## Basic information

| | |
|---|---|
| **2022/0417(COD)**<br><br>COD - Ordinary legislative procedure (ex-codecision procedure)<br>Regulation | Procedure completed |
| Fees and charges payable to the European Medicines Agency<br><br>Repealing Regulation 1995/297 1994/0220(CNS)<br>Repealing Regulation 2014/658 2013/0222(COD)<br>Amending Regulation 2017/745 2012/0266(COD)<br><br>**Subject**<br><br>4.20.04 Pharmaceutical products and industry<br>8.40.08 Agencies and bodies of the EU | |

## Key players

### European Parliament

| Committee responsible | Rapporteur | Appointed |
|---|---|---|
| ENVI Environment, Public Health and Food Safety | BUŞOI Cristian-Silviu (EPP) | 03/02/2023 |
| | Shadow rapporteur<br><br>CIUHODARU Tudor (S&D)<br><br>SOLÍS PÉREZ Susana (Renew)<br><br>RIVASI Michèle (Greens/EFA)<br><br>KOPCIŃSKA Joanna (ECR)<br><br>KONEČNÁ Kateřina (The Left) | |

| Committee for opinion | Rapporteur for opinion | Appointed |
|---|---|---|
| BUDG Budgets | VAN OVERTVELDT Johan (ECR) | 15/03/2023 |

### Council of the European Union

### European Commission

| Commission DG | Commissioner |
|---|---|
| Health and Food Safety | KYRIAKIDES Stella |

### European Economic and Social Committee

### European Committee of the Regions

## Key events

| Date | Event | Reference | Summary |
|---|---|---|---|
| 13/12/2022 | Legislative proposal published | COM(2022)0721 | Summary |
| 15/12/2022 | Committee referral announced in Parliament, 1st reading | | |
| 27/06/2023 | Vote in committee, 1st reading | | |
| 30/06/2023 | Committee report tabled for plenary, 1st reading | A9-0224/2023 | Summary |
| 12/07/2023 | Decision by Parliament, 1st reading | T9-0273/2023 | Summary |
| 12/07/2023 | Results of vote in Parliament | | |
| 12/07/2023 | Matter referred back to the committee responsible for interinstitutional negotiations | | |
| 24/10/2023 | Approval in committee of the text agreed at 1st reading interinstitutional negotiations | | |
| 12/12/2023 | Decision by Parliament, 1st reading | T9-0446/2023 | Summary |
| 12/12/2023 | Results of vote in Parliament | | |
| 23/01/2024 | Act adopted by Council after Parliament's 1st reading | | |
| 07/02/2024 | Final act signed | | |
| 14/02/2024 | Final act published in Official Journal | | |

## Technical information

| | |
|---|---|
| **Procedure reference** | 2022/0417(COD) |
| **Procedure type** | COD - Ordinary legislative procedure (ex-codecision procedure) |
| **Procedure subtype** | Legislation |
| **Legislative instrument** | Regulation |
| **Amendments and repeals** | Repealing Regulation 1995/297 1994/0220(CNS)<br>Repealing Regulation 2014/658 2013/0222(COD)<br>Amending Regulation 2017/745 2012/0266(COD) |
| **Legal basis** | Treaty on the Functioning of the European Union TFEU 114<br>Treaty on the Functioning of the European Union TFEU 168-p4 |
| **Other legal basis** | Rules of Procedure EP 165 |
| **Mandatory consultation of other institutions** | European Economic and Social Committee<br>European Committee of the Regions |
| **Stage reached in procedure** | Procedure completed |
| **Committee dossier** | ENVI/9/10980 |

## Documentation gateway

**European Parliament**

| Document type | Committee | Reference | Date | Summary |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| Committee draft report | | PE742.478 | 27/03/2023 | |
| Amendments tabled in committee | | PE747.008 | 04/05/2023 | |
| Specific opinion | BUDG | PE746.962 | 23/05/2023 | |
| Committee report tabled for plenary, 1st reading/single reading | | A9-0224/2023 | 30/06/2023 | Summary |
| Text adopted by Parliament, partial vote at 1st reading /single reading | | T9-0273/2023 | 12/07/2023 | Summary |
| Text adopted by Parliament, 1st reading/single reading | | T9-0446/2023 | 12/12/2023 | Summary |

