European Parliament
2019-2024

Plenary sitting

A9-0224/2023

30.6.2023

***I
REPORT

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
(COM(2022)0721 – C9-0426/2022 – 2022/0417(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Cristian-Silviu Buşoi

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

CONTENTS

Page

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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
(COM(2022)0721 – C9-0426/2022 – 2022/0417(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2022)0721),

– having regard to Article 294(2) and Articles 114, 168(4), points (b) and (c), of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0426/2022),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– after consulting the Committee of the Regions,

– having regard to the opinion of the European Economic and Social Committee of 24 January 2023[1],

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the letter from the Committee on Budgets,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0224/2023),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[1] Not yet published in the Official Journal.

Amendment 1
Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(1) The European Medicines Agency ('the Agency') plays a key role in ensuring that only safe, high-quality and efficacious medicinal products are placed on the Union market, thus contributing to the smooth functioning of the internal market and ensuring a high level of protection of human and animal health. It is therefore necessary to ensure sufficient resources are available to the Agency to finance its activities, including resources emanating from fees.	(1) The European Medicines Agency ('the Agency') plays a key role in ensuring that only safe, high-quality and efficacious medicinal products are placed on the Union market, thus contributing to the smooth functioning of the internal market and ensuring a high level of ***expertise and*** protection of human and animal health. It is therefore necessary to ensure sufficient resources are available to the Agency to ***attract and maintain the expertise required to fulfil its tasks and to*** finance its activities, including resources emanating from fees.

Amendment 2
Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) The fees payable to the Agency should be proportionate to the work carried out in relation to obtaining and maintaining a Union authorisation, and should be based on ***an*** evaluation of the Agency's estimations and forecasts as regards the workload and related costs for that work, as well as on an evaluation of the costs of the services provided to the Agency by the competent authorities of Member States that are responsible for regulating medicinal products, which act as rapporteurs and, where applicable, co-rapporteurs appointed by the scientific committees of the Agency.	(3) The fees payable to the Agency should be proportionate to the work carried out in relation to obtaining and maintaining a Union authorisation, and should be based on ***a transparent*** evaluation of the Agency's estimations and forecasts as regards the workload and related costs for that work, as well as on an evaluation of the costs of the services provided to the Agency by the competent authorities of Member States that are responsible for regulating medicinal products, which act as rapporteurs and, where applicable, co-rapporteurs appointed by the scientific committees of the Agency. ***The fees and fee structure should take into account any changes in the Union regulatory framework for medicinal products. Adequate financing should be provided for that critical public infrastructure to boost its expertise and ensure its***

sustainability through appropriate financing.

Amendment 3
Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) Following the COVID-19 pandemic and increased initiatives in the field of health at the Union level, the agency is faced with a constantly increasing workload, which entails additional budgetary needs in terms of staff and financial resources. The additional work, which includes following the adoption of Regulation (EU) 2022/123 of the European Parliament and of the Council[1a] and the creation of the European Health Data Space, should come with an appropriate funding from the Multiannual Financial Framework.
	[1a] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).

Amendment 4
Proposal for a regulation
Recital 4 b (new)

Text proposed by the Commission	*Amendment*
	(4b) Although the majority of its funding comes from private sources, the EMA is a public authority and it is of the utmost importance to safeguard its integrity and independence in order to ensure public trust in the legislative and regulatory framework for pharmaceuticals in the Union. Therefore,

	sufficient funding should be allocated to the Agency so that it can carry out its obligations and transparency commitments.

Amendment 5
Proposal for a regulation
Recital 4 c (new)

Text proposed by the Commission	*Amendment*
	(4c) The fees paid to the Agency should reflect the complex evaluations necessary to obtain and maintain a Union authorisation. It is appropriate to recognise the contributions from Member States' competent authorities, as well as the expenses incurred by them. It is particularly appropriate to recognise the synergies achieved through multinational assessment teams and support the collaborative efforts of those multinational teams. The Commission and the Agency should therefore monitor the development of multinational assessment teams when determining the changes that are necessary to the structure of remuneration of Member States.

Amendment 6
Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) Fees and charges should cover the cost of statutory services and activities of the Agency that is not already covered by the contributions to its revenue from other sources. All relevant Union legislation governing the Agency's activities and fees should be taken into account when establishing the fees and charges, including Regulation (EC) No 726/2004, Regulation (EU) 2019/6 of the European Parliament and of the Council[21] , Directive	(5) Fees and charges should cover the cost of statutory services and activities of the Agency that is not already covered by the contributions to its revenue from other sources. All relevant Union legislation governing the Agency's activities and fees should be taken into account when establishing the fees and charges, including Regulation (EC) No 726/2004, Regulation (EU) 2019/6 of the European Parliament and of the Council[21], Directive

2001/83/EC, Regulation (EC) No 1901/2006 of the European Parliament and of the Council[22] , Regulation (EC) No 141/2000 of the European Parliament and of the Council[23] , Regulation (EC) No 1394/2007 of the European Parliament and of the Council[24] , Commission Regulation (EC) No 2049/2005[25] , Commission Regulation (EC) No 1234/2008[26] , Regulation (EU) 2017/745 of the European Parliament and of the Council[27] , Regulation (EC) No 470/2009 of the European Parliament and of the Council[28] , Commission Regulation (EU) 2018/782[29] , Commission Implementing Regulation (EU) 2021/1281[30] and Commission Regulation (EC) No 2141/96[31] .

2001/83/EC, Regulation (EC) No 1901/2006 of the European Parliament and of the Council[22], Regulation (EC) No 141/2000 of the European Parliament and of the Council[23], Regulation (EC) No 1394/2007 of the European Parliament and of the Council[24], Commission Regulation (EC) No 2049/2005[25], Commission Regulation (EC) No 1234/2008[26], Regulation (EU) 2017/745 of the European Parliament and of the Council[27], Regulation (EC) No 470/2009 of the European Parliament and of the Council[28], ***Regulation (EU) 2022/123,*** Commission Regulation (EU) 2018/782[29], Commission Implementing Regulation (EU) 2021/1281[30]and Commission Regulation (EC) No 2141/96[31].

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[21] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

[22] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

[23] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).

[24] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

[25] Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and

[21] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

[22] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

[23] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).

[24] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

[25] Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and

of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises (OJ L 329, 16.12.2005, p. 4).

[26] Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7).

[27] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

[28] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

[29] Commission Regulation (EU) 2018/782 of 29 May 2018 establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009 (OJ L 132, 30.5.2018, p. 5).

