Proposal for a

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

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| | | · | | proposals and |
| | | | | comments |
| 1 | REGULATION OF THE EUROPEAN | | REGULATION OF THE | |
| | PARLIAMENT AND OF THE COUNCIL | | EUROPEAN PARLIAMENT | |
| | on fees and charges payable to the European | | AND OF THE COUNCIL on | |
| | Medicines Agency, amending Regulation | | fees and charges payable to the | |
| | (EU) 2017/745 of the European Parliament | | European Medicines Agency, | |
| | and of the Council and repealing Council | | amending Regulations (EU) | |
| | Regulation (EC) No 297/95 and Regulation | | 2017/745 and (EU) 2022/123 of | |
| | | | the European Parliament and of | |

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| | (EU) 658/2014 of the European Parliament | | the Council and repealing | |
| | and of the Council | | Council Regulation (EC) | |
| | | | No 297/95 and Regulation | |
| | | | (EU) 658/2014 of the European | |
| | | | Parliament and of the Council | |
| 2 | THE EUROPEAN PARLIAMENT AND | | THE EUROPEAN | |
| | THE COUNCIL OF THE EUROPEAN | | PARLIAMENT AND THE | |
| | UNION, | | COUNCIL OF THE | |
| | | | EUROPEAN UNION, | |
| 3 | Having regard to the Treaty on the | | Having regard to the Treaty on | |
| | Functioning of the European Union, and in | | the Functioning of the European | |
| | particular Article 114 and Article 168(4), | | Union, and in particular | |
| | points (b) and (c), thereof, | | Article 114 and Article 168(4), | |
| | | | points (b) and (c), thereof, | |
| 4 | Having regard to the proposal from the | | Having regard to the proposal | |
| | European Commission, | | from the European Commission, | |
| 5 | After transmission of the draft legislative | | After transmission of the draft | |
| | act to the national parliaments, | | legislative act to the national | |
| | | | parliaments, | |

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| 6 | Having regard to the opinion of the | | Having regard to the opinion of | |
| | European Economic and Social | | the European Economic and | |
| | Committee ¹ , | | Social Committee ² , | |
| | ¹ OJ C , , p | | ² OJ C , , p | |
| 7 | Having regard to the opinion of the | | Having regard to the opinion of | |
| | Committee of the Regions ³ , | | the Committee of the Regions ⁴ , | |
| | ³ OJ C , , p | | ⁴ OJ C , , p | |
| 8 | Acting in accordance with the ordinary | | Acting in accordance with the | |
| | legislative procedure, | | ordinary legislative procedure, | |
| 9 | Whereas: | | Whereas: | |
| 10 | (1) The European Medicines Agency | (1) The European Medicines | (1) The European Medicines | |
| | ('the Agency') plays a key role in ensuring | Agency ('the Agency') plays a | Agency ('the Agency') plays a | |
| | that only safe, high-quality and efficacious | key role in ensuring that only | key role in ensuring that only | |
| | medicinal products are placed on the Union | safe, high-quality and efficacious | safe, high-quality and | |
| | market, thus contributing to the smooth | medicinal products are placed on | efficacious medicinal products | |
| | functioning of the internal market and | the Union market, thus | are placed on the Union market, | |
| | ensuring a high level of protection of human | contributing to the smooth | thus contributing to the smooth | |

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| | and animal health. It is therefore necessary | functioning of the internal market | functioning of the internal | |
| | to ensure sufficient resources are available | and ensuring a high level of | market and ensuring a high level | |
| | to the Agency to finance its activities, | expertise and protection of | of protection of human and | |
| | including resources emanating from fees. | human and animal health. It is | animal health. It is therefore | |
| | | therefore necessary to ensure | necessary to ensure sufficient | |
| | | sufficient resources are available | resources are available to the | |
| | | to the Agency to attract and | Agency to finance its activities, | |
| | | maintain the expertise required | including resources emanating | |
| | | to fulfil its tasks and to finance | from fees, and to remunerate | |
| | | its activities, including resources | in a sustainable manner the | |
| | | emanating from fees. | fundamental contribution of | |
| | | | competent authorities of | |
| | | | Member States to the | |
| | | | scientific assessments of the | |
| | | | Agency. | |
| 11 | (2) The general objective of this | | (2) The general objective of | |
| | Regulation is to contribute to providing a | | this Regulation is to contribute | |
| | sound financial basis for the operations of | | to setting high standards of | |
| | the Agency by establishing cost-based fees | | quality and safety for | |

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| and charges to be levied by the Agency, as | | medicinal products for human | |
| well as cost-based remuneration to | | use and veterinary medicinal | |
| competent authorities of the Member States | | products and to ensuring high | |
| for the services they provide for the | | level of protection of public | |
| completion of the Agency's statutory tasks. | | and animal health, by | |
| Cost-based fees should take into account an | | providing a sound financial | |
| evaluation of costs of the Agency's | | basis for the operations of the | |
| activities and of the contributions of | | Agency. It by establish esing | |
| competent authorities of the Member States | | cost-based fees and charges to | |
| to its work. In addition, this Regulation | | be levied by the Agency, as well | |
| aims to establish a single framework for a | | as cost-based remuneration to | |
| streamlined fee system of the Agency and to | | competent authorities of the | |
| introduce regulatory flexibility for | | Member States for the services | |
| adjustment to that fee system in the future. | | they provide for the completion | |
| | | of the Agency's statutory tasks. | |
| | | Such remuneration should be | |
| | | provided through a single | |
| | | Union remuneration amount | |
| | | per relevant type of fee, | |

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| | | | regardless of the Member | |
| | | | State of origin of the | |
| | | | competetent authority. Cost- | |
| | | | based fees should take into | |
| | | | account an evaluation of costs | |
| | | | of the Agency's activities and of | |
| | | | the contributions of competent | |
| | | | authorities of the Member States | |
| | | | to its work. In addition, this | |
| | | | Regulation aims to establish a | |
| | | | single framework for a | |
| | | | streamlined fee system of the | |
| | | | Agency and to introduce | |
| | | | regulatory flexibility for | |
| | | | adjustment to that fee system in | |
| | | | the future. | |
| 11a | | | (2a) This Regulation should | |
| | | | only regulate fees and charges | |
| | | | which are to be levied by the | |

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| | | | Agency, whereas the | |
| | | | competence to decide on | |
| | | | possible fees levied by the | |
| | | | national competent authorities | |
| | | | remains with the Member | |
| | | | States. Applicants and | |
| | | | marketing authorisation | |
| | | | holders are not to be charged | |
| | | | twice for the same activity. | |
| 12 | (3) The fees payable to the Agency | (3) The fees payable to the | (3) The fees payable to the | |
| | should be proportionate to the work carried | Agency should be proportionate | Agency should be proportionate | |
| | out in relation to obtaining and maintaining | to the work carried out in relation | to the work carried out in | |
| | a Union authorisation, and should be based | to obtaining and maintaining a | relation to obtaining and | |
| | on an evaluation of the Agency's | Union authorisation, and should | maintaining a Union | |
| | estimations and forecasts as regards the | be based on <i>a transparent</i> | authorisation, and should be | |
| | workload and related costs for that work, as | evaluation of the Agency's | based on an evaluation of the | |
| | well as on an evaluation of the costs of the | estimations and forecasts as | Agency's estimations and | |
| | services provided to the Agency by the | regards the workload and related | forecasts as regards the | |
| | competent authorities of Member States that | costs for that work, as well as on | workload and related costs for | |

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| | | 0/ | comments |
| are responsible for regulating medicinal | an evaluation of the costs of the | that work, as well as on an | |
| products, which act as rapporteurs and, | services provided to the Agency | evaluation of the costs of the | |
| where applicable, co-rapporteurs appointed | by the competent authorities of | services provided to the Agency | |
| by the scientific committees of the Agency. | Member States that are | by the competent authorities of | |
| | responsible for regulating | Member States that are | |
| | medicinal products, which act as | responsible for regulating | |
| | rapporteurs and, where | medicinal products, which act as | |
| | applicable, co-rapporteurs | rapporteurs and, where | |
| | appointed by the scientific | applicable, co-rapporteurs | |
| | committees of the Agency. <i>The</i> | appointed by the scientific | |
| | fees and fee structure should | committees of the Agency. | |
| | take into account any changes in | | |
| | the Union regulatory framework | | |
| | for medicinal products. Adequate | | |
| | financing should be provided for | | |
| | that critical public infrastructure | | |
| | to boost its expertise and ensure | | |
| | its sustainability through | | |
| | appropriate financing. | | |

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| | | | 0 | comments |
| 13 | (4) Pursuant to Article 67(3) of | | (4) Pursuant to Article 67(3) | |
| | Regulation (EC) No 726/2004 of the | | of Regulation (EC) | |
| | European Parliament and of the Council ⁵ , | | No 726/2004 of the European | |
| | the revenue of the Agency consists of a | | Parliament and of the Council ⁷ , | |
| | contribution from the Union, a contribution | | the revenue of the Agency | |
| | from third countries participating in the | | consists of a contribution from | |
| | work of the Agency with which the Union | | the Union, a contribution from | |
| | has concluded international agreements for | | third countries participating in | |
| | this purpose, fees paid by undertakings for | | the work of the Agency with | |
| | obtaining and maintaining Union marketing | | which the Union has concluded | |
| | authorisations and for services provided by | | international agreements for this | |
| | the coordination group as regards the | | purpose, fees paid by | |
| | fulfilment of its tasks in accordance with | | undertakings for obtaining and | |
| | Articles 107c, 107e, 107g, 107k and 107q of | | maintaining Union marketing | |
| | Directive 2001/83/EC of the European | | authorisations and for services | |
| | Parliament and of the Council ⁶ , charges for | | provided by the coordination | |
| | other services provided by the Agency, and | | group as regards the fulfilment | |
| | Union funding in the form of grants for | | of its tasks in accordance with | |
| | participation in research and assistance | | Articles 107c, 107e, 107g, 107k | |

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| projects, in accordance with the Agency's | | and 107q of Directive | |
| financial rules and with the provisions of | | 2001/83/EC of the European | |
| the relevant instruments supporting the | | Parliament and of the Council ⁸ , | |
| policies of the Union. | | charges for other services | |
| | | provided by the Agency, and | |
| ⁵ Regulation (EC) No 726/2004 of the European | | Union funding in the form of | |
| Parliament and of the Council of 31 March 2004 | | grants for participation in | |
| laying down Union procedures for the authorisation | | research and assistance projects, | |
| and supervision of medicinal products for human and | | in accordance with the Agency's | |
| veterinary use and establishing a European | | financial rules and with the | |
| Medicines Agency, (OJ L 136 30.4.2004, p. 1). | | | |
| ⁶ Directive 2001/83/EC of the European Parliament | | provisions of the relevant | |
| and of the Council of 6 November 2001 on the | | instruments supporting the | |
| Community code relating to medicinal products for | | policies of the Union. | |
| human use (OJ L 311, 28.11.2001, p. 67). | | | |
| | | ⁷ Regulation (EC) No 726/2004 of the | |
| | | European Parliament and of the | |
| | | Council of 31 March 2004 laying | |
| | | down Union procedures for the | |
| | | authorisation and supervision of | |
| | | medicinal products for human and | |

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| | | | veterinary use and establishing a | |
| | | | European Medicines Agency, (OJ L | |
| | | | 136 30.4.2004, p. 1). | |
| | | | ⁸ Directive 2001/83/EC of the | |
| | | | European Parliament and of the | |
| | | | Council of 6 November 2001 on the | |
| | | | Community code relating to medicinal | |
| | | | products for human use (OJ L 311, | |
| | | | 28.11.2001, p. 67). | |
| 13a | | (4a) Following the COVID-19 | | |
| | | pandemic and increased | | |
| | | initiatives in the field of health at | | |
| | | the Union level, the agency is | | |
| | | faced with a constantly | | |
| | | increasing workload, which | | |
| | | entails additional budgetary | | |
| | | needs in terms of staff and | | |
| | | financial resources. The | | |
| | | additional work, which includes | | |
| | | following the adoption of | | |
| | | | | |

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| | | Regulation (EU) 2022/123 of the | | |
| | | European Parliament and of the | | |
| | | Council ^{1a} and the creation of the | | |
| | | European Health Data Space, | | |
| | | should come with an appropriate | | |
| | | funding from the Multiannual | | |
| | | Financial Framework. | | |
| | | Ia Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1). | | |
| 13b | | (4b) Although the majority of | | |
| | | its funding comes from private | | |
| | | sources, the Agency is a public | | |
| | | authority and it is of the utmost | | |
| | | importance to safeguard its | | |
| | | integrity and independence in | | |

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| | | order to ensure public trust in | | |
| | | the legislative and regulatory | | |
| | | framework for pharmaceuticals | | |
| | | in the Union. Therefore, | | |
| | | sufficient funding should be | | |
| | | allocated to the Agency so that it | | |
| | | can carry out its obligations and | | |
| | | transparency commitments. | | |
| 13c | | (4c) The fees paid to the | | |
| | | Agency should reflect the | | |
| | | complex evaluations necessary to | | |
| | | obtain and maintain a Union | | |
| | | authorisation. It is appropriate to | | |
| | | recognise the contributions from | | |
| | | Member States' competent | | |
| | | authorities, as well as the | | |
| | | expenses incurred by them. It is | | |
| | | particularly appropriate to | | |
| | | recognise the synergies achieved | | |

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| | | through multinational | | |
| | | assessment teams and support | | |
| | | the collaborative efforts of those | | |
| | | multinational teams. The | | |
| | | Commission and the Agency | | |
| | | should therefore monitor the | | |
| | | development of multinational | | |
| | | assessment teams when | | |
| | | determining the changes that are | | |
| | | necessary to the structure of | | |
| | | remuneration of Member States. | | |
| 14 | (5) Fees and charges should cover the | (5) Fees and charges should | (5) Fees and charges should | |
| | cost of statutory services and activities of | cover the cost of statutory | cover the cost of statutory | |
| | the Agency that is not already covered by | services and activities of the | services and activities of the | |
| | the contributions to its revenue from other | Agency that is not already | Agency that is not already | |
| | sources. All relevant Union legislation | covered by the contributions to its | covered by the contributions to | |
| | governing the Agency's activities and fees | revenue from other sources. All | its revenue from other sources. | |
| | should be taken into account when | relevant Union legislation | All relevant Union legislation | |
| | establishing the fees and charges, including | governing the Agency's activities | governing the Agency's | |