**Council of the EU**

| Document type | Reference | Date | Summary |
|---|---|---|---|
| Draft final act | 00059/2023/LEX | 07/02/2024 | |

**European Commission**

| Document type | Reference | Date | Summary |
|---|---|---|---|
| Legislative proposal | COM(2022)0721 | 13/12/2022 | Summary |
| Document attached to the procedure | SEC(2022)0440 | 13/12/2022 | |
| Document attached to the procedure | SWD(2022)0413 | 13/12/2022 | |
| Document attached to the procedure | SWD(2022)0414 | 13/12/2022 | |
| Document attached to the procedure | SWD(2022)0415 | 13/12/2022 | |
| Commission response to text adopted in plenary | SP(2024)56 | 22/03/2024 | |

**National parliaments**

| Document type | Parliament /Chamber | Reference | Date | Summary |
|---|---|---|---|---|
| Contribution | IT_CHAMBER | COM(2022)0721 | 21/03/2023 | |
| Contribution | SE_PARLIAMENT | COM(2022)0721 | 22/03/2023 | |
| Contribution | FR_SENATE | COM(2022)0721 | 11/05/2023 | |
| Contribution | PT_PARLIAMENT | COM(2022)0721 | 15/09/2023 | |

**Other institutions and bodies**

| Institution/body | Document type | Reference | Date | Summary |
|---|---|---|---|---|
| EESC | Economic and Social Committee: opinion, report | CES0215/2023 | 24/01/2023 | |

| Additional information | | |
|---|---|---|
| **Source** | **Document** | **Date** |
| European Commission | EUR-Lex | |

## Meetings with interest representatives published in line with the Rules of Procedure

### Rapporteurs, Shadow Rapporteurs and Committee Chairs

| Transparency | | | | |
|---|---|---|---|---|
| **Name** | **Role** | **Committee** | **Date** | **Interest representatives** |
| SOLÍS PÉREZ Susana | Shadow rapporteur | ENVI | 27/03/2023 | European Medicines Agency |
| BUŞOI Cristian-Silviu | Rapporteur | ENVI | 08/03/2023 | EFPIA - European Federation of Pharmaceutical Industries and Associations |
| BUŞOI Cristian-Silviu | Rapporteur | ENVI | 08/03/2023 | MEDICINES FOR EUROPE |

| Final act |
|---|
| Regulation 2024/0568<br>OJ L 000 14.02.2024, p. 0000<br><br>Corrigendum to final act 32024R0568R(02)<br>OJ OJ L 14.03.2025<br><br>Corrigendum to final act 32024R0568R(01)<br>OJ OJ L 23.04.2024 |

# Fees and charges payable to the European Medicines Agency

2022/0417(COD) - 12/07/2023 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 595 votes to 25, with 25 abstentions, **amendments** to the proposal for a regulation of the European Parliament and of the Council of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council.

The matter was referred back to the committee responsible for inter-institutional negotiations.

***Adequate funding***

Members pointed out that as a result of the COVID-19 pandemic and the increase in the number of health initiatives at EU level, the Agency is facing an ever-increasing workload, leading to additional budgetary needs in terms of staff and financial resources. In order to preserve the integrity of the Agency and its independence, and to ensure public confidence in the legislative and regulatory framework for pharmaceutical products in the EU, the Agency must have sufficient funding to carry out its obligations and transparency commitments.

***Payment of remuneration to competent authorities of the Member States for the provision of services to the Agency***

Where the Agency grants a full waiver of fees, the remuneration of rapporteurs and co-rapporteurs appointed by the competent authorities of the Member States should be reduced by 50% or 100%, as set out in Annex V.

***Taking account of inflation rates***

Inflation was high at the time of the proposal for this Regulation; it remains high in 2023 and is forecast by the European Central Bank to remain high in 2024. The corresponding amounts need to be updated to ensure that royalties, fees and remuneration payable are adjusted to take account of inflation before the date of application of the Regulation.

The Commission should therefore adopt a delegated act to amend the relevant Annexes to this Regulation on the basis of the inflation rate published four months before the date of application of the Regulation.

