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ANNEX 2

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REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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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 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 for the scientific advice co-ordinator.

1.2. A fee of EUR 24 300 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 and bioequivalence studies for generic veterinary medicinal products as defined in Article 4(9) of (EU) 2019/6.

The remuneration shall be EUR 10 100 for the scientific advice co-ordinator.

1.3. A fee of EUR 21 300 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 (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 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 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[1]

[1] 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).

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

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

3.3. A fee of EUR 24 300 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 1.7, to Commission Regulation (EU) 2018/782[2]. The remuneration shall be EUR 10 100 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 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 for the rapporteur and EUR 38 100 for the co-rapporteur.

4.2. A fee of EUR 267 700 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 for the rapporteur and EUR 35 300 for the co-rapporteur.

4.3. A fee of EUR 136 800 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 for the rapporteur and EUR 17 900 for the co-rapporteur.

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

[2] 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).

A fee of EUR 19 000 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 for the rapporteur and EUR 2 400 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 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 for the rapporteur and EUR 8 600 for the co-rapporteur.

6.2. A fee of EUR 47 500 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 for the rapporteur and EUR 7 600 for the co-rapporteur.

6.3. A fee of EUR 23 900 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 for the rapporteur and EUR 3 600 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 per variation and the remuneration shall be EUR 1 800 per variation for the rapporteur and EUR 1 800 for the co-rapporteur.

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

7. Referrals and arbitration procedures

7.1. A fee of EUR 152 700 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 for the rapporteur and EUR 9 600 for the co-rapporteur.

7.2. A fee of EUR 209 300 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 for the rapporteur and EUR 12 900 for the co-rapporteur.

7.3. A fee of EUR 147 200 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 for the rapporteur and EUR 7 700 for the co-rapporteur.

7.4. A fee of EUR 209 300 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 for the rapporteur and EUR 12 900 for the co-rapporteur.

7.5. A fee of EUR 147 200 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 for the rapporteur and EUR 7 700 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 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 for the rapporteur and EUR 3 600 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 shall apply per VAMF. The maximum total amount charged by the Agency shall not exceed EUR 71 700. The remuneration shall be EUR 3 600 for the rapporteur and EUR 3 600 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 for the rapporteur and EUR 10 800 for the co-rapporteur.

8.3. A fee of EUR 33 100 shall apply to an application for the review of a VAMF and its certification when submitted as a separate application for an antigen in vaccine(s) already authorised under the centralised, decentralised or mutual recognition procedure. The remuneration shall be EUR 5 000 for the rapporteur and EUR 5 000 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 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 for the rapporteur and EUR 3 600 for the co-rapporteur.

9.2. A fee of EUR 33 100 shall apply to an application for review of a vPTMF and its certification when submitted as a separate application for a platform in vaccines already authorised under the centralised, decentralised or mutual recognition procedure. The remuneration shall be EUR 5 000 for the rapporteur and EUR 5 000 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 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 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[3]. The remuneration shall be EUR 7 700 for the rapporteur;

(b) EUR 18 900 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 for the rapporteur.

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

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.

[3] 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).