Council of the European Union

Brussels, 11 October 2023
(OR. en)

14057/23

Interinstitutional File: 2022/0417(COD)

PHARM 134
SAN 580
MI 841
COMPET 979
CODEC 1834
VETER 96

OUTCOME OF PROCEEDINGS

From:	General Secretariat of the Council
To:	Delegations
No. Cion doc.:	16070/22 + ADD 1-7 + COR 1
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 - *Letter to the Chair of the European Parliament Committee on the Environment, Public Health and Food Safety*

Following the meeting of the Permanent Representatives Committee on 11 October 2023, which endorsed the final compromise text with a view to agreement, delegations are informed that the Presidency sent the attached letter, together with its Annex, to the Chair of the European Parliament Committee on the Environment, Public Health and Food Safety.

ANNEX

Council of the European Union

SGS 23 / 004347

Brussels, 11/10/2023

Mr Pascal CANFIN
Chair of the Committee on the Environment, Public Health and Food Safety
European Parliament
Rue Wiertz 60
B-1047 BRUSSELS

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

Dear Mr CANFIN

Following the informal negotiations on this proposal between the representatives of the three institutions, today the Permanent Representatives Committee agreed with the final compromise text.

I am therefore now in a position to inform you that, should the European Parliament adopt its position at first reading, in accordance with Article 294(3) TFEU, in the exact form of the text set out in the Annex to this letter (subject to revision by the lawyer-linguists of the two institutions), the Council, in accordance with Article 294(4) TFEU, will approve the European Parliament's position and the act shall be adopted in the wording which corresponds to the position of the European Parliament.

On behalf of the Council, I also wish to thank you for your close cooperation which should enable us to reach agreement on this file at first reading.

Yours sincerely

Raúl FUENTES MILANI
Chair of the
Permanent Representatives Committee (Part 1)

Copy:
- Ms Stella KYRIAKIDES, Commissioner
- Mr Cristian-Silviu BUŞOI, European Parliament rapporteur

Rue de la Loi/Wetstraat 175 – 1048 Bruxelles/Brussel – Belgique/België
Tél./Tel. +32 (0)2 281 61 11

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 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 expertises 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, and to remunerate in a sustainable manner the fundamental contribution of competent authorities of Member States to the scientific assessments of the Agency.

(2) The general objective of this Regulation is to contribute to providing a sound financial basis for the operations of the Agency, thus contributing to high standards of quality and safety for medicinal products for human use and veterinary medicinal products and to ensuring high level of protection of public and animal health. It establishes 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 Union remuneration amount per relevant type of fee, regardless of the Member State of origin of the competent 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.

(2a) This Regulation regulates fees and charges, which are to be levied by the Agency, whereas the competence to decide on possible fees levied by the national competent authorities remains with the Member States. Applicants and marketing authorisation holders are not to be charged twice for the same activity.

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

(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 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).

(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 may entail additional budgetary needs in terms of staff and financial resources. The additional work should come with appropriate funding as provided for in Regulation (EC) No 726/2004 including to ensure that the Agency can carry out its obligations and transparency commitments.

(4b) Although the majority of its funding comes from fees, 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 Union regulatory framework.

(4c) The fees paid to the Agency 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 therefore monitor developments and determine the changes that would be necessary to the structure of remuneration of Member States.

(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 (EU) 2017/746 of the European Parliament and of the Council[12], Regulation (EC) No 470/2009 of the European Parliament and of the Council[13], Regulation (EU) 2022/123, Commission Regulation (EU) 2018/782[14],

---

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).

12 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance. OJ L 117, 5.5.2017, p. 176–332

13 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).

14 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).

Commission Implementing Regulation (EU) 2021/1281[15]and Commission Regulation (EC) No 2141/96[16].

(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 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[17].

---

[15] 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).

[16] 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).

[17] 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. This should not apply to medicinal products for human use authorised to be placed on the market under Article 126a of Directive 2001/83/EC. 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[18], 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.

[18] 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 and renewals are equally 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, minor variations of Type I and renewals 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 can 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. Fees for inspections should be set by distinct inspection. Each distinct inspection should trigger a separate fee.

(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). In addition to commercial entities, not for profit organisations and the academic sector can play an important role in the development of medicines. However, fees may present an important hurdle for those entities not engaged in an economic activity. For that reason they should equally benefit from fee reductions provided that they are not owned or controlled by a commercial undertaking and have not concluded any agreements with any commercial undertaking concerning sponsorship or participation in the development of the medicinal product giving the commercial undertaking any rights to the final product. It is also appropriate to provide for reductions of the fees 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 and to closely monitor associated costs for competent authorities of the Member States and the Agency, in order to support the objectives of Regulation (EU) 2019/6. Therefore, the adjustment to inflation applied to the amounts in Annex II takes into account only fifty percent of the annual inflation rates for the calendar years 2021 and 2022 and of the forecast of the inflation for 2023.

(17) The Management Board of the Agency should be empowered to provide further fee or charge reductions for duly justified reasons of protection of public and animal health or for justified reasons for the support of specific types of products or applicants. 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.

(17a) It is recognised that improved access to information contributes to public awareness, gives the public the opportunity to express its observations and enables authorities to take due account of those observations. The general public should therefore have access to information on the granting by the Agency of reductions and/or waivers of the applicable fees and/or charges, after the removal of any commercially confidential information by the Agency where relevant as well as a breakdown of remunerated amounts to each Member State competent authority per activity. Regulation (EC) No 1049/2001[19] of the European Parliament and of the Council gives the fullest possible effect to the right of public access to documents and lays down the general principles and limits on such access. Nonetheless, certain public and private interests, such as personal data and commercially confidential information, should be protected by way of exceptions in accordance with Regulation (EC) No 1049/2001.

(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, 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 and what constitutes a distinct inspection, for each type of inspection. 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] 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).

(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 as defined in Commission Recommendation 2003/361/EC[20], fee reductions should apply to them. Such reductions are to be established on a basis that takes due account of the ability of SMEs to pay. In order to ensure consistency of the framework for support to SMEs with Commission Regulation (EC) No 2049/2005[21], current post-authorisation fee reduction rates should be granted to SMEs. Furthermore, microenterprises should be exempted from all post-authorisation fees.

[20] 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).

[21] 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).

(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 is to 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 are set in euro.

(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[22] should be used. The first adjustment to inflation should take into account the annual inflation rates for each calendar year following the inflation adjustment already applied to the amounts in the Annexes, up to the year 2024 included. The inflation rate already applied to the amounts in the annexes for 2023 is 5.9 %, which corresponds to the projected annual inflation for 2023 and 1.2% for 2024. The first adjustment to inflation should therefore also take into account the correction needed in view of the final annual inflation rate for 2023 and 2024.

[22] 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).

(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. This information is provided mainly via a special report adopted by the Management Board of the Agency, which contains justified recommendations to increase or decrease the amount of any fee, charge or remuneration, amend the Annexes, including on the basis of changes in the statutory tasks of the Agency, add fees and adapt the specification of activities for which the Agency collects fees or charges to changing conditions and requirements. 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[23]. 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. If a change of the fees were to result in an increased share on the side of the Agency, special consideration should be given that the aim of a cost-based, balanced, objective and fair distribution of fees between the Agency and the competent authorities of the Member States is maintained.

(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[24], in exceptional circumstances, a service may be provided without prior payment of the corresponding fee or charge.

---

[23] 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).

[24] 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[25], 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 charge 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.

28a) In order to allow for the prompt application of the measures provided for in this Regulation, it should enter into force on the day following that of its publication in the Official Journal of the European Union.

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;

[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).*

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

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, 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[26].

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.

[26] 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 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. Member States or Union institutions that have requested an assessment, an opinion or a service of the Agency shall not be subject to a fee or charge under this Regulation.

3. Without prejudice to Article 5(2), where 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 authrisation 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 types of applicants, selected for duly justified reasons, the Management Board of the Agency may grant, following a favourable opinion from the Commission, a total or partial reduction of the applicable fee or charge, in accordance with Article 8. The Agency shall make information on such reductions publicly available on the Agency's website, after deletion of all information of a commercially confidential nature.

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, 14 and 15 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 reductions, including the reasons for the reduction, publicly available on the Agency's website, after deletion of all information of a commercially confidential nature.