[30] Commission Implementing Regulation (EU) 2021/1281 of 2 August 2021 laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the

of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises (OJ L 329, 16.12.2005, p. 4).

[26] Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7).

[27] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

[28] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

[29] Commission Regulation (EU) 2018/782 of 29 May 2018 establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009 (OJ L 132, 30.5.2018, p. 5).

[30] Commission Implementing Regulation (EU) 2021/1281 of 2 August 2021 laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the

pharmacovigilance system master file for veterinary medicinal products (OJ L 279, 3.8.2021, p. 15).

[31] Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorization for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93 (OJ L 286, 8.11.1996, p. 6).

pharmacovigilance system master file for veterinary medicinal products (OJ L 279, 3.8.2021, p. 15).

[31] Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorization for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93 (OJ L 286, 8.11.1996, p. 6).

Amendment 7
Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) In line with the Joint Statement of the European Parliament, the Council of the EU and the Commission of 19 July 2012 on decentralised agencies, for bodies for which the revenue is constituted by fees and charges in addition to the Union contribution, fees should be set at a level that avoids a deficit or a significant accumulation of surplus, and should be revised when this is not the case. Therefore, a cost monitoring system should be put in place. The purpose of such monitoring system should be to detect significant changes of costs of the Agency that, taking into account the Union contribution and other non-fee revenue, could require a change in fees, charges or remuneration established under this regulation. That monitoring system should equally be able to detect, based on objective and verifiable information, significant changes of costs of remuneration of services provided to the Agency by the competent authorities of Member States, which act as rapporteurs and, where applicable, co-rapporteurs and by experts contracted by the Agency for the procedures of the expert panels on medical devices. Cost information relating to services remunerated by the Agency	(7) In line with the Joint Statement of the European Parliament, the Council of the EU and the Commission of 19 July 2012 on decentralised agencies, for bodies for which the revenue is constituted by fees and charges in addition to the Union contribution, fees should be set at a level that avoids a deficit or a significant accumulation of surplus, and should be revised when this is not the case. Therefore, a ***transparent*** cost monitoring system should be put in place. The purpose of such monitoring system should be to detect significant changes of costs of the Agency that, taking into account the Union contribution and other non-fee revenue, could require a change in fees, charges or remuneration established under this regulation. That monitoring system should equally be able to detect, based on objective and verifiable information, significant changes of costs of remuneration of services provided to the Agency by the competent authorities of Member States, which act as rapporteurs and, where applicable, co-rapporteurs and by experts contracted by the Agency for the procedures of the expert panels on medical devices. Cost information relating to services remunerated by the Agency

should be auditable in accordance with Article 257 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[32] .

[32] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

should be auditable in accordance with Article 257 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[32].

[32] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

Amendment 8
Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) In line with union policies, it is appropriate to provide for reductions of the fees to support specific sectors and applicants or marketing authorisation holders, such as micro-, small- and medium-sized enterprises (SMEs), or to respond to specific circumstances, such as products responding to recognised public health or animal health priorities or veterinary medicinal products intended for a limited market authorised in accordance with Article 23 of Regulation (EU) 2019/6.	(15) In line with union policies, it is appropriate to provide for reductions of the fees to support specific sectors and applicants or marketing authorisation holders, such as micro-, small- and medium-sized enterprises (SMEs), ***non-profit-organisations and the academic sector*** or to respond to specific circumstances, such as products responding to recognised public health or animal health priorities or veterinary medicinal products intended for a limited market authorised in accordance with Article 23 of Regulation (EU) 2019/6.

Amendment 9
Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) The Management Board of the	(17) The Management Board of the

Agency should be empowered to provide further fee reductions for justified reasons of protection of public and animal health. A favourable opinion from the Commission should be mandatory before granting further fee reductions, in order to ensure alignment with Union law and with overall policies of the Union. In addition, in duly justified exceptional cases, for imperative reasons of public or animal health, it should also be possible for the Executive Director of the Agency to reduce certain types of fees on the basis of a critical examination of the situation specific to each case.	Agency should be empowered to provide further fee reductions for ***duly*** justified reasons of protection of public and animal health. A favourable opinion from the Commission should be mandatory before granting further fee reductions, in order to ensure alignment with Union law and with overall policies of the Union***. For transparency purposes, the Agency should make information on the decisions for further fee reductions publicly available on its website, including on the recipients and the reasons for the decision for further fee reductions***. In addition, in duly justified exceptional cases, for imperative reasons of public or animal health, it should also be possible for the Executive Director of the Agency to reduce certain types of fees on the basis of a critical examination of the situation specific to each case. ***The Agency should ensure that such decisions of the Executive Director are made publicly available on its website and set out the reasons for those decisions.***

Amendment 10
Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) In order to provide flexibility, in particular to adapt to developments in science, the Management Board of the Agency should be enabled to specify working arrangements to facilitate the application of this Regulation, on a duly justified proposal from the Executive Director. In particular, the Management Board should be able to establish due dates and deadlines for payment, payment methods, timetables, detailed classifications, lists of additional fee reductions, and detailed amounts within the limits of an established range. A favourable opinion from the Commission should be mandatory before the proposal is put to the	(18) In order to provide flexibility, in particular to adapt to developments in science ***and to address unforeseen circumstances and medical needs***, the Management Board of the Agency should be enabled to specify working arrangements to facilitate the application of this Regulation, on a duly justified proposal from the Executive Director. In particular, the Management Board should be able to establish due dates and deadlines for payment, payment methods, timetables, detailed classifications, lists of additional fee reductions, and detailed amounts within the limits of an established range. A favourable opinion from the Commission

Management Board for adoption, in order to ensure alignment with Union law and with overall policies of the Union.

should be mandatory before the proposal is put to the Management Board for adoption, in order to ensure alignment with Union law and with overall policies of the Union.

