Council of the European Union

Brussels, 20 April 2023
(OR. en)

8423/23

Interinstitutional File: 2022/0417(COD)

LIMITE

PHARM 56
SAN 193
MI 304
COMPET 335
CODEC 639
VETER 42

WORKING DOCUMENT

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

Delegations will find in Annex the annexes as prepared by the Presidency on the above-mentioned subject to be examined at the meeting of the members of the Working Party on Pharmaceuticals and Medical Devices on 27 April 2023.

Changes compared to the Commission proposal are marked in **bold/underline** for additions and in ~~strikethrough~~ for deletions.

The attention of delegations is drawn to the fact that a general adjustment has been applied to all fees, both human and veterinary.

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 ~~55 200~~ **79 400** 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 ~~10 400~~ **20 200** for each of the two scientific advice co-ordinators.

1.2. A fee of EUR ~~44 700~~ **62 900** 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 ~~6 500~~ **13 400** for each of the two scientific advice co-ordinators.

1.3. A fee of EUR ~~37 200~~ **49 600** 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 ~~5 300~~ **9 700** for each of the two scientific advice co-ordinators.

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

2.1. A fee of EUR ~~549 800~~ **643 200** shall apply 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.

That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR ~~153 000~~ **183 600** for the rapporteur and EUR ~~143 300~~ **172 000** for the co-rapporteur.

2.2. In the event of multiple submissions of data packages submitted by the same prospective applicant for the same product, the fee set out in point 2.1 (b) shall only be charged once.

2.3. The amounts set out in point 2.1 shall be deducted from the respective fee and from the 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.

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

3.1. A fee of EUR ~~684 900~~ **803 700** 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 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 ~~217 300~~ **260 800** for the rapporteur and EUR ~~189 300~~ **227 200** for the co-rapporteur.

3.2. A fee of EUR ~~549 800~~ **643 200** 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 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 ~~153 000~~ **183 600** for the rapporteur and EUR ~~143 300~~ **172 000** for the co-rapporteur.

3.3. A fee of EUR ~~456 800~~ **533 000** 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 ~~141 500~~ **169 800** for the rapporteur and EUR ~~83 000~~ **99 600** for the co-rapporteur.

3.4. A fee of EUR ~~575 000~~ **677 800** 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 ~~236 500~~ **283 800** for the rapporteur and EUR ~~151 700~~ **182 000** for the co-rapporteur.

3.5. A fee of EUR ~~624 300~~ **728 700** 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 ~~160 600~~ **192 700** for the rapporteur and EUR ~~149 400~~ **179 300** for the co-rapporteur.

3.6. A fee of EUR ~~141 200~~ **233 600** shall apply to ~~any of the following:~~

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

~~(b) 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 ~~40 200~~ **118 900** for the rapporteur.

3.6a (new) A fee of EUR ~~141 200~~ **162 900** shall apply to ~~any of the following:~~

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

~~(d)~~ 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 ~~40~~ **48** 200 for the rapporteur.

3.7. A fee of EUR ~~339 700~~ **397 100** 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 ~~89 100~~ **106 900** for the rapporteur and EUR ~~89 100~~ **106 900** for the co-rapporteur.

3.8. A fee of EUR ~~27 600~~ **31 800** 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 ~~6 800~~ **8 200** for the rapporteur and EUR ~~1 000~~ **1 200** for the co-rapporteur.

4. Extension of a marketing authorisation within the meaning of Annex I to Commission Regulation (EC) No 1234/2008[1]

4.1. A fee of EUR ~~138 000~~ **161 300** 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 ~~45 300~~ **54 400** for the rapporteur and EUR ~~26 600~~ **31 900** for the co-rapporteur.

4.2. A fee of EUR ~~161 000~~ **188 300** 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 ~~55 300~~ **66 400** for the rapporteur and EUR ~~31 200~~ **37 400** for the co-rapporteur.

4.3. Without prejudice to points 4.1 and 4.2, a fee of EUR ~~27 600~~ **31 800** 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 ~~6 800~~ **8 200** for the rapporteur and EUR ~~1 000~~ **1 200** for the co-rapporteur.

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1 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. 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 ~~99 800~~ **175 300** 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 ~~29 400~~**64 400** for the rapporteur and EUR ~~29 400~~**64 400** for the co-rapporteur.

5.2. A fee of EUR ~~13 000~~**17 100** shall apply to an application for a major variation of type II not covered by point 5.1. The remuneration shall be EUR ~~6 800~~**10 100** for the rapporteur.

