EUROPEAN
COMMISSION

Brussels, 13.12.2022
COM(2022) 721 final

ANNEX 1

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to the

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}

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 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 for each of the two scientific advice co-ordinators.

1.2. A fee of EUR 44 700 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 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 for each of the two scientific advice co-ordinators.

1.3. A fee of EUR 37 200 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 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 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 for the rapporteur and EUR 143 300 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 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 for the rapporteur and EUR 189 300 for the co-rapporteur.

3.2. A fee of EUR 549 800 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 for the rapporteur and EUR 143 300 for the co-rapporteur.

3.3. A fee of EUR 456 800 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 for the rapporteur and EUR 83 000 for the co-rapporteur.

3.4. A fee of EUR 575 000 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 for the rapporteur and EUR 151 700 for the co-rapporteur.

3.5. A fee of EUR 624 300 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 for the rapporteur and EUR 149 400 for the co-rapporteur.

3.6. A fee of EUR 141 200 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 for the rapporteur.

3.7. A fee of EUR 339 700 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 for the rapporteur and EUR 89 100 for the co-rapporteur.

3.8. A fee of EUR 27 600 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 for the rapporteur and EUR 1 000 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 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 for the rapporteur and EUR 26 600 for the co-rapporteur.

4.2. A fee of EUR 161 000 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 for the rapporteur and EUR 31 200 for the co-rapporteur.

4.3. Without prejudice to points 4.1 and 4.2, a fee of EUR 27 600 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 for the rapporteur and EUR 1 000 for the co-rapporteur.

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

5.1. A fee of EUR 99 800 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 for the rapporteur and EUR 29 400 for the co-rapporteur.

5.2. A fee of EUR 13 000 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 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 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 shall apply to the assessment carried out in the context of a procedure initiated under Article 5(3) of Regulation (EC) No 726/2004. Such fee shall be waived in full. The remuneration shall be EUR 12 400 for the rapporteur and EUR 12 400 for the co-rapporteur.

[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).

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

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

6.4. A fee of EUR 128 200 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 for the rapporteur and EUR 6 800 for the co-rapporteur.

6.5. A fee of EUR 180 700 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 for the rapporteur and EUR 12 400 for the co-rapporteur.

6.6. A fee of EUR 172 100 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 for the rapporteur and EUR 17 500 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 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 for the rapporteur and EUR 17 500 for the co-rapporteur;

6.7.2. a fee of EUR 258 200 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 for the rapporteur and EUR 26 300 for the co-rapporteur;

6.7.3. a fee of EUR 314 100 where one or two active substances or combinations of active substances and two or more marketing authorisation holders are included in the assessment. The remuneration shall be EUR 32 000 for the rapporteur and EUR 32 000 for the co-rapporteur;

6.7.4. a fee of EUR 426 100 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 for the rapporteur and EUR 43 400 for the co-rapporteur.

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

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

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

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

A fee of EUR 29 700 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 4 100 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 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 for the rapporteur and EUR 8 600 for the co-rapporteur.

8.2. A charge of EUR 5 800 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 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 for the rapporteur and EUR 1 600 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 9.4 of this Annex shall apply.

8.4. A fee of EUR 17 000 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 for the rapporteur and EUR 1 900 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 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 for the rapporteur and EUR 8 600 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 10.1. 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 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. In that case, the remuneration per each second and subsequent VAMF shall be EUR 1 900 for the rapporteur and EUR 1 900 for the co-rapporteur.

9.3. A charge of EUR 5 800 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 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 for the rapporteur and EUR 1 500 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 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 for the rapporteur.

10.2. A fee of EUR 95 200 shall apply to an application for evaluating and certifying only the quality data pursuant to Article 18 of Regulation (EC) No 1394/2007. Such fee shall be waived in full. The remuneration shall be EUR 31 500 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 shall apply to an application for agreement of a paediatric investigation plan requested pursuant to Article 15 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 6 700 for the rapporteur.

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

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

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[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).

[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).

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

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

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 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 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 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 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 for the rapporteur.

[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).

15.2.2. EUR 44 100 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 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.