Amendment 11
Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) For their assessments, rapporteurs and co-rapporteurs and the other roles considered as equivalent for the purposes of this regulation in scientific advice and inspections rely on the scientific evaluations and resources of the competent authorities of Member States, while it is the responsibility of the Agency to coordinate the existing scientific resources put at its disposal by the Member States, in accordance with Article 55 of Regulation (EC) No 726/2004. In light of that, and to ensure appropriate resources for the scientific assessments relating to the procedures carried out at Union level, the Agency should remunerate the scientific assessment services provided by the rapporteurs and co-rapporteurs appointed by the Member States as members of the scientific committees of the Agency, or, where relevant, provided by rapporteurs and co-rapporteurs in the coordination group referred to in Article 27 of Directive 2001/83/EC. The amount of remuneration for the services provided by those rapporteurs and co-rapporteurs should be based on estimations of the workload involved and should be taken into account in setting the level of the fees charged by the Agency.	(19) For their assessments, rapporteurs and co-rapporteurs and the other roles considered as equivalent for the purposes of this regulation in scientific advice and inspections rely on the scientific evaluations and resources of the competent authorities of Member States, while it is the responsibility of the Agency to coordinate the existing scientific resources put at its disposal by the Member States, in accordance with Article 55 of Regulation (EC) No 726/2004. In light of that, and to ensure appropriate resources for the scientific assessments relating to the procedures carried out at Union level, the Agency should remunerate the scientific assessment services provided by the rapporteurs and co-rapporteurs appointed by the Member States as members of the scientific committees of the Agency, or, where relevant, provided by rapporteurs and co-rapporteurs in the coordination group referred to in Article 27 of Directive 2001/83/EC. The amount of remuneration for the services provided by those rapporteurs and co-rapporteurs should be based on estimations of the workload involved and should be taken into account in setting the level of the fees charged by the Agency. ***Based on a specific public interest benefitting both the Union and the Member States, where the Agency grants a total waiver of fees, the remuneration of rapporteurs and co-rapporteurs should be reduced by 50% or 100%, as specified in Annex V.***

Amendment 12
Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(26a) Member States should ensure that adequate financial resources are available to provide the national competent authorities with staff and other resources necessary to carry out the relevant activities associated with the fees and charges levied in accordance with this Regulation. Any revision of the fees and charges pursuant to Article 11 should also be taken into account.

Amendment 13
Proposal for a regulation
Recital 26 b (new)

Text proposed by the Commission	*Amendment*
	(26b) The calculation of the amounts of the fees, charges and remuneration take into account the inflation rate measured by means of the Harmonised Index of Consumer Prices published by Eurostat pursuant to Regulation (EU) No 2016/792 until the date of adoption of the proposal for this Regulation. The inflation rate was high when the proposal for this Regulation was submitted, remains high as measured in 2023, and, according to the forecast of the European Central Bank, is projected to remain high in 2024. 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.

Amendment 14
Proposal for a regulation
Article 2 – paragraph 1 – point 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) 'Academia' or 'academic sector' means public or private higher education establishments awarding academic degrees, public or private non-profit research organisations whose primary mission is to pursue research, and international European interest organisations;

Amendment 15
Proposal for a regulation
Article 2 – paragraph 1 – point 5 b (new)

Text proposed by the Commission	*Amendment*
	(5b) 'Non-profit organisation' or 'non-profit legal entity' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members;

Amendment 16
Proposal for a regulation
Article 2 – paragraph 1 – point 5 c (new)

Text proposed by the Commission	*Amendment*
	(5c) 'International European interest organisation' means an international organisation, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in the Union;

Amendment 17

Proposal for a regulation
Article 2 – paragraph 1 – point 6

Text proposed by the Commission	*Amendment*
(6) 'public health emergency' means a situation of public health emergency recognised by the Commission in accordance with Article ***12(1) of Decision No 1082/2013/EU*** of the European Parliament and of the Council[40].	(6) 'public health emergency' means a situation of public health emergency recognised by the Commission in accordance with Article ***23 of Regulation (EU) 2022/2371*** of the European Parliament and of the Council[40].
[40] ***Decision No 1082/2013/EU*** of the European Parliament and of the Council of ***22 October 2013*** on serious cross-border threats to health and repealing Decision ***No 2119/98/EC (OJ L 293, 5.11.2013, p. 1)***.	[40] ***Regulation (EU) 2022/2371*** of the European Parliament and of the Council of ***23 November 2022*** on serious cross-border threats to health and repealing Decision ***No 1082/2013/EU (OJ L 314, 6.12.2022, p. 56)***.

Amendment 18
Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Unless otherwise provided for in this Regulation, where fee reductions apply, the remuneration to competent authorities of the Member States payable in accordance with this Regulation shall not be reduced.	2. Unless otherwise provided for in this Regulation, where ***less than total*** fee reductions apply, the remuneration to competent authorities of the Member States payable in accordance with this Regulation shall not be reduced. ***However, unless otherwise provided for in this Regulation, where fee waivers are granted, the remuneration shall be reduced as laid down in Annex V.***

Amendment 19
Proposal for a regulation
Article 6 – paragraph 4

Text proposed by the Commission	*Amendment*
4. On a duly justified proposal from the Executive Director of the Agency, in	4. 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 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, in accordance with Article 8.	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, in accordance with Article 8. ***The Agency shall make information on such reductions publicly available on the Agency's website, setting out the reasons for the reduction.***

Amendment 20
Proposal for a regulation
Article 6 – paragraph 5

Text proposed by the Commission	*Amendment*
5. In exceptional circumstances and for imperative reasons of public or animal health, the Executive Director of the Agency may grant, on a case-by-case basis, total or partial reductions for the fees set out in Annexes I, II, III and IV, with the exception of the fees set out in points 6, 15 and 16 of Annex I, points 7 and 10 of Annex II and point 3 of Annex III. Any decision taken pursuant to this Article shall state the reasons on which it is based.	5. In exceptional circumstances and for ***duly justified*** imperative reasons of public or animal health, the Executive Director of the Agency may grant, on a case-by-case basis, total or partial reductions for the fees set out in Annexes I, II, III and IV, with the exception of the fees set out in points 6, 15 and 16 of Annex I, points 7 and 10 of Annex II and point 3 of Annex III. Any decision taken pursuant to this Article shall state the reasons on which it is based. ***The Agency shall make information on such decisions by the Executive Director, including the reasons for the reduction, publicly available on the Agency's website.***

Amendment 21
Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The amounts set out in the annexes shall be published on the website of the Agency.	1. The amounts set out in the annexes shall be published on the website of the Agency ***and shall be updated to reflect any changes.***

Amendment 22
Proposal for a regulation
Article 10 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency shall monitor its costs and the Executive Director of the Agency shall provide, as part of the annual activity report delivered to the European Parliament, the Council, the Commission and the Court of Auditors, detailed and substantiated information on the costs to be covered by fees and charges that are within the scope of this Regulation. That information shall include the performance information set out in Annex VI and a cost breakdown related to the previous calendar year and to a forecast for the following calendar year. The Agency shall also publish an overview of that information in its annual report.	2. The Agency shall monitor its costs and the Executive Director of the Agency shall provide, ***without delay*** as part of the annual activity report delivered to the European Parliament, the Council, the Commission and the Court of Auditors, detailed and substantiated information on the costs to be covered by fees and charges that are within the scope of this Regulation. That information shall include the performance information set out in Annex VI and ***other relevant information, in particular on the practical aspects of carrying out the activities for which the Agency collects fees or charges, and*** a cost breakdown related to the previous calendar year and to a forecast for the following calendar year. The Agency shall also publish ***without delay,*** an overview of that information in its annual report.