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| Regulation (EC) No 726/2004, Regulation | and fees should be taken into | activities and fees should be | |
| (EU) 2019/6 of the European Parliament | account when establishing the | taken into account when | |
| and of the Council ⁹ , Directive 2001/83/EC, | fees and charges, including | establishing the fees and | |
| Regulation (EC) No 1901/2006 of the | Regulation (EC) No 726/2004, | charges, including Regulation | |
| European Parliament and of the Council ¹⁰ , | Regulation (EU) 2019/6 of the | (EC) No 726/2004, Regulation | |
| Regulation (EC) No 141/2000 of the | European Parliament and of the | (EU) 2019/6 of the European | |
| European Parliament and of the Council ¹¹ , | Council ²¹ , Directive 2001/83/EC, | Parliament and of the Council ²⁰ , | |
| Regulation (EC) No 1394/2007 of the | Regulation (EC) No 1901/2006 of | Directive 2001/83/EC, | |
| European Parliament and of the Council ¹² , | the European Parliament and of | Regulation (EC) No 1901/2006 | |
| Commission Regulation (EC) No | the Council ²² , Regulation (EC) | of the European Parliament and | |
| 2049/2005 ¹³ , Commission Regulation (EC) | No 141/2000 of the European | of the Council ²¹ , Regulation | |
| No 1234/2008 ¹⁴ , Regulation (EU) 2017/745 | Parliament and of the Council ²³ , | (EC) No 141/2000 of the | |
| of the European Parliament and of the | Regulation (EC) No 1394/2007 of | European Parliament and of the | |
| Council ¹⁵ , Regulation (EC) No 470/2009 of | the European Parliament and of | Council ²² , Regulation (EC) No | |
| the European Parliament and of the | the Council ²⁴ , Commission | 1394/2007 of the European | |
| Council ¹⁶ , Commission Regulation (EU) | Regulation (EC) No 2049/2005 ²⁵ , | Parliament and of the Council ²³ , | |
| 2018/782 ¹⁷ , Commission Implementing | Commission Regulation (EC) No | Commission Regulation (EC) | |
| Regulation (EU) 2021/1281 ¹⁸ and | 1234/2008 ²⁶ , Regulation (EU) | No 2049/2005 ²⁴ , Commission | |
| Commission Regulation (EC) No 2141/96 ¹⁹ . | 2017/745 of the European | Regulation (EC) No | |

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| | Parliament and of the Council ²⁷ , | 1234/2008 ²⁵ , Regulation (EU) | |
| ⁹ Regulation (EU) 2019/6 of the European | Regulation (EC) No 470/2009 of | 2017/745 of the European | |
| Parliament and of the Council of 11 December 2018 | the European Parliament and of | Parliament and of the Council ²⁶ , | |
| on veterinary medicinal products and repealing | the Council ²⁸ , <i>Regulation (EU)</i> | Regulation (EU) 2017/746 of | |
| Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43). | 2022/123, Commission | the European Parliament and | |
| ¹⁰ Regulation (EC) No 1901/2006 of the European | Regulation (EU) 2018/782 ²⁹ , | of the Council ²⁷ , Regulation | |
| Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and | Commission Implementing | (EC) No 470/2009 of the | |
| amending Regulation (EEC) No 1768/92, Directive | Regulation (EU) 2021/1281 ³⁰ and | European Parliament and of the | |
| 2001/20/EC, Directive 2001/83/EC and Regulation | Commission Regulation (EC) No | Council ²⁸ , Commission | |
| (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1). | 2141/96 ³¹ . | Regulation (EU) 2018/782 ²⁹ , | |
| ¹¹ Regulation (EC) No 141/2000 of the European | | Commission Implementing | |
| Parliament and of the Council of 16 December 1999 | ²¹ Regulation (EU) 2019/6 of the | Regulation (EU) 2021/1281 ³⁰ | |
| on orphan medicinal products (OJ L 18, 22.1.2000, | European Parliament and of the Council of 11 December 2018 on veterinary | and Commission Regulation | |
| p. 1). 12 Regulation (EC) No 1394/2007 of the European | medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, | (EC) No 2141/96 ³¹ . | |
| Parliament and of the Council of 13 November 2007 | p. 43). ²² Regulation (EC) No 1901/2006 of the | | |
| on advanced therapy medicinal products and | European Parliament and of the Council | ²⁰ Regulation (EU) 2019/6 of the | |
| amending Directive 2001/83/EC and Regulation | of 12 December 2006 on medicinal products for paediatric use and | European Parliament and of the | |
| (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121). | amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation | Council of 11 December 2018 on veterinary medicinal products and | |

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| ¹³ Commission Regulation (EC) No 2049/2005 of 15 | (EC) No 726/2004 (OJ L 378, | repealing Directive 2001/82/EC (OJ L | |
| December 2005 laying down, pursuant to Regulation | 27.12.2006, p. 1). ²³ Regulation (EC) No 141/2000 of the | 4, 7.1.2019, p. 43). | |
| (EC) No 726/2004 of the European Parliament and | European Parliament and of the Council | ²¹ Regulation (EC) No 1901/2006 of | |
| of the Council, rules regarding the payment of fees | of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, | the European Parliament and of the | |
| to, and the receipt of administrative assistance from, | p. 1). | Council of 12 December 2006 on | |
| the European Medicines Agency by micro, small and | ²⁴ Regulation (EC) No 1394/2007 of the European Parliament and of the Council | medicinal products for paediatric use | |
| medium-sized enterprises (OJ L 329, 16.12.2005, p. | of 13 November 2007 on advanced therapy medicinal products and | and amending Regulation (EEC) No | |
| 4). | amending Directive 2001/83/EC and | 1768/92, Directive 2001/20/EC, | |
| ¹⁴ Commission Regulation (EC) No 1234/2008 of 24 | Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121). | Directive 2001/83/EC and Regulation | |
| November 2008 concerning the examination of | ²⁵ Commission Regulation (EC) No | (EC) No 726/2004 (OJ L 378, | |
| variations to the terms of marketing authorisations | 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No | 27.12.2006, p. 1). | |
| for medicinal products for human use and veterinary | 726/2004 of the European Parliament | ²² Regulation (EC) No 141/2000 of the | |
| medicinal products (OJ L 334, 12.12.2008, p. 7). | and of the Council, rules regarding the payment of fees to, and the receipt of | European Parliament and of the | |
| 15 Regulation (EU) 2017/745 of the European | administrative assistance from, the | Council of 16 December 1999 on | |
| Parliament and of the Council of 5 April 2017 on | European Medicines Agency by micro, small and medium-sized enterprises (OJ | orphan medicinal products (OJ L 18, | |
| medical devices, amending Directive 2001/83/EC, | L 329, 16.12.2005, p. 4). | 22.1.2000, p. 1). | |
| Regulation (EC) No 178/2002 and Regulation (EC) | ²⁶ Commission Regulation (EC) No 1234/2008 of 24 November 2008 | ²³ Regulation (EC) No 1394/2007 of | |
| No 1223/2009 and repealing Council Directives | concerning the examination of variations | the European Parliament and of the | |
| 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. | to the terms of marketing authorisations for medicinal products for human use | Council of 13 November 2007 on | |
| 1). | and veterinary medicinal products (OJ L | advanced therapy medicinal products | |
| 16 Regulation (EC) No 470/2009 of the European | 334, 12.12.2008, p. 7). ²⁷ Regulation (EU) 2017/745 of the | and amending Directive 2001/83/EC | |
| Parliament and of the Council of 6 May 2009 laying | European Parliament and of the Council of 5 April 2017 on medical devices, | | |

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| down Community procedures for the establishment | amending Directive 2001/83/EC, | and Regulation (EC) No 726/2004 (OJ | |
| of residue limits of pharmacologically active | Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and | L 324, 10.12.2007, p. 121). | |
| substances in foodstuffs of animal origin, repealing | repealing Council Directives | ²⁴ Commission Regulation (EC) No | |
| Council Regulation (EEC) No 2377/90 and | 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). | 2049/2005 of 15 December 2005 | |
| amending Directive 2001/82/EC of the European | ²⁸ Regulation (EC) No 470/2009 of the | laying down, pursuant to Regulation | |
| Parliament and of the Council and Regulation (EC) | European Parliament and of the Council of 6 May 2009 laying down Community | (EC) No 726/2004 of the European | |
| No 726/2004 of the European Parliament and of the | procedures for the establishment of | Parliament and of the Council, rules | |
| Council (OJ L 152, 16.6.2009, p. 11). | residue limits of pharmacologically active substances in foodstuffs of animal | regarding the payment of fees to, and | |
| ¹⁷ Commission Regulation (EU) 2018/782 of 29 | origin, repealing Council Regulation | the receipt of administrative assistance | |
| May 2018 establishing the methodological principles | (EEC) No 2377/90 and amending Directive 2001/82/EC of the European | from, the European Medicines Agency | |
| for the risk assessment and risk management | Parliament and of the Council and Regulation (EC) No 726/2004 of the | by micro, small and medium-sized | |
| recommendations referred to in Regulation (EC) No | European Parliament and of the Council | enterprises (OJ L 329, 16.12.2005, p. | |
| 470/2009 (OJ L 132, 30.5.2018, p. 5). | (OJ L 152, 16.6.2009, p. 11). ²⁹ Commission Regulation (EU) | 4). | |
| ¹⁸ Commission Implementing Regulation (EU) | 2018/782 of 29 May 2018 establishing | ²⁵ Commission Regulation (EC) No | |
| 2021/1281 of 2 August 2021 laying down rules for | the methodological principles for the risk assessment and risk management | 1234/2008 of 24 November 2008 | |
| the application of Regulation (EU) 2019/6 of the | recommendations referred to in | concerning the examination of | |
| European Parliament and of the Council as regards | Regulation (EC) No 470/2009 (OJ L 132, 30.5.2018, p. 5). | variations to the terms of marketing | |
| good pharmacovigilance practice and on the format, | ³⁰ Commission Implementing Regulation | authorisations for medicinal products | |
| content and summary of the pharmacovigilance | (EU) 2021/1281 of 2 August 2021 laying down rules for the application of | for human use and veterinary | |
| system master file for veterinary medicinal products | Regulation (EU) 2019/6 of the European | medicinal products (OJ L 334, | |
| (OJ L 279, 3.8.2021, p. 15). | Parliament and of the Council as regards good pharmacovigilance practice and on | 12.12.2008, p. 7). | |
| | the format, content and summary of the | | |
| | pharmacovigilance system master file | | |

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| ¹⁹ Commission Regulation (EC) No 2141/96 of 7 | for veterinary medicinal products (OJ L 279, 3.8.2021, p. 15). | ²⁶ Regulation (EU) 2017/745 of the | |
| November 1996 concerning the examination of an | ³¹ Commission Regulation (EC) No | European Parliament and of the | |
| application for the transfer of a marketing | 2141/96 of 7 November 1996 concerning the examination of an | Council of 5 April 2017 on medical | |
| authorization for a medicinal product falling within | application for the transfer of a | devices, amending Directive | |
| the scope of Council Regulation (EC) No 2309/93 | marketing authorization for a medicinal product falling within the scope of | 2001/83/EC, Regulation (EC) No | |
| (OJ L 286, 8.11.1996, p. 6). | Council Regulation (EC) No 2309/93 | 178/2002 and Regulation (EC) No | |
| | (OJ L 286, 8.11.1996, p. 6). | 1223/2009 and repealing Council | |
| | | Directives 90/385/EEC and 93/42/EEC | |
| | | (OJ L 117, 5.5.2017, p. 1). | |
| | | 27 Regulation (EU) 2017/746 of the | |
| | | European Parliament and of the | |
| | | Council of 5 April 2017 on in vitro | |
| | | diagnostic medical devices and | |
| | | repealing Directive 98/79/EC and | |
| | | Commission Decision 2010/227/EU | |
| | | (Text with EEA relevance. OJ L 117, | |
| | | 5.5.2017, p. 176–332) | |
| | | ²⁸ 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 | |

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| | | 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). | |
| | | ²⁹ 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). | |
| | | ³⁰ 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 | |

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| | | | pharmacovigilance system master file | |
| | | | for veterinary medicinal products (OJ | |
| | | | L 279, 3.8.2021, p. 15). | |
| | | | ³¹ 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 (E <u>E</u> C) No | |
| | | | 2309/93 (OJ L 286, 8.11.1996, p. 6). | |
| 15 | (6) Pursuant to Article 6(1) of | | (6) Pursuant to Article 6(1) | |
| | Regulation (EC) No 726/2004, each | | of Regulation (EC) | |
| | application for the authorisation of a | | No 726/2004, each application | |
| | medicinal product for human use is to be | | for the authorisation of a | |
| | accompanied by the fee payable to the | | medicinal product for human | |
| | Agency for the examination of that | | use is to be accompanied by the | |
| | application. Pursuant to Article 43(1) of | | fee payable to the Agency for | |
| | Regulation (EU) 2019/6, an application for a | | the examination of that | |

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| | centralised marketing authorisation for a | | application. Pursuant to Article | |
| | veterinary medicinal product is to be | | 43(1) of Regulation (EU) | |
| | accompanied by the fee payable to the | | 2019/6, an application for a | |
| | Agency for the examination of the | | centralised marketing | |
| | application. | | authorisation for a veterinary | |
| | | | medicinal product is to be | |
| | | | accompanied by the fee payable | |
| | | | to the Agency for the | |
| | | | examination of the application. | |
| 16 | (7) In line with the Joint Statement of | (7) In line with the Joint | (7) In line with the Joint | |
| | the European Parliament, the Council of the | Statement of the European | Statement of the European | |
| | EU and the Commission of 19 July 2012 on | Parliament, the Council of the EU | Parliament, the Council of the | |
| | decentralised agencies, for bodies for which | and the Commission of 19 July | EU and the Commission of | |
| | the revenue is constituted by fees and | 2012 on decentralised agencies, | 19 July 2012 on decentralised | |
| | charges in addition to the Union | for bodies for which the revenue | agencies, for bodies for which | |
| | contribution, fees should be set at a level | is constituted by fees and charges | the revenue is constituted by | |
| | that avoids a deficit or a significant | in addition to the Union | fees and charges in addition to | |
| | accumulation of surplus, and should be | contribution, fees should be set at | the Union contribution, fees | |
| | revised when this is not the case. Therefore, | a level that avoids a deficit or a | should be set at a level that | |

