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| Subject: | ANNEX 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 4

**ANNEX**

***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 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

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 shall apply. The remuneration shall be EUR 8 600 for the leading supervisory authority and EUR 5 200 for the supporting supervisory authority.

1.1.2. For any distinct Good Manufacturing Practice inspection outside the Union a fee of EUR 37 800 shall apply. The remuneration shall be EUR 15 600 for the leading supervisory authority and EUR 9 400 for the supporting supervisory authority.

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

1.1.4. For any distinct Good Clinical Practice inspection outside the Union a fee of EUR 44 200 shall apply. The remuneration shall be EUR 19 600 for the leading supervisory authority and EUR 10 400 for the supporting supervisory authority.

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

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

1.1.8. For any distinct pharmacovigilance inspection within or outside the Union a fee of EUR 52 700 shall apply. The remuneration shall be EUR 16 200 for the leading supervisory authority and EUR 10 100 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 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 shall apply to an application for the transfer of a marketing authorisation pursuant to Article 3 of Commission Regulation (EC) No 2141/96[1]. 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.

**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 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 for the rapporteur and EUR 1 300 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 shall apply. The additional remuneration of the national competent authority, where applicable, shall be EUR 600 for the rapporteur and EUR 600 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 to EUR 684 500. The range for the remuneration shall be EUR 1 000 to EUR 217 300 for

[1] 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).

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 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 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 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 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 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 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 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 to EUR 10 000. 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 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 for the rapporteur and EUR 23 500 for the co-rapporteur.

7.1.2. A fee of EUR 46 900 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 for the rapporteur and EUR 11 500 for the co-rapporteur.

7.1.3. For the purpose of 7.1.1. and 7.1.2., a fee of EUR 4 100 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 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 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 for the rapporteur and EUR 17 500 for the co-rapporteur.

*7.3. Companion diagnostic*

7.3.1. A fee of EUR 46 900 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 for the rapporteur.

A fee of EUR 4 100 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 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.