fee shall cover a single strength associated with one pharmaceutical form and one presentation.

A specific reduced fee of ►M12 EUR 180 200 ◄ 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 ►M10 EUR 10 800 ◄ 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 ►M10 EUR 7 000 ◄ for each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.

[1] OJ L 136, 30.4.2004, p. 1.
[2] 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).

▼M3

(c) Extension fee

An extension fee of ►M12 EUR 83 700 ◄ 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 ([1]), which has already been granted.

By derogation from the first subparagraph, a reduced extension fee falling within the range of ►M12 EUR 20 900 to EUR 62 700 ◄ 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 ►M10 EUR 7 000 ◄ for each additional presentation of the same extension submitted at the time of the extension application.

▼M1

2. *Variation*

(a) Type I variation fee

▼M3

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 ►M9 EUR 3 000 ◄. For Type IB variations, the fee shall be ►M10 EUR 7 000 ◄.

▼M1

In the event of the same variation being introduced, this fee shall cover all authorised strengths, pharmaceutical forms and presentations.

(b) Type II variation fee

▼M3

A Type II variation fee of ►M12 EUR 83 700 ◄ 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 ►M12 EUR 20 900 to EUR 62 700 ◄ 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.

▼M1

In the event of the same variation being introduced, this fee shall cover all authorised strengths, pharmaceutical forms and presentations.

([1]) OJ L 159, 27.6.2003, p. 24.

▼**M1**

3. *Renewal fee*

The fee for examininginformation available at the time of the five-yearly renewal of an authorisation to market a medicinal product shall be ►**M10** EUR 13 800 ◄. It shall be charged for each strength associated with a pharmaceutical form.

4. *Inspection fee*

▼**M3**

A fee of ►**M10** EUR 20 900 ◄ 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.

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).

▼**M1**

5. *Transfer fee*

The fee for a change in the holder of the marketing authorisations to which the transfer relates shall be ►**M10** EUR 7 000 ◄. This covers all authorised presentations of a given medicinal product.

▼**M3**

6. *Annual fee*

An annual fee of ►**M12** EUR 100 000 ◄ 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 ►**M12** EUR 24 900 to EUR 74 900 ◄ 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).

Article 4

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

Referral fee

A referral fee of ►**M12** EUR 69 400 ◄ 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.

▼M3

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.

▼M1

Article 5

▼M3

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

▼M1

1. *Authorisation to market a medicinal product*

(a) Full fee

▼M3

A full fee of ►M12 EUR 139 600 ◄ 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 ►M10 EUR 13 800 ◄ 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.

▼M1

The fee shall be increased by ►M10 EUR 7 000 ◄ for each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.

▼M3

In the case of immunological veterinary medicinal products, the full fee shall be reduced to ►M12 EUR 69 400 ◄, with each additional strength and/or pharmaceutical form and/or presentation entailing an increase of ►M10 EUR 7 000 ◄.

▼M1

For the purposes of this point (a), the number of target species is irrelevant.

▼M3

(b) Reduced fee

A reduced fee of ►M12 EUR 69 400 ◄ 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 ([1]). That fee shall cover a single strength associated with one pharmaceutical form and one presentation.

([1]) 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).

▼M3

A specific reduced fee of ►M12 EUR 117 800 ◄ 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 ►M10 EUR 13 800 ◄ 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 ►M10 EUR 7 000 ◄ 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 ►M12 EUR 34 900 ◄, with each additional strength and/or pharmaceutical form and/or presentation entailing an increase of ►M10 EUR 7 000 ◄.

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

(c) Extension fee

An extension fee of ►M12 EUR 34 900 ◄ 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 ►M12 EUR 8 700 to EUR 26 200 ◄ 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 ►M10 EUR 7 000 ◄ for each additional presentation of the same extension submitted at the time of the extension application.

▼M1

2. *Variation*

(a) Type I variation fee

▼M3

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 ►M9 EUR 3 000 ◄. For Type IB variations, the fee shall be ►M10 EUR 7 000 ◄.

