# Procedure file

## Basic information

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| CNS - Consultation procedure<br>Regulation | 1994/0220(CNS) | Procedure completed |
| European Agency for the Evaluation of Medicinal Products: fees payable<br><br>Amended by 1998/0135(CNS)<br>Amended by 2005/0023(CNS)<br>Repealed by 2022/0417(COD)<br><br>Subject<br>4.20.04 Pharmaceutical products and industry<br>8.40.08 Agencies and bodies of the EU | | |

## Key players

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| European Parliament | Committee responsible | Rapporteur | Appointed |
| | BUDG Budgets | PSE HAUG Jutta | 03/10/1994 |
| | Committee for opinion | Rapporteur for opinion | Appointed |
| | ENVI Environment, Public Health and Consumer Protection | | |
| | CONT Budgetary Control | PPE KELLETT-BOWMAN Edward T. | 12/10/1994 |
| Council of the European Union | Council configuration | Meeting | Date |
| | Competitiveness (Internal Market, Industry, Research and Space) | 1815 | 08/12/1994 |

## Key events

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| 27/05/1994 | Legislative proposal published | COM(1994)0167 | Summary |
| 30/09/1994 | Committee referral announced in Parliament | | |
| 05/12/1994 | Vote in committee | | Summary |
| 05/12/1994 | Committee report tabled for plenary, 1st reading/single reading | A4-0101/1994 | |
| 08/12/1994 | Debate in Council | 1815 | |
| 18/01/1995 | Debate in Parliament | | |
| 19/01/1995 | Decision by Parliament | T4-0012/1995 | Summary |
| 03/02/1995 | Modified legislative proposal published | COM(1995)0027 | Summary |

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|---|---|---|---|
| 10/02/1995 | Act adopted by Council after consultation of Parliament | | |
| 10/02/1995 | End of procedure in Parliament | | |
| 15/02/1995 | Final act published in Official Journal | | |

## Technical information

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| Procedure reference | 1994/0220(CNS) |
| Procedure type | CNS - Consultation procedure |
| Procedure subtype | Legislation |
| Legislative instrument | Regulation |
| | Amended by 1998/0135(CNS)<br>Amended by 2005/0023(CNS)<br>Repealed by 2022/0417(COD) |
| Legal basis | Rules of Procedure EP 163; EC before Amsterdam E 235 |
| Stage reached in procedure | Procedure completed |
| Committee dossier | BUDG/4/05954 |

## Documentation gateway

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| Legislative proposal | | COM(1994)0167<br>OJ C 398 31.12.1994, p. 0020 | 27/05/1994 | EC | Summary |
| Committee report tabled for plenary, 1st reading/single reading | | A4-0101/1994<br>OJ C 018 23.01.1995, p. 0005 | 05/12/1994 | EP | |
| Text adopted by Parliament, 1st reading/single reading | | T4-0012/1995<br>OJ C 043 20.02.1995, p. 0053-0073 | 19/01/1995 | EP | Summary |
| Modified legislative proposal | | COM(1995)0027<br>OJ C 084 06.04.1995, p. 0012 | 03/02/1995 | EC | Summary |
| Document attached to the procedure | | COM(2012)0543 | 25/09/2012 | EC | Summary |

## Additional information

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| European Commission | EUR-Lex |

## Final act

Regulation 1995/297
OJ L 035 15.02.1995, p. 0001 Summary

# European Agency for the Evaluation of Medicinal Products: fees payable

From 1995, the European Agency for the Evaluation of Medicinal Products would be called upon to examine requests for authorisation to market medicinal products from pharmaceutical companies, which would result in the collection of fees to provide revenue for the Agency's budget. This proposal for a regulation aimed to lay down the structure and the amount of fees paid by undertakings for the examination and revision of Community authorisations to market medicinal products and other services provided by the Agency. According to the proposal, an undertaking should pay a basic Community fee of ECU 200 000 for medicinal products for human use and ECU 100 000 for veterinary medicinal products with a view to obtaining an authorisation to market the said products as required by the centralised procedure. The proposal also provided for a number of other fees: - a reduced fee for applications which did not have to be supported by a full dossier (ECU 100 000 for products for human use; ECU 50 000 for veterinary products); - an extension fee when the applicant wished to extend the applications made for the same medicinal product (ECU 40 000 for products intended for human use; ECU 20 000 for veterinary products); -a

variation fee for minor administrative modifications of type I, which was fixed at ECU 5 000, and a variation fee for complex modifications of type II, which was fixed at ECU 40 000 for medicinal products for human use and at ECU 20 000 for veterinary products; - a renewal fee which was charged for the obligatory five-yearly renewal of the Community marketing authorisation (ECU 40 000 for products for human use; ECU 20 000 for veterinary products); - a flat-rate fee of ECU 10 000 for inspections which were undertaken subsequent to the issuing of a marketing authorisation, at the request of, or in the interest of, its holder; -a fee which was charged for the Agency's arbitration services in the event of disagreement between Member States as to the authorisation of a medicinal product in accordance with the decentralised procedure (ECU 40 000 for medicinal products for human use; ECU 20 000 for veterinary products). In exceptional circumstances - medicinal products treating a limited number of patients with a rare disease, SMEs, imperative reasons of public health - waivers and fee reductions could be granted. ?