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, 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, based on a transparent methodology, to be used by competent authorities of the Member States when providing to the Agency the financial information in accordance with Article 10(3).

The Management Board of the Agency shall also define in the working arrangements the scope of a distinct inspection, for each type of inspection. This shall include, where relevant, the medicinal product concerned, the site concerned, the activity concerned and the inspection team concerned.

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

Article 9

Due date and measures in case of non-payment

1. By *[OP: please insert date of application of this Regulation]* 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, in a timely manner 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 may include other relevant information, such as information related to the practical aspects of carrying out the activities of the Agency, and a cost breakdown related to the previous calendar year and to a forecast for the following calendar year. The Agency shall also publish in a timely manner, an overview of that information in its annual activity report.

2a. Yearly revenue received per type of fees and charges, including where reductions and waivers have been granted, and where fees and charges are due but not yet received by the Agency shall be published in its annual activity report.

The Agency's annual activity report shall furthermore list a detailed breakdown of all remunerated amounts paid to national authorities for their work

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 financial information on the nature and the extent of the financial impact on costs for services to the Agency. To that end, the common format facilitating comparison and consolidation, 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 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 shall start at the date [*OP: please insert date of application of this Regulation*], shall cover the period since the last inflation adjustment and shall thereafter take place 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 12 months after the date of application*] and at three-year intervals thereafter, the Executive Director of the Agency shall 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) 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) 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) adapt the specification of activities for which the Agency collects fees or charges to changing conditions and requirements.

   (d) increase, decrease or introduce any fee, charge or remuneration following a change in the statutory tasks of the Agency leading to a significant change in its costs;

6b. The special report shall be made publicly available in a timely manner on the Agency's website.

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

   (a) 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, 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 adopted in accordance with paragraph 6, which addresses any comments made and questions raised by the Commission.

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:

   (a) in case of a public health emergency;

   (b) in case of a change in the statutory tasks of the Agency;

   (c) in case there is 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 for cost-based remuneration to competent authorities of the Member States;

Article 11

Revision

1. The Commission is empowered to adopt delegated acts in accordance with Article 13 to amend the Annexes where 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);

   (d) the budgetary reporting of the Agency;

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 full costs of the services provided to the Agency in the scope of this Regulation by the competent authorities of the Member States, taking into account also the impact of such services on the sustainability of the operations of the Agency, including the services provided to the Agency by the National Competent Authorities, and a fair and objective allocation of fees, charges and remuneration.

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

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

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 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 established in accordance with the procedure under paragraph 13 of this Article 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 point (c), of Section 5.1 of Annex IX involving a manufacturer who is a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC.

The fees related to the advice provided by expert panels are payable to EMA pursuant to Article 30, point (f) of Regulation (EU) 2022/123 of the European Parliament and of the Council**.**[27]

The fees related to the advice provided by expert laboratories are payable to the Commission.’.

[27] 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).

Article 14a

Amendment to Regulation (EU) 2022/123

Article 30, point (f) of Regulation (EU) 2022/123, is replaced by the following:

‘(f) charge fees in accordance with Article 106(14) of Regulation (EU) 2017/745 and ensure that remuneration and expenses are provided to experts in accordance with implementing acts adopted by the Commission pursuant to Article 106(1) of Regulation (EU) 2017/745.’.

Article 15

Repeal

Regulations (EC) No 297/95 and (EU) No 658/2014 are repealed as of [*OP: please insert date of application of this Regulation*].

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.

Article 16

Transitional provisions

This Regulation shall not apply to annual fees, procedures and services for which the amount became due pursuant to Regulation (EC) No 297/95 or Regulation (EU) No 658/2014 before *[OP: please insert date of application*].

Article 17

Entry into force and date of application

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

It shall apply from 1 January 2025.

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*

ANNEX I

Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use

1. **Scientific advice provided by the Agency in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004**

1.1 A fee of EUR 98 400 shall apply to any of the following requests:

(a) a request on quality, non-clinical and clinical development;

(b) a request on quality and clinical development;

(c) a request on non-clinical and clinical development;

(d) a request on qualification of novel methodologies.

The remuneration shall be EUR 24 600 for each of the two scientific advice co-ordinators.

1.2 A fee of EUR 73 900 shall apply to any of the following requests:

(a) a request on clinical development;

(b) a request on quality and non-clinical development;

(c) a request on quality development and bioequivalence studies for generic medicinal products as defined in Article 10(2), point (b) of Directive 2001/83/EC.

The remuneration shall be EUR 18 500 for each of the two scientific advice co-ordinators.

1.3. A fee of EUR 51 900 shall apply to any of the following requests:

a) a request on quality development;

b) a request on non-clinical development;

c) a request on bioequivalence studies for generic medicinal products as defined in Article 10(2), point (b), of Directive 2001/83/EC.

The remuneration shall be EUR 12 300 for each of the two scientific advice co-ordinators

3. **Authorisation to market a medicinal product falling within the scope of Regulation (EC) No 726/2004**

3.1. A fee of EUR 865 200 shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 8(3) of Directive 2001/83/EC when the applicant claims a new active substance. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 272 200 for the rapporteur, EUR 237 100 for the co-rapporteur and EUR 25 500 for the PRAC-rapporteur.

3.2. A fee of EUR 690 700 shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 8(3) of Directive 2001/83/EC when the applicant claims a known active substance. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 191 600 for the rapporteur, EUR 179 500 for the co-rapporteur and EUR 18 600 for the PRAC-rapporteur.

3.3 A fee of EUR 571 100 shall apply to an application for a fixed combination medicinal product pursuant to Article 10b of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 177 200 for the rapporteur, EUR 104 000 for the co-rapporteur and EUR 14 100 for the PRAC-rapporteur.

3.4. A fee of EUR 732 400 shall apply to an application for a biological medicinal product which is similar to a reference biological product pursuant to Article 10(4) of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 296 200 for the rapporteur , EUR 190 000 for the co-rapporteur and EUR 24 300 for the PRAC-rapporteur.

3.5. A fee of EUR 780 900 shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 10a of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 201 200 for the rapporteur , EUR 187 100 for the co-rapporteur and EUR 19 400 for the PRAC-rapporteur.

3.6. A fee of EUR 177 900 shall apply to:

an application for a marketing authorisation for a generic medicinal product pursuant to Article 10(1) of Directive 2001/83/EC.

That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 78 300 for the rapporteur and EUR 3 900 for the PRAC-rapporteur.

3.6a A fee of EUR 172 800 shall apply to:

an application based on informed consent for a marketing authorisation for a medicinal product pursuant to Article 10c of Directive 2001/83/EC.

That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 50 400 for the rapporteur and EUR 2 500 for the PRAC-rapporteur.

3.7. A fee of EUR 426 100 shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 10(3) of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 111 600 for the rapporteur, EUR 111 600 for the co-rapporteur and EUR 11 200 for the PRAC-rapporteur.

3.8. A fee of EUR 33 300 shall apply to the second and to each subsequent application for a marketing authorisation submitted pursuant to Article 10(1), (3) or (4) of Directive 2001/83/EC on usage patent grounds where the reference medicinal product is subject to a usage patent. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 8 500 for the rapporteur and EUR 1 300 for the co-rapporteur.

3a. Scientific opinions and assessments prior to potential submission of an application for a marketing authorisation

3a.1. The amounts of the fees and the amounts of the corresponding remuneration laid down in point 3 shall apply [by analogy] to any of the following:

(a) an opinion on a medicinal product for compassionate use pursuant to Article 83 of Regulation (EC) No 726/2004;

(b) an assessment on an on-going basis of data packages of particulars and documents submitted to the Agency by a prospective applicant prior to a formal submission of an application for a marketing authorisation falling within the scope of Regulation (EC) No 726/2004.

3a.2. The amounts applicable pursuant to point 3a.1. (a) and 3a.1. (b) shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application.

3a.3. An additional fee and additional remuneration shall apply to the assessment set out in point 3a.1. (b). The amount of that additional fee and the amounts of the corresponding additional remuneration shall be equal to 15 (fifteen) percent of the respective amounts for an application for an authorisation to market a medicinal product falling within the scope of Regulation (EC) No 726/2004 that are laid down in point 3.

3a.4. In the event of multiple submissions of data packages submitted by the same prospective applicant for the same product, the fees applicable pursuant to point 3a.1. (b) and point 3a.3. shall only be charged once [,when the first data package is submitted].