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| a cost monitoring system should be put in | significant accumulation of | avoids a deficit or a significant | |
| place. The purpose of such monitoring | surplus, and should be revised | accumulation of surplus, and | |
| system should be to detect significant | when this is not the case. | should be revised when this is | |
| changes of costs of the Agency that, taking | Therefore, a <i>transparent</i> cost | not the case. Therefore, a cost | |
| into account the Union contribution and | monitoring system should be put | monitoring system should be put | |
| other non-fee revenue, could require a | in place. The purpose of such | in place. The purpose of such | |
| change in fees, charges or remuneration | monitoring system should be to | monitoring system should be to | |
| established under this regulation. That | detect significant changes of costs | detect significant changes of | |
| monitoring system should equally be able to | of the Agency that, taking into | costs of the Agency that, taking | |
| detect, based on objective and verifiable | account the Union contribution | into account the Union | |
| information, significant changes of costs of | and other non-fee revenue, could | contribution and other non-fee | |
| remuneration of services provided to the | require a change in fees, charges | revenue, could require a change | |
| Agency by the competent authorities of | or remuneration established under | in fees, charges or remuneration | |
| Member States, which act as rapporteurs | this regulation. That monitoring | established under this | |
| and, where applicable, co-rapporteurs and | system should equally be able to | regulation. That monitoring | |
| by experts contracted by the Agency for the | detect, based on objective and | system should equally be able to | |
| procedures of the expert panels on medical | verifiable information, significant | detect, based on objective and | |
| devices. Cost information relating to | changes of costs of remuneration | verifiable information, | |
| services remunerated by the Agency should | of services provided to the | significant changes of costs of | |

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| be auditable in accordance with Article 257 | Agency by the competent | remuneration of services | |
| of Regulation (EU, Euratom) 2018/1046 of | authorities of Member States, | provided to the Agency by the | |
| the European Parliament and of the | which act as rapporteurs and, | competent authorities of | |
| Council ³² . | where applicable, co-rapporteurs | Member States, which act as | |
| | and by experts contracted by the | rapporteurs and, where | |
| ³² Regulation (EU, Euratom) 2018/1046 of the | Agency for the procedures of the | applicable, co-rapporteurs and | |
| European Parliament and of the Council of 18 July | expert panels on medical devices. | by experts contracted by the | |
| 2018 on the financial rules applicable to the general | Cost information relating to | Agency for the procedures of the | |
| budget of the Union, amending Regulations (EU) No | services remunerated by the | expert panels on medical | |
| 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No | Agency should be auditable in | devices. Cost information | |
| 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, | accordance with Article 257 of | relating to services remunerated | |
| (EU) No 283/2014, and Decision No 541/2014/EU | Regulation (EU, Euratom) | by the Agency should be | |
| and repealing Regulation (EU, Euratom) No | 2018/1046 of the European | auditable in accordance with | |
| 966/2012 (OJ L 193, 30.7.2018, p. 1). | Parliament and of the Council ³² . | Article 257 of Regulation (EU, | |
| | | Euratom) 2018/1046 of the | |
| | ³² Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No | European Parliament and of the Council ³³ . | |

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| | | 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1). | Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1309/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1). | |
| 17 | (8) Fees should be levied on marketing | | (8) Fees should be levied on | |
| | authorisation applicants and holders on a | | marketing authorisation | |
| | fair basis whereby the fee charged is | | applicants and holders on a fair | |
| | proportionate to the assessment work. | | basis whereby the fee charged is | |
| | Therefore, for the purpose of charging some | | proportionate to the assessment | |
| | post-authorisation fees where products | | work. Therefore, for the purpose | |
| | authorised by the Member States are | | of charging some post- | |
| | included in the assessment performed by the | | authorisation fees where | |
| | Agency, a chargeable unit should be | | products authorised by the | |
| | established, irrespective not only of the | | Member States are included in | |
| | procedure under which the product has been | | the assessment performed by the | |

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| authorised, namely under Regulation (EC) | | Agency, a chargeable unit | |
| No 726/2004 or Regulation (EU) 2019/6 or | | should be established, | |
| Directive 2001/83/EC, but also of the way | | irrespective not only of the | |
| in which authorisation numbers are assigned | | procedure under which the | |
| by Member States or the Commission. For | | product has been authorised, | |
| medicinal products for human use, that | | namely under Regulation (EC) | |
| objective should be met by establishing the | | No 726/2004 or Regulation | |
| chargeable unit on the basis of the active | | (EU) 2019/6 or Directive | |
| substances and the pharmaceutical form of | | 2001/83/EC, but also of the way | |
| the products that are subject to the | | in which authorisation numbers | |
| obligation to be registered in the database | | are assigned by Member States | |
| referred to in Article 57(1), second | | or the Commission. This should | |
| subparagraph , point (l), of Regulation (EC) | | not apply to medicinal | |
| No 726/2004, based on information from | | products for human use | |
| the list of all medicinal products for human | | authorised to be placed on the | |
| use authorised in the Union referred to in | | market under Article 126a of | |
| Article 57(2), second subparagraph, of that | | Directive 2001/83/EC. For | |
| Regulation. The active substances should | | medicinal products for human | |
| not be taken into account when establishing | | use, that objective should be met | |

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| the chargeable unit in respect of | | by establishing the chargeable | |
| homeopathic medicinal products or herbal | | unit on the basis of the active | |
| medicinal products. For veterinary | | substances and the | |
| medicinal products, the same objective of | | pharmaceutical form of the | |
| fairness and proportionality should be met | | products that are subject to the | |
| by establishing the chargeable unit based on | | obligation to be registered in the | |
| information contained in the Union product | | database referred to in Article | |
| database referred to in Article 55(1) of | | 57(1), second subparagraph, | |
| Regulation (EU) 2019/6, such as the active | | point (l), of Regulation (EC) | |
| substances, the pharmaceutical form and the | | No 726/2004, based on | |
| strength of veterinary medicinal products, | | information from the list of all | |
| which are taken into account in the Product | | medicinal products for human | |
| Identifier referred to under Data Field ID | | use authorised in the Union | |
| 3.2 in Annex III to Commission | | referred to in Article 57(2), | |
| Implementing Regulation (EU) 2021/16 ³⁴ , | | second subparagraph, of that | |
| as well as the Permanent Identifier referred | | Regulation. The active | |
| to under Data Field ID 3.1 in Annex III to | | substances should not be taken | |
| that Implementing Regulation. | | into account when establishing | |
| | | the chargeable unit in respect of | |

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| ³⁴ Commission Implementing Regulation (EU) | | homeopathic medicinal products | |
| 2021/16 of 8 January 2021 laying down the | | or herbal medicinal products. | |
| necessary measures and practical arrangements for | | For veterinary medicinal | |
| the Union database on veterinary medicinal products | | products, the same objective of | |
| (Union product database) (OJ L 7, 11.1.2021, p. 1). | | fairness and proportionality | |
| | | should be met by establishing | |
| | | the chargeable unit based on | |
| | | information contained in the | |
| | | Union product database referred | |
| | | to in Article 55(1) of Regulation | |
| | | (EU) 2019/6, such as the active | |
| | | substances, the pharmaceutical | |
| | | form and the strength of | |
| | | veterinary medicinal products, | |
| | | which are taken into account in | |
| | | the Product Identifier referred to | |
| | | under Data Field ID 3.2 in | |
| | | Annex III to Commission | |
| | | Implementing Regulation (EU) | |

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| | | | $2021/16^{35}$, as well as the | |
| | | | Permanent Identifier referred to | |
| | | | under Data Field ID 3.1 in | |
| | | | Annex III to that Implementing | |
| | | | Regulation. | |
| | | | 35 Commission Implementing | |
| | | | Regulation (EU) 2021/16 of 8 January | |
| | | | 2021 laying down the necessary | |
| | | | measures and practical arrangements | |
| | | | for the Union database on veterinary | |
| | | | medicinal products (Union product | |
| | | | database) (OJ L 7, 11.1.2021, p. 1). | |
| 18 | (9) In order to take into account all the | | (9) In order to take into | |
| | marketing authorisations of medicinal | | account all the marketing | |
| | products granted to marketing authorisation | | authorisations of medicinal | |
| | holders, the number of chargeable units | | products granted to marketing | |
| | corresponding to those authorisations | | authorisation holders, the | |
| | should take into account the number of | | number of chargeable units | |
| | | | corresponding to those | |

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| | Member States in which the marketing | | authorisations should take into | |
| | authorisation is valid. | | account the number of Member | |
| | | | States in which the marketing | |
| | | | authorisation is valid. | |
| 19 | (10) In order to take account of the | | (10) In order to take account | |
| | variety of the statutory tasks of the Agency | | of the variety of the statutory | |
| | and of the rapporteurs and, where | | tasks of the Agency and of the | |
| | applicable, co-rapporteurs, fees should be | | rapporteurs and, where | |
| | levied per procedure, for costs relating to | | applicable, co-rapporteurs, fees | |
| | the assessment of medicinal products for | | should be levied per procedure, | |
| | human use and for veterinary medicinal | | for costs relating to the | |
| | products, and on an annual basis for costs | | assessment of medicinal | |
| | incurred by the Agency for other ongoing | | products for human use and for | |
| | activities that it carries out under its | | veterinary medicinal products, | |
| | mandate that benefit marketing | | and on an annual basis for costs | |
| | authorisation holders overall. For the | | incurred by the Agency for other | |
| | purpose of simplification, the costs related | | ongoing activities that it carries | |
| | to minor variations of Type I should equally | | out under its mandate that | |
| | | | benefit marketing authorisation | |

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| | be included in the annual fee on the basis of | | holders overall. For the purpose | |
| | an average estimation. | | of simplification, the costs | |
| | | | related to minor variations of | |
| | | | Type I <u>and renewals</u> should are | |
| | | | equally be included in the | |
| | | | annual fee on the basis of an | |
| | | | average estimation. | |
| 20 | (11) An annual fee for medicinal | | (11) An annual fee for | |
| | products authorised in accordance with the | | medicinal products authorised in | |
| | centralised procedure set out in Regulation | | accordance with the centralised | |
| | (EC) No 726/2004 or the centralised | | procedure set out in Regulation | |
| | procedure set out in Regulation (EU) 2019/6 | | (EC) No 726/2004 or the | |
| | should be levied to ensure coverage of the | | centralised procedure set out in | |
| | costs connected with the overall post- | | Regulation (EU) 2019/6 should | |
| | authorisation supervision and maintenance | | be levied to ensure coverage of | |
| | activities for those products. Those | | the costs connected with the | |
| | activities include the recording of the actual | | overall post-authorisation | |
| | marketing of medicinal products authorised | | supervision and maintenance | |
| | in accordance with Union procedures, the | | activities for those products. | |

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| maintenance of marketing authorisation | | Those activities include the | |
| dossiers and of the various databases | | recording of the actual | |
| managed by the Agency, and activities | | marketing of medicinal products | |
| contributing to a continuous follow-up of | | authorised in accordance with | |
| the risk-benefit balance of authorised | | Union procedures, the | |
| medicinal products. They also comprise | | maintenance of marketing | |
| access to and analysis of Union-wide health | | authorisation dossiers and of the | |
| data to support better decision-making | | various databases managed by | |
| throughout the product lifecycle on | | the Agency, minor variations | |
| medicines with valid and reliable real-world | | of Type I and renewals and | |
| evidence. The revenue from that annual fee | | activities contributing to a | |
| should be used to fund an annual | | continuous follow-up of the | |
| remuneration of the services of rapporteurs | | risk-benefit balance of | |
| and co-rapporteurs from competent | | authorised medicinal products. | |
| authorities of the Member States for their | | They also comprise access to | |
| respective contributions to the supervision | | and analysis of Union-wide | |
| and maintenance activities of the Agency. | | health data to support better | |
| | | decision-making throughout the | |
| | | product lifecycle on medicines | |

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| | | | with valid and reliable real- | |
| | | | world evidence. The revenue | |
| | | | from that annual fee should be | |
| | | | used to fund an annual | |
| | | | remuneration of the services of | |
| | | | rapporteurs and co-rapporteurs | |
| | | | from competent authorities of | |
| | | | the Member States for their | |
| | | | respective contributions to the | |
| | | | supervision and maintenance | |
| | | | activities of the Agency. | |
| 21 | (12) A specific annual fee should be | | (12) A specific annual fee | |
| | charged for medicinal products authorised | | should be charged for medicinal | |
| | in accordance with Directive 2001/83/EC | | products authorised in | |
| | and for veterinary medicinal products | | accordance with Directive | |
| | authorised by the Member States in | | 2001/83/EC and for veterinary | |
| | accordance with Regulation (EU) 2019/6 | | medicinal products authorised | |
| | specifically for the pharmacovigilance | | by the Member States in | |
| | activities carried out by the Agency that | | accordance with Regulation | |

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| benefit marketing authorisation holders | | (EU) 2019/6 specifically for the | |
| overall. Those activities relate to | | pharmacovigilance activities | |
| information technology, in particular | | carried out by the Agency that | |
| maintenance of the EudraVigilance database | | benefit marketing authorisation | |
| referred to in Article 24(1) of Regulation | | holders overall. Those activities | |
| (EC) No 726/2004, the Union product | | relate to information technology, | |
| database referred to in Article 55(1) of | | in particular maintenance of the | |
| Regulation (EU) 2019/6 and the Union | | EudraVigilance database | |
| pharmacovigilance database referred to in | | referred to in Article 24(1) of | |
| Article 74(1) of that Regulation, the | | Regulation (EC) No 726/2004, | |
| monitoring of selected medical literature | | the Union product database | |
| and the timely access to and analysis of | | referred to in Article 55(1) of | |
| Union-wide health data to support decision- | | Regulation (EU) 2019/6 and the | |
| making throughout the product lifecycle on | | Union pharmacovigilance | |
| medicines with valid and reliable real-world | | database referred to in | |
| evidence. | | Article 74(1) of that Regulation, | |
| | | the monitoring of selected | |
| | | medical literature and the timely | |
| | | access to and analysis of Union- | |