Amendment 23
Proposal for a regulation
Article 10 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. All fees received, including those where reductions and waivers have been granted, and fees which are due but not yet received by the Agency shall be published on the Agency's website and listed in its annual report.
	The Agency's annual report shall furthermore list a detailed breakdown of all remunerated amounts paid to national authorities for their work.

Amendment 24
Proposal for a regulation
Article 10 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Commission shall monitor the inflation rate, measured by means of the Harmonised Index of Consumer Prices published by Eurostat pursuant to Regulation (EU) No 2016/792, in relation to the amounts of fees, charges and remuneration set out in the Annexes to this Regulation. The monitoring exercise shall take place no earlier than [OP: please insert date one year after the date of application of this Regulation], and thereafter on an annual basis. Any adjustment, in line with inflation, to fees, charges and remuneration established in accordance with this regulation shall become applicable, at the earliest, on 1 January of the calendar year following the calendar year in which the monitoring exercise took place.	5. The Commission shall monitor the inflation rate, measured by means of the Harmonised Index of Consumer Prices published by Eurostat pursuant to Regulation (EU) No 2016/792, in relation to the amounts of fees, charges and remuneration set out in the Annexes to this Regulation. The monitoring exercise shall take place no earlier than [OP: please insert date one year after the date of application of this Regulation], and thereafter on an annual basis. ***On the basis of this exercise, the Commission shall draw up a report and submit it to the European Parliament and to the Council.*** Any adjustment, in line with inflation ***and following the annual activity report referred to in Article 10(2),*** to fees, charges and remuneration established in accordance with this regulation shall become applicable, at the earliest, on 1 January of the calendar year following the calendar year in which the monitoring exercise took place***.***

Amendment 25
Proposal for a regulation
Article 10 – paragraph 6 – introductory part

Text proposed by the Commission	*Amendment*
6. At the earliest on [OP: please insert date 3 years after the date of application] and at three-year intervals thereafter, the Executive Director of the Agency ***may***, where considered relevant in view of Article 11(2), and after consultation of the Management Board of the Agency, provide the Commission with a special report ***outlining,*** in an objective, fact-based and sufficiently detailed manner, ***justified***	6. At the earliest on [OP: please insert date 3 years after the date of application] and at three-year intervals thereafter, the Executive Director of the Agency ***shall***, where considered relevant in view of Article 11(2), and after consultation of the Management Board of the Agency, provide the Commission with a special report ***. The Agency shall publish the special report without delay and shall set out*** in an objective***, justified***, fact-based and

recommendations:	sufficiently detailed manner, ***the following*** recommendations:

Amendment 26
Proposal for a regulation
Article 10 – paragraph 6 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) to adapt any fee, charge or remuneration, or introduce a new fee, charge or remuneration following a change in the statutory tasks of the Agency resulting in a significant change in the respective costs;

Amendment 27
Proposal for a regulation
Article 10 – paragraph 6 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The special report shall be submitted to the European Parliament and to the Council for information.

Amendment 28
Proposal for a regulation
Article 10 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. With a view to supporting the Agency reach its conclusions in an efficient and effective manner, during the preparation of a report, the Agency shall organise consultations with stakeholders in order to receive input on the structure and level of fees, charges and remuneration, including the reasons for any change thereto.

Amendment 29
Proposal for a regulation

Article 10 – paragraph 6 b (new)

Text proposed by the Commission	*Amendment*
	6b. The special report shall be made publicly available without delay on the Agency's website. The special report shall include information on the stakeholders consulted in the preparation of that report.

Amendment 30
Proposal for a regulation
Article 10 – paragraph 8

Text proposed by the Commission	*Amendment*
8. The Commission may request any clarification or further substantiation of the report and its recommendations, if considered necessary. Following such a request, the Agency shall without undue delay provide the Commission with an updated version of the report which addresses any comments made and questions raised by the ***Commission***.	8. The Commission***, the European Parliament or the Council*** may request any clarification or further substantiation of the report and its recommendations, if considered necessary. Following such a request, the Agency shall without undue delay provide the Commission***, the European Parliament and the Council*** with an updated version of the report which addresses any comments made and questions raised by the ***respective institution***.

Amendment 31
Proposal for a regulation
Article 10 – paragraph 9 – introductory part

Text proposed by the Commission	*Amendment*
9. The reporting time interval referred to in paragraph 6 may be shortened in any of the following situations:	9. ***The time interval for the first special report as well as*** the reporting time interval referred to in paragraph 6 may be shortened in any of the following situations:

Amendment 32
Proposal for a regulation
Article 11 – paragraph -1 (new)

Text proposed by the Commission	*Amendment*
	-1. By ... [four months before the date of application of this Regulation], the Commission shall adopt, notwithstanding Article 10(5), a delegated act in accordance with Article 13, to amend Annexes I, II, III and IV, in order to adjust the amounts set out therein to the inflation rate published four months before ... [the date of application of this Regulation].

Amendment 33
Proposal for a regulation
Article 11 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) a change in the statutory tasks of the Agency leading to a significant change in its costs;	***deleted***

Amendment 34
Proposal for a regulation
Article 11 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) other relevant information, in particular on practical aspects for the execution of activities for which the Agency collects fees or charges.	***deleted***

Amendment 35
Proposal for a regulation
Article 11 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	By way of derogation from the first subparagraph, 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 shall 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 set out in Annex VI.

Amendment 36
Proposal for a regulation
Article 13 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Before adopting a delegated act, the Commission shall ***consult*** experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.	4. Before adopting a delegated act, the Commission shall ***take into account any opinions delivered by*** experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

Amendment 37
Proposal for a regulation
Article 17 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	The delegated act referred to in Article 11(-1) shall apply from ... [OP: please insert date of first day of the month following expiration of 6 months after entry into force].