3a.5. The respective amounts applicable pursuant to point 3a.1. (a) and 3a.1. (b) shall be deducted from the respective fee and from the respective remuneration to competent authorities of the Member States payable for a marketing authorisation application for the same product, where such application is submitted by the same applicant.

4. **Extension of a marketing authorisation within the meaning of Annex I to Commission Regulation (EC) No 1234/2008[28]**

4.1. A fee of EUR 168 500 shall apply to an application for an extension of a marketing authorisation requiring only chemical, pharmaceutical or biological documentation and for which no clinical or non-clinical data are submitted. That fee shall cover a single pharmaceutical form and a single associated strength. The remuneration shall be EUR 56 700 for the rapporteur and EUR 33 300 for the co-rapporteur.

4.2. A fee of EUR 196 800 shall apply to an application for an extension of a marketing authorisation not covered by point 4.1. That fee shall cover a single pharmaceutical form and a single associated strength. The remuneration shall be EUR 69 300 for the rapporteur and EUR 39 100 for the co-rapporteur.

4.3. Without prejudice to points 4.1 and 4.2, a fee of EUR 33 300 shall apply to each application for extension of a marketing authorisation on the basis of an application submitted under Article 10(1), (3) or (4) of Directive 2001/83/EC on usage patent grounds as referred to in point 3.8 of this Annex. The remuneration shall be EUR 8 500 for the rapporteur and EUR 1 300 for the co-rapporteur.

5. **Major variation of type II to the terms of a marketing authorisation in accordance with Commission Regulation (EC) No 1234/2008**

5.1. A fee of EUR 163 200 shall apply to an application for a major variation of type II as defined in Article 2(3) of Regulation (EC) No 1234/2008 ('major variation of type II') for an addition of a new therapeutic indication or modification of an approved indication. The remuneration shall be EUR 57 300 for the rapporteur and EUR 57 300 for the co-rapporteur.

5.2. A fee of EUR 22 000 shall apply to an application for a major variation of type II not covered by point 5.1. The remuneration shall be EUR 14 600 for the rapporteur.

[28] 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)

5.3. For each application for a major variation of type II that is grouped in a single application pursuant to Article 7 of Regulation (EC) No 1234/2008, the corresponding fee shall be charged as set out in points 5.1 and 5.2. Remuneration shall be paid in accordance with those points.

5.4. Where a work-sharing application pursuant to Article 20 of Regulation (EC) No 1234/2008 includes more than one centrally authorised product, the fees and remuneration specified in points 5.1 and 5.2 of this Annex shall apply to each variation of the first centrally authorised product, whereas a charge of EUR 900 shall apply to each variation of the second and subsequent centrally authorised product included in the application.

6. **Referrals and scientific opinions pursuant to Article 5(3) of Regulation (EC) No 726/2004**

6.1. A fee of EUR 163 900 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 15 500 for the rapporteur and EUR 15 500 for the co-rapporteur.

6.2. A fee of EUR 313 500 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 19 200 for the rapporteur and EUR 19 200 for the co-rapporteur.

6.3. A fee of EUR 98 900 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 3 500 for the rapporteur and EUR 3 500 for the co-rapporteur.

6.4. A fee of EUR 153 100 shall apply to the assessment carried out in the context of a procedure initiated under Article 30 of Directive 2001/83/EC. The remuneration shall be EUR 8 500 for the rapporteur and EUR 8 500 for the co-rapporteur.

6.5. A fee of EUR 216 200 shall apply to the assessment carried out in the context of a procedure initiated under Article 31 of Directive 2001/83/EC where the procedure is initiated as a result of the evaluation of data other than data relating to pharmacovigilance. The remuneration shall be EUR 15 500 for the rapporteur and EUR 15 500 for the co-rapporteur.

6.6. A fee of EUR 206 600 shall apply to the assessment carried out in accordance with a procedure initiated under Article 20 of Regulation (EC) No 726/2004 where that procedure is initiated as a result of the evaluation of data other than data relating to pharmacovigilance. The remuneration shall be EUR 21 900 for the rapporteur and EUR 21 900 for the co-rapporteur.

6.7. For an assessment carried out in the context of a procedure initiated as a result of the evaluation of pharmacovigilance data under Article 31(1), second subparagraph, Article 31(2) and Articles 107i, 107j and107k of Directive 2001/83/EC or under Article 20(8) of Regulation (EC) No 726/2004, the following fees shall apply:

6.7.1. a fee of EUR 219 900 where one active substance or combination of active substances and one marketing authorisation holder are included in the assessment. The remuneration shall be EUR 28 600 for the rapporteur and EUR 28 600 for the co-rapporteur;

6.7.2. a fee of EUR 310 000 where two or more active substances or combinations of active substances and one marketing authorisation holder are included in the assessment. The remuneration shall be EUR 32 900 for the rapporteur and EUR 32 900 for the co-rapporteur;

6.7.3. a fee of EUR 377 100 where one or two active substances or combinations of active substances and two or more marketing authorisation holders are included in the assessment. The remuneration shall be EUR 40 100 for the rapporteur and EUR 40 100 for the co-rapporteur;

6.7.4. a fee of EUR 511 600 where more than two active substances or combinations of active substances and two or more marketing authorisation holders are included in the assessment. The remuneration shall be EUR 54 400 for the rapporteur and EUR 54 400 for the co-rapporteur.

6.8. Where two or more marketing authorisation holders are involved in the procedures referred to in points 6.4, 6.5, 6.6 and 6.7, the amount payable by each marketing authorisation holder shall be calculated by the Agency in two steps, as follows:

(a) by dividing the total amount of the fee among the marketing authorisation holders proportionally to the number of chargeable units-human corresponding to products included in the procedure which are held by each of those marketing authorisation holders;

(b) by subsequently applying, where relevant, the fee reduction laid down in Annex V.

7. **Evaluation of traditional herbal medicinal products in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004**

A fee of EUR 34 900 shall apply to a request for scientific advice from the Committee on Herbal Medicinal Products related to traditional herbal medicinal products. The remuneration shall be EUR 4 500 for the rapporteur.

8. **Certification of compliance with Union legislation for a plasma master file (PMF) in accordance with Part III of Annex I of Directive 2001/83/EC**

8.1. A fee of EUR 69 000 shall apply to an application for review of a PMF and its initial certification pursuant to Part III, point 1.1 of Annex I to Directive 2001/83/EC. The remuneration shall be EUR 10 800 for the rapporteur and EUR 10 800 for the co-rapporteur.

8.2. A charge of EUR 6 900 shall apply to the issuing of an initial PMF certification where it is submitted simultaneously with an application for a marketing authorisation for a medicinal product under the centralised procedure. The PMF documentation shall be evaluated within the centralised marketing authorisation application.

8.3. A fee of EUR 12 800 shall apply to an application for review and certification of a major variation of type II to the PMF pursuant to Regulation (EC) No 1234/2008. The remuneration shall be EUR 2 000 for the rapporteur and EUR 2 000 for the co-rapporteur.

For two or more major variations of type II grouped in a single application pursuant to Regulation (EC) No 1234/2008, the fee and remuneration laid down in point 8.4 of this Annex shall apply.

8.4. A fee of EUR 20 400 shall apply for an application for review and annual re-certification of a PMF which may include any variation pursuant to Regulation (EC) No 1234/2008 submitted simultaneously with the application for a PMF annual re-certification. The remuneration shall be EUR 2 400 for the rapporteur and EUR 2 400 for the co-rapporteur.

9. **Certification of compliance with Union legislation for a vaccine antigen master file (VAMF) in accordance with Part III of Annex I of Directive 2001/83/EC**

9.1. A fee of EUR 69 000 shall apply for an application for review of a VAMF and its initial certification not submitted simultaneously with a new application for marketing authorisation under the centralised procedure pursuant to Part III, point 1.2 of Annex I to Directive 2001/83/EC. The remuneration shall be EUR 10 800 for the rapporteur and EUR 10 800 for the co-rapporteur.

9.2. In the case of a group of antigens aimed at preventing a single infectious disease, a fee shall be charged for the VAMF application for one antigen and remuneration shall be paid pursuant to point 9.1. The second and subsequent VAMF applications submitted simultaneously for antigens as part of the same group shall be charged a fee of EUR 9 500 per VAMF. The maximum total amount charged by the Agency for VAMF applications submitted simultaneously for antigens as part of the same group shall not exceed EUR 82 800. In that case, the remuneration per each second and subsequent VAMF shall be EUR 2 400 for the rapporteur and EUR 2 400 for the co-rapporteur.