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| | | | wide health data to support | |
| | | | decision-making throughout the | |
| | | | product lifecycle on medicines | |
| | | | with valid and reliable real- | |
| | | | world evidence. | |
| 22 | (13) Charges should be levied for | | (13) Charges should can be | |
| | activities and services of an administrative | | levied for activities and services | |
| | nature, such as issuing certificates, that are | | of an administrative nature, such | |
| | not covered by a fee provided for in this | | as issuing certificates, that are | |
| | Regulation, whereas fees levied by the | | not covered by a fee provided | |
| | Agency should correspond to services of a | | for in this Regulation, whereas | |
| | scientific nature provided by the Agency | | fees levied by the Agency | |
| | under its mandate, which contribute to the | | should-correspond to services of | |
| | assessment relating to medicinal products | | a scientific nature provided by | |
| | and the maintenance of authorised products, | | the Agency under its mandate, | |
| | including a continuous monitoring of the | | which contribute to the | |
| | risk-benefit balance. | | assessment relating to medicinal | |
| | | | products and the maintenance of | |
| | | | authorised products, including a | |

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| | | | | proposals and |
| | | | 0/ | comments |
| | | | continuous monitoring of the | |
| | | | risk-benefit balance. Fees for | |
| | | | inspections should be set by | |
| | | | distinct inspection. Each | |
| | | | disctinct inspection should | |
| | | | trigger a separate fee. | |
| 23 | (14) Where a fee is reduced by 100 %, | | (14) Where a fee is reduced | |
| | the theoretical full amount of that fee should | | by 100 %, the theoretical full | |
| | still be provided for, for reasons of | | amount of that fee should still | |
| | transparency and cost recovery. | | be provided for, for reasons of | |
| | | | transparency and cost recovery. | |
| 24 | (15) In line with union policies, it is | (15) In line with union | (15) In line with union | |
| | appropriate to provide for reductions of the | policies, it is appropriate to | policies, it is appropriate to | |
| | fees to support specific sectors and | provide for reductions of the fees | provide for reductions of the | |
| | applicants or marketing authorisation | to support specific sectors and | fees to support specific sectors | |
| | holders, such as micro-, small- and medium- | applicants or marketing | and applicants or marketing | |
| | sized enterprises (SMEs), or to respond to | authorisation holders, such as | authorisation holders, such as | |
| | specific circumstances, such as products | micro-, small- and medium-sized | micro-, small- and medium- | |
| | responding to recognised public health or | enterprises (SMEs), non-profit- | sized enterprises (SMEs), or to | |

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| | | | 0 | comments |
| | animal health priorities or veterinary | organisations and the academic | respond to specific | |
| | medicinal products intended for a limited | sector or to respond to specific | circumstances, such as products | |
| | market authorised in accordance with | circumstances, such as products | responding to recognised public | |
| | Article 23 of Regulation (EU) 2019/6. | responding to recognised public | health or animal health priorities | |
| | | health or animal health priorities | or veterinary medicinal products | |
| | | or veterinary medicinal products | intended for a limited market | |
| | | intended for a limited market | authorised in accordance with | |
| | | authorised in accordance with | Article 23 of Regulation (EU) | |
| | | Article 23 of Regulation (EU) | 2019/6. | |
| | | 2019/6. | | |
| 25 | (16) The market for veterinary medicinal | | (16) The market for | |
| | products is smaller and more fragmented | | veterinary medicinal products is | |
| | compared to the market for medicinal | | smaller and more fragmented | |
| | products for human use. Therefore, it is | | compared to the market for | |
| | appropriate to provide for a reduction of the | | medicinal products for human | |
| | annual fee and of some specific fees for | | use. Therefore, it is appropriate | |
| | veterinary medicinal products. | | to provide for a reduction of the | |
| | | | annual fee and of some specific | |
| | | | fees for veterinary medicinal | |

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| | | | | proposals and |
| | | | 0/ | comments |
| | | | products and to closely monitor | |
| | | | associated costs for competent | |
| | | | authorities of the Member | |
| | | | States and the Agency, in | |
| | | | order to support the objectives | |
| | | | of Regulation (EU) 2019/6. | |
| | | | Therefore, the adjustment to | |
| | | | inflation applied to the | |
| | | | amounts in Annex II takes into | |
| | | | account only fifty percent of | |
| | | | the annual inflation rates for | |
| | | | the calendar years 2021 and | |
| | | | <u>2022.</u> | |
| 26 | (17) The Management Board of the | (17) The Management Board | (17) The Management Board | |
| | Agency should be empowered to provide | of the Agency should be | of the Agency should be | |
| | further fee reductions for justified reasons | empowered to provide further fee | empowered to provide further | |
| | of protection of public and animal health. A | reductions for <i>duly</i> justified | fee or charge reductions for | |
| | favourable opinion from the Commission | reasons of protection of public | justified reasons of protection of | |
| | should be mandatory before granting further | and animal health. A favourable | public and animal health or for | |

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| | | | proposals and |
| | | 0/ | comments |
| fee reductions, in order to ensure alignment | opinion from the Commission | justified reasons for the | |
| with Union law and with overall policies of | should be mandatory before | support of specific types of | |
| the Union. In addition, in duly justified | granting further fee reductions, in | products or applicants. A | |
| exceptional cases, for imperative reasons of | order to ensure alignment with | favourable opinion from the | |
| public or animal health, it should also be | Union law and with overall | Commission should be | |
| possible for the Executive Director of the | policies of the Union. For | mandatory before granting | |
| Agency to reduce certain types of fees on | transparency purposes, the | further fee reductions, in order | |
| the basis of a critical examination of the | Agency should make | to ensure alignment with Union | |
| situation specific to each case. | information on the decisions for | law and with overall policies of | |
| | further fee reductions publicly | the Union. In addition, in duly | |
| | available on its website, | justified exceptional cases, for | |
| | including on the recipients and | such as imperative reasons of | |
| | the reasons for the decision for | public or animal health, it | |
| | further fee reductions. In | should also be possible for the | |
| | addition, in duly justified | Executive Director of the | |
| | exceptional cases, for imperative | Agency to reduce certain types | |
| | reasons of public or animal | of fees on the basis of a critical | |
| | health, it should also be possible | examination of the situation | |
| | for the Executive Director of the | specific to each case. | |

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| | | | | proposals and |
| | | | 0/ | comments |
| | | Agency to reduce certain types of | | |
| | | fees on the basis of a critical | | |
| | | examination of the situation | | |
| | | specific to each case. The Agency | | |
| | | should ensure that such | | |
| | | decisions of the Executive | | |
| | | Director are made publicly | | |
| | | available on its website and set | | |
| | | out the reasons for those | | |
| | | decisions. | | |
| 27 | (18) In order to provide flexibility, in | (18) In order to provide | (18) In order to provide | |
| | particular to adapt to developments in | flexibility, in particular to adapt | flexibility, in particular to adapt | |
| | science, the Management Board of the | to developments in science and to | to developments in science, the | |
| | Agency should be enabled to specify | address unforeseen | Management Board of the | |
| | working arrangements to facilitate the | circumstances and medical | Agency should be enabled to | |
| | application of this Regulation, on a duly | needs, the Management Board of | specify working arrangements to | |
| | justified proposal from the Executive | the Agency should be enabled to | facilitate the application of this | |
| | Director. In particular, the Management | specify working arrangements to | Regulation, on a duly justified | |
| | Board should be able to establish due dates | facilitate the application of this | proposal from the Executive | |

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| | | | proposals and |
| | | | comments |
| and deadlines for payment, payment | Regulation, on a duly justified | Director. In particular, the | |
| methods, timetables, detailed classifications, | proposal from the Executive | Management Board should be | |
| lists of additional fee reductions, and | Director. In particular, the | able to establish due dates and | |
| detailed amounts within the limits of an | Management Board should be | deadlines for payment, payment | |
| established range. A favourable opinion | able to establish due dates and | methods, timetables, detailed | |
| from the Commission should be mandatory | deadlines for payment, payment | classifications, lists of additional | |
| before the proposal is put to the | methods, timetables, detailed | fee reductions, and detailed | |
| Management Board for adoption, in order to | classifications, lists of additional | amounts within the limits of an | |
| ensure alignment with Union law and with | fee reductions, and detailed | established range and a | |
| overall policies of the Union. | amounts within the limits of an | common format sufficiently | |
| | established range. A favourable | flexible for financial | |
| | opinion from the Commission | information to be provided by | |
| | should be mandatory before the | the National Competent | |
| | proposal is put to the | Authorities to the Agency and | |
| | Management Board for adoption, | what constitutes a distinct | |
| | in order to ensure alignment with | inspection, for each type of | |
| | Union law and with overall | inspection. A favourable | |
| | policies of the Union. | opinion from the Commission | |
| | | should be mandatory before the | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | 0 | comments |
| | | | proposal is put to the | |
| | | | Management Board for | |
| | | | adoption, in order to ensure | |
| | | | alignment with Union law and | |
| | | | with overall policies of the | |
| | | | Union. | |
| 28 | (19) For their assessments, rapporteurs | (19) For their assessments, | (19) For their assessments, | |
| | and co-rapporteurs and the other roles | rapporteurs and co-rapporteurs | rapporteurs and co-rapporteurs | |
| | considered as equivalent for the purposes of | and the other roles considered as | and the other roles considered as | |
| | this regulation in scientific advice and | equivalent for the purposes of this | equivalent for the purposes of | |
| | inspections rely on the scientific evaluations | regulation in scientific advice and | this regulation in scientific | |
| | and resources of the competent authorities | inspections rely on the scientific | advice and inspections rely on | |
| | of Member States, while it is the | evaluations and resources of the | the scientific evaluations and | |
| | responsibility of the Agency to coordinate | competent authorities of Member | resources of the competent | |
| | the existing scientific resources put at its | States, while it is the | authorities of Member States, | |
| | disposal by the Member States, in | responsibility of the Agency to | while it is the responsibility of | |
| | accordance with Article 55 of Regulation | coordinate the existing scientific | the Agency to coordinate the | |
| | (EC) No 726/2004. In light of that, and to | resources put at its disposal by the | existing scientific resources put | |
| | ensure appropriate resources for the | Member States, in accordance | at its disposal by the Member | |

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| | | | proposals and |
| | | 0 | comments |
| scientific assessments relating to the | with Article 55 of Regulation | States, in accordance with | |
| procedures carried out at Union level, the | (EC) No 726/2004. In light of | Article 55 of Regulation (EC) | |
| Agency should remunerate the scientific | that, and to ensure appropriate | No 726/2004. In light of that, | |
| assessment services provided by the | resources for the scientific | and to ensure appropriate | |
| rapporteurs and co-rapporteurs appointed by | assessments relating to the | resources for the scientific | |
| the Member States as members of the | procedures carried out at Union | assessments relating to the | |
| scientific committees of the Agency, or, | level, the Agency should | procedures carried out at Union | |
| where relevant, provided by rapporteurs and | remunerate the scientific | level, the Agency should | |
| co-rapporteurs in the coordination group | assessment services provided by | remunerate the scientific | |
| referred to in Article 27 of Directive | the rapporteurs and co- | assessment services provided by | |
| 2001/83/EC. The amount of remuneration | rapporteurs appointed by the | the rapporteurs and co- | |
| for the services provided by those | Member States as members of the | rapporteurs appointed by the | |
| rapporteurs and co-rapporteurs should be | scientific committees of the | Member States as members of | |
| based on estimations of the workload | Agency, or, where relevant, | the scientific committees of the | |
| involved and should be taken into account | provided by rapporteurs and co- | Agency, or, where relevant, | |
| in setting the level of the fees charged by | rapporteurs in the coordination | provided by rapporteurs and co- | |
| the Agency. | group referred to in Article 27 of | rapporteurs in the coordination | |
| | Directive 2001/83/EC. The | group referred to in Article 27 of | |
| | amount of remuneration for the | Directive 2001/83/EC. The | |

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| | | | | proposals and |
| | | | | comments |
| | | services provided by those | amount of remuneration for the | |
| | | rapporteurs and co-rapporteurs | services provided by those | |
| | | should be based on estimations of | rapporteurs and co-rapporteurs | |
| | | the workload involved and should | should be based on estimations | |
| | | be taken into account in setting | of the workload involved and | |
| | | the level of the fees charged by | should be taken into account in | |
| | | the Agency. Based on a specific | setting the level of the fees | |
| | | public interest benefitting both | charged by the Agency. | |
| | | the Union and the Member | | |
| | | States, where the Agency grants | | |
| | | a total waiver of fees, the | | |
| | | remuneration of rapporteurs and | | |
| | | co-rapporteurs should be | | |
| | | reduced by 50% or 100%, as | | |
| | | specified in Annex V. | | |
| 29 | (20) In line with the policy of the Union | | (20) In line with the policy of | |
| | to support SMEs within the meaning of | | the Union to support SMEs <u>as</u> | |
| | Commission Recommendation | | defined in within the meaning | |
| | 2003/361/EC ³⁶ , fee reductions should apply | | of Commission | |

