EUROPEAN
COMMISSION

Brussels, 13.12.2022
COM(2022) 721 final

2022/0417 (COD)

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

{SEC(2022) 440 final} - {SWD(2022) 413 final} - {SWD(2022) 414 final} -
{SWD(2022) 415 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Article 67(3) of the founding Regulation[1] of the European Medicines Agency (EMA, the Agency) stipulates that fees and charges are part of the revenues of the Agency. Article 86a of that regulation, as amended by Regulation (EU) 2019/5[2], provides that the Commission is to put forward, as appropriate, legislative proposals with a view to update the regulatory framework for fees payable to the Agency in relation to medicinal products for human use and veterinary medicinal products (VMP).

Over the years, the legal framework governing EMA fees has become rather complex, requiring some legislative simplification. EMA fees are currently laid down in two separate regulations: Council Regulation (EC) No 297/95 and Regulation (EU) No 658/2014. Both regulations convey the will of the co-legislators that revisions of fees levied by the Agency should be based on an evaluation of the costs of the Agency and the costs of the tasks carried out by competent authorities in Member States[3].

Following changes introduced recently to the EMA Founding Regulation[4] (the EMA Regulation) and to the rules applicable to the authorisation of veterinary medicinal products, the provisions applicable to the fee system need to be adapted. In particular, the current legislation does not envisage fees in support of new or changed activities introduced by Regulation (EU) 2019/6[5] (VMP Regulation), which became applicable in January 2022. In addition, Regulation (EU) 2022/123 introduced new activities for the Agency that require further adjustments of the costs that the EMA fees should take into account[6]. The structure of the EMA's revenue sources should also be aligned with the provisions in Article 67 of the EMA Regulation. In particular, the EMA is able to levy not only fees, but also charges for services and activities of the Agency for which a fee is not levied.

---

1 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).

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

3 Council Regulation (EC) No 297/95, Article 12.

4 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).

5 OJ L 4, 7.1.2019, p. 43.

6 More specifically, the legislative financial statement of the proposal (COM(2020) 725 final) envisages full coverage of the costs related to the regulation through the Union contribution laid down in Article 67(3)(a) of Regulation (EC) No 726/2004, except for specific objective No 3, i.e. *'Allow timely access and analysis of EU-wide health data to support better decision-making throughout the product lifecycle on medicines (development, authorisation, performance monitoring) with valid and reliable real-world evidence'* (*'node reuse data'*), which is covered only until 2023, i.e. the set-up phase. The present proposal therefore includes funding for the activities aimed at achieving the above-mentioned objective No 3, more specifically the operational phase of those activities, through fee income.

When establishing a new fee system for veterinary medicinal products, the characteristics and specificities of the veterinary sector should be taken into account[7].

This revision also aims to address the following problems identified by the recent evaluation of the EMA fee system[8]:

1) complexity of the fee system due to the many different categories and types of fees it currently establishes;

2) misalignment of some fees with underlying costs;

3) lack of any fees or national competent authority remuneration for some procedural activities;

4) misalignment with the underlying costs of certain remuneration paid to national competent authorities in Member States; and

5) discrepancy between the main EMA Fee Regulation (Council Regulation (EC) No 297/95) and the Pharmacovigilance Fee Regulation (Regulation (EU) No 658/2014), which differ in their approach to determining the amount of national competent authority remuneration and in the approach to national competent authority remuneration in the case of reduced fees[9].

By addressing these specific problems, the general objective of this proposal is to contribute to providing a sound financial basis to support the EMA's operations, including remuneration for services to the EMA rendered by national competent authorities, in line with the applicable legislation. This translates into the objective of providing for fee and remuneration amounts that are cost-based, following a thorough evaluation of the costs of the Agency and its various statutory tasks and the cost of the contributions of competent authorities of the Member States to its work.

In addition, the proposal aims to streamline the system by simplifying the fee structure to the extent possible and by addressing the unnecessary complexity of the corresponding legal framework through bringing together in a single legal instrument fee rules that are currently governed by the two EMA Fees Regulations.

Finally, a key objective pursued by this proposal is to make the fee system future-proof by introducing regulatory flexibility in the way it is adjusted, on an objective basis.

This initiative is part of the Regulatory Fitness Programme (REFIT).

- **Consistency with existing policy provisions in the policy area**

This proposal repeals the two current EMA Fee Regulations, Council Regulation (EC) No 297/95 and Regulation (EU) No 658/2014.

---

7 The veterinary sector operates under different market conditions from the human sector. Notably, there is a general absence of public reimbursement schemes, there are various drivers of investment and price-setting mechanisms resulting in considerably lower prices, and it is rather fragmented due to the various species to which it caters and their relative geographical and market importance.

8 Evaluation of the European Medicines Agency's fee system (SWD(2019) 336 final).

9 In accordance with Regulation (EU) No 658/2014, national competent authority remuneration is proportionately reduced in the case of fee reductions whereas the Rules for implementation of Council Regulation (EC) No 297/95 do not provide for a reduction in national competent authority remuneration in proportion to applicable fee reductions.

Fees and charges proposed are levied for EMA activities as set out in Regulation (EC) 726/2004, Regulation (EU) 2019/6.