9.3. A charge of EUR 6 900 shall apply to an application for issuing each VAMF certification where it is submitted simultaneously with a new application for marketing authorisation under the centralised procedure.

9.4. A fee of EUR 12 800 shall apply to an application for review and certification of a major variation of type II to the VAMF pursuant to Regulation (EC) No 1234/2008. The remuneration shall be EUR 1900 for the rapporteur and EUR 1900 for the co-rapporteur.

For each major variation of type II that is grouped in a single application made pursuant to Regulation (EC) No 1234/2008 a fee shall be charged as set out in the first subparagraph of this point.

10. **Certification of quality and non-clinical data relating to advanced therapy medicinal products (ATMPs) developed by small and medium-sized enterprises (SMEs) in accordance with Regulation (EC) No 1394/2007 of the European Parliament and of the Council**

10.1 A fee of EUR 173 100 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[29]. Such fee shall be waived in full. The remuneration shall be EUR 59 400 for the rapporteur.

10.2. A fee of EUR 115 100 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 39 500 for the rapporteur.

[29] 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).

11. **Paediatric applications in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council[30]**

11.1. A fee of EUR 38 100 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 8 400 for the rapporteur.

11.2. A fee of EUR 21 300 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 8 000 for the rapporteur.

11.3. A fee of EUR 14 400 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 2 300 for the rapporteur.

11.4. A fee of EUR 9 600 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 1 300 for the rapporteur.

12. **Orphan designation in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council[31]**

A fee of EUR 20 000 shall apply to an application for or reassessment of 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 1 900 for the rapporteur.

---

[30] 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).

[31] 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).

13. **Scientific opinion on the evaluation of medicinal product intended exclusively for markets outside the Union**

A fee and corresponding remuneration as specified in points 1 to 5 of this Annex and sections 1, 3, 4 and 5 of Annex IV and points 6.1, 6.2 and 6.4 thereof shall apply for an application for a scientific opinion following the evaluation of a medicinal product intended exclusively for markets outside the Union pursuant to Article 58 of Regulation (EC) No 726/2004.

14. **Periodic safety update reports**

14.1 A fee of EUR 34 100 shall apply per procedure for the assessment of periodic safety update reports referred to in Articles 107e and 107g of Directive 2001/83/EC and in Article 28 of Regulation (EC) No 726/2004. The remuneration shall be EUR 17 300 for the rapporteur.

14.2. Where two or more marketing authorisation holders are subject to the obligation to submit periodic safety update reports in the context of the procedures referred to in point 14.1, the amount payable by each marketing authorisation holder shall be calculated by the Agency in two steps, as follows:

(a) by dividing the total amount of the fee among the marketing authorisation holders proportionally to the number of chargeable units-human corresponding to products included in the procedure which are held by each of those marketing authorisation holders;

(b) by subsequently applying, where relevant, the fee reduction laid down in point 1 of Annex V.

15. **Post-authorisation safety studies**

15.1. A fee of EUR 104 700 shall apply to an assessment carried out under Articles 107n to 107q of Directive 2001/83/EC and Article 28b of Regulation (EC) No 726/2004 of post-authorisation safety studies as referred to in Article 21a, point (b), or Article 22a(1), point (a), of Directive 2001/83/EC, or in Article 9(4), point (cb), or Article 10a(1), point (a), of Regulation (EC) No 726/2004, that are conducted in more than one Member State.

15.2 The fee shall be charged in two instalments, as follows:

15.2.1. EUR 53 500 shall be due on the date of the start of the procedure for the assessment of the draft protocol referred to in Article 107n of Directive 2001/83/EC; the remuneration shall be EUR 22 300 for the rapporteur.

15.2.2 EUR 53 500 shall be due at the date of the start of the procedure for the assessment of the final study report, as referred to in Article 107p of Directive 2001/83/EC, by the Pharmacovigilance Risk Assessment Committee; the remuneration shall be EUR 22 300 for the rapporteur.

15.3. Where the obligation to conduct a post-authorisation safety study is imposed by the Commission on more than one marketing authorisation holder, the same concerns apply to more than one medicinal product and the marketing authorisation holders concerned conduct a joint post-authorisation safety study, the Agency shall calculate the amount payable by each marketing authorisation holder in two steps, as follows:

(a) by evenly dividing the total amount of the fee among those marketing authorisation holders;

(b) by subsequently applying the fee reduction as set out in point 1 of Annex V, where relevant.

15.4 Marketing authorisation holders who are charged the fee under this point shall be exempted from the payment of any other fee charged by the Agency or competent authorities of the Member State for the submission of the studies referred to in paragraph 15.1.

ANNEX II

Fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products

1. **Scientific advice in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004**

1.1. A fee of EUR 35 100 shall apply to any of the following requests:

(a) a request on quality, safety and clinical development;

(b) a request on quality and clinical development;

(c) a request on safety and clinical development;

The remuneration shall be EUR 16 700 for the scientific advice co-ordinator.

1.2. A fee of EUR 25 700 shall apply to any of the following requests:

(a) a request on clinical development;

(b) a request on quality and safety development;

(c) a request on quality development and bioequivalence studies for generic veterinary medicinal products as defined in Article 4(9) of Regulation (EU) 2019/6.

The remuneration shall be EUR 10 700 for the scientific advice co-ordinator.

1.3. A fee of EUR 22 600 shall apply to a request related to any of the following:

(a) a request on quality development;

(b) a request on safety development;

(c) a request on bioequivalence studies for generic veterinary medicinal products as defined in Article 4(9) of Regulation (EU) 2019/6;

(d) a request for preliminary risk profile;

(e) a request related to setting a new maximum residue limit.

The remuneration shall be EUR 6 500 for the scientific advice co-ordinator.

2. **Request for classification of a veterinary medicinal product as intended for a limited market as defined in Article 4, point (29), of Regulation (EU) 2019/6 and for consideration for eligibility for authorisation in accordance with Article 23 of that Regulation**

A charge of EUR 5 500 shall apply to a request for classification of a veterinary medicinal product as intended for a limited market within the meaning of Article 4(29) of Regulation (EU) 2019/6 and for consideration for eligibility for authorisation pursuant to Article 23 of Regulation (EU) 2019/6.

3. **Establishment, modification or extension of a maximum residue limit (MRL) in accordance with the procedure laid down in Regulation (EC) No 470/2009 of the European Parliament and of the Council[32]**

3.1. A fee of EUR 89 700 shall apply to an application to set an initial MRL for a given substance. The remuneration shall be EUR 22 700 for the rapporteur and EUR 10 900 for the co-rapporteur.

3.2. A fee of EUR 56 100 shall apply to each application to modify or to extend an existing MRL. The remuneration shall be EUR 11 200 for the rapporteur and EUR 10 300 for the co-rapporteur.

3.3. A fee of EUR 25 700 shall apply to the assessment to determine whether a chemical-unlike biological substance requires a full MRL evaluation or not pursuant to Annex I, Section I.7, to Commission Regulation (EU) 2018/78233. The remuneration shall be EUR 10 700 for the rapporteur.

4. **Authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6**

[32] 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).

[33] 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).

4.1. A fee of EUR 313 000 shall apply to an application for a marketing authorisation for a veterinary medicinal product pursuant to Articles 8, 23 or Article 25 of Regulation (EU) 2019/6 where the applicant claims a new active substance. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application, irrespective of the number of target species. The remuneration shall be EUR 113 300 for the rapporteur and EUR 40 400 for the co-rapporteur.

4.2. A fee of EUR 283 600 shall apply to an application for a marketing authorisation for a veterinary medicinal product pursuant to Articles 8, 20, 22, 23 or Article 25 of Regulation (EU) 2019/6 where the applicant claims a known active substance. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application, irrespective of the number of target species. The remuneration shall be EUR 87 000 for the rapporteur and EUR 37 400 for the co-rapporteur.