Amendment 38
Proposal for a regulation
Annex I – point 1 – point 1.1 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
A fee of EUR ***55 200*** shall apply to any of the following requests:	A fee of EUR ***94 000*** shall apply to any of the following requests:

Amendment 39
Proposal for a regulation
Annex I – point 1 – point 1.1 – paragraph 2

Text proposed by the Commission	*Amendment*
The remuneration shall be EUR ***10 400*** for each of the two scientific advice co-ordinators.	The remuneration shall be EUR ***23 500*** for each of the two scientific advice co-ordinators.

Amendment 40
Proposal for a regulation
Annex I – point 1 – point 1.2 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
A fee of EUR ***44 700*** shall apply to any of the following requests:	A fee of EUR ***70 600*** shall apply to any of the following requests:

Amendment 41
Proposal for a regulation
Annex I – point 1 – point 1.2 – paragraph 2

Text proposed by the Commission	*Amendment*
The remuneration shall be EUR ***6 500*** for each of the two scientific advice co-ordinators.	The remuneration shall be EUR ***17 650*** for each of the two scientific advice co-ordinators.

Amendment 42
Proposal for a regulation
Annex I – point 1 – point 1.3 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
A fee of EUR ***37 200*** shall apply to any of the following requests:	A fee of EUR ***46 900*** shall apply to any of the following requests:

Amendment 43
Proposal for a regulation
Annex I – point 1 – point 1.3 – paragraph 2

Text proposed by the Commission	*Amendment*
The remuneration shall be EUR ***5 300*** for each of the two scientific advice co-ordinators.	The remuneration shall be EUR ***11 730*** for each of the two scientific advice co-ordinators.

Amendment 44
Proposal for a regulation
Annex I – point 6 – point 6.1

Text proposed by the Commission	*Amendment*
6.1. A fee of EUR 136 700 shall apply to the assessment carried out in the context of a procedure initiated under Article 5(3) of Regulation (EC) No 726/2004. Such fee shall be waived in full. The remuneration shall be EUR ***12 400*** for the rapporteur and EUR ***12 400*** for the co-rapporteur.	6.1. A fee of EUR 136 700 shall apply to the assessment carried out in the context of a procedure initiated under Article 5(3) of Regulation (EC) No 726/2004. Such fee shall be waived in full. The remuneration shall be EUR ***6 200*** for the rapporteur and EUR ***6 200*** for the co-rapporteur.

Amendment 45
Proposal for a regulation
Annex I – point 6 – point 6.2

Text proposed by the Commission	*Amendment*
6.2. A fee of EUR 262 400 shall apply to the assessment carried out in the context of a procedure initiated under Article 13 of Regulation (EC) No 1234/2008. Such fee shall be waived in full. The remuneration shall be EUR ***15 300*** for the rapporteur and EUR ***15 300*** for the co-rapporteur.	6.2. A fee of EUR 262 400 shall apply to the assessment carried out in the context of a procedure initiated under Article 13 of Regulation (EC) No 1234/2008. Such fee shall be waived in full. The remuneration shall be EUR ***7 650*** for the rapporteur and EUR ***7 650*** for the co-rapporteur.

Amendment 46
Proposal for a regulation
Annex I – point 6 – point 6.3

Text proposed by the Commission	*Amendment*
6.3. A fee of EUR 83 000 shall apply to the assessment carried out in the context of a procedure initiated under Article 29(4) of Directive 2001/83/EC. Such fee shall be waived in full. The remuneration shall be EUR ***2 800*** for the rapporteur and EUR ***2***	6.3. A fee of EUR 83 000 shall apply to the assessment carried out in the context of a procedure initiated under Article 29(4) of Directive 2001/83/EC. Such fee shall be waived in full. The remuneration shall be EUR ***1 400*** for the rapporteur and EUR ***1***

800 for the co-rapporteur.	***400*** for the co-rapporteur.

Amendment 47
Proposal for a regulation
Annex I – point 10 – point 10.1

Text proposed by the Commission	*Amendment*
10.1. A fee of EUR 143 200 shall apply to an application for evaluating and certifying the quality and non-clinical data pursuant to Article 18 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council[43] . Such fee shall be waived in full. The remuneration shall be EUR ***47 400*** for the rapporteur.	10.1. A fee of EUR 143 200 shall apply to an application for evaluating and certifying the quality and non-clinical data pursuant to Article 18 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council[43]. Such fee shall be waived in full. The remuneration shall be EUR ***23 700*** for the rapporteur.
[43] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).	[43] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

Amendment 48
Proposal for a regulation
Annex I – point 10 – point 10.2

Text proposed by the Commission	*Amendment*
10.2. A fee of EUR 95 200 shall apply to an application for evaluating and certifying only the quality data pursuant to Article 18 of Regulation (EC) No 1394/2007. Such fee shall be waived in full. The remuneration shall be EUR ***31 500*** for the rapporteur.	10.2. A fee of EUR 95 200 shall apply to an application for evaluating and certifying only the quality data pursuant to Article 18 of Regulation (EC) No 1394/2007. Such fee shall be waived in full. The remuneration shall be EUR ***15 750*** for the rapporteur.

Amendment 49
Proposal for a regulation
Annex I – point 11 – point 11.1

Text proposed by the Commission	*Amendment*

11.1. A fee of EUR 31 700 shall apply to an application for agreement of a paediatric investigation plan requested pursuant to Article 15 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR ***6 700*** for the rapporteur.	11.1. A fee of EUR 31 700 shall apply to an application for agreement of a paediatric investigation plan requested pursuant to Article 15 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR ***3 350*** for the rapporteur.

Amendment 50
Proposal for a regulation
Annex I – point 11 – point 11.2

Text proposed by the Commission	*Amendment*
11.2. A fee of EUR 17 600 shall apply to an application for a modification of an agreed paediatric investigation plan pursuant to Article 22 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR ***6 400*** for the rapporteur.	11.2. A fee of EUR 17 600 shall apply to an application for a modification of an agreed paediatric investigation plan pursuant to Article 22 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR ***3 200*** for the rapporteur.

Amendment 51
Proposal for a regulation
Annex I – point 11 – point 11.3

Text proposed by the Commission	*Amendment*
11.3. A fee of EUR 12 000 shall apply to an application for a product-specific waiver pursuant to Article 13 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR ***1 800*** for the rapporteur.	11.3. A fee of EUR 12 000 shall apply to an application for a product-specific waiver pursuant to Article 13 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR ***900*** for the rapporteur.