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 ~~800~~ **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 ~~136 700~~**156 700** shall apply to the assessment carried out in the context of a procedure initiated under Article 5(3) of Regulation (EC) No 726/2004. Such fee shall be waived in full. The remuneration shall be EUR ~~12 400~~**14 900** for the rapporteur and EUR ~~12 400~~**14 900** for the co-rapporteur.

6.2. A fee of EUR ~~262 400~~**299 800** shall apply to the assessment carried out in the context of a procedure initiated under Article 13 of Regulation (EC) No 1234/2008. Such fee shall be waived in full. The remuneration shall be EUR ~~15 300~~**18 400** for the rapporteur and EUR ~~15 300~~**18 400** for the co-rapporteur.

6.3. A fee of EUR ~~83 000~~**94 600** shall apply to the assessment carried out in the context of a procedure initiated under Article 29(4) of Directive 2001/83/EC. Such fee shall be waived in full. The remuneration shall be EUR ~~2 800~~**3 400** for the rapporteur and EUR ~~2 800~~**3 400** for the co-rapporteur.

6.4. A fee of EUR ~~128 200~~**146 400** 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 ~~6 800~~**8 200** for the rapporteur and EUR ~~6 800~~**8 200** for the co-rapporteur.

6.5. A fee of EUR ~~180 700~~**206 700** 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 ~~12 400~~**14 900** for the rapporteur and EUR ~~12 400~~**14 900** for the co-rapporteur.

6.6. A fee of EUR ~~172 100~~**197 600** 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 ~~17 500~~**21 000** for the rapporteur and EUR ~~17 500~~**21 000** 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 ~~172 100~~**210 200** where one active substance or combination of active substances and one marketing authorisation holder are included in the assessment. The remuneration shall be EUR ~~17 500~~**27 300** for the rapporteur and EUR ~~17 500~~**27 300** for the co-rapporteur;

6.7.2. a fee of EUR ~~258 200~~**296 400** 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 ~~26 300~~**31 600** for the rapporteur and EUR ~~26 300~~**31 600** for the co-rapporteur;

6.7.3. a fee of EUR ~~314 100~~**360 600** 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 ~~32 000~~**38 400** for the rapporteur and EUR ~~32 000~~**38 400** for the co-rapporteur;

6.7.4. a fee of EUR ~~426 100~~**489 200** 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 ~~43 400~~**52 100** for the rapporteur and EUR ~~43 400~~**52 100** 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 ~~29 700~~**34 000** 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 **9**~~1~~00 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 ~~57 200~~**66 000** 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 ~~8 600~~**10 300** for the rapporteur and EUR ~~8 600~~**10 300** for the co-rapporteur.

8.2. A charge of EUR ~~5 800~~**6 600** 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 ~~10 600~~**12 200** 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 ~~1 600~~**1 900** for the rapporteur and EUR 1 **9**~~6~~00 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 ~~9~~**8**.4 of this Annex shall apply.

8.4. A fee of EUR ~~17 000~~**19 500** 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 ~~1 900~~**2 300** for the rapporteur and EUR ~~1 900~~**2 300** 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 ~~57 200~~**66 000** 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 ~~8 600~~**10 300** for the rapporteur and EUR ~~8 600~~**10 300** 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 ~~10~~**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 ~~7 800~~**9 100** 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 ~~68 600~~**78 000**. In that case, the remuneration per each second and subsequent VAMF shall be EUR ~~1 900~~**2 300** for the rapporteur and EUR ~~1 900~~**2 300** for the co-rapporteur.

9.3. A charge of EUR ~~5 800~~**6 600** 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 ~~10 600~~**12 200** 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 1 ~~500~~ **800** for the rapporteur and EUR 1 ~~500~~ **800** 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 ~~143 200~~**165 600** 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[2]. Such fee shall be waived in full. The remuneration shall be EUR ~~47 400~~**56 900** for the rapporteur.

[2] 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).

10.2. A fee of EUR ~~95 200~~**110 100** 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 ~~31 500~~**37 800** for the rapporteur.

11. Paediatric applications in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council[3]

11.1. A fee of EUR ~~31 700~~**36 400** shall apply to an application for agreement of a paediatric investigation plan requested pursuant to Article 15 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR ~~6 700~~**8 000** for the rapporteur.

11.2. A fee of EUR ~~17 600~~**20 400** shall apply to an application for a modification of an agreed paediatric investigation plan pursuant to Article 22 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR ~~6 400~~**7 700** for the rapporteur.

