Council of the European Union

Brussels, 28 March 2023
(OR. en)

Interinstitutional File: 2022/0417(COD)

7350/1/23
REV 1

LIMITE

PHARM 41
SAN 134
MI 183
COMPET 192
CODEC 356
VETER 26

WORKING DOCUMENT

From:	Presidency
To:	Delegations
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council *- Revised Presidency compromise text*

Delegations will find in Annex a draft revised text as prepared by the Presidency on the above-mentioned subject to be examined at the meeting of the members of the Working Party on Pharmaceuticals and Medical Devices on 28 March 2023.

Changes compared to the Presidency compromise (7350/23) discussed at the working party on 27 March 2023 are in ***bold underlined and italics***. Deletions are in ~~strikethrough~~.

ANNEX

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), points (b) and (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

---

1 OJ C , , p. .

2 OJ C , , p. .

(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.

(2) The general objective of this Regulation is to contribute to providing a sound financial basis for the operations of the Agency by establishing cost-based fees and charges to be levied by the Agency, as well as cost-based remuneration to competent authorities of the Member States for the services they provide for the completion of the Agency's statutory tasks. **Such remuneration should be provided through a single remuneration amount per relevant type of fee, regardless of the Member State of origin of the competetent authority.** Cost-based fees should take into account an evaluation of costs of the Agency's activities and of the contributions of competent authorities of the Member States to its work. In addition, this Regulation aims to establish a single framework for a streamlined fee system of the Agency and to introduce regulatory flexibility for adjustment to that fee system in the future.

(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.

(4) Pursuant to Article 67(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council[3], the revenue of the Agency consists of a contribution from the Union, a contribution from third countries participating in the work of the Agency with which the Union has concluded international agreements for this purpose, fees paid by undertakings for obtaining and maintaining Union marketing authorisations and for services provided by the coordination group as regards the fulfilment of its tasks in accordance with Articles 107c, 107e, 107g, 107k and 107q of Directive 2001/83/EC of the European Parliament and of the Council[4], charges for other services provided by the Agency, and Union funding in the form of grants for participation in research and assistance projects, in accordance with the Agency's financial rules and with the provisions of the relevant instruments supporting the policies of the Union.

---

[3] 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 and veterinary use and establishing a European Medicines Agency, (OJ L 136 30.4.2004, p. 1).

[4] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(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[5], Directive 2001/83/EC, Regulation (EC) No 1901/2006 of the European Parliament and of the Council[6], Regulation (EC) No 141/2000 of the European Parliament and of the Council[7], Regulation (EC) No 1394/2007 of the European Parliament and of the Council[8], Commission Regulation (EC) No 2049/2005[9], Commission Regulation (EC) No 1234/2008[10], Regulation (EU) 2017/745 of the European Parliament and of the Council[11], Regulation (EC) No 470/2009 of the European

---

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 (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).

7 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).

8 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).

9 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).

10 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).

11 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).

Parliament and of the Council[12], Commission Regulation (EU) 2018/782[13], Commission Implementing Regulation (EU) 2021/1281[14] and Commission Regulation (EC) No 2141/96[15].

---

12 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).

13 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).

14 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).

15 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).

(6) Pursuant to Article 6(1) of Regulation (EC) No 726/2004, each application for the authorisation of a medicinal product for human use is to be accompanied by the fee payable to the Agency for the examination of that application. Pursuant to Article 43(1) of Regulation (EU) 2019/6, an application for a centralised marketing authorisation for a veterinary medicinal product is to be accompanied by the fee payable to the Agency for the examination of the application.

(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 should be auditable in accordance with Article 257 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[16].

---

16 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).