4.3. A fee of EUR 144 900 shall apply for any of the following applications

(a) an application for a marketing authorisation for a generic veterinary medicinal product pursuant to Article 18 of Regulation (EU) 2019/6;

(b) an application for a marketing authorisation for a hybrid veterinary medicinal product pursuant to Article 19 of Regulation (EU) 2019/6;

(c) an application based on informed consent for a marketing authorisation for a veterinary medicinal product pursuant to Article 21 of Regulation (EU) 2019/6.

That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application, irrespective of the number of target species. The remuneration shall be EUR 32 600 for the rapporteur and EUR 19 000 for the co-rapporteur.

5. **Re-examination of a marketing authorisation for limited markets**

A fee of EUR 20 100 shall apply to an application for a re-examination of a marketing authorisation for a limited market pursuant to Article 24(3) of Regulation (EU) 2019/6. The remuneration shall be EUR 3 300 for the rapporteur and EUR 2 500 for the co-rapporteur.

6. **Variations to the terms of a marketing authorisation, requiring assessment in accordance with Articles 64, 65 and 66 of Regulation (EU) 2019/6**

6.1. A fee of EUR 93 000 shall apply to a variation requiring assessment introducing changes of active substance(s), strength, pharmaceutical form, route of administration or food-producing target species, which are to be assessed within 90 days in accordance with Article 66(3) of Regulation (EU) 2019/6. That fee shall be charged for each single pharmaceutical form or each single associated strength/potency. The remuneration shall be EUR 30 300 for the rapporteur and EUR 9 100 for the co-rapporteur.

6.2. A fee of EUR 50 300 shall apply to variations requiring assessment that introduce changes to safety, efficacy or pharmacovigilance, which are to be assessed within 60 or 90 days, as the case may be, in accordance with Article 66(3) of Regulation (EU) 2019/6. The remuneration shall be EUR 10 400 for the rapporteur and EUR 8 100 for the co-rapporteur.

6.3. A fee of EUR 25 300 shall apply to variations requiring assessment introducing quality changes only, which are to be assessed within 60 days in accordance with Article 66(3) of Regulation (EU) 2019/6. The remuneration shall be EUR 3 800 for the rapporteur and EUR 3 800 for the co-rapporteur.

6.4. Where several variations requiring assessment are grouped in a single application under Article 64 of Regulation (EU) 2019/6, the corresponding fee as set out in points 6.1, 6.2 and 6.3 of this Annex shall apply to each of the first two variations. Remuneration shall be paid in accordance with those points. For the third and subsequent variations, the fee shall be EUR 12 700 per variation and the remuneration shall be EUR 1 900 per variation for the rapporteur and EUR 1 900 for the co-rapporteur.

6.5. Where a work-sharing application pursuant to Article 65 of Regulation (EU) 2019/6 includes more than one centrally authorised product, the fees and remuneration specified in points 6.1, 6.2 and 6.3 of this Annex shall apply for each variation to the first centrally authorised product, whereas a charge of EUR 800 shall apply for each variation to the second and subsequent centrally authorised product included in the same application.

7. Referrals and arbitration procedures

7.1. A fee of EUR 161 800 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 22 400 for the rapporteur and EUR 10 200 for the co-rapporteur.

7.2. A fee of EUR 221 700 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 30 900 for the rapporteur and EUR 13 700 for the co-rapporteur.

7.3. A fee of EUR 155 900 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 18 500 for the rapporteur and EUR 8 200 for the co-rapporteur.

7.4. A fee of EUR 221 700 shall apply to the assessment carried out in the context of a procedure initiated under Article 82 of Regulation (EU) 2019/6. The remuneration shall be EUR 30 900 for the rapporteur and EUR 13 700 for the co-rapporteur.

7.5. A fee of EUR 155 900 shall apply for the assessment carried out in the context of a procedure initiated under Article 129(3) or Article 130(4) of Regulation (EU) 2019/6. The remuneration shall be EUR 18 500 for the rapporteur and EUR 8 200 for the co-rapporteur.

7.6. Where two or more marketing authorisation holders are involved in the procedures referred to in points 7.4 or 7.5, the amount payable by each marketing authorisation holder shall be calculated by the Agency in two steps, as follows:

(a) by dividing the total amount of the fee among the marketing authorisation holders proportionally to the number of chargeable units – veterinary corresponding to products included in the procedure which are held by each of those marketing authorisation holders;

(b) by subsequently applying the fee reduction laid down in point 1 of Annex V, where relevant.

8. Certification of compliance with Union legislation for vaccine antigen master files (VAMF)

8.1. A fee of EUR 25 300 shall apply to an application for review of a VAMF and its certification pursuant to point V.2 of Annex II to Regulation (EU) 2019/6 when it is submitted simultaneously with an initial application for marketing authorisation for a veterinary medicinal product under the centralised procedure containing the named antigen. The remuneration shall be EUR 3 800 for the rapporteur and EUR 3 800 for the co-rapporteur.

8.2. For multiple VAMF applications submitted simultaneously in the context of the same initial marketing authorisation application, a fee of EUR 25 300 shall apply per VAMF. The maximum total amount charged by the Agency shall not exceed EUR 76 000. The remuneration shall be EUR 3 800 for the rapporteur and EUR 3 800 for the co-rapporteur. For multiple VAMF applications submitted simultaneously in the context of the same initial marketing authorisation application, the remuneration shall not exceed EUR 11 400 for the rapporteur and EUR 11 400 for the co-rapporteur.

8.3. A fee of EUR 35 100 shall apply to an application for the review of a VAMF and its certification when submitted as a separate application for an antigen in vaccine(s) already authorised under the centralised, decentralised or mutual recognition procedure. The remuneration shall be EUR 5 300 for the rapporteur and EUR 5 300 for the co-rapporteur.

8.4. Section 6 [of this Annex] shall apply by analogy to variations to a certified VAMF.

9. Certification of compliance with Union legislation for vaccine platform technology master files (vPTMF)

9.1. A fee of EUR 25 300 shall apply to an application for review of a vPTMF and its certification pursuant to point V.4 of Annex II to Regulation (EU) 2019/6 when submitted simultaneously with an initial application for marketing authorisation for a veterinary medicinal product under the centralised procedure containing the named platform. The remuneration shall be EUR 3 800 for the rapporteur and EUR 3 800 for the co-rapporteur

9.2. A fee of EUR 35 100 shall apply to an application for review of a vPTMF and its certification when submitted as a separate application for a platform in vaccines already authorised under the centralised, decentralised or mutual recognition procedure. The remuneration shall be EUR 5 300 for the rapporteur and EUR 5 300 for the co-rapporteur

9.3. Section 6 of this Annex shall apply by analogy to variations to a certified vPTMF.

10. Assessment of post-marketing surveillance studies

10.1. A fee of EUR 40 000 shall apply to the assessment of post-marketing surveillance studies pursuant to Article 76(3) of Regulation (EU) 2019/6 that are conducted in more than one Member States

10.2. The fee shall be charged as follows:

(a) EUR 20 000 shall be due at the date of the start of the procedure for the approval of the draft study protocol as referred to in Article 15(3) of Commission Implementing Regulation (EU) 2021/1281[34]. The remuneration shall be EUR 8 200 for the rapporteur;

(b) EUR 20 000 shall be due at the date of the start of the procedure for the assessment of the final study report as referred to in Article 15(5) of Implementing Regulation (EU) 2021/1281. The remuneration shall be EUR 8 200 for the rapporteur.

10.3. Where the obligation to conduct a post-marketing surveillance study is imposed on more than one marketing authorisation holder and the marketing authorisation holders concerned conduct a joint post-marketing surveillance study, the Agency shall calculate the fee to be charged in two steps, as follows:

(a) by evenly dividing the total amount of the fee among those marketing authorisation holders;

(b) by subsequently applying the fee reduction as set out in Annex V, point 1, where relevant.

[34] 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).

11. Scientific opinions in the context of cooperation with international organisations for animal health for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union

A fee and corresponding remuneration as specified in points 1, 3, 4 and 6 of this Annex and in points 1, 3, 4 and 5 of Annex IV and points 6.1, 6.2 and 6.4 of that Annex to this Regulation shall apply for an application for a scientific opinion for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union pursuant to Article 138 of Regulation (EU) 2019/6.