*Reductions of fees and charges*

It is proposed that, on a duly justified proposal from the Executive Director of the Agency, in particular for the protection of public or animal health or for the support of specific types of products or types of applicants, selected for duly justified reasons, the Management Board of the Agency may grant, following a favourable opinion from the Commission, a total or partial reduction of the applicable amount. The Agency should make information on such reductions **publicly available** on the Agency's website, setting out the reasons for the reduction.

*Transparency and monitoring*

The amounts set out in the Annexes should be published on the website of the Agency and should be updated to reflect any changes.

The Agency should monitor its costs and its Executive Director should provide without delay, in his annual activity report to the European Parliament, the Council, the Commission and the Court of Auditors, detailed and substantiated information on the costs to be covered by the fees and charges covered by the Regulation. This information should include information relating in particular to the practical aspects of carrying out the activities for which the Agency levies fees or charges.

All fees received, including those where reductions and waivers have been granted, and fees which are due but not yet received by the Agency should be **published on the Agency's website** and listed in its annual report. The Agency's annual report should furthermore list a detailed breakdown of all remunerated amounts paid to national authorities for their work.

*Revision*

The amended text stated that the Commission may take into account other factors that could have a substantive impact on the Agency's budget, including but not limited to its workload and potential risks related to fluctuations in its fee revenues. The level of fees should be set at a level which ensures that the revenue derived from them, when combined with other sources of revenue of the Agency, is sufficient to cover the costs of the services delivered in accordance with the key performance indicators and transparency principles.

*Annexes*

The amended text revises the Annexes regarding fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use and veterinary medicinal products. Members proposed that a total reduction to the fee for protocol assistance and scientific advice requests on medicinal products should be granted to **applicants from academia or the academic sector**. They also requested that a fee reduction of **30%** (instead of 20%) be applied to the annual pharmacovigilance fee.

# Fees and charges payable to the European Medicines Agency

2022/0417(COD) - 30/06/2023 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Cristian-Silviu BUŞOI (EPP, RO) on the proposal for a regulation of the European Parliament and of the Council of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658 /2014 of the European Parliament and of the Council.

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

*Payment of remuneration to competent authorities of the Member States for the provision of services to the Agency*

Where the Agency grants a full waiver of fees, the remuneration of rapporteurs and co-rapporteurs appointed by the competent authorities of the Member States should be reduced by 50% or 100%, as set out in Annex V.

*Monitoring inflation rates*

The Commission should monitor the inflation rate, in relation to the amounts of fees, charges and remuneration set out in the Annexes to this Regulation. The relevant amounts should be updated to ensure that the fees, charges and remuneration payable are adjusted for such inflation before the date of application of this Regulation. The Commission should therefore adopt a delegated act to amend the relevant Annexes to this Regulation on the basis of the inflation rate published four months before the date of application of this regulation.

*Reductions of fees and charges*

It is proposed that, on a duly justified proposal from the Executive Director of the Agency, in particular for the protection of public or animal health or for the support of specific types of products or types of applicants, selected for duly justified reasons, the Management Board of the Agency may grant, following a favourable opinion from the Commission, a total or partial reduction of the applicable amount. The Agency should make information on such reductions publicly available on the Agency's website, setting out the reasons for the reduction.

*Revision*

The report stated that the Commission may take into account other factors that could have a substantive impact on the Agency's budget, including but not limited to its workload and potential risks related to fluctuations in its fee revenues. The level of fees should be set at a level which ensures that the revenue derived from them, when combined with other sources of revenue of the Agency, is sufficient to cover the costs of the services delivered in accordance with the key performance indicators and transparency principles.

*Annexes*

The amended text revises the Annexes regarding fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use and veterinary medicinal products. Members proposed that a total reduction to the fee for protocol assistance and **scientific advice** requests on medicinal products should be granted to applicants from academia or the academic sector. They also requested that a fee reduction of 30% (instead of 20%) be applied to the annual pharmacovigilance fee.

*Transparency and monitoring*

The amounts set out in the Annexes should be published on the website of the Agency and should be updated to reflect any changes. All fees received, including those where reductions and waivers have been granted, and fees which are due but not yet received by the Agency should be published on the Agency's website and listed in its annual report. The Agency's annual report should furthermore list a detailed breakdown of all remunerated amounts paid to national authorities for their work.