(8) Fees should be levied on marketing authorisation applicants and holders on a fair basis whereby the fee charged is proportionate to the assessment work. Therefore, for the purpose of charging some post-authorisation fees where products authorised by the Member States are included in the assessment performed by the Agency, a chargeable unit should be established, irrespective not only of the procedure under which the product has been authorised, namely under Regulation (EC) No 726/2004 or Regulation (EU) 2019/6 or Directive 2001/83/EC, but also of the way in which authorisation numbers are assigned by Member States or the Commission. For medicinal products for human use, that objective should be met by establishing the chargeable unit on the basis of the active substances and the pharmaceutical form of the products that are subject to the obligation to be registered in the database referred to in Article 57(1), second subparagraph , point (l), of Regulation (EC) No 726/2004, based on information from the list of all medicinal products for human use authorised in the Union referred to in Article 57(2), second subparagraph, of that Regulation. The active substances should not be taken into account when establishing the chargeable unit in respect of homeopathic medicinal products or herbal medicinal products. For veterinary medicinal products, the same objective of fairness and proportionality should be met by establishing the chargeable unit based on information contained in the Union product database referred to in Article 55(1) of Regulation (EU) 2019/6, such as the active substances, the pharmaceutical form and the strength of veterinary medicinal products, which are taken into account in the Product Identifier referred to under Data Field ID 3.2 in Annex III to Commission Implementing Regulation (EU) 2021/16[17], as well as the Permanent Identifier referred to under Data Field ID 3.1 in Annex III to that Implementing Regulation.

(9) In order to take into account all the marketing authorisations of medicinal products granted to marketing authorisation holders, the number of chargeable units corresponding to those authorisations should take into account the number of Member States in which the marketing authorisation is valid.

---

17 Commission Implementing Regulation (EU) 2021/16 of 8 January 2021 laying down the necessary measures and practical arrangements for the Union database on veterinary medicinal products (Union product database) (OJ L 7, 11.1.2021, p. 1).

(10) In order to take account of the variety of the statutory tasks of the Agency and of the rapporteurs and, where applicable, co-rapporteurs, fees should be levied per procedure, for costs relating to the assessment of medicinal products for human use and for veterinary medicinal products, and on an annual basis for costs incurred by the Agency for other ongoing activities that it carries out under its mandate that benefit marketing authorisation holders overall. For the purpose of simplification, the costs related to minor variations of Type I should equally be included in the annual fee on the basis of an average estimation.

(11) An annual fee for medicinal products authorised in accordance with the centralised procedure set out in Regulation (EC) No 726/2004 or the centralised procedure set out in Regulation (EU) 2019/6 should be levied to ensure coverage of the costs connected with the overall post-authorisation supervision and maintenance activities for those products. Those activities include the recording of the actual marketing of medicinal products authorised in accordance with Union procedures, the maintenance of marketing authorisation dossiers and of the various databases managed by the Agency, and activities contributing to a continuous follow-up of the risk-benefit balance of authorised medicinal products. They also comprise access to and analysis of Union-wide health data to support better decision-making throughout the product lifecycle on medicines with valid and reliable real-world evidence. The revenue from that annual fee should be used to fund an annual remuneration of the services of rapporteurs and co-rapporteurs from competent authorities of the Member States for their respective contributions to the supervision and maintenance activities of the Agency.

(12) A specific annual fee should be charged for medicinal products authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by the Member States in accordance with Regulation (EU) 2019/6 specifically for the pharmacovigilance activities carried out by the Agency that benefit marketing authorisation holders overall. Those activities relate to information technology, in particular maintenance of the EudraVigilance database referred to in Article 24(1) of Regulation (EC) No 726/2004, the Union product database referred to in Article 55(1) of Regulation (EU) 2019/6 and the Union pharmacovigilance database referred to in Article 74(1) of that Regulation, the monitoring of selected medical literature and the timely access to and analysis of Union-wide health data to support decision-making throughout the product lifecycle on medicines with valid and reliable real-world evidence.