11.3. A fee of EUR ~~12 000~~**13 700** shall apply to an application for a product-specific waiver pursuant to Article 13 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR ~~1 800~~**2 200** for the rapporteur.

11.4. A fee of EUR ~~8 000~~**9 100** shall apply to a request for compliance check with the paediatric investigation plan pursuant to Article 23 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR ~~1 000~~**1 200** for the rapporteur.

12. Orphan designation in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council[4]

A fee of EUR ~~16 800~~**19 200** shall apply to an application for the designation of an orphan medicinal product pursuant to Regulation (EC) No 141/2000. Such fee shall be waived in full. The remuneration shall be EUR ~~1 500~~**1 800** for the rapporteur.

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3 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).

4 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 ~~27 000~~**32 600** 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 ~~12 900~~**16 600** 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 ~~88 200~~**100 100** 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 ~~44 100~~**51 200** 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 ~~17 800~~**21 400** for the rapporteur.

15.2.2. EUR ~~44 100~~**51 200** 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 ~~17 800~~**21 400** 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 ~~33 100~~**38 500** 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 ~~15 800~~**18 000** for the scientific advice co-ordinator.

1.2. A fee of EUR ~~24 300~~**28 200** 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 ~~10 100~~**12 100** for the scientific advice co-ordinator.

1.3. A fee of EUR ~~21 300~~**24 600** 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 ~~6 100~~**7 300** 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 ~~5 200~~**5 900** 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[5]

3.1. A fee of EUR ~~84 700~~**98 200** shall apply to an application to set an initial MRL for a given substance. The remuneration shall be EUR ~~21 400~~**25 700** for the rapporteur and EUR ~~10 300~~ **12 400** for the co-rapporteur.

3.2. A fee of EUR ~~53 000~~**61 500** shall apply to each application to modify or to extend an existing MRL. The remuneration shall be EUR ~~10 600~~**12 700** for the rapporteur and EUR ~~9 700~~**11 600** for the co-rapporteur.

3.3. A fee of EUR ~~24 300~~**28 200** 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**~~1~~.7, to Commission Regulation (EU) 2018/782[6]. The remuneration shall be EUR ~~10 100~~**12 100** 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

4.1. A fee of EUR ~~295 500~~**344 800** 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 ~~107 000~~**128 400** for the rapporteur and EUR ~~38 100~~**45 700** for the co-rapporteur.

4.2. A fee of EUR ~~267 700~~**311 400** 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 ~~82 100~~**98 500** for the rapporteur and EUR ~~35 300~~**42 400** for the co-rapporteur.

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5 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).

6 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).

4.3. A fee of EUR ~~136 800~~**158 400** 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 ~~30 800~~**37 000** for the rapporteur and EUR ~~17 900~~**21 500** for the co-rapporteur.

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

A fee of EUR ~~19 000~~**21 900** 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 ~~3 100~~**3 700** for the rapporteur and EUR ~~2 400~~**2 900** 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 ~~87 800~~**102 100** 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 ~~28 600~~**34 300** for the rapporteur and EUR ~~8 600~~**10 300** for the co-rapporteur.

6.2. A fee of EUR ~~47 500~~**55 000** 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 ~~9 800~~**11 800** for the rapporteur and EUR ~~7 600~~**9 100** for the co-rapporteur.

6.3. A fee of EUR ~~23 900~~**29 700** 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 ~~3 600~~**4 300** for the rapporteur and EUR ~~3 600~~**4 300** 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 ~~12 000~~**13 900** per variation and the remuneration shall be EUR ~~1 800~~**2 200** per variation for the rapporteur and EUR ~~1 800~~**2 200** 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~~ **900** 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 ~~152 700~~**175 300** shall apply to an assessment carried out in the context of a procedure initiated under Article 54(8) of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR ~~21 100~~**25 300** for the rapporteur and EUR ~~9 600~~**11 500** for the co-rapporteur.

7.2. A fee of EUR ~~209 300~~**240 300** shall apply to the assessment carried out in the context of a procedure initiated under Article 70(11) of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR ~~29 200~~**35 000** for the rapporteur and EUR ~~12 900~~**15 500** for the co-rapporteur.

7.3. A fee of EUR ~~147 200~~**168 700** shall apply to the assessment carried out pursuant to Article 141(1), points (c) and (e), of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR ~~17 500~~**21 000** for the rapporteur and EUR ~~7 700~~**9 200** for the co-rapporteur.

