P9_TA(2023)0273

Fees and charges payable to the European Medicines Agency

Amendments adopted by the European Parliament on 12 July 2023 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)) [1]

(Ordinary legislative procedure: first reading)

(C/2024/4033)

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	(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***

[1] The matter was referred back for interinstitutional negotiations to the committee responsible, pursuant to Rule 59(4), fourth subparagraph (A9-0224/2023).

Text proposed by the Commission	*Amendment*
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.	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 Agency 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 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]) .	(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]), ***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]).
([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).	([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).	([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).	([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).	([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).	([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).

Text proposed by the Commission	*Amendment*
([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).	([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).	([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).	([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).	([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).	([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).	([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	(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

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

Text proposed by the Commission	*Amendment*
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.	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 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.	(17) The Management Board of the 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 Management Board for adoption, in order to ensure alignment with Union law and with overall policies of the Union.	(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 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	(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

Text proposed by the Commission	*Amendment*
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.	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

Text proposed by the Commission	*Amendment*
	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]).

Text proposed by the Commission	*Amendment*
(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. 26)***.

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 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.	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 ***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	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

Text proposed by the Commission	*Amendment*
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.	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	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

Text proposed by the Commission	*Amendment*
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.	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*** recommendations:	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 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 ***2 800*** for the co-rapporteur.	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 ***1 400*** 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.

Text proposed by the Commission	*Amendment*
(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 full. The remuneration shall be EUR ***1 000*** for the rapporteur.	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 ***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.

Text proposed by the Commission	*Amendment*
	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.