(13) Charges should be levied for activities and services of an administrative nature, such as issuing certificates, that are not covered by a fee provided for in this Regulation, whereas fees levied by the Agency should correspond to services of a scientific nature provided by the Agency under its mandate, which contribute to the assessment relating to medicinal products and the maintenance of authorised products, including a continuous monitoring of the risk-benefit balance.

(14) Where a fee is reduced by 100 %, the theoretical full amount of that fee should still be provided for, for reasons of transparency and cost recovery.

(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.

(16) The market for veterinary medicinal products is smaller and more fragmented compared to the market for medicinal products for human use. Therefore, it is appropriate to provide for a reduction of the annual fee and of some specific fees for veterinary medicinal products.

(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.

(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 ***and a common format sufficiently flexible for financial information to be provided by the National Competent Authorities to the Agency***. 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.

(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.

(20) In line with the policy of the Union to support SMEs within the meaning of Commission Recommendation 2003/361/EC[18], fee reductions should apply to them. Such reductions should be established on a basis that takes due account of the ability of SMEs to pay. In order to ensure that the current framework for support to SMEs remains unchanged until a possible revision of Commission Regulation (EC) No 2049/2005[19], current post-authorisation fee reduction rates should be granted to SMEs. Furthermore, microenterprises should be exempted from all post-authorisation fees.

(21) Generic medicinal products for human use and generic veterinary medicinal products, medicinal products for human use and veterinary medicinal products authorised under the provisions relating to well-established medicinal use, homeopathic medicinal products for human use and homeopathic veterinary medicinal products, as well as herbal medicinal products for human use should be subject to a reduced annual pharmacovigilance fee, as those medicinal products generally have a well-established safety profile. However, in cases where such medicinal products are subject of any of the pharmacovigilance procedures carried out at Union level, the full fee should be charged in view of the work involved.

(22) In order to avoid a disproportionate administrative workload for the Agency, fee reductions and fee exemptions should be applied on the basis of a declaration of the marketing authorisation holder or applicant claiming to be entitled to such a measure. The submission of incorrect information in that respect should be discouraged by means of the application of a specific charge if the Agency establishes that such incorrect information has been submitted.

(23) For reasons of predictability and clarity, the amounts of the fees, charges and remuneration should be set in euro.

---

18 Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (2003/361/EC) (OJ L 124, 20.5.2003, p. 36).

19 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).

(24) The amounts of the fees and charges and the remuneration to competent authorities of the Member States should be adjusted, where appropriate, to take account of significant changes in costs, detected through cost monitoring, and to take account of inflation. For the purpose of taking into account the impact of inflation, the Harmonised Index of Consumer Prices published by Eurostat pursuant to Regulation (EU) No 2016/792 of the European Parliament and of the Council[20] should be used.

(25) In order to ensure swift adjustment of the structure and amounts of fees, charges and remuneration to competent authorities of the Member States to significant changes of costs or processes, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the relevant amounts and the activities subject to fees and charges and remuneration, on the basis of objective information related to costs or changes to the regulatory framework. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[21]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(26) In order to ensure cost recovery, the Agency should provide services by virtue of the tasks entrusted to it only after the corresponding fee or charge has been paid in its entirety. However, in accordance with Article 71, fourth subparagraph, of Commission Delegated Regulation (EU) 2019/715[22], in exceptional circumstances, a service may be provided without prior payment of the corresponding fee or charge.

---

20 Regulation (EU) 2016/792 of the European Parliament and of the Council of 11 May 2016 on harmonised indices of consumer prices and the house price index, and repealing Council Regulation (EC) No 2494/95 (OJ L 135, 24.5.2016, p. 11).

21 Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12.5.2016, p. 1).

22 Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council. (OJ L 122, 10.5.2019, p. 1).

(27) In accordance with Article 30 of Regulation (EU) 2022/123[23], the Agency provides, on behalf of the Commission, the secretariat for the expert panels designated in accordance with Regulation (EU) 2017/745. The provision in Article 106 of Regulation (EU) 2017/745 concerning the payment of fees for advice provided by expert panels should therefore be amended in order to allow the Agency to receive those fees, once such fees are established by the Commission in accordance with that Regulation.