ANNEX III

Annual fees and remuneration

1. Annual fee for medicinal products for human use authorised in accordance with Regulation (EC) No 726/2004

1.1. An annual fee of EUR 60 300 shall apply to each marketing authorisation of a medicinal product for human use authorised on the basis of an application submitted under Article 10(1) and (3) and Article 10c of Directive 2001/83/EC. The remuneration shall be EUR 8 000 for the rapporteur , EUR 7 000 for the co-rapporteur and EUR 1 500 for the PRAC-rapporteur.

1.2. An annual fee of EUR 118 100 shall apply to each marketing authorisation of a medicinal product for human use authorised on the basis of an application submitted under Article 10(4) of Directive 2001/83/EC. The remuneration shall be EUR 16 200 for the rapporteur , EUR 14 300 for the co-rapporteur and EUR 3 000 for the PRAC-rapporteur.

1.3. An annual fee of EUR 232 400 shall apply to each marketing authorisation of a medicinal product for human use not covered by point 1.1 or 1.2. The remuneration shall be EUR 32 200 for the rapporteur , EUR 28 400 for the co-rapporteur and EUR 6 100 for the PRAC-rapporteur.

1.3a. The annual fees as specified in points 1.1, 1.2 and 1.3 shall relate to the preceding year.

2. Annual fee for veterinary medicinal products authorised through the centralised procedure in accordance with Regulation (EU) 2019/6

2.1. An annual fee of EUR 26 200 for shall apply for each marketing authorisation of a veterinary medicinal product authorised pursuant to Article 18, 19 or 21 of Regulation (EU) 2019/6. The remuneration shall be EUR 6 300 for the rapporteur and EUR 5 800 for the co-rapporteur.

2.2 An annual fee of EUR 106 400 shall apply to each marketing authorisation not covered by point 2.1. The remuneration shall be EUR 25 600 for the rapporteur and EUR 23 500 for the co-rapporteur.

2.2a. The annual fees as specified in points 2.1 and 2.2 shall relate to the preceding year.

3. Annual pharmacovigilance fee for medicinal products for human use authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by competent authorities of the Member States in accordance with Regulation (EU) 2019/6

3.1. For medicinal products for human use authorised in accordance with Directive 2001/83/EC, a fee of EUR 230 per chargeable unit-human, shall apply once per year for the Agency's pharmacovigilance activities including analysis of Union-wide health data to support better decision-making with real world evidence. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.

3.2 For veterinary medicinal products authorised by competent authorities of the Member States in accordance with Chapter III, Sections 2 to 5 of Regulation (EU) 2019/6, a fee of EUR 90 per chargeable unit-veterinary shall apply once per year for the Agency's pharmacovigilance activities. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.

3.3 The total payable amount of the annual fees referred to in points 3.1 and 3.2 for each marketing authorisation holder shall be calculated by the Agency on the basis of the number of chargeable units-human and chargeable units-veterinary, respectively, which correspond to the information recorded on 1 July of each year.

3.4. The annual fees referred to in points 3.1 and 3.2 shall be due on 1 July of every year and shall cover the period from 1 January to 31 December of that calendar year.

ANNEX IV

Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices

1. Inspections pursuant to Article 8(2), 19 and Article 57(1), point (i) of Regulation (EC) No 726/2004 and Article 126(2) of Regulation No 2019/6

1.1. Inspections in relation to medicinal products for human use and veterinary medicinal products

1.1.1. For any distinct Good Manufacturing Practice inspection within the Union a fee of EUR 30 300 shall apply. The remuneration shall be EUR 10 800 for the leading authority and EUR 6 500 for the supporting authority.

1.1.2. For any distinct Good Manufacturing Practice inspection outside the Union a fee of EUR 48.700 shall apply. The remuneration shall be EUR 20 900 for the leading authority and EUR 12 600 for the supporting authority.

1.1.3. For any distinct Good Clinical Practice inspection within the Union a fee of EUR 45 600 shall apply. The remuneration shall be EUR 18 400 for the leading authority and EUR 11 400 for the supporting authority.

1.1.4. For any distinct Good Clinical Practice inspection outside the Union a fee of EUR 57 000 shall apply. The remuneration shall be EUR 26 300 for the leading authority and EUR 13 900 for the supporting authority.

1.1.5. For any distinct Plasma Master File inspection within or outside the Union a fee of EUR 46 100 shall apply. The remuneration shall be EUR 17 900 for the leading authority and EUR 11 000 for the supporting authority.

1.1.6. For any consecutive Plasma Master File inspection within or outside the Union a fee of EUR 44 300 shall apply. The remuneration shall be EUR 16 800 for the leading authority and EUR 10 300 for the supporting authority.

1.1.7. For any distinct Good Laboratory Practice inspection within or outside the Union a fee of EUR 42 900 shall apply. The remuneration shall be EUR 16 500 for the leading authority and EUR 10 900 for the supporting authority.

1.1.8. For any distinct pharmacovigilance inspection within or outside the Union a fee of EUR 64 300 shall apply. The remuneration shall be EUR 20 300 for the leading authority and EUR 12 700 for the supporting authority.

1.2. If a scheduled inspection is cancelled 30 calendar days or less before the first day of the inspection for reasons attributable to the applicant, the applicable fee referred to in point 1.1 shall apply.

1.3. If a scheduled inspection is cancelled more than 30 calendar days before the first day of the inspection for reasons attributable to the applicant, a charge of EUR 1 000 shall apply.

1.4. The supervisory authorities shall charge the applicant the travel expenses separately from the fee specified in this Annex, based on actual cost. In case of a cancelled inspection as per points 1.2 or 1.3, the applicant shall be charged for any travel expenses already incurred by the inspecting authority on the date of cancellation for which that authority is not able to obtain reimbursement.

2. Transfer of a marketing authorisation

A charge of EUR 4 400 shall apply to an application for the transfer of a marketing authorisation pursuant to Article 3 of Commission Regulation (EC) No 2141/96[35]. This covers all authorised presentations of a given medicinal product.

The charge shall be levied to the marketing authorisation holder that requested the transfer, according to the application submitted to the Agency.

[35] 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 (EEC) No 2309/93 (OJ L 286, 8.11.1996, p. 6).

3. Pre-submission requests by a prospective applicant prior to a potential submission of an application for a marketing authorisation falling within the scope of the centralised procedure

3.1. A fee of EUR 8 600 shall apply to each eligibility request submitted with a notification of intention to submit an application for a marketing authorisation falling within the scope of Regulation (EC) No 726/2004 or the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6. The fee shall cover any costs related to pre-submission activities up until the potential submission of the marketing authorisation application. The fee shall apply irrespective of whether or not a marketing authorisation application for the concerned product is subsequently submitted. If an eligibility request with a notification of intention to submit an application for a marketing authorisation has not been submitted, the fee shall apply in addition to the applicable authorisation fee.

The remuneration of the national competent authority, where applicable, shall be EUR 1 600 for the rapporteur and EUR 1 600 for the co-rapporteur.

3.2. Where the applicant changes the intended submission date by more than 60 days, an additional fee of EUR 4 200 shall apply. The additional remuneration of the national competent authority, where applicable, shall be EUR 800 for the rapporteur and EUR 800 for the co-rapporteur.

4. Re-examination of an opinion of the Committees referred to in Article 56(1) of Regulation (EC) No 726/2004 and in Article 139(1) of Regulation (EU) 2019/6

The fee for the re-examination of an opinion of any of the committees referred to in Article 56(1) of Regulation (EC) No 726/2004 and in Article 139(1) of Regulation (EU) 2019/6 shall be 30% of the fee applicable to the initial opinion in accordance with points 3, 4, 5 and 6 of Annex I and points 3, 4, 6 and 7 of Annex II to this Regulation. The remuneration to the rapporteur and the co-rapporteur shall be calculated based on the same proportion of the respective remuneration.

5. Scientific services referred to in Article 4(1)

The range for fees for scientific services referred to in Article 4(1) shall be EUR 5 000 to EUR 841 100. The range for the remuneration shall be EUR 1 300 to EUR 272 200 for the rapporteur and the co-rapporteur. The applicable amounts of the fee and the remuneration within the above ranges shall be determined in accordance with Article 8.

6. Administrative services

6.1. Administrative charge

A charge of EUR 4 400 shall apply for applications subject to a fee set out in Annex I or II in any of the following situations:

(a) the application is withdrawn after 24 hours of its submission and prior to completion of the administrative validation;

(b) the application has been rejected following the conclusion of the administrative validation.