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| | | | proposals and |
| | | 0/ | comments |
| to them. Such reductions should be | | Recommendation | |
| established on a basis that takes due account | | $2003/361/EC^{38}$, fee reductions | |
| of the ability of SMEs to pay. In order to | | should apply to them. Such | |
| ensure that the current framework for | | reductions should beare to be | |
| support to SMEs remains unchanged until a | | established on a basis that takes | |
| possible revision of Commission Regulation | | due account of the ability of | |
| (EC) No 2049/2005 ³⁷ , current post- | | SMEs to pay. In order to ensure | |
| authorisation fee reduction rates should be | | consistency of that the current | |
| granted to SMEs. Furthermore, | | framework for support to SMEs | |
| microenterprises should be exempted from | | withremains unchanged until a | |
| all post-authorisation fees. | | possible revision of Commission | |
| | | Regulation (EC) | |
| ³⁶ Commission Recommendation of 6 May 2003 | | No 2049/2005 ³⁹ , current post- | |
| concerning the definition of micro, small and | | authorisation fee reduction rates | |
| medium-sized enterprises (2003/361/EC) (OJ L 124, | | should be granted to SMEs. | |
| 20.5.2003, p. 36). | | Furthermore, microenterprises | |
| ³⁷ Commission Regulation (EC) No 2049/2005 of 15 | | , | |
| December 2005 laying down, pursuant to Regulation | | should be exempted from all | |
| (EC) No 726/2004 of the European Parliament and | | post-authorisation fees. | |
| of the Council, rules regarding the payment of fees | | | |

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| | | | | proposals and |
| | | | | comments |
| | to, and the receipt of administrative assistance from, | | ³⁸ Commission Recommendation of 6 | |
| | the European Medicines Agency by micro, small and | | May 2003 concerning the definition of | |
| | medium-sized enterprises (OJ L 329, 16.12.2005, p. | | micro, small and medium-sized | |
| | 4). | | enterprises (2003/361/EC) (OJ L 124, | |
| | | | 20.5.2003, p. 36). | |
| | | | ³⁹ Commission Regulation (EC) No | |
| | | | 2049/2005 of 15 December 2005 | |
| | | | laying down, pursuant to Regulation | |
| | | | (EC) No 726/2004 of the European | |
| | | | Parliament and of the Council, rules | |
| | | | regarding the payment of fees to, and | |
| | | | the receipt of administrative assistance | |
| | | | from, the European Medicines Agency | |
| | | | by micro, small and medium-sized | |
| | | | enterprises (OJ L 329, 16.12.2005, p. | |
| | | | 4). | |
| 30 | (21) Generic medicinal products for | | (21) Generic medicinal | |
| | human use and generic veterinary medicinal | | products for human use and | |
| | products, medicinal products for human use | | generic veterinary medicinal | |
| | and veterinary medicinal products | | products, medicinal products for | |
| | authorised under the provisions relating to | | human use and veterinary | |

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| | | 0/ | comments |
| well-established medicinal use, | | medicinal products authorised | |
| homeopathic medicinal products for human | | under the provisions relating to | |
| use and homeopathic veterinary medicinal | | well-established medicinal use, | |
| products, as well as herbal medicinal | | homeopathic medicinal products | |
| products for human use should be subject to | | for human use and homeopathic | |
| a reduced annual pharmacovigilance fee, as | | veterinary medicinal products, | |
| those medicinal products generally have a | | as well as herbal medicinal | |
| well-established safety profile. However, in | | products for human use should | |
| cases where such medicinal products are | | be subject to a reduced annual | |
| subject of any of the pharmacovigilance | | pharmacovigilance fee, as those | |
| procedures carried out at Union level, the | | medicinal products generally | |
| full fee should be charged in view of the | | have a well-established safety | |
| work involved. | | profile. However, in cases | |
| | | where such medicinal products | |
| | | are subject of any of the | |
| | | pharmacovigilance procedures | |
| | | carried out at Union level, the | |
| | | full fee should be is to be | |

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| | | | | comments |
| | | | charged in view of the work | |
| | | | involved. | |
| 31 | (22) In order to avoid a disproportionate | | (22) In order to avoid a | |
| | administrative workload for the Agency, fee | | disproportionate administrative | |
| | reductions and fee exemptions should be | | workload for the Agency, fee | |
| | applied on the basis of a declaration of the | | reductions and fee exemptions | |
| | marketing authorisation holder or applicant | | should be applied on the basis of | |
| | claiming to be entitled to such a measure. | | a declaration of the marketing | |
| | The submission of incorrect information in | | authorisation holder or applicant | |
| | that respect should be discouraged by means | | claiming to be entitled to such a | |
| | of the application of a specific charge if the | | measure. The submission of | |
| | Agency establishes that such incorrect | | incorrect information in that | |
| | information has been submitted. | | respect should be discouraged | |
| | | | by means of the application of a | |
| | | | specific charge if the Agency | |
| | | | establishes that such incorrect | |
| | | | information has been submitted. | |

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| | | | | comments |
| 32 | (23) For reasons of predictability and | | (23) For reasons of | |
| | clarity, the amounts of the fees, charges and | | predictability and clarity, the | |
| | remuneration should be set in euro. | | amounts of the fees, charges and | |
| | | | remuneration should beare set | |
| | | | in euro. | |
| 33 | (24) The amounts of the fees and charges | | (24) The amounts of the fees | |
| | and the remuneration to competent | | and charges and the | |
| | authorities of the Member States should be | | remuneration to competent | |
| | adjusted, where appropriate, to take account | | authorities of the Member States | |
| | of significant changes in costs, detected | | should be adjusted, where | |
| | through cost monitoring, and to take | | appropriate, to take account of | |
| | account of inflation. For the purpose of | | significant changes in costs, | |
| | taking into account the impact of inflation, | | detected through cost | |
| | the Harmonised Index of Consumer Prices | | monitoring, and to take account | |
| | published by Eurostat pursuant to | | of inflation. For the purpose of | |
| | Regulation (EU) No 2016/792 of the | | taking into account the impact | |
| | European Parliament and of the Council ⁴⁰ | | of inflation, the Harmonised | |
| | should be used. | | Index of Consumer Prices | |
| | | | published by Eurostat pursuant | |

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| | | | comments |
| ⁴⁰ Regulation (EU) 2016/792 of the European | | to Regulation (EU) | |
| Parliament and of the Council of 11 May 2016 on | | No 2016/792 of the European | |
| harmonised indices of consumer prices and the house | | Parliament and of the Council ⁴¹ | |
| price index, and repealing Council Regulation (EC) | | should be used. The first | |
| No 2494/95 (OJ L 135, 24.5.2016, p. 11). | | adjustment to inflation should | |
| | | take into account the annual | |
| | | inflation rates for each | |
| | | calendar year following the | |
| | | | |
| | | inflation adjustment already | |
| | | applied to the amounts in the | |
| | | Annexes, up to the year 2022 | |
| | | included. | |
| | | | |
| | | ⁴¹ Regulation (EU) 2016/792 of the | |
| | | European Parliament and of the | |
| | | Council of 11 May 2016 on | |
| | | harmonised indices of consumer prices | |
| | | and the house price index, and | |
| | | repealing Council Regulation (EC) No 2494/95 (OJ L 135, 24.5.2016, p. 11). | |
| | | 2474/33 (OJ L 133, 24.3.2010, p. 11). | |

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| | | | | proposals and |
| | | | | comments |
| 34 | (25) In order to ensure swift adjustment | | (25) In order to ensure swift | |
| | of the structure and amounts of fees, | | adjustment of the structure and | |
| | charges and remuneration to competent | | amounts of fees, charges and | |
| | authorities of the Member States to | | remuneration to competent | |
| | significant changes of costs or processes, | | authorities of the Member States | |
| | the power to adopt acts in accordance with | | to significant changes of costs | |
| | Article 290 of the Treaty on the Functioning | | or processes, the power to adopt | |
| | of the European Union should be delegated | | acts in accordance with | |
| | to the Commission in respect of the relevant | | Article 290 of the Treaty on the | |
| | amounts and the activities subject to fees | | Functioning of the European | |
| | and charges and remuneration, on the basis | | Union should be delegated to | |
| | of objective information related to costs or | | the Commission in respect of | |
| | changes to the regulatory framework. It is of | | the relevant amounts and the | |
| | particular importance that the Commission | | activities subject to fees and | |
| | carry out appropriate consultations during | | charges and remuneration, on | |
| | its preparatory work, including at expert | | the basis of objective | |
| | level, and that those consultations be | | information related to costs or | |
| | conducted in accordance with the principles | | changes to the regulatory | |
| | laid down in the Interinstitutional | | framework. This information is | |

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| | | | proposals and |
| | | 0 | comments |
| Agreement of 13 April 2016 on Better Law- | | provided mainly via a special | |
| Making ⁴² . In particular, to ensure equal | | report adopted by the | |
| participation in the preparation of delegated | | Management Board of the | |
| acts, the European Parliament and the | | Agency, which contains | |
| Council receive all documents at the same | | <u>justified recommendations to</u> | |
| time as Member States' experts, and their | | increase or decrease the | |
| experts systematically have access to | | amount of any fee, charge or | |
| meetings of Commission expert groups | | remuneration, amend the | |
| dealing with the preparation of delegated | | Annexes, including on the | |
| acts. | | basis of changes in the | |
| | | statutory tasks of the Agency, | |
| ⁴² Interinstitutional Agreement between the | | add fees and adapt the | |
| European Parliament, the Council of the European | | specification of activities. It is | |
| Union and the European Commission on Better Law- | | of particular importance that the | |
| Making (OJ L 123, 12.5.2016, p. 1). | | Commission carry out | |
| | | appropriate consultations during | |
| | | its preparatory work, including | |
| | | at expert level, and that those | |
| | | consultations be conducted in | |

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| | | | comments |
| | | accordance with the principles | |
| | | laid down in the | |
| | | Interinstitutional Agreement of | |
| | | 13 April 2016 on Better Law- | |
| | | Making ⁴³ . In particular, to | |
| | | ensure equal participation in the | |
| | | preparation of delegated acts, | |
| | | the European Parliament and the | |
| | | Council receive all documents at | |
| | | the same time as Member States' | |
| | | experts, and their experts | |
| | | systematically have access to | |
| | | meetings of Commission expert | |
| | | groups dealing with the | |
| | | preparation of delegated acts. If | |
| | | a change of the fees were to | |
| | | result in an increased share on | |
| | | the side of the Agency, special | |
| | | consideration should be given | |

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| | | | | comments |
| | | | that the aim of a balanced, | |
| | | | objective and fair distribution | |
| | | | of fees between the Agency | |
| | | | and the competent authorities | |
| | | | of the Member States is | |
| | | | maintained. | |
| | | | | |
| | | | ⁴³ Interinstitutional Agreement | |
| | | | between the European Parliament, the | |
| | | | Council of the European Union and the | |
| | | | European Commission on Better Law- | |
| 2.5 | | | Making (OJ L 123, 12.5.2016, p. 1). | |
| 35 | (26) In order to ensure cost recovery, the | | (26) In order to ensure cost | |
| | Agency should provide services by virtue of | | recovery, the Agency should | |
| | the tasks entrusted to it only after the | | provide services by virtue of the | |
| | corresponding fee or charge has been paid | | tasks entrusted to it only after | |
| | in its entirety. However, in accordance with | | the corresponding fee or charge | |
| | Article 71, fourth subparagraph, of | | has been paid in its entirety. | |
| | Commission Delegated Regulation (EU) | | However, in accordance with | |

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| | 2019/715 ⁴⁴ , in exceptional circumstances, a | | Article 71, fourth subparagraph, | |
| | service may be provided without prior | | of Commission Delegated | |
| | payment of the corresponding fee or charge. | | Regulation (EU) 2019/715 ⁴⁵ , in | |
| | | | exceptional circumstances, a | |
| | 44 Commission Delegated Regulation (EU) 2019/715 | | service may be provided without | |
| | of 18 December 2018 on the framework financial | | prior payment of the | |
| | regulation for the bodies set up under the TFEU and | | corresponding fee or charge. | |
| | Euratom Treaty and referred to in Article 70 of | | | |
| | Regulation (EU, Euratom) 2018/1046 of the | | 45 Commission Delegated Regulation | |
| | European Parliament and of the Council. (OJ L 122, | | (EU) 2019/715 of 18 December 2018 | |
| | 10.5.2019, p. 1). | | on the framework financial regulation | |
| | | | for the bodies set up under the TFEU | |
| | | | and Euratom Treaty and referred to in | |
| | | | Article 70 of Regulation (EU, | |
| | | | Euratom) 2018/1046 of the European | |
| | | | Parliament and of the Council. (OJ L | |
| | | | 122, 10.5.2019, p. 1). | |
| 35a | | (26a) Member States should | | |
| | | ensure that adequate financial | | |
| | | resources are available to | | |

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| | | | 0 | comments |
| | | provide the national competent | | |
| | | authorities with staff and other | | |
| | | resources necessary to carry out | | |
| | | the relevant activities associated | | |
| | | with the fees and charges levied | | |
| | | in accordance with this | | |
| | | Regulation. Any revision of the | | |
| | | fees and charges pursuant to | | |
| | | Article 11 should also be taken | | |
| | | into account. | | |
| 35b | | (26b) The calculation of the | | |
| | | amounts of the fees, charges and | | |
| | | remuneration take into account | | |
| | | the inflation rate measured by | | |
| | | means of the Harmonised Index | | |
| | | of Consumer Prices published by | | |
| | | Eurostat pursuant to Regulation | | |
| | | (EU) No 2016/792 until the date | | |
| | | of adoption of the proposal for | | |

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| | | 0/ | comments |
| | this Regulation. The inflation | | |
| | rate was high when the proposal | | |
| | for this Regulation was | | |
| | submitted, remains high as | | |
| | measured in 2023, and, | | |
| | according to the forecast of the | | |
| | European Central Bank, is | | |
| | projected to remain high in 2024. | | |
| | The relevant amounts should be | | |
| | updated to ensure that the fees, | | |
| | charges and remuneration | | |
| | payable are adjusted for such | | |
| | inflation before the date of | | |
| | application of this Regulation. | | |
| | The Commission should | | |
| | therefore adopt a delegated act to | | |
| | amend the relevant Annexes to | | |
| | this Regulation on the basis of | | |
| | the inflation rate published four | | |