Consistency with fee reductions and exemptions set out in Regulation (EC) No 2049/2005, Regulation (EC) No 1901/2006, Regulation (EC) No 141/2000, and Regulation (EC) No 1394/2007 is ensured through the correlation table in Annex VII.

- **Consistency with other Union policies**

The proposal is consistent with the SME (small and medium enterprises) strategy[10] and its pillar aimed at reducing regulatory burden and improving market access. This consistency is ensured through specific fee reductions for post-authorisation procedures, in addition to fee reductions provided for in Commission Regulation (EC) No 2049/2005.

The proposal also takes into account the Joint Statement and Common Approach on decentralised agencies[11]. In particular, the proposal includes a requirement for a positive opinion by the Commission before working arrangements for the application of the regulation can by adopted by the Management Board of the Agency or before the Board decides to grant further fee reductions. This is consistent with the role of the Commission to monitor whether the Agency's Management Board takes decisions that are in compliance with the mandate of the Agency, EU law and EU policy objectives[12].

By offering fee incentives to certain types of veterinary medicinal products, such as immunological products, which often prevent diseases whose treatment relies on the use of antimicrobials, the proposal is also consistent with the Commission objective under the Farm to Fork Strategy[13] of halving by 2030 EU sales of antimicrobials for farmed animals and aquaculture.

This proposal is presented in the context of the respective evaluation and assessment of impacts relating to the EMA fee legislation, as part of the same process. It is presented ahead of the revision of the EU basic pharmaceutical legislation, in order to allow for a more agile EMA fee system, with quicker adjustments to possible changes stemming from that revision, through the flexibility of Commission delegated acts. The timing of the proposal also takes into account the timeline of the legislative financial statement of the proposal (COM(2020) 725 final) of Regulation (EU) 2022/123. This has a specific objective No 3 '*Allow timely access and analysis of EU-wide health data to support better decision-making throughout the product lifecycle on medicines (development, authorisation, performance monitoring) with valid and reliable real-world evidence*' ('*node reuse data*'). In line with this, funding for the operational phase of EMA activities, making it possible to achieve the above-mentioned objective, should be switched from the EU EMA budget contribution to

10 (COM(2020) 103 final).

11 https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf.

12 Joint Statement of the European Parliament, the Council of the EU and the European Commission of 19 July 2012 on decentralised agencies, Common Approach, V. Accountability, controls and transparency and relations with stakeholders, *59. Alert/warning system.*

13 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *A Farm to Fork Strategy for a fair, healthy and environmentally friendly food system*, COM(2020) 381 final.

fee income as of 2024. Thus the proposal is also consistent with the digital health policy.

The proposal also contributes to administrative simplification and reduction of burden by reducing the number of legal instruments setting EMA fees from two to one.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The proposed regulation has a dual legal basis: Article 114 and Article 168(4)(c) and (b) of the Treaty on the Functioning of the European Union (TFEU).

The proposed regulation is based, firstly, on Article 114 TFEU. Differences between national legislative, regulatory and administrative provisions on medicinal products tend to hinder intra-EU trade and therefore directly affect the operation of the internal market. This regulation will ensure in particular the availability of the necessary financial resources for the application of EU procedures for the assessment of serious safety issues for nationally authorised products, which, among other things, prevent or eliminate obstacles that could result from parallel procedures at national level. Therefore, this regulation will contribute to the smooth functioning of the internal market and the common post-marketing surveillance of medicinal products.

The proposed regulation is based, secondly, on Article 168(4)(c) and (b) TFEU. It aims to support the goal of setting high standards of efficacy, quality and safety of medicinal products and measures in the veterinary fields that have as their direct objective the protection of public health.

In accordance with Articles 168(4) and 4(2)(k) TFEU, this EU competence is – like the one under Article 114 TFEU - a shared competence that is exercised through the adoption of the proposed regulation.

The proposed regulation ensures the availability of sufficient financial resources to support the performance and assessment activities that are necessary to guarantee that high standards are not only applied for the authorisation of products but also maintained once the product is authorised.

Article 168(4)(c) and (b) TFEU cannot serve as the sole legal basis. It needs to be complemented by the legal basis of Article 114 TFEU, which, as set out above, pursues equally as objectives the establishment and functioning of the internal market, and the setting of high standards of quality and safety for medicinal products. Both objectives are pursued simultaneously and are inseparably linked, so that one is not secondary to the other.

- **Subsidiarity (for non-exclusive competence)**

The EMA is a decentralised agency of the EU. Therefore, decisions on its funding and the fees it may charge can only be taken at EU level. Only the EU can act to enable the Agency to charge fees and to define the levels of those fees. EU action is therefore justified and necessary.

This Regulation only regulates fees and charges which that are to be levied by the Agency, for its statutory tasks. The competence to decide on possible fees levied by the national competent authorities remains with the Member States, including in

relation to possible adaptation of such fees as the statutory tasks of the Agency evolve.

- **Proportionality**

The proposal does not go beyond what is necessary to achieve the general objective pursued, i.e. to introduce fees to ensure the necessary funding for the proper implementation of EU pharmaceutical legislation. The proposal addresses the problems that have been identified only in respect of EMA fees, based on costs related to EMA activities. Contributions and respective costs of national competent authorities are taken into account only insofar as they contribute to an EMA activity. Thus, to achieve its aims, the EU only takes those actions that it needs to take and does not go beyond them.