The charge laid down in the first subparagraph shall apply also for applications in relation to procedures and services for which the applicable fee is waived in said Annexes.

In the cases referred to in the previous subparagraph, the corresponding fee shall not be levied.

In addition to the applicable fee or charge set out in Annexes I, II or Annex III, a charge of EUR 4 400 shall also apply to applications where a marketing authorisation holder or an applicant claiming, or having claimed, to be entitled to a fee reduction, fails to demonstrate that it is entitled to such a reduction. This charge shall be charged in full also to SMEs, where applicable.

6.2. Certificates of medicinal products as referred to in Article 127 of Directive 2001/83/EC and in Article 98 of Regulation (EU) 2019/6

6.2.1 A charge of EUR 200 shall apply to each request for a ~~set of~~ certificate~~s~~ issued by the Agency for a medicinal product, using the standard procedure for issuing the certificate.

6.2.2. A charge of EUR 500 shall apply to each request for a ~~set of~~ certificate~~s~~ issued by the Agency for a medicinal product, using the urgent procedure for issuing the certificate.

6.3. Notification of parallel distribution in accordance with Article 57(1), point (o), of Regulation (EC) No 726/2004

6.3.1. A charge of EUR 1 400 shall apply to each initial notification for each presentation of a medicinal product, for one Member State of destination having one or more official languages or for several Member States of destination having the same official language. That charge shall cover any subsequent safety update notification relating to the initial notification.

6.3.2. A charge of EUR 400 shall apply to each notification of a bulk change. That charge shall cover all initial notifications approved by the date of submission of the notification of bulk changes.

6.3.3. A charge of EUR 400 shall apply to each annual update notification. That charge shall cover all the presentations belonging to the same medicinal product for one Member State of destination having one or more official languages, or for several Member States of destination having the same official language. No charge shall apply if there have been no regulatory updates in the past twelve months or if the product was dormant.

6.4. Administrative services referred to in Article 4(2)

The range of charges for other administrative services referred to in Article 4(2) shall be from EUR 120 to EUR 11 900. The applicable amounts of the charge within the above range shall be determined in accordance with Article 8.

7. Consultation on medical devices

7.1. Ancillary substances incorporated in medical devices

7.1.1. A fee of EUR 114 700 shall apply to a consultation on one or more ancillary medicinal substances pursuant to section 5.2 of Annex IX to Regulation (EU) 2017/745, where the medicinal substance(s) from the specified manufacturer has not been evaluated by the Agency or a competent authority designated by the Member States in accordance with Directive 2001/83/EC (hereafter 'medicinal products authority') in connection with a previous marketing authorisation or through a previous consultation by a notified body. One application may include a range of strength or concentrations of the ancillary substance(s) or a range of similar devices from the same medical device manufacturer incorporating the same substance(s) or both. The remuneration shall be EUR 29 400 for the rapporteur and EUR 29 400 for the co-rapporteur.

7.1.2. A fee of EUR 57 200 shall apply to a consultation on one or more ancillary medicinal substance(s) pursuant to section 5.2 of Annex IX to Regulation (EU) 2017/745, where the medicinal substance(s) from the specified manufacturer has been evaluated by a medicinal products authority in connection with a previous marketing authorisation or through a previous consultation by a notified body. One application may include a range of strengths or concentrations of the ancillary substance(s) or a range of similar devices from the same medical device manufacturer incorporating the same substance(s) or both. The remuneration shall be EUR 14 400 for the rapporteur and EUR 14 400 for the co-rapporteur.

7.1.3. For the purpose of 7.1.1. and 7.1.2., a fee of EUR 5 000 shall apply to a consultation, pursuant to section 5.2, point (f), of Annex IX to Regulation (EU) 2017/745, regarding a change with respect to an ancillary medicinal substance incorporated in a device. The remuneration shall be EUR 1 800 for the rapporteur.

7.2. Medical devices composed of a substance or a combination of substances that are systemically absorbed to achieve their intended purpose.

A fee of EUR 86 100 shall apply to a consultation on a medical device or a range of similar devices composed of a substance or a combination of substances that are absorbed by or locally dispersed in the human body, pursuant to section 5.4 of Annex IX, to Regulation (EU) 2017/745. The remuneration shall be EUR 21 900 for the rapporteur and EUR 21 900 for the co-rapporteur.

7.3. Companion diagnostic

7.3.1. A fee of EUR 56 500 shall apply to a consultation on the suitability of a companion diagnostic in relation to a concerned medicinal product, pursuant to Article 48(3) or (4), of Regulation (EU) 2017/746, and section 5.2 of Annex IX, or section 3, point (k), of Annex X to that Regulation. The remuneration shall be EUR 14 800 for the rapporteur.

A fee of EUR 5 000 shall apply to a consultation on a change affecting the suitability of the companion diagnostic in relation to the medicinal product concerned, pursuant to section 5.2, point (f), of Annex IX to Regulation (EU) 2017/746. The remuneration shall be EUR 1 800 for the rapporteur.

7.4. The fees set out in points 7.1, 7.2 and 7.3 shall be charged to the medical device manufacturer that, according to the application form submitted to the Agency, requested the assessment of conformity of the medical device for which the notified body is consulting the Agency.

ANNEX V

Fee reductions

1. Fee reductions granted to micro, small- and medium-sized enterprises

1.1. The following total or partial reductions to the fees laid down in this Regulation shall be granted to micro, small and medium-sized enterprises:

1.1.1 for a small or medium-sized enterprise, a fee reduction of 40 % of the applicable amount shall apply to the following fees:

(a) extension of a marketing authorisation for medicinal products for human use pursuant to section 4 of Annex I;

(b) major type-II variations for medicinal products for human use pursuant to section 5 of Annex I, excluding point 5.4 of that section;

(c) referral procedures for medicinal products for human use pursuant to points 6.4 to 6.7 of Annex I;

(d) request for scientific advice by the Committee on Herbal Medicinal Products related to traditional herbal medicinal products pursuant to section 7 of Annex I;

(e) certification of compliance with Union legislation for plasma master files pursuant to section 8 of Annex I;

(f) certification of compliance with Union legislation regarding vaccine antigen master files (VAMF) pursuant to section 9 of Annex I;

(g) assessment of periodic safety update reports for medicinal products for human use pursuant to section 14 of Annex I;

(h) assessment of post-authorisation safety studies for medicinal products for human use pursuant to section 15 of Annex I;

(i) variations requiring assessment pursuant to section 6 of Annex II, excluding point 6.5 of that section;

(j) referral procedures for veterinary medicinal products pursuant to points 7.4 to 7.5 of Annex II;

(k) certification of compliance with Union legislation regarding VAMF pursuant to section 8 of Annex II;

(l) certification of compliance with Union legislation regarding vaccine platform technology master files (vPTMF) pursuant to section 9 of Annex II;

(m) assessment of post-marketing surveillance studies for veterinary medicinal products pursuant to section 10 of Annex II;

(n) annual fee, for medicinal products for human use or for veterinary medicinal products, or both, pursuant to section 1 or 2, respectively, of Annex III;

(o) pharmacovigilance annual fee, for medicinal products for human use or veterinary medicinal products pursuant to Annex III;

(p) transfer of a marketing authorisation to another micro-, small- or medium-sized enterprise, both for medicinal products for human use and veterinary medicinal products pursuant to section 2 of Annex IV;

1.1.1. for a small or medium-sized enterprise, a fee reduction of 90 % of the applicable amount shall apply to a consultation on medical devices pursuant to section 7 of Annex IV, where the medical device manufacturer has been assigned the small and medium-sized enterprise status by the Agency;

1.1.2. for a micro enterprise, a reduction of 100 % shall apply to the fees set out in points 1.1.1. and 1.1.2.

1.2. The fee reductions set out in point 1.1.1 shall apply in addition to fee reductions and incentives provided for in Regulation (EC) No 2049/2005 or in the Union pharmaceutical legislation.

1.3. The reductions set out in point 1.1 shall not be granted to SMEs acting as applicant or marketing authorisation holder for the relevant medicinal product by virtue of a contractual arrangement with a non-SME legal entity. Such contractual arrangements shall be declared to the Agency ahead of any service listed under point 1.1.1.

1a. Fee reductions applied to entities not engaged in an economic activity

1a.1 The fees set out in Annex I, point 1 and Annex II, point 1, shall be waived in case the Scientific advice provided by the Agency in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004 is provided to entities not engaged in an economic activity.