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| | | | | comments |
| | | months before the date of | | |
| | | application of this Regulation. | (C) | |
| 36 | (27) In accordance with Article 30 of | | (27) In accordance with | |
| | Regulation (EU) 2022/123 ⁴⁶ , the Agency | | Article 30 of Regulation (EU) | |
| | provides, on behalf of the Commission, the | | 2022/123 ⁴⁷ , the Agency | |
| | secretariat for the expert panels designated | | provides, on behalf of the | |
| | in accordance with Regulation (EU) | | Commission, the secretariat for | |
| | 2017/745. The provision in Article 106 of | | the expert panels designated in | |
| | Regulation (EU) 2017/745 concerning the | | accordance with Regulation | |
| | payment of fees for advice provided by | | (EU) 2017/745. The provision | |
| | expert panels should therefore be amended | | in Article 106 of Regulation | |
| | in order to allow the Agency to receive | | (EU) 2017/745 concerning the | |
| | those fees, once such fees are established by | | payment of fees for advice | |
| | the Commission in accordance with that | | provided by expert panels | |
| | Regulation. | | should therefore be amended in | |
| | | | order to allow the Agency to | |
| | ⁴⁶ Regulation (EU) 2022/123 of the European | | receive charge those fees, once | |
| | Parliament and of the Council of 25 January 2022 on | | such fees are established by the | |
| | a reinforced role for the European Medicines Agency | | | |

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| | | | | comments |
| | in crisis preparedness and management for medicinal | | Commission in accordance with | |
| | products and medical devices (OJ L 20, 31.1.2022, p. | | that Regulation. | |
| | 1). | | | |
| | | | 47 Regulation (EU) 2022/123 of the | |
| | | | European Parliament and of the | |
| | | | Council of 25 January 2022 on a | |
| | | | reinforced role for the European | |
| | | | Medicines Agency in crisis | |
| | | | preparedness and management for | |
| | | | medicinal products and medical | |
| | | | devices (OJ L 20, 31.1.2022, p. 1). | |
| 37 | (28) Since the objective of this | | (28) Since the objective of | |
| | Regulation, namely to ensure appropriate | | this Regulation, namely to | |
| | funding of Agency activities carried out at | | ensure appropriate funding of | |
| | Union level, cannot sufficiently be achieved | | Agency activities carried out at | |
| | by the Member States but can rather, by | | Union level, cannot sufficiently | |
| | reason of the scale of the measure, be better | | be achieved by the Member | |
| | achieved at Union level, the Union may | | States but can rather, by reason | |
| | adopt measures, in accordance with the | | of the scale of the measure, be | |
| | principle of subsidiarity as set out in | | better achieved at Union level, | |

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| | | | 0 | comments |
| | Article 5 of the Treaty on European Union. | | the Union may adopt measures, | |
| | In accordance with the principle of | | in accordance with the principle | |
| | proportionality, as set out in that Article, | | of subsidiarity as set out in | |
| | this Regulation does not go beyond what is | | Article 5 of the Treaty on | |
| | necessary in order to achieve that objective, | | European Union. In accordance | |
| | | | with the principle of | |
| | | | proportionality, as set out in that | |
| | | | Article, this Regulation does not | |
| | | | go beyond what is necessary in | |
| | | | order to achieve that objective. | |
| 37a | | | 28a) In order to allow for | |
| | | | the prompt application of the | |
| | | | measures provided for in this | |
| | | | Regulation, it should enter | |
| | | | into force on the day following | |
| | | | that of its publication in the | |
| | | | Official Journal of the | |
| | | | European Union. | |

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| | | | | comments |
| 38 | HAVE ADOPTED THIS REGULATION: | | HAVE ADOPTED THIS | |
| | | | REGULATION: | |
| 39 | Article I | | Article 1 | |
| | Subject matter | | Subject matter and scope | |
| 40 | This Regulation lays down the following: | | <u>1.</u> This Regulation lays | <u>1.</u> This Regulation |
| | | | down the following: | lays down the following: |
| 41 | (a) the amounts of the fees and charges | | (a) the amounts of the fees | (a) the amounts of |
| | established on cost-based evaluation and | | and charges established on cost- | the fees and charges |
| | levied by the European Medicines Agency | | based evaluation and levied by | established on cost- |
| | (the 'Agency') for assessment activities | | the European Medicines Agency | based evaluation and |
| | relating to obtaining and maintaining a | | (the 'Agency') for assessment | levied by the European |
| | Union authorisation to market medicinal | | activities relating to obtaining | Medicines Agency (the |
| | products for human use and veterinary | | and maintaining a Union | 'Agency') for |
| | medicinal products and for other services | | authorisation to market | assessment activities |
| | provided or tasks carried out by the Agency, | | medicinal products for human | relating to obtaining and |
| | as provided for in Regulations (EC) | | use and veterinary medicinal | maintaining a Union |
| | 726/2004 and (EU) 2019/6; | | products and for other services | authorisation to market |
| | | | provided or tasks carried out by | medicinal products for |
| | | | the Agency, as provided for in | human use and |

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| | | | | proposals and |
| | | | 0 | comments |
| | | | Regulations (EC) 726/2004 and | veterinary medicinal |
| | | | (EU) 2019/6; | products and for other |
| | | | | services provided or |
| | | | | tasks carried out by the |
| | | | | Agency, as provided for |
| | | | | in Regulations (EC) |
| | | | | 726/2004 and (EU) |
| | | | | 2019/6; |
| 42 | (b) the corresponding amounts of | | (b) the corresponding | (b) the |
| | remuneration established on cost-based | | amounts of remuneration | corresponding amounts |
| | evaluation and payable by the Agency to the | | established on cost-based | of remuneration |
| | competent authorities of the Member States | | evaluation and payable by the | established on cost- |
| | for the services provided by rapporteurs | | Agency to the competent | based evaluation and |
| | and, where applicable, co-rapporteurs from | | authorities of the Member States | payable by the Agency |
| | competent authorities of the Member States, | | for the services provided by | to the competent |
| | or by other roles considered as equivalent | | rapporteurs and, where | authorities of the |
| | for the purposes of this regulation, as | | applicable, co-rapporteurs from | Member States for the |
| | referred to in the Annexes to this | | competent authorities of the | services provided by |
| | Regulation; and | | Member States, or by other roles | rapporteurs and, where |

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| | | | | proposals and |
| | | | | comments |
| | | | considered as equivalent for the | applicable, co- |
| | | | purposes of this regulation, as | rapporteurs from |
| | | | referred to in the Annexes to | competent authorities of |
| | | | this Regulation; and | the Member States, or |
| | | | | by other roles |
| | | | | considered as equivalent |
| | | | | for the purposes of this |
| | | | | regulation, as referred to |
| | | | | in the Annexes to this |
| | | | | Regulation; and |
| 43 | (c) the monitoring of costs of activities | | (c) the monitoring of costs | (c) the monitoring of |
| | and services provided by the Agency and of | | of activities and services | costs of activities and |
| | costs for remuneration referred to in point | | provided by the Agency and of | services provided by the |
| | (b). | | costs for remuneration referred | Agency and of costs for |
| | | | to in point (b). | remuneration referred to |
| | | | | in point (b). |
| 43a | | | 2. Medicinal products for | 2. Medicinal |
| | | | human use which are | products for human |
| | | | | use which are |

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| | | | | comments |
| | | | authorised to be placed on the | authorised to be placed |
| | | | market in accordance with | on the market in |
| | | | Article 126a of Directive | accordance with |
| | | | 2001/83/EC shall not be | Article 126a of |
| | | | subject to the fees for | Directive 2001/83/EC |
| | | | pharmacovigilance activities | shall not be subject to |
| | | | set out in the Annexes to this | the fees for |
| | | | Regulation. | <u>pharmacovigilance</u> |
| | | | | activities set out in the |
| | | | | Annexes to this |
| | | | | Regulation. |
| 44 | Article 2 | | Article 2 | |
| | Definitions | | Definitions | |
| 45 | For the purposes of this Regulation, the | | For the purposes of this | For the purposes of this |
| | following definitions shall apply: | | Regulation, the following | Regulation, the |
| | | | definitions shall apply: | following definitions |
| | | | | shall apply: |
| 46 | (1) 'chargeable unit in relation to | | (1) 'chargeable unit in | (1) 'chargeable unit |
| | medicinal products for human use' | | relation to medicinal products | in relation to medicinal |

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| | | 0/ | comments |
| ('chargeable unit - human') means a unit | | for human use' ('chargeable unit | products for human use' |
| defined by a unique combination of the | | - human') means a unit defined | ('chargeable unit - |
| following dataset derived from information | | by a unique combination of the | human') means a unit |
| on all medicinal products authorised in the | | following dataset derived from | defined by a unique |
| Union held by the Agency, and consistent | | information on all medicinal | combination of the |
| with the obligation of marketing | | products authorised in the Union | following dataset |
| authorisation holders referred to in | | held by the Agency, and | derived from |
| Article 57(2), points (b) and (c), of | | consistent with the obligation of | information on all |
| Regulation (EC) No 726/2004 to submit such | | marketing authorisation holders | medicinal products |
| information to the database referred to in | | referred to in Article 57(2), | authorised in the Union |
| Article 57(1), second subparagraph, point | | points (b) and (c), of Regulation | held by the Agency, and |
| (l), of that Regulation: | | (EC) No 726/2004 to submit | consistent with the |
| | | such information to the database | obligation of marketing |
| | | referred to in Article 57(1), | authorisation holders |
| | | second subparagraph, point (l), | referred to in |
| | | of that Regulation: | Article 57(2), points (b) |
| | | | and (c), of Regulation |
| | | | (EC) No 726/2004 to |
| | | | submit such information |

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| | | | 0 | comments |
| | | | | to the database referred |
| | | | (C) | to in Article 57(1), |
| | | | | second subparagraph, |
| | | | | point (l), of that |
| | | | | Regulation: |
| 47 | (a) name of the medicinal product, as | | (a) name of the medicinal | (a) name of the |
| | defined in Article 1, point (20), of Directive | | product, as defined in Article 1, | medicinal product, as |
| | 2001/83/EC; | | point (20), of Directive | defined in Article 1, |
| | | | 2001/83/EC; | point (20), of Directive |
| | | | | 2001/83/EC; |
| 48 | (b) marketing authorisation holder; | | (b) marketing authorisation | (b) marketing |
| | | | holder; | authorisation holder; |
| 49 | (c) the Member State in which the | | (c) the Member State in | (c) the Member |
| | marketing authorisation is valid; | | which the marketing | State in which the |
| | | | authorisation is valid; | marketing authorisation |
| | | | | is valid; |
| 50 | (d) active substance or a combination of | | (d) active substance or a | (d) active substance |
| | active substances, except in the case of | | combination of active | or a combination of |
| | homeopathic medicinal products or herbal | | substances, except in the case of | active substances, |

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| | medicinal products, as defined in Article 1, | | homeopathic medicinal products | except in the case of |
| | points 5 and 30, respectively, of Directive | | or herbal medicinal products, as | homeopathic medicinal |
| | 2001/83/EC; | | defined in Article 1, points 5 and | products or herbal |
| | | | 30, respectively, of Directive | medicinal products, as |
| | | | 2001/83/EC; | defined in Article 1, |
| | | | | points 5 and 30, |
| | | | | respectively, of |
| | | | | Directive 2001/83/EC; |
| 51 | (e) pharmaceutical form; | | (e) pharmaceutical form; | (e) pharmaceutical |
| | | | | form; |
| 52 | (2) 'chargeable unit in relation to | | (2) 'chargeable unit in | (2) 'chargeable unit |
| | veterinary medicinal products' ('chargeable | | relation to veterinary medicinal | in relation to veterinary |
| | unit - veterinary') means a unit defined by | | products' ('chargeable unit - | medicinal products' |
| | the unique combination of the following data | | veterinary') means a unit | ('chargeable unit - |
| | fields contained in the Union product | | defined by the unique | veterinary') means a |
| | database established pursuant to | | combination of the following | unit defined by the |
| | Article 55(1) of Regulation (EU) 2019/6: | | data fields contained in the | unique combination of |
| | | | Union product database | the following data fields |
| | | | established pursuant to | contained in the Union |

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| | | | Article 55(1) of Regulation (EU) | product database |
| | | | 2019/6: | established pursuant to |
| | | | | Article 55(1) of |
| | | | | Regulation (EU) 2019/6: |
| 53 | (a) the Permanent Identifier referred to | | (a) the Permanent Identifier | (a) the Permanent |
| | under Data Field ID 3.1 in Annex III to | | referred to under Data Field ID | Identifier referred to |
| | Implementing Regulation (EU) 2021/16; | | 3.1 in Annex III to | under Data Field ID 3.1 |
| | | | Implementing Regulation (EU) | in Annex III to |
| | | | 2021/16; | Implementing |
| | | | | Regulation (EU) |
| | | | | 2021/16; |
| 54 | (b) the Product Identifier referred to | | (b) the Product Identifier | (b) the Product |
| | under Data Field ID 3.2 in Annex III to | | referred to under Data Field ID | Identifier referred to |
| | Implementing Regulation (EU) 2021/16; | | 3.2 in Annex III to | under Data Field ID 3.2 |
| | | | Implementing Regulation (EU) | in Annex III to |
| | | | 2021/16; | Implementing |
| | | | | Regulation (EU) |
| | | | | 2021/16; |

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| | | | | comments |
| 55 | (3) 'medium-sized enterprise' means a | | (3) 'medium-sized | (3) 'medium-sized |
| | medium-sized enterprise within the meaning | | enterprise' means a medium- | enterprise' means a |
| | of Recommendation 2003/361/EC; | | sized enterprise within the | medium-sized enterprise |
| | | | meaning of Recommendation | within the meaning of |
| | | | 2003/361/EC; | Recommendation |
| | | | | 2003/361/EC; |
| 56 | (4) 'small enterprise' means a small | | (4) 'small enterprise' means | (4) 'small |
| | enterprise within the meaning of | | a small enterprise within the | enterprise' means a |
| | Recommendation 2003/361/EC; | | meaning of Recommendation | small enterprise within |
| | | | 2003/361/EC; | the meaning of |
| | | | | Recommendation |
| | | | | 2003/361/EC; |
| 57 | (5) 'microenterprise' means a | | (5) 'microenterprise' means | (5) 'microenterprise' |
| | microenterprise within the meaning of | | a microenterprise within the | means a microenterprise |
| | Recommendation 2003/361/EC; | | meaning of Recommendation | within the meaning of |
| | | | 2003/361/EC; | Recommendation |
| | | | | 2003/361/EC; |
| 57a | | (5a) 'Academia' or 'academic | | |
| | | sector' means public or private | | |