▼M1

In the event of the same variation being introduced, this fee shall cover all authorised strengths, pharmaceutical forms and presentations.

▼M3

(b) Type II variation fee

A Type II variation fee of ►M12 EUR 41 800 ◄ 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 ►M12 EUR 10 500 to EUR 31 500 ◄ 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 ►M10 EUR 7 000 ◄.

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.

▼M1

3. *Renewal fee*

The fee for examining information available at the time of the five-yearly renewal of an authorisation to market a medicinal product shall be ►M10 EUR 7 000 ◄. It shall be charged for each strength associated with a pharmaceutical form.

4. *Inspection fee*

▼M3

A fee of ►M10 EUR 20 900 ◄ 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.

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).

▼M1

5. *Transfer fee*

The fee for a change in the holder of the marketing authorisations to which the transfer relates shall be ►M10 EUR 7 000 ◄. This covers all authorised presentations of a given medicinal product.

▼M3

6. *Annual fee*

An annual fee of ►M12 EUR 33 400 ◄ 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 ►M10 EUR 8 300 to EUR 24 900 ◄ 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).

Article 6

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

Referral fee

A referral fee of ►M12 EUR 41 800 ◄ 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.

▼M1

Article 7

▼M3

Establishment of maximum residue limits (MRL) for veterinary medicinal products in accordance with the procedures laid down in Regulation (EEC) No 2377/90 [1]

▼M1

►M3 ——————— ◄ *Fees for establishing MRL*

A full MRL fee of ►M12 EUR 69 400 ◄ shall be charged for an application to set an initial MRL for a given substance.

▼M3

An additional fee of ►M10 EUR 20 900 ◄ shall apply for each application to modify an existing MRL, as included in one of the Annexes to Regulation (EEC) No 2377/90.

[1] 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).

▼**M1**

MRL fees shall be deducted from the fee payable for an application for marketing authorisation or an application to extend a marketing authorisation for the medicinal product containing the substance for which an MRL has been set where such applications are submitted by the same applicant. However, this deduction may total no more than one half of the fee to which it applies.

▼**M3**

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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 ►**M12** EUR 83 700 ◄.

When it concerns veterinary medicinal products, the fee shall be ►**M12** EUR 41 800 ◄.

By derogation from the second subparagraph, a reduced scientific advice fee falling within the range of ►**M12** EUR 20 900 to EUR 62 700 ◄ 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 ►**M12** EUR 10 500 to EUR 31 500 ◄ 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 ►**M12** EUR 278 800 ◄.

When it concerns veterinary medicinal products, the fee shall be ►**M12** EUR 139 600 ◄.

▼M3

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 ►M12 EUR 3 000 to EUR 240 300 ◄ 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 ►M12 EUR 3 000 to EUR 120 300 ◄ 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 ►M10 EUR 7 000 ◄ 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).

▼M1

Article 9

Possible fee reductions

Without prejudice to more specific provisions of Community law, in exceptional circumstances and for imperative reasons of public or animal health, fee reductions may be granted case by case by the Executive Director after consultation of the competent scientific committee. Any decision taken pursuant to this Article shall state the reasons on which it is based.

▼M3

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.

▼M3

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.

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 ([1]). 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 ([2]).

([1]) 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).

([2]) 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).

▼M1

Article 11

Implementing rules

1. On a proposal from the Executive Director and following a favourable opinion from the Commission, the Agency's Management Board shall fix the rules for repaying a part of the resources deriving from the annual fees to the competent national authorities involved in Community market supervision.

▼M3

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.

▼M1

3. In the event of disagreement as to the classification of an application in one of the fee categories laid down in this Regulation, the Executive Director shall give a ruling after consultation of the competent scientific committee.

Article 12

Amendment

Any amendment to this Regulation shall be adopted by the Council acting by a qualified majority after consulting the European Parliament, on a proposal from the Commission.

▼M3

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.

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).

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.

▼B

Article ►M1 *13* ◄

Entry into force and legal effect

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

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