►**B**

# 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:

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| | | 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 |
| ►**M13** | Commission Regulation (EU) 2017/612 of 30 March 2017 | L 86 | 7 | 31.3.2017 |
| ►**M14** | Commission Regulation (EU) 2018/471 of 21 March 2018 | L 79 | 19 | 22.3.2018 |
| ►**M15** | Commission Regulation (EU) 2019/480 of 22 March 2019 | L 82 | 15 | 25.3.2019 |
| ►**M16** | Commission Regulation (EU) 2020/422 of 19 March 2020 | L 84 | 11 | 20.3.2020 |
| ►**M17** | Commission Regulation (EU) 2022/510 of 29 March 2022 | L 103 | 3 | 31.3.2022 |

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

▼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 ►M17 EUR 313 200 ◄ 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 ►M17 EUR 31 500 ◄ 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 ►M17 EUR 7 800 ◄ 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.

▼**M3**

(b) Reduced fee

A reduced fee of ►**M17** EUR 121 500 ◄ 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 [1]. That fee shall cover a single strength associated with one pharmaceutical form and one presentation.

A specific reduced fee of ►**M17** EUR 202 500 ◄ 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 ►**M17** EUR 12 100 ◄ 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 ►**M17** EUR 7 800 ◄ 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 ►**M17** EUR 94 000 ◄ 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 [2], which has already been granted.

By derogation from the first subparagraph, a reduced extension fee falling within the range of ►**M17** EUR 23 700 to EUR 70 600 ◄ 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 ►**M17** EUR 7 800 ◄ for each additional presentation of the same extension submitted at the time of the extension application.

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

▼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 ►M17 EUR 3 500 ◄. For Type IB variations, the fee shall be ►M17 EUR 7 800 ◄.

▼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 ►M17 EUR 94 000 ◄ 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 ►M17 EUR 23 700 to EUR 70 600 ◄ 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.

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 ►M17 EUR 15 400 ◄. It shall be charged for each strength associated with a pharmaceutical form.

4. *Inspection fee*

▼M3

A fee of ►M17 EUR 23 700 ◄ 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 ►M17 EUR 7 800 ◄. This covers all authorised presentations of a given medicinal product.

▼M3

6. *Annual fee*

An annual fee of ►M17 EUR 112 200 ◄ 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 ►M17 EUR 27 900 to EUR 84 100 ◄ 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 ►M17 EUR 77 900 ◄ 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.

▼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 ►M17 EUR 156 700 ◄ 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 ►M17 EUR 15 400 ◄ 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 ►M17 EUR 7 800 ◄ 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 ►M17 EUR 77 900 ◄, with each additional strength and/or pharmaceutical form and/or presentation entailing an increase of ►M17 EUR 7 800 ◄.

▼M1

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

▼M3

(b) Reduced fee

A reduced fee of ►M17 EUR 77 900 ◄ 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.

A specific reduced fee of ►M17 EUR 132 400 ◄ 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 ►M17 EUR 15 400 ◄ 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 ►M17 EUR 7 800 ◄ 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 ►M17 EUR 39 200 ◄, with each additional strength and/or pharmaceutical form and/or presentation entailing an increase of ►M17 EUR 7 800 ◄.

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

(c) Extension fee

An extension fee of ►M17 EUR 39 200 ◄ 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 ►M17 EUR 9 700 to EUR 29 500 ◄ 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 ►M17 EUR 7 800 ◄ for each additional presentation of the same extension submitted at the time of the extension application.

([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).

▼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 ►M17 EUR 3 500 ◄. For Type IB variations, the fee shall be ►M17 EUR 7 800 ◄.

▼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 ►M17 EUR 46 900 ◄ 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 ►M17 EUR 11 800 to EUR 35 400 ◄ 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 ►M17 EUR 7 800 ◄.

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.

▼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 ►M17 EUR 7 800 ◄. It shall be charged for each strength associated with a pharmaceutical form.

4. *Inspection fee*

▼M3

A fee of ►M17 EUR 23 700 ◄ 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 ►M17 EUR 7 800 ◄. This covers all authorised presentations of a given medicinal product.

▼M3

6. *Annual fee*

An annual fee of ►M17 EUR 37 600 ◄ 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 ►M17 EUR 9 200 to EUR 27 900 ◄ 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 ►M17 EUR 46 900 ◄ 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 ►M17 EUR 77 900 ◄ shall be charged for an application to set an initial MRL for a given substance.

▼M3

An additional fee of ►M17 EUR 23 700 ◄ 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 ►**M17** EUR 94 000 ◄.

When it concerns veterinary medicinal products, the fee shall be ►**M17** EUR 46 900 ◄.

By derogation from the second subparagraph, a reduced scientific advice fee falling within the range of ►**M17** EUR 23 700 to EUR 70 600 ◄ 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 ►**M17** EUR 11 800 to EUR 35 400 ◄ 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 ►**M17** EUR 313 200 ◄.

When it concerns veterinary medicinal products, the fee shall be ►**M17** EUR 156 700 ◄.

▼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 ►M17 EUR 3 500 to EUR 269 900 ◄ 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 ►M17 EUR 3 500 to EUR 135 100 ◄ 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 ►M17 EUR 7 800 ◄ 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).

▼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.