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| | | higher education establishments | | |
| | | awarding academic degrees, | | |
| | | public or private non-profit | | |
| | | research organisations whose | | |
| | | primary mission is to pursue | | |
| | | research, and international | | |
| | | European interest organisations; | | |
| 57b | | (5b) 'Non-profit organisation' | | |
| | | or 'non-profit legal entity' means | | |
| | | a legal entity which by its legal | | |
| | | form is non-profit-making or | | |
| | | which has a legal or statutory | | |
| | | obligation not to distribute | | |
| | | profits to its shareholders or | | |
| | | individual members; | | |
| 57c | | (5c) 'International European | | |
| | | interest organisation' means an | | |
| | | international organisation, the | | |
| | | majority of whose members are | | |

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| | | | 0 | comments |
| | | Member States or associated | | |
| | | countries, and whose principal | | |
| | | objective is to promote scientific | | |
| | | and technological cooperation in | | |
| | | the Union; | | |
| 58 | (6) 'public health emergency' means a | (6) 'public health emergency' | (6) 'public health | (6) 'public health |
| | situation of public health emergency | means a situation of public health | emergency' means a situation of | emergency' means a |
| | recognised by the Commission in accordance | emergency recognised by the | public health emergency | situation of public |
| | with Article 12(1) of Decision | Commission in accordance with | recognised by the Commission | health emergency |
| | No 1082/2013/EU of the European | Article 23 of Regulation (EU) | in accordance with | recognised by the |
| | Parliament and of the Council ⁴⁸ . | 2022/2371 of the European | Article 23(1) of Regulation | Commission in |
| | | Parliament and of the Council ⁴⁰ . | (EU) 2022/2371 of the | accordance with |
| | ⁴⁸ Decision No 1082/2013/EU of the European | | European Parliament and of | Article 23(1) of |
| | Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing | ⁴⁰ <i>Regulation (EU) 2022/2371</i> of the European Parliament and of the Council | the Council 12(1) of Decision | Regulation (EU) |
| | Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1). | C 2 2 1 2022 · | No 1082/2013/EU of the | 2022/2371 of the |
| | , | Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26). | European Parliament and of the | European Parliament |
| | | 0.12.2022, p. 20j. | Council ⁴⁸ . | and of the Council |
| | | | | 12(1) of Decision |
| | | | | |

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| | | | ⁴⁹ Decision No 1082/2013/EU of the | No 1082/2013/EU of |
| | | | European Parliament and of the | the European Parliament |
| | | | Council of 22 October 2013 on serious | and of the Council ⁴⁸ . |
| | | | eross-border threats to health and | |
| | | | repealing Decision No 2119/98/EC | |
| | | | (OJ L 293, 5.11.2013, p. 1). | |
| | | | Regulation (EU) 2022/2371 of the | |
| | | | European Parliament and of the | |
| | | | Council of 23 November 2022 on | |
| | | | serious cross-border threats to | |
| | | | health and repealing Decision No | |
| | | | 1082/2013/EU OJ L 314, 6.12.2022, | |
| | | | <u>p. 26–63</u> | |
| 59 | Article 3 | | Article 3 | Article 3 |
| | Types of fees and charges | | Types of fees and charges | Types of fees and |
| | | | | charges |
| 60 | The Agency may levy the following types of | | The Agency may levy the | The Agency may levy |
| | fees or charges: | | following types of fees or | the following types of |
| | | | charges: | fees or charges: |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | comments |
| 61 | (a) fees and charges for assessment | | (a) fees and charges for | (a) fees and charges |
| | procedures and services relating to medicinal | | assessment procedures and | for assessment |
| | products for human use, set out in Annex I; | | services relating to medicinal | procedures and services |
| | | | products for human use, set out | relating to medicinal |
| | | | in Annex I; | products for human use, |
| | | | | set out in Annex I; |
| 62 | (b) fees for and charges for assessment | | (b) fees for and charges for | (b) fees for and |
| | procedures and services relating to | | assessment procedures and | charges for assessment |
| | veterinary medicinal products, set out in | | services relating to veterinary | procedures and services |
| | Annex II; | | medicinal products, set out in | relating to veterinary |
| | | | Annex II; | medicinal products, set |
| | | | | out in Annex II; |
| 63 | (c) annual fees for authorised medicinal | | (c) annual fees for | (c) annual fees for |
| | products for human use and for authorised | | authorised medicinal products | authorised medicinal |
| | veterinary medicinal products, set out in | | for human use and for | products for human use |
| | Annex III; | | authorised veterinary medicinal | and for authorised |
| | | | products, set out in Annex III; | veterinary medicinal |
| | | | | products, set out in |
| | | | | Annex III; |

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| | | | | comments |
| 64 | (d) other fees and charges for medicinal | | (d) other fees and charges | (d) other fees and |
| | products for human use, veterinary medicinal | | for medicinal products for | charges for medicinal |
| | products and consultations on medical | | human use, veterinary medicinal | products for human use, |
| | devices, set out in Annex IV. | | products and consultations on | veterinary medicinal |
| | | | medical devices, set out in | products and |
| | | | Annex IV. | consultations on medical |
| | | | | devices, set out in |
| | | | | Annex IV. |
| 65 | Article 4 | | Article 4 | Article 4 |
| | Additional fees and charges | | Additional fees and charges | Additional fees and |
| | | | | charges |
| 66 | 1. The Agency may levy a scientific | | 1. The Agency may levy a | 1. The Agency may |
| | service fee for scientific services it provides | | scientific service fee for | levy a scientific service |
| | if these services are not covered by another | | scientific services it provides if | fee for scientific |
| | fee or charge provided for in this Regulation. | | these services are not covered by | services it provides if |
| | The amount of the scientific service fee shall | | another fee or charge provided | these services are not |
| | take into account the workload involved. Its | | for in this Regulation. The | covered by another fee |
| | minimum and maximum amount and, where | | amount of the scientific service | or charge provided for in |
| | relevant, the corresponding remuneration to | | fee shall take into account the | this Regulation. The |

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| | | | | comments |
| | the rapporteurs and, where relevant, co- | | workload involved. Its minimum | amount of the scientific |
| | rapporteurs, are set out in point 5 of Annex | | and maximum amount and, | service fee shall take |
| | IV. | | where relevant, the | into account the |
| | | | corresponding remuneration to | workload involved. Its |
| | | | the rapporteurs and, where | minimum and maximum |
| | | | relevant, co-rapporteurs, are set | amount and, where |
| | | | out in point 5 of Annex IV. | relevant, the |
| | | | | corresponding |
| | | | | remuneration to the |
| | | | | rapporteurs and, where |
| | | | | relevant, co-rapporteurs, |
| | | | | are set out in point 5 of |
| | | | | Annex IV. |
| 67 | 2. The Agency may levy a charge for | | 2. The Agency may levy a | 2. The Agency may |
| | administrative services it provides, at the | | charge for administrative | levy a charge for |
| | request of a third party, if these services are | | services it provides, at the | administrative services it |
| | not covered by another fee or charge | | request of a third party, if these | provides, at the request |
| | provided for in this Regulation. The amount | | services are not covered by | of a third party, if these |
| | of the charge for administrative services shall | | another fee or charge provided | services are not covered |

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| | | | | comments |
| | take into account the workload involved. Its | | for in this Regulation. The | by another fee or charge |
| | minimum and maximum amount are set out | | amount of the charge for | provided for in this |
| | in point 6.4 of Annex IV. | | administrative services shall | Regulation. The amount |
| | | | take into account the workload | of the charge for |
| | | | involved. Its minimum and | administrative services |
| | | | maximum amount are set out in | shall take into account |
| | | | point 6.4 of Annex IV. | the workload involved. |
| | | | | Its minimum and |
| | | | | maximum amount are |
| | | | | set out in point 6.4 of |
| | | | | Annex IV. |
| 68 | 3. Fees and charges levied pursuant to | | 3. Fees and charges levied | 3. Fees and charges |
| | paragraphs 1 and 2 shall be set by the | | pursuant to paragraphs 1 and 2 | levied pursuant to |
| | Management Board of the Agency following | | shall be set by the Management | paragraphs 1 and 2 shall |
| | a favourable opinion by the Commission, in | | Board of the Agency following a | be set by the |
| | accordance with the procedure established | | favourable opinion by the | Management Board of |
| | under Article 8. The applicable amounts | | Commission, in accordance with | the Agency following a |
| | shall be published on the website of the | | the procedure established under | favourable opinion by |
| | Agency. | | Article 8. The applicable | the Commission, in |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | 0 | comments |
| | | | amounts shall be published on | accordance with the |
| | | | the website of the Agency. | procedure established |
| | | | | under Article 8. The |
| | | | | applicable amounts shall |
| | | | | be published on the |
| | | | | website of the Agency. |
| 69 | 4. The Commission shall take into | | 4. The Commission shall | 4. The Commission |
| | account any fees and charges levied in | | take into account any fees and | shall take into account |
| | accordance with this Article in any revision | | charges levied in accordance | any fees and charges |
| | of this Regulation. | | with this Article in any revision | levied in accordance |
| | | | of this Regulation. | with this Article in any |
| | | | | revision of this |
| | | | | Regulation. |

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| | | | | proposals and |
| | | | 0 | comments |
| 70 | Article 5 | | Article 5 | Article 5 |
| | Payment of remuneration to competent | | Payment of remuneration to | Payment of |
| | authorities of the Member States for the | | competent authorities of the | remuneration to |
| | provision of services to the Agency | | Member States for the | competent authorities |
| | | | provision of services to the | of the Member States |
| | | | Agency | for the provision of |
| | | | | services to the Agency |
| 71 | 1. The Agency shall pay the | | 1. The Agency shall pay | 1. The Agency |
| | remuneration referred to in Article 1(b) in | | the remuneration referred to in | shall pay the |
| | accordance with the amounts of | | Article 1(b) in accordance with | remuneration referred to |
| | remuneration provided for in this Regulation. | | the amounts of remuneration | in Article 1(b) in |
| | | | provided for in this Regulation. | accordance with the |
| | | | | amounts of |
| | | | | remuneration provided |
| | | | | for in this Regulation. |
| 72 | 2. Unless otherwise provided for in this | 2. Unless otherwise provided | 2. Unless otherwise | Linked with discussion |
| | Regulation, where fee reductions apply, the | for in this Regulation, where <i>less</i> | provided for in this Regulation, | on annexes |
| | remuneration to competent authorities of the | than total fee reductions apply, | where fee reductions <i>or waivers</i> | |
| | | the remuneration to competent | apply, the remuneration to | |

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| | | | | proposals and |
| | | | 0 | comments |
| | Member States payable in accordance with | authorities of the Member States | competent authorities of the | |
| | this Regulation shall not be reduced. | payable in accordance with this | Member States payable in | |
| | | Regulation shall not be reduced. | accordance with this Regulation | |
| | | However, unless otherwise | shall not be reduced. | |
| | | provided for in this Regulation, | | |
| | | where fee waivers are granted, | | |
| | | the remuneration shall be | | |
| | | reduced as laid down in Annex | | |
| | | V. | | |
| 73 | 3. The remuneration to competent | | 3. The remuneration to | 3. The |
| | authorities of the Member States shall be | | competent authorities of the | remuneration to |
| | paid in accordance with the written contract | | Member States shall be paid in | competent authorities of |
| | referred to in Article 62(3), first | | accordance with the written | the Member States shall |
| | subparagraph, of Regulation (EC) | | contract referred to in | be paid in accordance |
| | No 726/2004. The remuneration shall be | | Article 62(3), first subparagraph, | with the written contract |
| | paid in euro. Any bank charges related to the | | of Regulation (EC) | referred to in |
| | payment of such remuneration shall be borne | | No 726/2004. The remuneration | Article 62(3), first |
| | by the Agency. Detailed rules concerning the | | shall be paid in euro. Any bank | subparagraph, of |
| | payment of remuneration shall be established | | charges related to the payment | Regulation (EC) |

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| | | | | proposals and |
| | | | | comments |
| | by the Management Board of the Agency, in | | of such remuneration shall be | No 726/2004. The |
| | accordance with Article 8 of this Regulation. | | borne by the Agency. Detailed | remuneration shall be |
| | | | rules concerning the payment of | paid in euro. Any bank |
| | | | remuneration shall be | charges related to the |
| | | | established by the Management | payment of such |
| | | | Board of the Agency, in | remuneration shall be |
| | | | accordance with Article 8 of this | borne by the Agency. |
| | | | Regulation. | Detailed rules |
| | | | | concerning the payment |
| | | | | of remuneration shall be |
| | | | | established by the |
| | | | | Management Board of |
| | | | | the Agency, in |
| | | | | accordance with |
| | | | | Article 8 of this |
| | | | | Regulation. |
| 74 | Article 6 | | Article 6 | Article 6 |
| | Reductions of fees and charges | | Reductions of fees and charges | Reductions of fees and |
| | | | | charges |