# Fees and charges payable to the European Medicines Agency

2022/0417(COD) - 13/12/2022 - Legislative proposal

PURPOSE: to ensure appropriate funding of the European Medicines Agency (EMA) activities carried out at Union level.

PROPOSED ACT: Regulation of the European Union and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: the European Medicines Agency (EMA) plays a key role in ensuring that all medicinal products placed on the EU market are safe, effective and of high quality, thereby contributing to the proper functioning of the internal market while ensuring a high level of human and animal health protection. It is therefore necessary to ensure that it has sufficient resources to finance its activities, in particular from the fees it collects.

Over the years, the legal framework governing EMA fees has become rather complex, requiring some legislative simplification. When establishing a new fee system for veterinary medicinal products, the characteristics and specificities of the veterinary sector should be taken into account.

This revision also aims to **address the following problems** identified by the recent evaluation of the EMA fee system:

- complexity of the fee system due to the many different categories and types of fees it currently establishes;

- misalignment of some fees with underlying costs;

- lack of any fees or national competent authority remuneration for some procedural activities;

- misalignment with the underlying costs of certain remuneration paid to national competent authorities in Member States; and

- discrepancy between the main EMA Fee Regulation and the Pharmacovigilance Fee Regulation, which differ in their approach to determining the amount of national competent authority remuneration and in the approach to national competent authority remuneration in the case of reduced fees.

By addressing these specific problems, the general objective of this proposal is to **contribute to providing a sound financial basis to support the EMA's operations**, including remuneration for services to the EMA rendered by national competent authorities, in line with the applicable legislation.

The proposal also aims to: (i) **streamline the system by simplifying the fee structure** to the extent possible and by addressing the unnecessary complexity of the corresponding legal framework through bringing together in a single legal instrument fee rules that are currently governed by the two EMA Fees Regulations, (ii) **make the fee system future-proof** by introducing regulatory flexibility in the way it is adjusted, on an objective basis.

CONTENT: the general objective of this Regulation is to **contribute to providing a sound financial basis for the operations of the Agency** by establishing cost-based fees and charges to be levied by the Agency, as well as cost-based remuneration to competent authorities of the Member States for the services they provide for the completion of the Agency's statutory tasks.

This Regulation lays down the following:

- the amounts of the fees and charges established on cost-based evaluation and **levied** by the European Medicines Agency (the 'Agency') for assessment activities relating to obtaining and maintaining a Union authorisation to market medicinal products for human use and veterinary medicinal products and for other services provided or tasks carried out by the Agency;

- the corresponding amounts of **remuneration** established on cost-based evaluation and payable by the Agency to the competent authorities of the Member States for the services provided by rapporteurs and, where applicable, co-rapporteurs from competent authorities of the Member States, or by other roles considered as equivalent for the purposes of this regulation, as referred to in the Annexes to this Regulation; and

- the **monitoring of costs of activities and services** provided by the Agency and of costs for remuneration.

In order to have a fair system, it is proposed to identify a **harmonised unit** by which relevant pharmacovigilance-related fees would be charged with regard to nationally authorised products.

The proposal:

- describes the types of fees and charges than can be levied by the EMA and refer to the relevant annexes where the corresponding amounts are laid down with, where relevant, the amounts for remuneration to the national competent authorities in Member States;

- deals with the conditions of remuneration paid to national competent authorities in relation to fees levied by the Agency;

- sets out applicable fee reductions and related rules and refers to the relevant annex where the reductions are set out: the EMA Executive Director is empowered to grant further fee reductions in exceptional circumstances, while the Management Board of the Agency is empowered, following a favourable opinion from the Commission, to grant further reductions in non-exceptional circumstances for justified reasons, such as for protection of public and animal health;

- concerns the conditions and rules pertaining to payment of fees and charges.

- mandates the Management Board of the Agency to specify detailed technical arrangements to facilitate the application of the proposed regulation;

- deals with due dates and provides for the possibility for the Executive Director to suspend services in the case of non-payment;

- sets out requirements for transparency of the amounts provided for by the proposed regulation and provides for monitoring of costs and inflation and reporting;

- sets out the conditions for a review of the amounts laid down in the Regulation, following a cost-based approach.