7.4. A fee of EUR ~~209 300~~**240 300** 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 ~~29 200~~**35 000** for the rapporteur and EUR ~~12 900~~**15 500** for the co-rapporteur.

7.5. A fee of EUR ~~147 200~~**168 700** 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 ~~17 500~~**21 000** for the rapporteur and EUR ~~7 700~~**9 200** 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 ~~23 900~~**27 600** 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 ~~3 600~~**4 300** for the rapporteur and EUR ~~3 600~~**4 300** 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 ~~23 900~~**27 600** shall apply per VAMF. The maximum total amount charged by the Agency shall not exceed EUR ~~71 700~~**82 000**. The remuneration shall be EUR ~~3 600~~**4 300** for the rapporteur and EUR ~~3 600~~**4 300** 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 ~~10 800~~**13 000** for the rapporteur and EUR ~~10 800~~**13 000** for the co-rapporteur.

8.3. A fee of EUR ~~33 100~~**38 200** 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 ~~5 000~~**6 000** for the rapporteur and EUR ~~5 000~~**6 000** 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 ~~23 900~~**27 600** 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 ~~3 600~~**4 300** for the rapporteur and EUR ~~3 600~~**4 300** for the co-rapporteur.

9.2. A fee of EUR ~~33 100~~**38 200** 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 ~~5 000~~**6 000** for the rapporteur and EUR ~~5 000~~**6 000** 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 ~~37 800~~**42 900** 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 ~~18 900~~**21 900** 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[7]. The remuneration shall be EUR ~~7 700~~**9 200** for the rapporteur;

(b) EUR ~~18 900~~**21 900** 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 ~~7 700~~**9 200** for the rapporteur.

10.3. Where the obligation to conduct a post-~~authorisation~~ **marketing** surveillance study is imposed on more than one marketing authorisation holder and the marketing authorisation holders concerned conduct a joint post-~~authorisation safety~~ **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.

[7] 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 ~~48 900~~**56 300** 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 ~~6 400~~**7 700** for the rapporteur and EUR ~~5 600~~**6 700** for the co-rapporteur.

1.2. An annual fee of EUR ~~95 600~~**110 100** 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 ~~12 900~~**15 500** for the rapporteur and EUR ~~11 400~~**13 700** for the co-rapporteur.

1.3. An annual fee of EUR ~~188 000~~**216 500** 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 ~~25 700~~**30 800** for the rapporteur and EUR ~~22 700~~**27 200** for the co-rapporteur.

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 ~~21 500~~**25 000** 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 ~~5 000~~**6 000** for the rapporteur and EUR ~~4 600~~**5 500** for the co-rapporteur.

2.2 An annual fee of EUR ~~87 500~~**101 800** shall apply to each marketing authorisation not covered by point 2.1. The remuneration shall be EUR ~~20 400~~**24 500** for the rapporteur and EUR ~~18 800~~**22 600** for the co-rapporteur.

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 ~~190~~ **220** 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 ~~80~~ **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 ~~24 800~~**29 000** shall apply. The remuneration shall be EUR ~~8 600~~**10 300** for the leading supervisory authority and EUR ~~5 200~~**6 200** for the supporting supervisory authority.

1.1.2. For any distinct Good Manufacturing Practice inspection outside the Union a fee of EUR 37– 800**[72 500]** shall apply. The remuneration shall be EUR 15– 600 **[34 000]** for the leading supervisory authority and EUR 9– 400 **[24 000]** for the supporting supervisory authority.[8]

1.1.3. For any distinct Good Clinical Practice inspection within the Union a fee of EUR ~~37 100~~**43 700** shall apply. The remuneration shall be EUR ~~14 700~~**17 600** for the leading supervisory authority and EUR ~~9 100~~**10 900** for the supporting supervisory authority.

1.1.4. For any distinct Good Clinical Practice inspection outside the Union a fee of EUR 44 200**[67 100]** shall apply. The remuneration shall be EUR 19 600**[32 000]** for the leading supervisory authority and EUR 10– 400**[19 000]** for the supporting supervisory authority.[9]

1.1.5. For any distinct Plasma Master File inspection within or outside the Union a fee of EUR 36 100**[56 500]** shall apply. The remuneration shall be EUR 13 400**[20 000]** for the leading supervisory authority and EUR 8 200**[20 000]** for the supporting supervisory authority.