- **Choice of the instrument**

Since the Treaty on the Functioning of the European Union became applicable, all legislative procedures are normally based on the previous co-decision procedure involving both the Council and the European Parliament. Therefore, for legal certainty, it is proposed to create a new regulation of the Council and the European Parliament, which will be subject to the ordinary legislative procedure (Article 294 of the TFEU).

The adoption of a proposal for a regulation on fees and charges collected by the European Medicines Agency aims to ensure that the Agency has appropriate funding to properly implement the applicable legislation, taking into account the EU budget contribution. Moreover, the EMA fee system should be sufficiently flexible to adapt to changes to the Agency's mandate, in order to make it future-proof and resilient in times of crisis. In parallel, the EMA fee system should also have the necessary agility to respond to future developments in science and possible changes in the complexity of scientific assessments that are required by existing regulatory procedures.

For the above reasons, it is proposed that the annexes to this regulation should be amendable by delegated acts. The annexes lay down the cases where a fee is charged and where remuneration is paid to national competent authorities, as well as the amounts of those fees and the amounts for national competent authorities' remuneration and the applicable fee reductions. This proposal is justified by the need for agility of the EMA fee system and the fact that it does not grant discretionary powers. Indeed, all activities of the Agency are either funded by budget contributions or grants, the main budget contribution being the EU budget contribution, or by a fee that includes in its calculation, where relevant, remuneration for national competent authorities for services to the Agency performed by rapporteurs and co-rapporteurs, or by a charge. It is proposed that the Commission may act based on the information in its possession on:

- new costs or significant changes in existing costs due in particular to a change in the legal tasks of the Agency stemming from future amendments to the respective legal frameworks; or
- a significant change in the inflation rate; or
- a significant change in the costs of performing the existing tasks of the Agency, in particular in relation to the outcome of a cost monitoring system, including based on a special report delivered by the Agency or information from the budgetary reporting of the Agency .

3. RESULTS OF *EX POST* EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- ***Ex post* evaluations/fitness checks of existing legislation**

The evaluation[14] of the EMA fee system identified the following problems.

i) The fee system is too complex due to many different categories and types of fees and is therefore difficult to apply and not easily predictable.

ii) There is misalignment of some fees with the underlying costs. Fees for some assessment procedures exceed the total EMA and national competent authority costs of delivering them (e.g. major variations), while fees for some other assessment procedures fall short of costs (e.g. initial marketing authorisation procedures). Furthermore, no fee exists for some assessment procedures that create costs and, consequently, no remuneration is provided to national competent authorities for their participation in such activities (e.g. assessment procedures related to paediatric investigation plans and orphan designation).

iii) There is misalignment with underlying costs of some remunerations paid to national competent authorities. National competent authorities receive more remuneration than their incurred eligible costs for certain assessments (e.g. variations) and less than their incurred eligible costs for others (e.g. assessment of initial marketing authorisation).

iv) The Fee Regulation and Pharmacovigilance Fee Regulation differ in their approach to determining the amount of national competent authorities' remuneration and in the distribution of the financial burden of fee incentives between the EMA and national competent authorities. This creates a lack of coherence within the fee system.

These problems are addressed by the proposal, as follows.

i) The complexity of the fee system is reduced by including some post-authorisation activities under the annual fee for centrally authorised products.

ii) Fees are better aligned to costs, and some new fees and remuneration amounts are introduced. These fees and remuneration amounts have been calculated using a budget model of the Agency. This relies on an evaluation of cost of assessment procedures and maintenance activities based on data from national competent authorities and the EMA.

iii) Remuneration for national competent authorities is better aligned with costs and is included in the calculation of fees that are determined as an output of the above-mentioned model.

iv) A unified approach is proposed for determining national competent authorities' remuneration (such that national competent authorities remuneration is not reduced when fee reductions apply).

- **Stakeholder consultations**

Due to the highly technical nature of the measures under consideration and their limited direct relevance, no public consultation was conducted during the impact

[14] Evaluation of the European Medicines Agency's fee system, SWD(2019) 336 final evaluation_ema_fee_swd2019336_en_0.pdf (europa.eu).

assessment process. Instead, the six key stakeholder groups (EMA; national ministries and national competent authorities; EU pharmaceutical industry associations for human and veterinary medicines; research associations; and wider EU stakeholder associations, including healthcare professional and patient and consumer associations) concerned by the EMA fee system were consulted via a targeted survey.

These surveys were followed up by a series of targeted interviews with seven national competent authorities, the EMA and the Heads of Medicines Agencies (HMA). A brief description of the subjects discussed is set out in the paragraphs below.

