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Subject:	ANNEXES 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

Delegations will find attached document COM(2022) 721 final.

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ANNEX 5

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REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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{SEC(2022) 440 final} - {SWD(2022) 413 final} - {SWD(2022) 414 final} -
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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 of Annex I;

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

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

(h) assessment of post-authorisation safety studies for medicinal products for human use pursuant to section 16 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 7.7 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;

1.1.2. 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;

1.1.3. 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 in accordance with 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 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.