(28) Since the objective of this Regulation, namely to ensure appropriate funding of Agency activities carried out at Union level, cannot sufficiently be achieved by the Member States but can rather, by reason of the scale of the measure, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter *and scope*

1. This Regulation lays down the following:

(a) the amounts of the fees and charges established on cost-based evaluation and levied by the European Medicines Agency (the 'Agency') for assessment activities relating to obtaining and maintaining a Union authorisation to market medicinal products for human use and veterinary medicinal products and for other services provided or tasks carried out by the Agency, as provided for in Regulations (EC) 726/2004 and (EU) 2019/6;

---

23 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).*

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

(c) the monitoring of costs of activities and services provided by the Agency and of costs for remuneration referred to in point (b).

2. Medicinal products which are authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC shall be excluded from the scope of this Regulation.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) 'chargeable unit in relation to medicinal products for human use' ('chargeable unit - human') means a unit defined by a unique combination of the following dataset derived from information on all medicinal products authorised in the Union held by the Agency**~~, except for the medicinal products authorised to be placed on the market under Article 126a of Directive 2001/83/EC~~**, and consistent with the obligation of marketing authorisation holders referred to in Article 57(2), points (b) and (c), of Regulation (EC) No 726/2004 to submit such information to the database referred to in Article 57(1), second subparagraph, point (l), of that Regulation:

(a) name of the medicinal product, as defined in Article 1, point (20), of Directive 2001/83/EC;

(b) marketing authorisation holder;

(c) the Member State in which the marketing authorisation is valid;

(d) active substance or a combination of active substances, except in the case of homeopathic medicinal products or herbal medicinal products, as defined in Article 1, points 5 and 30, respectively, of Directive 2001/83/EC;

(e) pharmaceutical form;

(2) 'chargeable unit in relation to veterinary medicinal products' ('chargeable unit - veterinary') means a unit defined by the unique combination of the following data fields contained in the Union product database established pursuant to Article 55(1) of Regulation (EU) 2019/6:

(a) the Permanent Identifier referred to under Data Field ID 3.1 in Annex III to Implementing Regulation (EU) 2021/16;

(b) the Product Identifier referred to under Data Field ID 3.2 in Annex III to Implementing Regulation (EU) 2021/16;

(3) 'medium-sized enterprise' means a medium-sized enterprise within the meaning of Recommendation 2003/361/EC;

(4) 'small enterprise' means a small enterprise within the meaning of Recommendation 2003/361/EC;

(5) 'microenterprise' means a microenterprise within the meaning of Recommendation 2003/361/EC;

(6) 'public health emergency' means a situation of public health emergency recognised by the Commission in accordance with Article **23(1) of Regulation (EU) 2022/2371 of the European Parliament and of the Council** ~~12(1) of Decision No 1082/2013/EU of the European Parliament and of the Council~~ [24].

---

[24] ~~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).~~ **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. 26–63**

Article 3

Types of fees and charges

The Agency may levy the following types of fees or charges:

(a) fees and charges for assessment procedures and services relating to medicinal products for human use, set out in Annex I;

(b) fees for and charges for assessment procedures and services relating to veterinary medicinal products, set out in Annex II;

(c) annual fees for authorised medicinal products for human use and for authorised veterinary medicinal products, set out in Annex III;

(d) other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices, set out in Annex IV.

Article 4

Additional fees and charges

1. The Agency may levy a scientific service fee for scientific services it provides if these services are not covered by another fee or charge provided for in this Regulation. The amount of the scientific service fee shall take into account the workload involved. Its minimum and maximum amount and, where relevant, the corresponding remuneration to the rapporteurs and, where relevant, co-rapporteurs, are set out in point 5 of Annex IV.