- Asked about issues relating to governance, good administration and financial stability, consultees' feedback focused on financial stability. All stakeholders generally underlined the importance of a proper financing of EMA activities and national competent authorities' contributions, with national competent authorities indicating that an overall decrease in their remuneration relative to the current situation would not be sustainable. This was taken into account by the Commission to the extent that any proposal for a revised fee system should be cost-based, i.e. the way the fees are calculated and set should have as its guiding principle the recovery of the respective costs incurred. The fee amounts presented in this proposal have therefore been recalculated as compared with those presented during the consultation process, using a less granular approach to assessing eligible costs for activities of national competent authorities that are not directly attributable to a specific assessment procedure but represent a service to the EMA. In particular, a revised approach was applied when calculating the annual fee for centrally authorised products and the related annual remuneration to national competent authorities.
- The need for financial predictability and simplification was also raised by those consulted, including in terms of the role of annual versus procedural fees. Following consultations, a new option emerged that sought a middle way with respect to simplification, whereby the costs of some minor post-authorisation procedures are included in the annual fee calculation, but major post-authorisation procedures still attract a fee per procedure. This represents a simplification of the existing system while taking into account a major requirement of the legislation for a cost-based approach. It is this option which forms the basis of the present proposal.
- Certain specificities of the veterinary sector highlighted by stakeholders during the consultations were taken into account by proposing targeted fee reductions for veterinary products.
- With regard to monitoring and adjusting of the amounts for fees and remunerations, the proposal takes into account the views expressed during consultations that the system should be flexible in order to be future-proof. It therefore proposes the delegation of powers to the Commission to amend fee and remuneration amounts based on a monitoring mechanism or a change in the legal tasks of the Agency.
- Applying country coefficients to national competent authorities remuneration, although bringing the remuneration closer to the cost base, was unanimously rejected by stakeholders as unfair and too burdensome. It does not therefore form part of this proposal.

- **Impact assessment**

The proposal is supported by an impact assessment in the accompanying staff working document. The Regulatory Scrutiny Board issued an opinion on the impact assessment on 13 May 2022. The impact assessment received a positive opinion with reservations. The opinion of the Board and the final impact assessment and its executive summary are published together with this proposal.

Four alternative policy options were assessed against a do-the-minimum baseline option. The do-the-minimum baseline option is the reference scenario, consisting of the current fee system, which remains unchanged, while taking into account the newly introduced provisions for the veterinary sector (to the extent possible without legal change) and the legislative financial statement of the proposal (COM(2020) 725 final) of Regulation (EU) 2022/123. In this way, and given the aim to ensure the specific objective No 3 is achieved (activities related to access and reuse of real-world data), funding for the operational phase of the respective EMA activities would be switched from the EU EMA budget contribution to fee income as from 2024.

- The first option (Option 1) consisted of aligning the fee system with the provisions introduced by the VMP Regulation, including recalculation of fees for the veterinary sector in line with the cost-based principle. For human medicines, the related fees and national competent authorities' remuneration remain unchanged under this option.
- The second option (Option 2) aligned the fee system with the VMP Regulation and also aligned fees and remuneration amounts for both veterinary and human medicines with the respective costs of the EMA and national competent authorities for carrying out the work. Thus, Option 2 introduced a cost-based fee system for all national competent authorities' activities, while the overall architecture of the system remained unchanged as compared with the baseline and Option 1.
- The third option (Option 3) built on Option 2, not only introducing a cost-based fee system for human and veterinary activities, but also significantly simplifying the fee system structure for both human and veterinary medicines. A reduced number of procedural fees were applied for post-authorisation non-pharmacovigilance activities for human and veterinary medicines. Procedural fees were levied for pre-authorisation activities (human and veterinary), inspections and only some major post-authorisation activities (e.g. referrals)[15]. The annual fee for centrally authorised products covered a broader set of costs as compared with the current system, including those non-pharmacovigilance post-authorisation procedures for which a procedural fee is no longer levied. National competent authority remuneration for those post-authorisation procedures, which are charged under this option through the centrally authorised product annual fee, was no longer per procedure and was included in the annual remuneration paid to national competent authorities via the annual fee for centrally authorised products.

[15] A referral is a procedure used to resolve at the level of the EMA issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines.

- The fourth option (Option 3 Light) was a lighter version of the third option, which simplified the fee system structure to a lesser extent. This option was developed in response to feedback received on the inception impact assessment requesting the Commission to consider an option with a more modest level of simplification, as compared with Option 3, in order to remain closer to the cost, as and when it occurs. Under Option 3 Light, fewer procedural activities were covered by annual fees compared with Option 3 (mainly assessment of minor variations and of renewals of authorisations) while procedural fees were maintained for a larger number of activities (mainly major variations).

All options were assessed on the basis of a detailed financial model of the Agency's budget (cost and revenue), including the cost for remuneration to national competent authorities, and detailed projections. The financial model developed for the assessment of the policy options used as an input estimated costs of activities of the Agency and of contributions of national competent authorities, as well as estimated level of activities (frequencies). Workload data for the Agency and competent authorities of the Member States were collected during a vast data gathering exercise initiated by the Agency's Management Board, with the full participation of the Agency and competent authorities of the Member States represented at the Management Board. Frequencies and unitary cost were estimated in detail during the evaluation and were further updated for the purpose of the impact assessment. The detailed outputs of the financial model were presented for consultation to stakeholders during the impact assessment. The feedback to those targeted consultations was taken into account in a subsequent update of the model calculations and the final updated output was used for this proposal.