Amendment 52
Proposal for a regulation
Annex I – point 11 – point 11.4

Text proposed by the Commission	*Amendment*
11.4. A fee of EUR 8 000 shall apply to a request for compliance check with the paediatric investigation plan pursuant to Article 23 of Regulation (EC) No 1901/2006. Such fee shall be waived in	11.4. A fee of EUR 8 000 shall apply to a request for compliance check with the paediatric investigation plan pursuant to Article 23 of Regulation (EC) No 1901/2006. Such fee shall be waived in

full. The remuneration shall be EUR ***1 000*** for the rapporteur.	full. The remuneration shall be EUR ***500*** for the rapporteur.

Amendment 53
Proposal for a regulation
Annex I – point 12 – paragraph 2

Text proposed by the Commission	*Amendment*
A fee of EUR 16 800 shall apply to an application for the designation of an orphan medicinal product pursuant to Regulation (EC) No 141/2000. Such fee shall be waived in full. The remuneration shall be EUR ***1 500*** for the rapporteur.	A fee of EUR 16 800 shall apply to an application for the designation of an orphan medicinal product pursuant to Regulation (EC) No 141/2000. Such fee shall be waived in full. The remuneration shall be EUR ***750*** for the rapporteur.

Amendment 54
Proposal for a regulation
Annex II – point 7 – point 7.1

Text proposed by the Commission	*Amendment*
7.1. A fee of EUR 152 700 shall apply to an assessment carried out in the context of a procedure initiated under Article 54(8) of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR ***21 100*** for the rapporteur and EUR ***9 600*** for the co-rapporteur.	7.1. A fee of EUR 152 700 shall apply to an assessment carried out in the context of a procedure initiated under Article 54(8) of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR ***10 550*** for the rapporteur and EUR ***4 800*** for the co-rapporteur.

Amendment 55
Proposal for a regulation
Annex II – point 7 – point 7.2

Text proposed by the Commission	*Amendment*
7.2. A fee of EUR 209 300 shall apply to the assessment carried out in the context of a procedure initiated under Article 70(11) of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR ***29 200*** for the rapporteur and EUR ***12 900*** for the co-rapporteur.	7.2. A fee of EUR 209 300 shall apply to the assessment carried out in the context of a procedure initiated under Article 70(11) of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR ***14 600*** for the rapporteur and EUR ***6 450*** for the co-rapporteur.

Amendment 56
Proposal for a regulation
Annex II – point 7 – point 7.3

Text proposed by the Commission	*Amendment*
7.3. A fee of EUR 147 200 shall apply to the assessment carried out pursuant to Article 141(1), points (c) and (e), of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR ***17 500*** for the rapporteur and EUR ***7 700*** for the co-rapporteur.	7.3. A fee of EUR 147 200 shall apply to the assessment carried out pursuant to Article 141(1), points (c) and (e), of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR ***8 750*** for the rapporteur and EUR ***3 850*** for the co-rapporteur.

Amendment 57
Proposal for a regulation
Annex V – point 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Fee reductions granted to academia and the non-profit research sector
	1. A total reduction to the fee for protocol assistance and scientific advice requests on medicinal products shall be granted to applicants from academia or the academic sector.
	2. Applicants from academia or the academic sector which are not financed or managed by private profit organisations in the pharmaceutical sector (PPO), or have not concluded any operating agreements with any PPO concerning their sponsorship or participation to the specific research project for which a fee exemption is sought shall provide the following:
	(a) the Legal Entity Form (LEF) and the "founding document" (or any other suitable document provided during the application process);
	(b) evidence of the place of establishment, which may be the founding document or any other suitable document proving that the entity's seat is located in the Union,

Iceland, Liechtenstein or Norway;

(c) proof that the applicant is not under direct or indirect control of any PPO.

For the purposes of paragraph 2, point (c), control may, in particular, take either of the following forms:

(i) the direct or indirect holding of more than 50 % of the nominal value of the issued share capital in the applicant, or of a majority of the voting rights of the shareholders or associates of that applicant, or

(ii) the direct or indirect holding, in fact or in law, of decision-making powers in the applicant.

Upon receipt of a scientific advice request, the Agency shall check the applicant's declaration of eligibility and the acceptability of the declaration based on defined template as well as the supporting documents.

The Agency shall reserve its right to conduct an ex-post check and to request evidence confirming that the criteria for the fee exemption are fulfilled at any time before the adoption of the final advice letter.

3. Where reductions apply pursuant to point 1a, no remuneration shall be paid to the national competent authorities in Member States.

Amendment 58
Proposal for a regulation
Annex V – point 8 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
A fee reduction of ***20 %*** shall apply to the annual pharmacovigilance fee set out in section 3 of Annex III for the following medicinal products:	A fee reduction of ***30%*** shall apply to the annual pharmacovigilance fee set out in section 3 of Annex III for the following medicinal products:

Amendment 59
Proposal for a regulation
Annex VI – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The following information shall relate to each calendar year:	The following information shall relate to each calendar year ***and shall be made publicly available on the Agency's website***:

Amendment 60
Proposal for a regulation
Annex VI – paragraph 1 – point 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) number of fee reductions granted as per executive decisions set out in Article 6;

Amendment 61
Proposal for a regulation
Annex VI – paragraph 1 – point 6

Text proposed by the Commission	*Amendment*
(6) number of working hours spent by the rapporteur and the co-rapporteurs and experts contracted for the procedures of the expert panels on medical devices per procedures on the basis of the information provided to the Agency by the national competent authorities concerned. The procedures to be included shall be decided by the Management Board based on a proposal by the Agency.	(6) number of working hours spent by the rapporteur and the co-rapporteurs***, including hours spent by experts and others employed by the competent authorities of the Member States to assist them,*** and experts contracted for the procedures of the expert panels on medical devices per procedures on the basis of the information provided to the Agency by the national competent authorities concerned. The procedures to be included shall be decided by the Management Board based on a proposal by the Agency.

Amendment 62
Proposal for a regulation
Annex VI – paragraph 1 – point 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) any performance indicators relevant to scientific service fees or charges for administrative services levied in accordance with Article 4(1) and (2) of this Regulation;

Amendment 63
Proposal for a regulation
Annex VI – paragraph 1 – point 6 b (new)

Text proposed by the Commission	*Amendment*
	(6b) any additional relevant key performance indicators that impact the evolving workload of the Agency and national competent authorities in the Member States in the Union pharmaceutical regulatory framework, including procedures for the authorisation and supervision of medicinal products.

EXPLANATORY STATEMENT

The Commission Proposal lays down a framework for the European Medicines Agency's fee system. According to Regulation (EC) No 726/2004 , fees and charges are part of the revenues of the Agency, and subsequent amendments require the Commission to propose updates to the fee regulatory framework for medicinal products for human and veterinary use, where appropriate.