2. The Agency may levy a charge for administrative services it provides, at the request of a third party, if these services are not covered by another fee or charge provided for in this Regulation. The amount of the charge for administrative services shall take into account the workload involved. Its minimum and maximum amount are set out in point 6.4 of Annex IV.

3. Fees and charges levied pursuant to paragraphs 1 and 2 shall be set by the Management Board of the Agency following a favourable opinion by the Commission, in accordance with the procedure established under Article 8. The applicable amounts shall be published on the website of the Agency.

4. The Commission shall take into account any fees and charges levied in accordance with this Article in any revision of this Regulation.

Article 5

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

1. The Agency shall pay the remuneration referred to in Article 1(b) in accordance with the amounts of remuneration provided for in this Regulation.

2. Unless otherwise provided for in this Regulation, where fee reductions ***or waivers*** apply, the remuneration to competent authorities of the Member States payable in accordance with this Regulation shall not be reduced.

3. The remuneration to competent authorities of the Member States shall be paid in accordance with the written contract referred to in Article 62(3), first subparagraph, of Regulation (EC) No 726/2004. The remuneration shall be paid in euro. Any bank charges related to the payment of such remuneration shall be borne by the Agency. Detailed rules concerning the payment of remuneration shall be established by the Management Board of the Agency, in accordance with Article 8 of this Regulation.

Article 6

Reductions of fees and charges

1. The Agency shall apply the reductions set out in Annex V.

2. Where an assessment, an opinion or a service of the Agency is requested either by a Member State or by a Union institution, the Agency shall ***not levy the respective fee or charge to that Member State or Union institution.*** ~~waive the respective fee or charge, as applicable, in full~~.

3. ***Without prejudice to Article 5(2),*** ~~W~~***w***here the applicant or marketing authorisation holder may also benefit from another reduction provided for in Union legislation, only the reduction that is the most favourable to the applicant or marketing authorisation holder shall apply.

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 ***fee or charge*** ~~amount~~, in accordance with Article 8.

5. In exceptional circumstances ~~and for~~ **such as** 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, 1**4**~~5~~ and 1**5**~~6~~ 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.

Article 7

Payment of fees and charges

1. Fees and charges due under this Regulation shall be paid in euro.

2. Payment of the fees and charges shall be made after the payer has received a request for payment issued by the Agency specifying the deadline for payment.

3. Payment of the fees and charges shall be made by means of a transfer to the bank account of the Agency specified in the request for payment. Any bank charges related to that payment shall be borne by the payer.

4. The deadline for payment shall be considered to have been complied with only if the full amount has been paid in due time. The date on which the full amount of the payment is received in the bank account held by the Agency shall constitute the date on which the payment has been made.

Article 8

Working arrangements

The Management Board of the Agency shall, on a justified proposal from the Executive Director and following a favourable opinion from the Commission, establish working arrangements to facilitate the application of this Regulation, including payment methods of the fees and charges levied by the Agency**,** ~~and~~ the mechanism for payment of remuneration to competent authorities of the Member States under this Regulation***, a total or partial reduction in accordance with Article 6(4)*** **and a common format to be used by competent authorities of the Member States when providing to the Agency the financial information in accordance with Article 10(3)**.

Those arrangements shall be made publicly available on the Agency's website.

Article 9

Due date and measures in case of non-payment

1. The due dates of the fees or charges levied in accordance with this Regulation shall be specified in the working arrangements set out in accordance with Article 8 of this Regulation. Due account shall be taken of the deadlines of the assessment procedures provided for in Regulations (EC) No 726/2004 and (EU) 2019/6 and in Directive 2001/83/EC.