Lastly, it is proposed that the annexes to this regulation should be amendable by **delegated acts**. The annexes lay down the cases where a fee is charged and where remuneration is paid to national competent authorities, as well as the amounts of those fees and the amounts for national competent authorities' remuneration and the applicable fee reductions.

# Fees and charges payable to the European Medicines Agency

2022/0417(COD) - 12/12/2023 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 562 votes to 35, with 6 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission's proposal as follows:

***General objective***

The general objective of this Regulation is to contribute to providing a sound financial basis for the operations of the Agency, thus contributing to ensuring a high level of protection of public and animal health. It should establish cost-based fees and charges to be levied by the Agency, as well as cost-based remuneration to competent authorities of the Member States for the services they provide for the completion of the Agency's statutory tasks.

Medicinal products for human use which are authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC shall not be subject to the fees for pharmacovigilance activities set out in the Annexes to this Regulation.

***Appropriate funding***

The amended text points out that, following the COVID-19 pandemic and a rise in the number of initiatives in the field of health at Union level, the Agency is faced with a constantly increasing workload, which can entail additional budgetary needs in terms of staff and financial resources. The additional workload should be accompanied by appropriate funding to ensure, among other things, that the Agency can fulfil its obligations and transparency commitments.

Given that the Agency is a public authority, it is of utmost importance to safeguard its integrity and independence in order to maintain public trust in the Union regulatory framework.

***Reductions and deferrals of fees and charges***

Member States or Union institutions that have requested an assessment, opinion or a service from the Agency should not be subject to fees or charges under this Regulation.

On a reasoned proposal from the Executive Director of the Agency, in particular for the protection of public or animal health or for the support of specific types of products or types of applicants, selected for duly justified reasons, the Management Board of the Agency may grant, following a favourable opinion from the Commission, a total or partial reduction of the applicable fee or charge. The Agency should make information on such reductions publicly available on its website, after deletion of all information of a commercially confidential nature.

**Non-profit organisations and academia** should also benefit from fee reductions provided that they are not owned or controlled by a commercial undertaking and that they have not concluded agreements with any commercial undertaking concerning sponsorship or participation in the development of the medicinal product which would give the commercial undertaking any rights to the final medicinal product.

*Access to information*

The general public should have access to information on the granting by the Agency of reductions or waivers of fees and charges and on the amounts of remuneration paid to competent authorities of the Member States, broken down by Member State and by activity. That information should not include, however, any commercially confidential information. The Agency should therefore remove such information in advance, where relevant.

*Adjustments related to inflation*

The amounts of the fees and charges of the Agency and of the remuneration to competent authorities of the Member States should be adjusted, where appropriate, to take account of significant changes in costs, detected through cost monitoring, and to take account of inflation.

According to the amended text, the first adjustment of fees, charges and remuneration due to inflation should take into account the annual inflation rates for each calendar year following the inflation adjustment already applied to the amounts in the Annexes, up to and including 2024. The inflation rate already applied to the amounts in the Annexes for 2023 is 5.9 %, which corresponds to the projected annual inflation for 2023, and 1.2 % for 2024. The first adjustment due to inflation should therefore also take into account the correction needed in view of the final annual inflation rate for 2023 and 2024.

*Revision*

Any revision of the fees and charges and of the remuneration paid to competent authorities of the Member States provided for in this Regulation should be based on the Commission's evaluation of the Agency’s costs and revenues and of the full costs of the services provided to the Agency within the scope of this Regulation by the competent authorities of the Member States, taking into account also the impact of such services on the sustainability of the operations of the Agency, including the services provided to the Agency by the competent authorities of the Member States, and a fair and objective allocation of fees, charges and remuneration.

The Commission may take into account any factors that could have a substantive impact on the Agency’s costs, including but not limited to the **workload** associated with its activities, and potential risks related to fluctuations in its fee revenue. The fees and charges should be set at a level which ensures that the Agency has sufficient revenue to cover the costs of the services delivered.

*Annexes*

The amended text revises the annexes concerning fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use and veterinary medicinal products.

In any revision of the Annexes, the amounts of remuneration paid to competent authorities of the Member States provided for in this Regulation should be maintained as a single amount of remuneration irrespective of the Member State of the competent authority concerned.