## European Agency for the Evaluation of Medicinal Products: fees payable

The Committee adopted the HAUG report on the Regulation relating to fees payable to the European Agency for the Evaluation of Medicinal Products. Through these amendments the Committee called on the Agency to indicate in its annual statement the estimates concerning the fees for the following financial year and to do this separately from the estimation of overall expenditure and the possible contribution by the Community. It stressed that fees constituted the Community's resources and were used to fund the Agency, with any surplus being assigned to the EU budget. Finally, the Committee took the view that a possible modification of the fees system should be based on Article 189B. ?

## European Agency for the Evaluation of Medicinal Products: fees payable

In adopting the HAUG report, Parliament approved the regulation on fees payable to the European Agency for the Evaluation of Medicinal Products. In its amendments Parliament stated that: - fees should constitute Community resources and any surplus should be assigned to the Community budget; - the Agency's annual estimate should include figures relating to fees for the following financial year; - the codecision procedure (Article 189B) should be applied to the modification of the fees system. ?

## European Agency for the Evaluation of Medicinal Products: fees payable

The modified proposal incorporates Parliament's amendment which provides for estimates concerning revenues obtained from fees collected for the following financial year to be included in the annual estimate adopted by the Agency's Management Board under the provision of Article 57 (5) of Regulation No 2309/93. In addition, the proposal partly incorporates the amendment which provides for any Agency budget surplus to be considered under the Community budget, by proposing that a clause providing for these surplus amounts to be deducted from the Community contribution be included in the system. However, the Commission rejected those amendments which used the procedure under Article 189B of the Treaty for introducing any modifications to the regulation. ?

## European Agency for the Evaluation of Medicinal Products: fees payable

OBJECTIVE : Council Regulation (EC) No 297/95 lays down the structure and the amount of fees paid by undertakings for the examination and revision of Community authorizations to market medicinal products and other services provided by the European Agency for the Evaluation of Medicinal Products.

SUBSTANCE : Undertakings have to pay a basic Community fee of ECU 140,000 for medicinal products for human use, and ECU 70,000 for veterinary medicinal products, with a view to obtaining an authorization to market the said products as required by the centralized procedure.

The Regulation also provides for a number of other fees as follows:

- a reduced fee for applications which do not have to be supported by a full dossier (ECU 70,000 for products for human use; ECU 35,000 for veterinary products);
- an extension fee when the applicant wishes to extend the applications made for the same medicinal product (ECU 40,000 for products intended for human use; ECU 20,000 for veterinary products);
-a variation fee for minor administrative modifications of type I, which is fixed at ECU 5,000, and a variation fee for complex modifications of type II, which is fixed at ECU 40,000 for medicinal products for human use and at ECU 20,000 for veterinary products;
- a renewal fee which is charged for the obligatory five-yearly renewal of the Community marketing authorization (ECU 10,000 for products for human use; ECU 5,000 for veterinary products);
- a flat-rate fee of ECU 10,000 for inspections which are undertaken subsequent to the issuing of a marketing authorization, at the request of, or in the interest of, its holder;
- a fee which is charged for the Agency's arbitration services in the event of disagreement between Member States as to the authorization of a medicinal product in accordance with the decentralized procedure (ECU 30,000 for medicinal products for human use; ECU 15,000 for veterinary products). In exceptional circumstances, and for imperative reasons of public or animal health, waivers and fee reductions may be granted on a case by case basis.

The Agency shall indicate in its annual estimate intended for the establishment of the preliminary draft budget of the Commission the estimates concerning revenues obtained from fees for the following financial year.

Date of entry into force of the Regulation: 16.02.1995.

## European Agency for the Evaluation of Medicinal Products: fees payable

The Commission presents a communication aiming to update the financial statement accompanying Regulation (EC) n° 297/95 in order to reflect the actual staffing needs of the European Medicines Agency.

The European Medicines Agency was set up by Regulation (EC) No 726/2004 of the European Parliament and of the Council. This Regulation establishes that the revenue of the Agency shall consist of a contribution from the European Union, and the fees paid by the undertaking for obtaining and maintaining a Community marketing authorisation and for other services provided by the Agency.

Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency sets out the different types of fees payable for services provided, including the possibility for waivers and reductions of certain fees. The corresponding financial statements (if applicable) for Regulation (EC) No 297/95 and its amendments in 19984, 20035 and 2005 did not provide for the human resources required to handle fee-related applications.

The Budgetary Authority agreed to additional staff for fee-related activities in 2010. For 2011 and 2012 no additional fee-financed staffing was provided; the additional posts agreed for 2012 correspond to the implementation of the new pharmacovigilance activities only.

In the draft budget for 2013, the Commission agreed on an increase of the Agencys establishment plan with 21 additional posts, to be financed by fees from the industry. With this Communication, the Commission presents the factors that justify this increase, these being:

- the fee-related activities of EMA have developed substantially since 2010, entailing an expansion of workload for the Agency, yet with no corresponding increase in staff;
- at the same time, the fee-related income of the Agency, based on recovery orders/invoices sent, increased from EUR 171,9 million in 2010 to EUR 179,8 million in 2011 and is estimated to increase further to EUR 200.8 million in 2013. This corresponds to a 5.9% increase for the period 2010-12 and a 16.8% increase over the period 2010-13, which translates into the corresponding increase in workload.

These recent developments in fee-related activities are of a long-term nature and the Agency requires 21 additional temporary agents as of 2013. The initial financial statement should therefore be revised to adapt to the reality of the agency's staffing needs. The extra staff will be funded by the fee income generated through these activities and is therefore neutral for the EU budget.

The Commission emphasises that the current fee-financed increase in staffing is not linked to the implementation of the new pharmacovigilance legislation, applicable as of July 2012.