2. Where the payment of any fee or charge levied in accordance with this Regulation is overdue and without prejudice to the Agency's capacity to institute legal proceedings to ensure payment pursuant to Article 71 of Regulation (EC) No 726/2004, the Executive Director of the Agency may decide that the Agency will not provide the services or will not carry out the procedures to which the respective fee or charge relates, or that the Agency will suspend any ongoing or future services and procedures until the respective fee or charge has been paid, including relevant interest as provided for in Article 99 of Regulation (EU, Euratom) 2018/1046.

Article 10

Transparency and monitoring

1. The amounts set out in the annexes shall be published on the website of the Agency.

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.

3. Evidence of significant changes in the costs of services provided to the Agency, excluding any effect of inflationary adjustments and any costs for activities that do not constitute a service to the Agency, may be provided by competent authorities of the Member States responsible for medicinal products or by experts contracted for the procedures of the expert panels on medical devices to the Agency. Such information may be provided once per calendar year or less frequently, as a complement to the information provided in accordance with Annex VI. Such evidence shall be based on duly justified ~~and specific official~~ financial information on the nature and the extent of the financial impact on costs for services to the Agency. To that end, ~~the Agency may~~ **~~shall~~** ~~provide~~ ***the*** ~~a~~ common format facilitating comparison and consolidation**~~, as referred to~~** ***~~established~~*** **in** ***accordance with*** **Article 8** ***shall be used***. The competent authorities of the Member States and the experts contracted **to the Agency** for the procedures of the expert panels on medical devices ~~to the Agency~~ shall provide such information in the format provided by the Agency, together with any supporting information allowing to verify the correctness of the amounts submitted. The Agency shall review and aggregate that information and shall use it, in accordance with paragraph 6, as a source for the special report provided for in that paragraph.

4. Article 257 of Regulation (EU, Euratom) 2018/1046 shall apply to the information provided to the Agency in accordance with paragraph 3 of this Article and Annex VI to this Regulation.

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~~ **start at the date** [*OP: please insert date* ***of the 1 January of the calendar year following*** ~~*one year after*~~ *the date of application of this Regulation*]**, and shall thereafter take place** ~~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.

6. At the earliest on [*OP: please insert date ~~3~~ **1** years~~ after the date of application*] and at three-year intervals thereafter, the Executive Director of the Agency ~~may~~ **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 **adopted by the Management Board of the Agency** outlining, in an objective, fact-based and sufficiently detailed manner, justified recommendations **to**:

   (a) ~~to~~ increase or decrease the amount of any fee, charge or remuneration, following a significant change in the respective costs as identified, documented and justified in the report;

   (b) ~~to~~ amend any other element of the Annexes pertaining to the levying of fees and charges, including additional fees and charges referred to in Article 4;

   (c) ~~**to amend the information on practical aspects for the execution of activities**~~ ***adapt the specification of activities*** **for which the Agency collects fees or charges** ***to changing conditions and requirements.***

7. The special report referred to in paragraph 6 and the recommendations it contains shall be based on the following:

   (a) ~~continuous~~ monitoring of the information referred to in paragraphs 2 and 3 and of the cost of the activities necessary for the fulfilment of the statutory tasks of the Agency, aimed at identifying significant changes to the cost base of services and activities of the Agency;

   (b) objective and verifiable information**,** ~~and~~ ***including*** quantification**,** that directly supports the relevance of the recommended adjustments.

8. The Commission may request any clarification or further substantiation of the report and its recommendations, if considered necessary. Following such a request, the **Executive Director of** the Agency shall without undue delay provide the Commission with an updated version of the report ~~**as referred to** *adopted*~~ **in** ***accordance with*** **paragraph 6** which addresses any comments made and questions raised by the Commission.

9. The **time interval to 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:

(a) in the case of a public health emergency;

(b) in the case of a change of the legal mandate of the Agency;

(c) in the case there is ~~clear and compelling~~ evidence of significant changes in the costs or the cost-revenue balance of the Agency**:**

(d) in ***case there is evidence of significant changes in the costs*** ~~including costs~~ for cost-based remuneration to competent authorities of the Member States;

(~~d~~*e*) upon request of the Management Board of the Agency.