The current legal framework for EMA fees has indeed become complicated over the years, as EMA fees are currently governed by two separate regulations: Council Regulation (EC) No 297/95 on fees payable to the European Agency for the Evaluation of Medicinal Products , and Regulation (EU) No 658/2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use . In both regulations, the co-legislators have introduced the principle that revisions to the fees charged by the Agency should be based on an evaluation of the costs incurred by the Agency and the competent authorities in the Member States for the tasks carried out. In addition, there is a need to revise the legal structure governing EMA fees, particularly in light of additional activities the Agency is tasked with and which necessitate a re-evaluation of costs. Additionally, the rules applicable to the authorisation of veterinary medicinal products laid down in Regulation (EU) 2019/6 (VMP Regulation), which became applicable in January 2022, require further updates to the EMA fee framework.

The Commission Proposal seeks to simplify the current legal framework by amending Regulation (EU) 2017/745 and repealing the above mentioned regulations on EMA fees. The aim is to create a coherent piece of legislation that addresses the problems identified in the recent evaluation of the EMA fee system, which was published by the Commission in September 2019. One of the Proposal's main aims is to establish cost-based fee and remuneration amounts by evaluating the costs associated with the Agency's statutory tasks and the contributions made by competent authorities. Additionally, the Proposal seeks to simplify the fee structure as much as possible to streamline the system. Lastly, to ensure the fee system is adaptable for the future, the Proposal plans to make the fee system future-proof by introducing regulatory flexibility in the way it is adjusted, on an objective basis.

The Proposal maintains that fees should be based on an evaluation of costs and outlines the specific amounts of fees, charges, and remuneration in the relevant Annexes. Additionally, the Proposal introduces a monitoring and reporting framework, whereby the Agency collects and monitors data relating to the cost of activities and reports to the Commission. This includes the possibility for the EMA Executive Director to present a factual and quantified ad hoc special report based on monitoring and to recommend amendments to the fees, charges, and remunerations. The Commission would then be empowered to adopt delegated acts to modify the amounts in the annexes based on this ad-hoc report or the budgetary reporting of the Agency, a monitoring of inflation rates, a change in EU legislation with respect to tasks of the Agency, or new information on practical aspects of implementation of activities that attract a fee or a charge. The EMA Management Board is tasked with specifying technical arrangements to facilitate the application of the proposed regulation, such as payment methods of fees and charges as well as the mechanism for remunerating national competent authorities, subject to a positive opinion by the Commission.

Rapporteur's considerations

The Rapporteur welcomes the Commission Proposal as a way to establish a predictable and cost-based financing system for the EMA that is at the same time flexible and agile. The Rapporteur stresses that the costs should reflect hours-worked and appreciates the accounting exercise carried out by the Commission to better reflect the work involved in different procedures.

The EMA is to a large extent assisted by National Competent Authorities (NCAs) in carrying out its mandated tasks. The Union's supervisory system for medicinal products and medical devices therefore depends both on the expertise at central level in the Agency and on the willingness of the NCAs to assist the EMA as rapporteurs, co-rapporteurs and coordinators The fees must therefore truly reflect the costs to the NCAs and ensure world-class pharmaceutical supervision in the Union.

The Rapporteur notes that certain fees have changed significantly compared to the current tasks of the Agency. In particular, it is noted that the fees for scientific advice have been significantly reduced compared to the current system. There is a significant risk that the reduced fees and remuneration to the NCAs will lead to a reduction in the availability of scientific advice to the pharmaceutical industry and delays in the authorisation process. The Rapporteur therefore considers it necessary to maintain the current fees for scientific advice.

On the other hand, it is noted that the application fee for marketing authorisation of biosimilar products has increased significantly compared to the current level. As the time required for the evaluation of a biosimilar application may now be shorter than in the past, the Rapporteur considers it appropriate to slightly reduce this fee. In addition, the increase in the pharmacovigilance fee for generic medicines may reduce the incentive to bring generics to the market. The Rapporteur therefore considers it appropriate to slightly increase the reduction for this fee.

It is also noted that the EPSCO Council at its meeting on 14 March 2023 identified additional fees that will be reviewed as part of the legislative process. The Rapporteur stands ready to review any additional fees and remuneration as part of the legislative process and to ensure that all fees are set at a level that adequately finances the activities of the EMA and the NCAs.

Finally, the Rapporteur notes with concern that the first envisaged amendment of the Annexes due to inflation is only proposed after the end of the first full year of application of the Regulation. Given the high levels of inflation around the time of adoption of the Proposal, it will be necessary to update the fees as close as possible to actual inflation before the full application of the Regulation.

23.5.2023

LETTER OF THE COMMITTEE ON BUDGETS

Mr Pascal Canfin
Chair
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: Opinion on the Commission proposal 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 (2022/0417(COD))

Dear Mr Chair,

Under the procedure referred to above, the Committee on Budgets' Coordinators decided at their meeting of 31 January 2023 to adopt an opinion in the form of a letter. The committee adopted the opinion at its meeting[1] on 23/05/2023 and mandated me to convey the position set out below.

Background to the proposal

Article 67(3) of the founding Regulation[2] of the European Medicines Agency (EMA, the Agency) stipulates that fees and charges are part of the revenues of the Agency and Article 86a of that regulation, as amended by Regulation (EU) 2019/5[3], provides that the Commission is to put forward, as appropriate, legislative proposals with a view to update the regulatory

[1] The following were present for the final vote: Olivier Chastel (2nd Vice-Chair), Margarida Marques (3rd Vice-Chair), Niclas Herbst (4th Vice-Chair), Anna-Michelle Asimakopoulou, José Manuel Fernandes, Jan Olbrycht, Karlo Ressler, Rainer Wieland, (for EPP) and Asim Ademov (for EPP pursuant to Rule 209(7)), Pietro Bartolo, Pascal Durand, Eider Gardiazabal Rubial, Camilla Laureti (for S&D), Vlad Gheorghe, Moritz Körner, Nils Torvalds (for Renew), Rasmus Andresen, David Cormand, Alexandra Geese, Francisco Guerreiro (for Verts/ALE), Valentino Grant, Joachim Kuhs (for ID), Zbigniew Kuźmiuk, Bogdan Rzońca (for ECR) and Andor Deli (for NI)

[2] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[3] Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 4, 7.1.2019, p. 24).

framework for fees payable to the Agency in relation to medicinal products for human use and veterinary medicinal products (VMP).