The analysis of the options was based on a range of indicators relating to:

- performance as regards cost coverage (on aggregate, and also for individual activities, analysed both for the EMA and for contributions from national competent authorities);
- capacity of the system to adjust to changes;
- balance between simplicity, i.e. fewer fee levels, and more granular cost-based approach, i.e. more fee levels;
- capacity to finance fee incentives;
- adaptability to exceptional circumstances;
- predictability;
- administrative burden;
- position of small and medium-sized enterprises (SMEs);
- impact on research and innovation; and
- functioning of the internal market.

Indicators related to cost-reflectiveness were given the highest relative weight in the analysis. This is due to the clear requirement in the legislation that any revision of fees should be based on cost estimations. The validity of this approach was clearly confirmed by the feedback to consultations from all types of stakeholders, where the emphasis was on cost-reflectiveness. The next greatest weighting was given to the indicators related to the simplification of the fee system, as the need for simplification had been clearly identified during the evaluation and in the

consultations. The minimisation of administrative burden was also important, being a general principle of all EU legislation.

On these criteria, Option 1 performed noticeably worse than the other options. This is the result of Option 1 doing especially poorly on cost-reflectiveness, assessed through several indicators on both an aggregate and granular level.

Comparing Option 3 with Option 3 Light, they differed in terms of alignment to granular costs, predictability, and administrative burden, and on the balance achieved between the two major criteria, i.e. the cost-based approach and simplicity. Option 3 Light scored relatively better overall than Option 3 since cost-reflectiveness is the single most important indicator and it scored higher in terms of achieving the balance with simplicity as well.

The differences between Options 2 and 3 were less pronounced than the differences between Options 3 and 3 Light. Option 2 achieved a higher score than both Options 3 and 3 Light in terms of alignment to individual (granular) costs, but a lower score in terms of predictability, administrative burden, and balance achieved between cost-based approach and simplicity.

The choice between Options 3 and 3 Light was finely balanced. In the final analysis, Option 3 Light was preferred because it had the merit of achieving some improvements in simplicity compared with the current fee system, while at the same time introducing cost-reflective fees for all activities at a sufficiently granular level.

The Regulatory Scrutiny Board of the Commission issued a positive opinion with reservations that were addressed in the Staff Working Document accompanying this initiative. Interlinkages and coherence with the upcoming revision of the EMA founding regulation were mentioned, which is addressed via the flexibility sought with the provisions enabling the Commission to update the annexes of the proposed regulation. In addressing the RSB comments, the trade-offs between cost alignment, simplicity and the flexibility objectives were better explained, with cost-alignment being singled out as the objective carrying the most relative weight, as required by the legislation. Further, the impact assessment report clarifies that internal efficiency improvement measures rather relate to the founding regulation of EMA, whereas the objective of the fee legislation is to cover the relevant costs. The report also clarifies that country coefficients for national competent authorities remuneration would lead to significant administrative burden, outweighing any marginal benefits. It also explains that national competent authorities' remuneration is calculated based on a weighted average cost as opposed to the highest cost. A clarification is provided that the baseline (no change to the legislation) is not a viable way forward, in particular it as cannot provide full alignment to the changes in the veterinary sector and full alignment to EMA projected costs, in particular for activities related to allowing timely access and analysis of EU-wide health data to support better decision-making throughout the product lifecycle on medicines with valid and reliable real-world evidence. Impacts on fee payers are presented by types of fees. The overall impact of this initiative on the development and availability of medicines is equally clarified by comparison with estimated development costs. It is clarified that there are no significant social, environmental or fundamental rights impacts. It is equally clarified that the impact on the administrative burden is neutral (or possibly positive through the relative simplification of the system achieved under the preferred option).

The initiative is consistent with the climate-neutrality objectives, as does not impact on the EU greenhouse gas emissions, due to the nature and the scope of the initiative.

Regulatory fitness and simplification

In line with EU policy to support SMEs, fee reductions are proposed for SMEs within the meaning of Commission Recommendation 2003/361/EC. Reductions include those already provided for in Commission Regulation (EC) No 2049/2005 and, in order to take due account of the ability of SMEs to pay, further reductions to post-authorisation fees.

Consistent with EU policy, microenterprises within the meaning of the above-mentioned Recommendation are exempt from all post-authorisation fees established under this Regulation.

The proposal is consistent with the principles of digital-ready policymaking in several aspects.

- It takes into account the digitalisation of minor variations (changes to the terms of a marketing authorisation, e.g. the processing of variations that do not require assessment in the EU database on veterinary medicinal products (Union Product Database).
- It provides for publication of fee-related information on the website of the Agency.
- The respective definitions of 'chargeable unit' for products for human and use and veterinary products are consistent with the IT tools used by the Agency, in the human and veterinary areas, consistent with a user-centric and ready-for-automation process.
- The information flows between the Agency and applicants/marketing authorisation holders and between the Agency and national competent authorities are taken into account.

The proposal also contributes to administrative simplification by bringing together fee rules in a single legal instrument.

- **Fundamental rights**

The proposal has no impact on the protection of fundamental rights.

