## Basic information

**COD - Ordinary legislative procedure (ex-codecision procedure)**

Regulation

Fees and charges payable to the European Medicines Agency
- Repealing Regulation 1995/297 1994/0220(CNS)
- Amending Regulation 2017/745 2012/0266(COD)
- Repealing Regulation 2014/658 2013/0222(COD)

**Subject**
- 4.20.04 Pharmaceutical products and industry
- 8.40.08 Agencies and bodies of the EU

## Awaiting Council's 1st reading position

## Key players

### European Parliament

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<th>Committee responsible</th>
<th>Rapporteur</th>
<th>Appointed</th>
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<td><strong>ENVI</strong> Environment, Public Health and Food Safety</td>
<td>BUŞOI Cristian-Silviu</td>
<td>03/02/2023</td>
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<tr>
<td></td>
<td>CIUHODARU Tudor</td>
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<td></td>
<td>SOLÍS PÉREZ Susana</td>
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<td></td>
<td>RIVASI Michèle</td>
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<td></td>
<td>KOPCIŃSKA Joanna</td>
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<td>KONEČNÁ Kateřina</td>
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### Committee for opinion

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<th>Rapporteur for opinion</th>
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<td>BUDD Budgets</td>
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### Council of the European Union

### European Commission

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<td>Health and Food Safety</td>
<td>KYRIAKIDES Stella</td>
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### European Economic and Social Committee

### European Committee of the Regions
### Key events

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### Technical information

- **Procedure reference**: 2022/0417(COD)
- **Procedure type**: COD - Ordinary legislative procedure (ex-codecision procedure)
- **Procedure subtype**: Legislation
- **Legislative instrument**: Regulation
  - Repealing Regulation 1995/297 1994/0220(CNS)
  - Amending Regulation 2017/745 2012/0266(COD)
  - Repealing Regulation 2014/658 2013/0222(COD)
- **Legal basis**: Treaty on the Functioning of the EU TFEU 114; Treaty on the Functioning of the EU TFEU 168-p4
- **Other legal basis**: Rules of Procedure EP 159
- **Mandatory consultation of other institutions**: European Economic and Social Committee
  - European Committee of the Regions
- **Stage reached in procedure**: Awaiting Council's 1st reading position
- **Committee dossier**: ENVI/9/10980

### Documentation gateway

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Fees and charges payable to the European Medicines Agency

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 EMA's operations 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**


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.

**Revisions**

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**

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.

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<table>
<thead>
<tr>
<th>Transparency</th>
<th>SOLIS PÉREZ Susana</th>
<th>Shadow rapporteur</th>
<th>27/03/2023</th>
<th>European Medicines Agency</th>
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<tr>
<td></td>
<td>BU?OI Cristian-Silviu</td>
<td>Rapporteur</td>
<td>08/03/2023</td>
<td>MEDICINES FOR EUROPE</td>
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<td>BU?OI Cristian-Silviu</td>
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<td>08/03/2023</td>
<td>EFPIA - European Federation of Pharmaceutical Industries and Associations</td>
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