2025/90239

14.3.2025

Corrigendum to Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95

(Official Journal of the European Union L, 2024/568, 14 February 2024)

1. On page 13, Article 10(4), second subparagraph, last sentence:

   for: 'The Agency shall review and aggregate that information and shall use it, in accordance with paragraph 6, as a source for the special report provided for in that paragraph.',

   read: 'The Agency shall review and aggregate that information and shall use it, in accordance with paragraph 7, as a source for the special report provided for in that paragraph.'.

2. On page 23, Annex I, Section 15, point 15.1:

   for: '15.1. A fee of EUR 104 700 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.',

   read: '15.1. A fee of EUR 107 000 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.'.

3. On page 31, Annex IV, Section 6, point 6.1, last paragraph:

   for: 'In addition to the applicable fee or charge set out in Annex I, II or III, a charge of EUR 4 400 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. That charge shall be levied in full also to SMEs, where applicable.',

   read: 'In addition to the applicable fee or charge set out in Annex I, II or III, a charge of EUR 4 400 shall also apply to applications where a marketing authorisation holder or an applicant claiming, or having claimed, to be entitled to a fee or charge reduction, fails to demonstrate that it is entitled to such a reduction. That charge shall be levied in full also to SMEs, where applicable.'.

4. On page 34, Annex V, the title:

   for: '**Fee reductions and deferrals**',

   read: '**Fee and charge reductions and deferrals**'.

5. On page 34, Annex V, Section 1:

   for: '1. Fee reductions granted to SMEs

   1.1. The following total or partial reductions to the fees laid down in this Regulation shall be granted to SMEs:

   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:',

read: '1. Fee and charge reductions granted to SMEs

1.1. The following total or partial reductions to the fees and charges laid down in this Regulation shall be granted to SMEs:

1.1.1. for a small or medium-sized enterprise, a reduction of 40 % of the applicable amount shall apply to the following fees and charges:'.

6. On page 34, Annex V, Section 1, point 1.1.1(n):

for: '(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;',

read: '(n) annual fee for medicinal products for human use or for veterinary medicinal products pursuant to Section 1 or 2, respectively, of Annex III;'.

7. On page 34, Annex V, Section 1, point 1.1.3:

for: '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.',

read: '1.1.3. for a micro enterprise, a reduction of 100 % shall apply to the fees and charges set out in points 1.1.1. and 1.1.2.'.

8. On page 35, Annex V, Section 1, point 1.2:

for: '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.',

read: '1.2. The reductions set out in point 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.'.

9. On page 35, Annex V, Section 1, point 1.3:

for: '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.',

read: '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.'.

10. On page 35, Annex V, Section 3, point 3.2:

for: '3.2. In addition to the deferral provided for in point 3.1, for regulatory activities within the framework of the submission of a core dossier for a pandemic vaccine and the follow-up submission of a pandemic variation, a fee reduction of 100 % shall apply in the following cases:',

read: '3.2. In addition to the deferral provided for in point 3.1, for regulatory activities within the framework of the submission of a core dossier for a pandemic vaccine and the follow-up submission of a pandemic variation, a fee and charge reduction of 100 % shall apply in the following cases:'.

11. On page 35, Annex V, Section 4, point (a):

for: '(a) initial marketing authorisation application pursuant to Section 3 of Annex I to this Regulation;',

read: '(a) initial marketing authorisation application pursuant to Section 2 of Annex I to this Regulation;'.

12. On page 35, Annex V, Section 5:

for: '5. Immunological veterinary medicinal products

A fee reduction of 50 % shall apply to immunological veterinary medicinal products for the following activities:',

read: '5. Immunological veterinary medicinal products

A fee and charge reduction of 50 % shall apply to immunological veterinary medicinal products for the following activities:'.

13. On page 37, Annex V, Section 7, point 7.2:

for: '7.2. Where a reduction applies pursuant to point 6.1, no remuneration shall be paid to competent authorities of the Member States for the annual fees referred to in point 6.1.',

read: '7.2. Where a reduction applies pursuant to point 7.1, no remuneration shall be paid to competent authorities of the Member States for the annual fees referred to in point 7.1.'.

14. On page 37, Annex V, Section 8:

for: '8. 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 5 and 6 of this Annex.',

read: '8. 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 5, 6 and 7 of this Annex.'.

15. On page 39, Annex VII, Correlation table:

for:

'Regulation (EC) No 297/95	This Regulation
Article 8(1)	Annex I, Section 1 and Annex II, section 1
Article 3(1)	Annex I, Section 3
Article 7	Annex II, Section 3
Article 5(1)	Annex II, Section 4
Article 3(4)	Annex IV, Section 1
Article 5(4)	Annex IV, Section 1
Article 8(2)	Annex IV, Section 5
Article 8(3)	Annex IV, points 6.1 (except for the last paragraph), 6.2 and 6.4'

read:

'Regulation (EC) No 297/95	This Regulation
Article 8(1)	Annex I, Section 1 and Annex II, section 1
Article 3(1)	Annex I, Sections 2 and 4
Article 7	Annex II, Section 3

‘Regulation (EC) No 297/95	This Regulation
Article 5(1)	Annex II, Section 4
Article 3(4)	Annex IV, Section 1
Article 5(4)	Annex IV, Section 1
Article 8(2)	Annex IV, Section 5
Article 8(3)	Annex IV, points 6.1 (except for the last paragraph), 6.2 and 6.4’