4. BUDGETARY IMPLICATIONS

The multiannual financial framework until 2027 is fully respected by the amounts calculated for this proposal. This proposal does not have implications on the EU budget and its contribution to the EMA budget. The proposal will not result in the need for additional resources to effectively manage the fee system.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The proposal aims to put in place a monitoring framework, whereby the Agency collects and monitors data relating to the cost of activities, including remuneration to national competent authorities, and flags to the Commission significant trends on an objective basis. The Agency will monitor the implementation, application and compliance of these new provisions with a view to assessing their effectiveness.

The experience gathered with the monitoring framework will be used for the next evaluation of the EMA fee legislation and the fee system it governs.

- **Detailed explanation of the specific provisions of the proposal**

The first two articles provide the subject matter and the definitions relevant to the proposed regulation.

In particular, in order to have a fair system, in Article 2 it was considered necessary to identify a harmonised unit by which relevant pharmacovigilance-related fees would be charged with regard to nationally authorised products, as there are different ways in the EU of assigning authorisation numbers to, and of counting, medicinal products. To facilitate adverse reaction reporting and signal detection[16], it is necessary to describe with maximum precision medicinal products at unit level in order to take account of differences in strength, pharmaceutical forms, routes of administration, etc.

For medicinal products for human use, the structure of the database described in Article 57(2) of Regulation (EU) 726/2004 neutralises these differences by means of individual entries. These entries have been chosen as a chargeable unit, as it is the case currently under Regulation (EU) No 658/2014.

This proposal introduces a similar approach with regard to veterinary medicinal products, for which the Union Product Database, referred to in Article 55 of Regulation (EU) 2019/6, will be the system that will be used for calculating the chargeable units. That database being more recent, the definition is even more precise and includes the pharmaceutical form, with chargeable units for veterinary products being counted with a level of granularity when setting the fee levels that would ensure they cover the corresponding costs.

Articles 3 and 4 describe the types of fees and charges than can be levied by the EMA and refer to the relevant annexes where the corresponding amounts are laid down with, where relevant, the amounts for remuneration to the national competent authorities in Member States.

Article 5 deals with the conditions of remuneration paid to national competent authorities in relation to fees levied by the Agency.

Article 6 sets out applicable fee reductions and related rules and refers to the relevant annex where the reductions are set out. The Article also empowers the EMA Executive Director to grant further fee reductions in exceptional circumstances, while the Management Board of the Agency is empowered, following a favourable opinion from the Commission, to grant further reductions in non-exceptional circumstances for justified reasons, such as for protection of public and animal health.

Articles 7 deals with conditions and rules pertaining to payment of fees and charges.

Article 8 mandates the Management Board of the Agency to specify detailed technical arrangements to facilitate the application of the proposed regulation, such as payment methods of fees and charges and the precise mechanism under which the remuneration provided for by the proposed regulation is paid to national competent authorities. A positive opinion by the Commission is required to ensure consistency with EU legislation, in line with the Joint Statement and Common Approach on decentralised agencies.

[16] Signal detection is the initial step in a continuous process aimed at determining whether there are new risks associated with an active substance or a medicinal product or whether known risks have changed.

Article 9 deals with due dates and provides for the possibility for the Executive Director to suspend services in the case of non-payment.

Article 10 sets out requirements for transparency of the amounts provided for by the proposed regulation and provides for monitoring of costs and inflation and reporting. It provides for the possibility for the EMA Executive Director to present to the Commission a factual and quantified ad hoc special report based on the above monitoring and to recommend amendment of the fees, charges and remuneration laid down in the annexes.

Article 11 sets out the conditions for a review of the amounts laid down in the Regulation, following a cost-based approach. It enables the Commission to adopt delegated acts to amend the annexes, based on the above-mentioned ad hoc report or the budgetary reporting of the Agency, a monitoring of the inflation rate, a change in EU legislation with respect to tasks of the Agency or new information on practical aspects of implementation of activities that attract a fee or a charge.

Article 12 sets out how the Agency will provide budgetary estimates, including detailed information on income from various types of fees and charges.

Article 13 sets out the conditions for the Commission to adopt delegated acts to amend the annexes.

Article 14 provides the legal basis for fees in accordance with the procedure under Article 106(14) of Regulation (EU) No 2017/745 to be charged by the Agency.

Article 15 repeals the two current EMA Fee Regulations that the present proposal replaces.

Article 16 specifies the conditions for applicability of the proposed regulation in relation to its date of entry application.

Article 17 provides the date of entry into force and application.

Annexes I and II set out fees, charges and remuneration for procedures and services relating to, respectively, medicinal products for human use and veterinary medicinal products.

Annex III sets out annual fees and remuneration for medicinal products for human use and veterinary medicinal products.

Annex IV sets out various other fees and charges for both medicinal products for human use and veterinary medicinal products, as well as consultations on medical devices – for inspections, transfer of authorisations, pre-submission services, re-examination of opinions and other scientific and administrative services.

Annex V sets out fee reductions for specific applicants and products.

Annex VI sets out the performance information provided by the Agency, including information collected from national competent authorities in Member States.

2022/0417 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

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

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

Acting in accordance with the ordinary legislative procedure,

Whereas:

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

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

(3) The fees payable to the Agency should be proportionate to the work carried out in relation to obtaining and maintaining a Union authorisation, and should be based on an evaluation of the Agency's estimations and forecasts as regards the workload and related costs for that work, as well as on an evaluation of the costs of the services provided to the Agency by the competent authorities of Member States that are

[1] OJ C , , p. .
[2] OJ C , , p. .

responsible for regulating medicinal products, which act as rapporteurs and, where applicable, co-rapporteurs appointed by the scientific committees of the Agency.