Article 11

Revision

1. The Commission is empowered to adopt delegated acts in accordance with Article 13 to amend the Annexes where it deems it justified in view of any of the following:

(a) a special report received by the Commission in accordance with Article 10(6);

(b) the findings from the monitoring of the inflation rate referred to in Article 10(5);

(c) a change in the statutory tasks of the Agency leading to a significant change in its costs;

(d) the budgetary reporting of the Agency;

~~(e) other relevant information, in particular on practical aspects for the execution of activities for which the Agency collects fees or charges.~~

2. Any revision of the fees and charges and of the remuneration paid to competent authorities of the Member States provided for in this Regulation shall be based on the Commission's evaluation of the Agency's costs and revenues and of the relevant costs of the services provided to the Agency by the competent authorities of the Member States**, taking into account also the sustainability of the Union regulatory network** ***including a fair and objective allocation of fees, charges and remuneration***.

3. ***In any revision of the Annexes,*** ~~T~~***t*****he** ***amounts of*** **remuneration paid to competent authorities of the Member States provided for in this Regulation shall be maintained as** ~~a~~ **single** ***amounts of*** **remuneration** ~~amount~~ ***irrespective of the Member State of the competent authority concerned*** ~~in any revision of the Annexes.~~

Article 12

Estimate of the Agency's budget

The Agency shall, when producing an estimate of revenue and expenditure for the following financial year in accordance with Article 67(6) of Regulation (EC) No 726/2004, include detailed information on income from each type of fees and charges and respective remuneration. In accordance with the typology of fees and charges set out in Article 3 of this Regulation, that information shall distinguish, respectively, between the following:

(a) medicinal products for human use and consultations on medical devices;

(b) veterinary medicinal products;

(c) annual fees, by type;

(d) other fees and charges, by type.

A breakdown by type of procedure may be provided by the Agency in an annex to the single programming document produced in accordance with Article 32(1) of Delegated Regulation (EU) 2019/715.

Article 13

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 11(1) shall be conferred on the Commission for a period of 5 years from *[tbc] 20[xx]*. The Commission shall draw up a report in respect of the delegation of power not later than ~~6~~ **9** months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.

3. The delegation of power referred to in Article 11(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 11(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or of the Council.

[*Article 14*

Amendment to Regulation (EU) No 2017/745

Article 106 of Regulation (EU) No 2017/745, paragraph 14 is replaced by the following:

‘14. The fees payable to EMA in accordance with the procedure under paragraph 13 of this Article related to the advice provided by expert panels for which EMA provides the secretariat in accordance with Article 30 of Regulation (EU) 2022/123 of the European Parliament and of the Council[25] shall be set in a transparent manner and on the basis of the costs for the services provided. The fees payable shall be reduced in the case of a clinical evaluation consultation procedure initiated in accordance with section 5.1, point (c), of Annex IX to this Regulation involving a manufacturer who is a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC.’.][26]

Article 15

Repeal

Regulations (EC) No 297/95 and (EU) No 658/2014 are repealed.

References to Regulation (EC) No 297/95 shall be construed as references to this Regulation and read in accordance with the correlation table in Annex VII to this Regulation.

---

25 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).

26 The Presidency is reflecting on the comment by one delegation on this article.

Article 16

Transitional provisions

1. This Regulation shall not apply to procedures and services for which the payable amount became due before *[OP: please insert date of application*].

2. With regard to annual fees set out in Annex III, this Regulation shall not apply **in the year *[OP: please insert calendar year of application]*** to products for which an annual fee has become due pursuant to Regulation (EC) No 297/95 or Regulation (EU) No 658/2014 ***in that year.*** ~~in the year *[OP: please insert calendar year of application]*~~.

Article 17

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*OP: please insert date of first day of the month following expiration of ~~6~~ **9** months after entry into force*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*