EMA fees are currently laid down in two separate regulations: Council Regulation (EC) No 297/95 and Regulation (EU) No 658/2014 and both regulations convey the will of the co-legislators that revisions of fees levied by the Agency should be based on an evaluation of the costs of the Agency and the costs of the tasks carried out by competent authorities in Member States[4].

Position of the Committee on Budgets

The Committee on Budgets agrees with the Commission analysis that over the years, the legal framework governing EMA fees has become rather complex and welcomes therefore the proposed legislative simplification. In particular, it agrees that following changes introduced to the EMA Founding Regulation (EC) No 726/2004, to Regulation (EU) 2019/6[5] and to Regulation (EU) 2022/123[6], the provisions applicable to the fee system need to be adapted. 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 Committee on Budgets notes that following a thorough evaluation of the costs of the Agency and its various statutory tasks and the cost of the contributions of competent authorities of the Member States to its work, the Commission proposal is to provide for fee and remuneration amounts that are cost-based. It counts therefore on the Commissions analysis that the proposal does not have implications on the EU budget and its contribution to the EMA budget and that the proposal will not result in the need for additional resources to effectively manage the fee system.

In the event of new evidence or changes to this approach introduced by the co-legislators during the negotiations, the Committee on Budgets stands ready to assess the potential budgetary consequences.

Yours sincerely,

Johan Van Overtveldt

[4] Council Regulation (EC) No 297/95, Article 12.
[5] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43)
[6] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1)

PROCEDURE – COMMITTEE RESPONSIBLE

Title	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
References	COM(2022)0721 – C9-0426/2022 – 2022/0417(COD)
Date submitted to Parliament	13.12.2022
Committee responsible Date announced in plenary	ENVI 15.12.2022
Committees asked for opinions Date announced in plenary	BUDG 15.12.2022
Rapporteurs Date appointed	Cristian-Silviu Buşoi 3.2.2023
Discussed in committee	26.4.2023
Date adopted	27.6.2023
Result of final vote	+: 81 –: 2 0: 3
Members present for the final vote	Mathilde Androuët, Maria Arena, Margrete Auken, Marek Paweł Balt, Traian Băsescu, Aurélia Beigneux, Hildegard Bentele, Sergio Berlato, Alexander Bernhuber, Malin Björk, Delara Burkhardt, Pascal Canfin, Sara Cerdas, Maria Angela Danzì, Esther de Lange, Christian Doleschal, Bas Eickhout, Cyrus Engerer, Agnès Evren, Pietro Fiocchi, Heléne Fritzon, Malte Gallée, Gianna Gancia, Andreas Glueck, Catherine Griset, Martin Hojsík, Pär Holmgren, Jan Huitema, Yannick Jadot, Adam Jarubas, Karin Karlsbro, Petros Kokkalis, Joanna Kopcińska, Sylvia Limmer, Javi López, César Luena, Marian-Jean Marinescu, Fulvio Martusciello, Marina Mesure, Tilly Metz, Silvia Modig, Alessandra Moretti, Grace O'Sullivan, Nikos Papandreou, Francesca Peppucci, Stanislav Polčák, Jessica Polfjärd, Erik Poulsen, Nicola Procaccini, María Soraya Rodríguez Ramos, Maria Veronica Rossi, Ivan Vilibor Sinčić, Edina Tóth, Achille Variati, Mick Wallace, Emma Wiesner, Michal Wiezik, Tiemo Wölken, Anna Zalewska
Substitutes present for the final vote	João Albuquerque, Biljana Borzan, Milan Brglez, Catherine Chabaud, Christophe Clergeau, Antoni Comín i Oliveres, Rosanna Conte, Norbert Lins, Marisa Matias, Sara Matthieu, Max Orville, Manuela Ripa, Robert Roos, Massimiliano Salini, Christel Schaldemose, Róża Thun und Hohenstein, Sarah Wiener
Substitutes under Rule 209(7) present for the final vote	Franc Bogovič, Lena Düpont, Roman Haider, Jarosław Kalinowski, Rob Rooken, Bert-Jan Ruissen, Domènec Ruiz Devesa, Simone Schmiedtbauer, Sara Skyttedal, Romana Tomc
Date tabled	30.6.2023

FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

81	+
ECR	Sergio Berlato, Pietro Fiocchi, Joanna Kopcińska, Nicola Procaccini, Rob Rooken, Robert Roos, Bert-Jan Ruissen, Anna Zalewska
ID	Rosanna Conte, Gianna Gancia, Maria Veronica Rossi
NI	Antoni Comín i Oliveres, Maria Angela Danzì, Ivan Vilibor Sinčić, Edina Tóth
PPE	Traian Băsescu, Hildegard Bentele, Alexander Bernhuber, Franc Bogovič, Christian Doleschal, Lena Düpont, Agnès Evren, Adam Jarubas, Jarosław Kalinowski, Esther de Lange, Norbert Lins, Marian-Jean Marinescu, Fulvio Martusciello, Francesca Peppucci, Stanislav Polčák, Jessica Polfjärd, Massimiliano Salini, Simone Schmiedtbauer, Sara Skyttedal, Romana Tomc
Renew	Pascal Canfin, Catherine Chabaud, Andreas Glueck, Martin Hojsík, Jan Huitema, Karin Karlsbro, Max Orville, Erik Poulsen, María Soraya Rodríguez Ramos, Róża Thun und Hohenstein, Emma Wiesner, Michal Wiezik
S&D	João Albuquerque, Maria Arena, Marek Paweł Balt, Biljana Borzan, Milan Brglez, Delara Burkhardt, Sara Cerdas, Christophe Clergeau, Cyrus Engerer, Heléne Fritzon, Javi López, César Luena, Alessandra Moretti, Nikos Papandreou, Domènec Ruiz Devesa, Christel Schaldemose, Achille Variati, Tiemo Wölken
The Left	Malin Björk, Petros Kokkalis, Marisa Matias, Marina Mesure, Silvia Modig, Mick Wallace
Verts/ALE	Margrete Auken, Bas Eickhout, Malte Gallée, Pär Holmgren, Yannick Jadot, Sara Matthieu, Tilly Metz, Grace O'Sullivan, Manuela Ripa, Sarah Wiener

2	-
ID	Roman Haider, Sylvia Limmer

3	0
ID	Mathilde Androuët, Aurélia Beigneux, Catherine Griset

Key to symbols:
+ : in favour
- : against
0 : abstention