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

(5) Fees and charges should cover the cost of statutory services and activities of the Agency that is not already covered by the contributions to its revenue from other sources. All relevant Union legislation governing the Agency's activities and fees should be taken into account when establishing the fees and charges, including Regulation (EC) No 726/2004, Regulation (EU) 2019/6 of the European Parliament and of the Council[5], Directive 2001/83/EC, Regulation (EC) No 1901/2006 of the European Parliament and of the Council[6], Regulation (EC) No 141/2000 of the European Parliament and of the Council[7], Regulation (EC) No 1394/2007 of the European Parliament and of the Council[8], Commission Regulation (EC) No 2049/2005[9], Commission Regulation (EC) No 1234/2008[10], Regulation (EU) 2017/745 of the European Parliament and of the Council[11], Regulation (EC) No 470/2009 of the European Parliament and of the Council[12], Commission Regulation (EU) 2018/782[13],

---

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

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

5 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 (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

Commission Implementing Regulation (EU) 2021/1281[14] and Commission Regulation (EC) No 2141/96[15].

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

(7) In line with the Joint Statement of the European Parliament, the Council of the EU and the Commission of 19 July 2012 on decentralised agencies, for bodies for which the revenue is constituted by fees and charges in addition to the Union contribution, fees should be set at a level that avoids a deficit or a significant accumulation of surplus, and should be revised when this is not the case. Therefore, a cost monitoring system should be put in place. The purpose of such monitoring system should be to detect significant changes of costs of the Agency that, taking into account the Union contribution and other non-fee revenue, could require a change in fees, charges or remuneration established under this regulation. That monitoring system should equally be able to detect, based on objective and verifiable information, significant changes of costs of remuneration of services provided to the Agency by the competent authorities of Member States, which act as rapporteurs and, where applicable, co-rapporteurs and by experts contracted by the Agency for the procedures of the expert panels on medical devices. Cost information relating to services remunerated by the Agency should be auditable in accordance with Article 257 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[16].

(8) Fees should be levied on marketing authorisation applicants and holders on a fair basis whereby the fee charged is proportionate to the assessment work. Therefore, for the purpose of charging some post-authorisation fees where products authorised by the Member States are included in the assessment performed by the Agency, a chargeable unit should be established, irrespective not only of the procedure under which the product has been authorised, namely under Regulation (EC) No 726/2004 or Regulation (EU) 2019/6 or Directive 2001/83/EC, but also of the way in which authorisation numbers are assigned by Member States or the Commission. For

---

substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

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

14 Commission Implementing Regulation (EU) 2021/1281 of 2 August 2021 laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products (OJ L 279, 3.8.2021, p. 15).

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

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

medicinal products for human use, that objective should be met by establishing the chargeable unit on the basis of the active substances and the pharmaceutical form of the products that are subject to the obligation to be registered in the database referred to in Article 57(1), second subparagraph , point (l), of Regulation (EC) No 726/2004, based on information from the list of all medicinal products for human use authorised in the Union referred to in Article 57(2), second subparagraph, of that Regulation. The active substances should not be taken into account when establishing the chargeable unit in respect of homeopathic medicinal products or herbal medicinal products. For veterinary medicinal products, the same objective of fairness and proportionality should be met by establishing the chargeable unit based on information contained in the Union product database referred to in Article 55(1) of Regulation (EU) 2019/6, such as the active substances, the pharmaceutical form and the strength of veterinary medicinal products, which are taken into account in the Product Identifier referred to under Data Field ID 3.2 in Annex III to Commission Implementing Regulation (EU) 2021/16[17], as well as the Permanent Identifier referred to under Data Field ID 3.1 in Annex III to that Implementing Regulation.

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

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

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

(12) A specific annual fee should be charged for medicinal products authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products

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

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

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

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

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

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

(17) The Management Board of the Agency should be empowered to provide further fee reductions for justified reasons of protection of public and animal health. A favourable opinion from the Commission should be mandatory before granting further fee reductions, in order to ensure alignment with Union law and with overall policies of the Union. In addition, in duly justified exceptional cases, for imperative reasons of public or animal health, it should also be possible for the Executive Director of the Agency to reduce certain types of fees on the basis of a critical examination of the situation specific to each case.

(18) In order to provide flexibility, in particular to adapt to developments in science, the Management Board of the Agency should be enabled to specify working arrangements to facilitate the application of this Regulation, on a duly justified proposal from the Executive Director. In particular, the Management Board should be able to establish due dates and deadlines for payment, payment methods, timetables, detailed classifications, lists of additional fee reductions, and detailed amounts within the limits of an established range. A favourable opinion from the Commission should be mandatory before the proposal is put to the Management Board for adoption, in order to ensure alignment with Union law and with overall policies of the Union.