1.1.6. For any consecutive Plasma Master File inspection within or outside the Union a fee of EUR 36 100**[56 500]** shall apply. The remuneration shall be EUR 13- 400**[20 000]** for the leading supervisory authority and EUR 8- 200**[20 000]** for the supporting supervisory authority.

[8] The proposals for 1.1.2, 1.1.4, 1.1.5 and 1.1.6 in square brackets were calculated based on the suggestions by delegations under the assumption of one fee per site. The Presidency is, however, reflecting on the possibility to clarify that the same approach as the current system should apply, in which several fees per inspection can be charged, and how to recalculate the fees.

1.1.7. For any distinct Good Laboratory Practice inspection within or outside the Union a fee of EUR ~~34 900~~**41 000** shall apply. The remuneration shall be EUR ~~13 200~~**15 800** for the leading supervisory authority and EUR ~~8 700~~**10 400** for the supporting supervisory authority.

1.1.8. For any distinct pharmacovigilance inspection within or outside the Union a fee of EUR ~~52 700~~**61 500** shall apply. The remuneration shall be EUR ~~16 200~~**19 400** for the leading supervisory authority and EUR ~~10 100~~**12 100** for the supporting supervisory 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, a charge of EUR ~~840~~ **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 ~~3 700~~**4 200** shall apply to an application for the transfer of a marketing authorisation pursuant to Article 3 of Commission Regulation (EC) No 2141/96[10]. 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.

[10] 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).

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 ~~7 100~~**8 200** 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 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 ~~1 300~~**1 600** for the rapporteur and EUR ~~1 300~~**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 ~~3 500~~**4 000** shall apply. The additional remuneration of the national competent authority, where applicable, shall be EUR ~~600~~ **700** for the rapporteur and EUR ~~600~~ **700** 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 ~~4 100~~**4 800** to EUR ~~684 500~~**805 100**. The range for the remuneration shall be EUR ~~1 000~~**1 200** to EUR ~~217 300~~**261 000** 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 ~~3 700~~**4 200** 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.

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 ~~3 700~~**4 200** 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.

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 ~~140~~ **160** shall apply to each request for a set of certificates issued by the Agency for a medicinal product, using the standard procedure for issuing the certificate.

6.2.2. A charge of EUR ~~420~~ **480** shall apply to each request for a set of certificates 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 ~~1 200~~**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 ~~350~~ **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 ~~350~~ **400** shall apply to each annual update notification. That charge shall cover all the presentations belonging to the same ~~pharmaceutical form of 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 ~~100~~ **110** to EUR ~~10 000~~**11 300**. 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 ~~94 000~~**109 700** 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 ~~23 500~~**28 200** for the rapporteur and EUR ~~23 500~~**28 200** for the co-rapporteur.

7.1.2. A fee of EUR ~~46 900~~**54 700** 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 ~~11 500~~**13 800** for the rapporteur and EUR ~~11 500~~**13 800** for the co-rapporteur.

7.1.3. For the purpose of 7.1.1. and 7.1.2., a fee of EUR ~~4 100~~**4 700** 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 ~~1 400~~**1 700** 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 ~~70 600~~**82 400** 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 ~~17 500~~**21 000** for the rapporteur and EUR ~~17 500~~**21 000** for the co-rapporteur.

7.3. Companion diagnostic

7.3.1. A fee of EUR ~~46 900~~**54 000** 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 ~~11 800~~**14 200** for the rapporteur.

A fee of EUR ~~4 100~~**4 700** 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 ~~1 400~~**1 700** 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 ~~support and~~ 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 ~~9~~**8** of Annex I;

(f) certification of compliance with Union legislation regarding vaccine antigen master files (VAMF) pursuant to section ~~10~~**9** of Annex I;

(g) assessment of periodic safety update reports for medicinal products for human use pursuant to section ~~15~~ **14** of Annex I;

(h) assessment of post-authorisation safety studies for medicinal products for human use pursuant to section ~~16~~ **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**~~7~~ 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~~, point 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.

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 ~~Union~~ **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 ~~influenza~~ 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**~~9~~ 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 bluetongue, pandemic 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 20 % 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:

(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 this regulation** as set out in Annex V]**[11] and number of applicants 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,** and experts contracted for the procedures of the expert panels on medical devices per procedures on the basis of the information provided to the Agency by the national competent authorities concerned. The procedures to be included shall be decided by the Management Board based on a proposal by the Agency.

11 The Presidency is reflecting on how to refer to all the Regulations in recital 5 for which there are fee reductions or waivers and not just to those in this Regulation.

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