2. Applications relating to core dossier medicinal products to be used in a human pandemic situation

2.1. The payment of the fee for an application for a marketing authorisation of a medicinal product to be used in a human pandemic situation shall be deferred until the pandemic situation is duly recognised, either by the World Health Organisation or by the Commission in accordance with Article 23(1) of Regulation (EU) 2022/2371 on serious cross-border threats to health and repealing Decision No 1082/2013/EU.

Such deferral shall not exceed 5 years.

2.2. In addition to the deferral provided for in point 2.1, for regulatory activities within the framework of the submission of a core dossier for a pandemic vaccine and the follow-up submission of a pandemic variation, a fee reduction of 100 % shall apply in the following cases:

(a) pre-submission activities pursuant to section 3 of Annex IV;

(b) scientific advice pursuant to section 1 of Annex I;

(c) extension of marketing authorisation pursuant to section 4 of Annex I;

(d) major type-II variation pursuant to section 5 of Annex I;

(e) annual fee pursuant to section 1 of Annex III.

Those reductions shall apply until the human pandemic situation is duly recognised.

2.3. Where reductions apply pursuant to point 2.2, no remuneration shall be paid to the national competent authorities for the annual fees referred to in point 2.2(e).

3. Applications submitted under Article 30 of Regulation (EC) No 1901/2006

A 50 % fee reduction shall apply to paediatric use marketing authorisation applications submitted under Article 30 of Regulation (EC) No 1901/2006 for the following services:

(a) initial marketing authorisation application pursuant to section 3 of Annex I, to this Regulation;

(b) pre-authorisation inspection pursuant to section 1 of Annex IV, to this Regulation;

(c) extension of a marketing authorisation pursuant to section 4 of Annex I, to this Regulation, in the first year from granting of the marketing authorisation;

(d) major type-II variation pursuant to section 5 of Annex I, to this Regulation, in the first year from granting of a marketing authorisation;

(e) annual fee pursuant to section 1 of Annex III, to this Regulation, in the first year from granting of a marketing authorisation;

(f) post-authorisation inspection pursuant to section 1 of Annex IV, to this Regulation, in the first year from granting of a marketing authorisation.

4. Immunological veterinary medicinal products

A fee reduction of 50 % shall apply to immunological veterinary medicinal products for the following activities:

(a) scientific advice pursuant to section 1 of Annex II;

(b) request for classification of a veterinary medicinal product as intended for a limited market as defined in Article 4, point 29 of Regulation (EU) 2019/6 and for consideration for eligibility for authorisation according to Article 23 of that Regulation, pursuant to section 2 of Annex II, to this Regulation;

(c) authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6, pursuant to section 4 of Annex II, to this Regulation;

(d) variations to the terms of a marketing authorisation requiring assessment in accordance with Article 66 of Regulation (EU) 2019/6, pursuant to Annex II, section 6, to this Regulation. In the specific case of point 6.5 of Annex II, the reduction shall apply to the variations subject to a fee and shall not apply to the variations subject to a charge;

(e) certification of compliance with Union legislation for VAMF pursuant to section 8 of Annex II;

(f) certification of compliance with Union legislation for vPTMF pursuant to section 9 of Annex II;

(g) assessment of post-marketing surveillance studies pursuant to section 10 of Annex II;

(h) annual fee pursuant to section 2 of Annex III;

(i) pre-submission services pursuant to section 3 of Annex IV.

5. Veterinary medicinal products for limited markets

5.1. A fee reduction of 50 % shall apply to veterinary medicinal products classified as intended for a limited market within the meaning of Article 4(29) of Regulation (EU) 2019/6 and considered eligible for authorisation or authorised pursuant to Article 23 of that Regulation, for the following activities:

(a) scientific advice pursuant to section 1 of Annex II, to this Regulation;

(b) applications for establishment, modification or extension of a maximum residue limit pursuant to section 3 of Annex II, to this Regulation;

(c) authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6 pursuant to Article 23 of that Regulation, pursuant to point 4.1 or 4.2 of Annex II, to this Regulation;

(d) variations to the terms of a marketing authorisation requiring assessment in accordance with Article 66 of Regulation (EU) 2019/6, pursuant to section 6 of Annex II. In the specific case of point 6.5 of Annex II, the reduction shall apply to the variations subject to a fee and shall not apply to the variations subject to a charge;

(e) certification of compliance with Union legislation for VAMF pursuant to section 8 of Annex II to this Regulation;

(f) certification of compliance with Union legislation for vPTMF pursuant to section 9 of Annex II to this Regulation;

(g) assessment of post-marketing surveillance studies pursuant to section 10 of Annex II, to this Regulation;

(h) annual fee pursuant to section 2 of Annex III, to this Regulation;

(i) pre-submission services pursuant section 3 to Annex IV, to this Regulation.

5.2. A reduction of 100 % shall apply to the fee for extension of maximum residues limits set out in section 3 of Annex II, when such extension does not require assessment of data.

6. Veterinary vaccines against certain major epizootic diseases

6.1. A fee reduction of 100 % shall apply to the annual fee for vaccines against infection with bluetongue virus (serotypes 1-24), highly pathogenic avian influenza, foot and mouth disease and classical swine fever, where the vaccine is authorised under normal circumstances and the product has not been marketed within the Union at any time during the totality of the period covered by the fee.

6.2. Where a reduction applies pursuant to point 6.1, no remuneration shall be paid to the national competent authorities for the annual fees referred to in point 6.1.

7. Annual fee for veterinary medicinal products

A fee reduction of 25 % shall apply to the annual fee for veterinary medicinal products set out in section 2 of Annex III, with the exclusion of those products already listed in sections 4 and 5 of this Annex.

8. Annual pharmacovigilance fee for generic, homeopathic and herbal medicinal products

A fee reduction of 25 % shall apply to the annual pharmacovigilance fee set out in section 3 of Annex III for the following medicinal products

(a) medicinal products for human use as referred to in Article 10(1) and Article 10a of Directive 2001/83/EC;

(b) homeopathic medicinal products for human use;

(c) herbal medicinal products for human use;

(d) veterinary medicinal products as referred to in Articles 18 and 22 of Regulation (EU) 2019/6;

(e) homeopathic veterinary medicinal products;

(f) homeopathic veterinary medicinal products registered in accordance with Article 87 of Regulation (EU) 2019/6.

ANNEX VI

Performance information

The following information shall relate to each calendar year and shall be made publicly available on the Agency's website:

(1) the overall cost and breakdown of Agency staff and non-staff costs relating to the fees and charges referred to in Article 3;

(2) number of Agency staff involved and the overall costs for obtaining and maintaining a Union authorisation to market medicinal products for human use and veterinary medicinal products and for other services of the Agency;

(3) number of procedures for obtaining and maintaining a Union authorisation to market medicinal products for human use and veterinary medicinal products and for other services of the Agency;

(4) number and amount of fee reductions or waivers granted per type of fee reduction or waiver under Union Legislation and number of applicants or holders concerned;

(5) attribution of rapporteurs, co-rapporteurs, or roles considered as equivalent for the purposes of this regulation as referred to in the Annexes to this regulation, per Member State, per type of procedure;

(6) number of working hours spent by the rapporteur and the co-rapporteurs or roles considered as equivalent for the purposes of this regulation as referred to in the Annexes to this regulation, including hours spent by experts and others employed by the competent authorities of the Member States to assist them, and number of working hours spent by experts contracted for the procedures of the expert panels on medical devices. Information shall be provided per type of procedures on the basis of the information provided to the Agency by the national competent authorities concerned. The types of procedures to be included shall be decided by the Management Board based on a proposal by the Agency.

(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;

(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.

ANNEX VII

Correlation table

Regulation 297/95	This Regulation	
Article 8(1)	Annex I, point 1 and Annex II, point 1	
Article 3(1)	Annex I, point 3	
Article 7	Annex II, point 3	
Article 5(1)	Annex II, point 4	
Article 3(4)	Annex IV, point 1	
Article 5(4)	Annex IV, point 1	
Article 8(2)	Annex IV, point 5	
Article 8(3)	Annex IV, points 6.1, 6.2 and 6.4	Annex IV, points 6.1 (except for the last paragraph), 6.2 and 6.4