(19) For their assessments, rapporteurs and co-rapporteurs and the other roles considered as equivalent for the purposes of this regulation in scientific advice and inspections rely

on the scientific evaluations and resources of the competent authorities of Member States, while it is the responsibility of the Agency to coordinate the existing scientific resources put at its disposal by the Member States, in accordance with Article 55 of Regulation (EC) No 726/2004. In light of that, and to ensure appropriate resources for the scientific assessments relating to the procedures carried out at Union level, the Agency should remunerate the scientific assessment services provided by the rapporteurs and co-rapporteurs appointed by the Member States as members of the scientific committees of the Agency, or, where relevant, provided by rapporteurs and co-rapporteurs in the coordination group referred to in Article 27 of Directive 2001/83/EC. The amount of remuneration for the services provided by those rapporteurs and co-rapporteurs should be based on estimations of the workload involved and should be taken into account in setting the level of the fees charged by the Agency.

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

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

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

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

(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

---

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

[19] Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises (OJ L 329, 16.12.2005, p. 4).

inflation. For the purpose of taking into account the impact of inflation, the Harmonised Index of Consumer Prices published by Eurostat pursuant to Regulation (EU) No 2016/792 of the European Parliament and of the Council[20] should be used.

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

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

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

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

---

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

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

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

23 Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

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;

(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).

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 12(1) of Decision No 1082/2013/EU of the European Parliament and of the Council[24].

Article 3

Types of fees and charges

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

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

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

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

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

Article 4

Additional fees and charges

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

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

[24] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

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 apply, the remuneration to competent authorities of the Member States payable in accordance with this Regulation shall not be reduced.

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

Article 6

Reductions of fees and charges

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

2. Where an assessment, an opinion or a service of the Agency is requested either by a Member State or by a Union institution, the Agency shall waive the respective fee or charge, as applicable, in full.

3. 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 authorisation holder shall apply.

4. On a duly justified proposal from the Executive Director of the Agency, in particular for the protection of public or animal health or for the support of specific types of products or applicants, selected for duly justified reasons, the Management Board of the Agency may grant, following a favourable opinion from the Commission, a total or partial reduction of the applicable amount, in accordance with Article 8.

5. In exceptional circumstances and for imperative reasons of public or animal health, the Executive Director of the Agency may grant, on a case-by-case basis, total or partial reductions for the fees set out in Annexes I, II, III and IV, with the exception of the fees set out in points 6, 15 and 16 of Annex I, points 7 and 10 of Annex II and point 3 of Annex III. Any decision taken pursuant to this Article shall state the reasons on which it is based.

Article 7

Payment of fees and charges

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

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

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

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

Article 8

Working arrangements

The Management Board of the Agency shall, on a justified proposal from the Executive Director and following a favourable opinion from the Commission, establish working arrangements to facilitate the application of this Regulation, including payment methods of the fees and charges levied by the Agency and the mechanism for payment of remuneration to competent authorities of the Member States under this Regulation.

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

Article 9

Due date and measures in case of non-payment

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

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

Article 10

Transparency and monitoring

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

2. The Agency shall monitor its costs and the Executive Director of the Agency shall provide, as part of the annual activity report delivered to the European Parliament, the Council, the Commission and the Court of Auditors, detailed and substantiated

information on the costs to be covered by fees and charges that are within the scope of this Regulation. That information shall include the performance information set out in Annex VI and a cost breakdown related to the previous calendar year and to a forecast for the following calendar year. The Agency shall also publish an overview of that information in its annual report.

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

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

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

6. At the earliest on [*OP: please insert date 3 years after the date of application*] and at three-year intervals thereafter, the Executive Director of the Agency may, where considered relevant in view of Article 11(2), and after consultation of the Management Board of the Agency, provide the Commission with a special report outlining, in an objective, fact-based and sufficiently detailed manner, justified recommendations:

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

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

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

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

(b) objective and verifiable information and 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 Agency shall without undue delay provide the Commission with an updated version of the report which addresses any comments made and questions raised by the Commission.

9. The reporting time interval referred to in paragraph 6 may be shortened in any of the following situations:

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

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

(c) in the case there is clear and compelling evidence of significant changes in the costs or the cost-revenue balance of the Agency, including 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 it deems it justified in view of any of the following:

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

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

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

(d) the budgetary reporting of the Agency;

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

2. Any revision of the fees and charges and of the remuneration paid to competent authorities of the Member States provided for in this Regulation shall be based on the Commission's evaluation of the Agency’s costs and revenues and of the relevant costs of the services provided to the Agency by the competent authorities of the Member States.

Article 12

Estimate of the Agency’s budget

The Agency shall, when producing an estimate of revenue and expenditure for the following financial year in accordance with Article 67(6) of Regulation (EC) No 726/2004, include detailed information on income from each type of fees and charges and respective

remuneration. In accordance with the typology of fees and charges set out in Article 3 of this Regulation, that information shall distinguish, respectively, between the following:

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

(b) veterinary medicinal products;

(c) annual fees, by type;

(d) other fees and charges, by type.

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

Article 13

Exercise of the delegation

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

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

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

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

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

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

Article 14

Amendment to Regulation (EU) No 2017/745

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

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

Article 15

Repeal

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

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

Article 16

Transitional provisions

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

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

Article 17

Entry into force and date of application

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

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

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

Done at Brussels,

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

[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).