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| | | | | proposals and |
| | | | | comments |
| 75 | 1. The Agency shall apply the | | 1. The Agency shall apply | 1. The Agency |
| | reductions set out in Annex V. | | the reductions set out in Annex | shall apply the |
| | | | V. | reductions set out in |
| | | | | Annex V. |
| 76 | 2. Where an assessment, an opinion or a | | 2. Where an assessment, an | |
| | service of the Agency is requested either by | | opinion or a service of the | |
| | a Member State or by a Union institution, the | | Agency is requested either by a | |
| | Agency shall waive the respective fee or | | Member State or by a Union | |
| | charge, as applicable, in full. | | institution, the Agency shall | |
| | | | may waive the respective fee | |
| | | | or charge, as applicable. The | |
| | | | Agency shall not levy the | |
| | | | respective fee or charge to any | |
| | | | Member State or Union | |
| | | | institution. waive the respective | |
| | | | fee or charge, as applicable, in | |
| | | | full. | |
| 77 | 3. Where the applicant or marketing | | 3. Without prejudice to | Without prejudice to |
| | authorisation holder may also benefit from | | Article 5(2), Wwhere the | Article 5(2), Wwhere |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | 0 | comments |
| | another reduction provided for in Union | | applicant or marketing | the applicant or |
| | legislation, only the reduction that is the most | | authorisation holder may also | marketing authorisation |
| | favourable to the applicant or marketing | | benefit from another reduction | holder may also benefit |
| | authorisation holder shall apply. | | provided for in Union | from another reduction |
| | | | legislation, only the reduction | provided for in Union |
| | | | that is the most favourable to the | legislation, only the |
| | | | applicant or marketing | reduction that is the |
| | | | authrisation holder shall apply. | most favourable to the |
| | | | | applicant or marketing |
| | | | | authrisation holder shall |
| | | | | apply. |
| 78 | 4. On a duly justified proposal from the | 4. On a duly justified | 4. On a duly justified | |
| | Executive Director of the Agency, in | proposal from the Executive | proposal from the Executive | |
| | particular for the protection of public or | Director of the Agency, in | Director of the Agency, in | |
| | animal health or for the support of specific | particular for the protection of | particular for the protection of | |
| | types of products or applicants, selected for | public or animal health or for the | public or animal health or for | |
| | duly justified reasons, the Management | support of specific types of | the support of specific types of | |
| | Board of the Agency may grant, following a | products or types of applicants, | products or applicants, selected | |
| | favourable opinion from the Commission, a | selected for duly justified reasons, | for duly justified reasons, the | |

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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | 0/ | comments |
| | total or partial reduction of the applicable | the Management Board of the | Management Board of the | |
| | amount, in accordance with Article 8. | Agency may grant, following a | Agency may grant, following a | |
| | | favourable opinion from the | favourable opinion from the | |
| | | Commission, a total or partial | Commission, a total or partial | |
| | | reduction of the applicable | reduction of the applicable <u>fee</u> | |
| | | amount, in accordance with | or charge amount, in | |
| | | Article 8. <i>The Agency shall make</i> | accordance with Article 8. | |
| | | information on such reductions | | |
| | | publicly available on the | | |
| | | Agency's website, setting out the | | |
| | | reasons for the reduction. | | |
| 79 | 5. In exceptional circumstances and for | 5. In exceptional | 5. In exceptional | |
| | imperative reasons of public or animal | circumstances and for duly | circumstances and for such as | |
| | health, the Executive Director of the Agency | <i>justified</i> imperative reasons of | imperative reasons of public or | |
| | may grant, on a case-by-case basis, total or | public or animal health, the | animal health, the Executive | |
| | partial reductions for the fees set out in | Executive Director of the Agency | Director of the Agency may | |
| | Annexes I, II, III and IV, with the exception | may grant, on a case-by-case | grant, on a case-by-case basis, | |
| | of the fees set out in points 6, 15 and 16 of | basis, total or partial reductions | total or partial reductions for the | |
| | Annex I, points 7 and 10 of Annex II and | for the fees set out in Annexes I, | fees set out in Annexes I, II, III | |

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| | | | | proposals and |
| | | | | comments |
| | point 3 of Annex III. Any decision taken | II, III and IV, with the exception | and IV, with the exception of | |
| | pursuant to this Article shall state the reasons | of the fees set out in points 6, 15 | the fees set out in points 6, 1 <u>4</u> 5 | |
| | on which it is based. | and 16 of Annex I, points 7 and | and 1 <u>5</u> 6 of Annex I, points 7 | |
| | | 10 of Annex II and point 3 of | and 10 of Annex II and point 3 | |
| | | Annex III. Any decision taken | of Annex III. Any decision | |
| | | pursuant to this Article shall state | taken pursuant to this Article | |
| | | the reasons on which it is based. | shall state the reasons on which | |
| | | The Agency shall make | it is based. | |
| | | information on such decisions by | | |
| | | the Executive Director, including | | |
| | | the reasons for the reduction, | | |
| | | publicly available on the | | |
| | | Agency's website. | | |
| 80 | Article 7 | | Article 7 | Article 7 |
| | Payment of fees and charges | | Payment of fees and charges | Payment of fees and |
| | | | | charges |
| 81 | 1. Fees and charges due under this | | 1. Fees and charges due | 1. Fees and charges |
| | Regulation shall be paid in euro. | | under this Regulation shall be | due under this |
| | | | paid in euro. | |

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| | | | | proposals and |
| | | | 0 | comments |
| | | | | Regulation shall be paid |
| | | | | in euro. |
| 82 | 2. Payment of the fees and charges shall | | 2. Payment of the fees and | 2. Payment of the |
| | be made after the payer has received a | | charges shall be made after the | fees and charges shall be |
| | request for payment issued by the Agency | | payer has received a request for | made after the payer has |
| | specifying the deadline for payment. | | payment issued by the Agency | received a request for |
| | | | specifying the deadline for | payment issued by the |
| | | | payment. | Agency specifying the |
| | | | | deadline for payment. |
| 83 | 3. Payment of the fees and charges shall | | 3. Payment of the fees and | 3. Payment of the |
| | be made by means of a transfer to the bank | | charges shall be made by means | fees and charges shall be |
| | account of the Agency specified in the | | of a transfer to the bank account | made by means of a |
| | request for payment. Any bank charges | | of the Agency specified in the | transfer to the bank |
| | related to that payment shall be borne by the | | request for payment. Any bank | account of the Agency |
| | payer. | | charges related to that payment | specified in the request |
| | | | shall be borne by the payer. | for payment. Any bank |
| | | | | charges related to that |
| | | | | payment shall be borne |
| | | | | by the payer. |

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| | | | | proposals and |
| | | | | comments |
| 84 | 4. The deadline for payment shall be | | 4. The deadline for | 4. The deadline for |
| | considered to have been complied with only | | payment shall be considered to | payment shall be |
| | if the full amount has been paid in due time. | | have been complied with only if | considered to have been |
| | The date on which the full amount of the | | the full amount has been paid in | complied with only if |
| | payment is received in the bank account held | | due time. The date on which the | the full amount has been |
| | by the Agency shall constitute the date on | | full amount of the payment is | paid in due time. The |
| | which the payment has been made. | | received in the bank account | date on which the full |
| | | | held by the Agency shall | amount of the payment |
| | | | constitute the date on which the | is received in the bank |
| | | | payment has been made. | account held by the |
| | | | | Agency shall constitute |
| | | | | the date on which the |
| | | | | payment has been made. |
| 85 | Article 8 | | Article 8 | Article 8 |
| | Working arrangements | | Working arrangements | Working |
| | | | | arrangements |
| 86 | The Management Board of the Agency shall, | | The Management Board of the | The Management Board |
| | on a justified proposal from the Executive | | Agency shall, on a justified | of the Agency shall, on a |
| | Director and following a favourable opinion | | proposal from the Executive | justified proposal from |

| Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | proposals and |
| | | | comments |
| from the Commission, establish v | vorking | Director and following a | the Executive Director |
| arrangements to facilitate the applica | ntion of | favourable opinion from the | and following a |
| this Regulation, including payment n | nethods | Commission, establish working | favourable opinion from |
| of the fees and charges levied by the | Agency | arrangements to facilitate the | the Commission, |
| and the mechanism for payme | ent of | application of this Regulation, | establish working |
| remuneration to competent authoritie | s of the | including payment methods of | arrangements to |
| Member States under this Regulation | | the fees and charges levied by | facilitate the application |
| | | the Agency ₂ and the mechanism | of this Regulation, |
| | | for payment of remuneration to | including payment |
| | | competent authorities of the | methods of the fees and |
| | | Member States under this | charges levied by the |
| | | Regulation, a total or partial | Agency, and the |
| | | reduction in accordance with | mechanism for payment |
| | | Article 6(4) and a common | of remuneration to |
| | | format, based on a | competent authorities of |
| | | transparent methodology, to | the Member States |
| | | be used by competent | under this Regulation, a |
| | | authorities of the Member | total or partial |
| | | States when providing to the | reduction in |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
|-----|---------------------|---------------------------|---------------------------------|----------------------------|
| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| | | | Agency the financial | accordance with |
| | | | information in accordance | Article 6(4) and a |
| | | | with Article 10(3). | common format, based |
| | | | | on a transparent |
| | | | | methodology, to be |
| | | | | used by competent |
| | | | | authorities of the |
| | | | | Member States when |
| | | | | providing to the |
| | | | | Agency the financial |
| | | | | information in |
| | | | | accordance with |
| | | | | <u>Article 10(3)</u> . |
| | | | | |
| 86a | | | The Management Board of the | The Management |
| | | | Agency shall also define in the | Board of the Agency |
| | | | working arrangements the | shall also define in the |
| | | | scope of a distinct inspection, | working arrangements |
| | | | for each type of inspection. | the scope of a distinct |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | | | This shall include, where | inspection, for each |
| | | | relevant, the medicinal | type of inspection. This |
| | | | product concerned, the site | shall include, where |
| | | | concerned, the activity | relevant, the medicinal |
| | | | concerned and the inspection | product concerned, the |
| | | | team concerned. | site concerned, the |
| | | | | activity concerned and |
| | | | | the inspection team |
| | | | | concerned. |
| 87 | Those arrangements shall be made publicly | | Those arrangements shall be | Those arrangements |
| | available on the Agency's website. | | made publicly available on the | shall be made publicly |
| | | | Agency's website. | available on the |
| | | | | Agency's website. |
| 88 | Article 9 | | Article 9 | Article 9 |
| | Due date and measures in case of non- | | Due date and measures in case | Due date and measures |
| | payment | | of non-payment | in case of non-payment |
| 89 | 1. The due dates of the fees or charges | | 1. By [OP: please insert date | 1. By [OP: please |
| | levied in accordance with this Regulation | | of application of this Regulation] | insert date of application |
| | shall be specified in the working | | $\pm \underline{t}$ the due dates of the fees or | of this Regulation Tthe |

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| | arrangements set out in accordance with | | charges levied in accordance | due dates of the fees or |
| | Article 8 of this Regulation. Due account | | with this Regulation shall be | charges levied in |
| | shall be taken of the deadlines of the | | specified in the working | accordance with this |
| | assessment procedures provided for in | | arrangements set out in | Regulation shall be |
| | Regulations (EC) No 726/2004 and (EU) | | accordance with Article 8 of this | specified in the working |
| | 2019/6 and in Directive 2001/83/EC. | | Regulation. Due account shall | arrangements set out in |
| | | | be taken of the deadlines of the | accordance with Article |
| | | | assessment procedures provided | 8 of this Regulation. |
| | | | for in Regulations (EC) | Due account shall be |
| | | | No 726/2004 and (EU) 2019/6 | taken of the deadlines of |
| | | | and in Directive 2001/83/EC. | the assessment |
| | | | | procedures provided for |
| | | | | in Regulations (EC) |
| | | | | No 726/2004 and (EU) |
| | | | | 2019/6 and in Directive |
| | | | | 2001/83/EC. |
| 90 | 2. Where the payment of any fee or | | 2. Where the payment of | 2. Where the |
| | charge levied in accordance with this | | any fee or charge levied in | payment of any fee or |
| | Regulation is overdue and without prejudice | | accordance with this Regulation | charge levied in |

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| | | 0 | comments |
| to the Agency's capacity to institute legal | | is overdue and without prejudice | accordance with this |
| proceedings to ensure payment pursuant to | | to the Agency's capacity to | Regulation is overdue |
| Article 71 of Regulation (EC) No 726/2004, | | institute legal proceedings to | and without prejudice to |
| the Executive Director of the Agency may | | ensure payment pursuant to | the Agency's capacity to |
| decide that the Agency will not provide the | | Article 71 of Regulation (EC) | institute legal |
| services or will not carry out the procedures | | No 726/2004, the Executive | proceedings to ensure |
| to which the respective fee or charge relates, | | Director of the Agency may | payment pursuant to |
| or that the Agency will suspend any | | decide that the Agency will not | Article 71 of Regulation |
| ongoing or future services and procedures | | provide the services or will not | (EC) No 726/2004, the |
| until the respective fee or charge has been | | carry out the procedures to | Executive Director of |
| paid, including relevant interest as provided | | which the respective fee or | the Agency may decide |
| for in Article 99 of Regulation (EU, | | charge relates, or that the | that the Agency will not |
| Euratom) 2018/1046. | | Agency will suspend any | provide the services or |
| | | ongoing or future services and | will not carry out the |
| | | procedures until the respective | procedures to which the |
| | | fee or charge has been paid, | respective fee or charge |
| | | including relevant interest as | relates, or that the |
| | | provided for in Article 99 of | Agency will suspend |
| | | | any ongoing or future |

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| | | | | proposals and |
| | | | | comments |
| | | | Regulation (EU, Euratom) | services and procedures |
| | | | 2018/1046. | until the respective fee |
| | | | | or charge has been paid, |
| | | | | including relevant |
| | | | | interest as provided for |
| | | | | in Article 99 of |
| | | | | Regulation (EU, |
| | | | | Euratom) 2018/1046. |
| 91 | Article 10 | | Article 10 | Article 10 |
| | Transparency and monitoring | | Transparency and monitoring | Transparency and |
| | | | | monitoring |
| 92 | 1. The amounts set out in the annexes | 1. The amounts set out in the | 1. The amounts set out in | 1. The amounts set |
| | shall be published on the website of the | annexes shall be published on the | the annexes shall be published | out in the annexes shall |
| | Agency. | website of the Agency and shall | on the website of the Agency. | be published on the |
| | | be updated to reflect any | | website of the Agency. |
| | | changes. | | |
| 93 | 2. The Agency shall monitor its costs | 2. The Agency shall monitor | 2. The Agency shall | 2. The Agency |
| | and the Executive Director of the Agency | its costs and the Executive | monitor its costs and the | shall monitor its costs |
| | shall provide, as part of the annual activity | Director of the Agency shall | Executive Director of the | and the Executive |

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| | | | proposals and |
| | | 0 | comments |
| report delivered to the European Parliament, | provide, without delay as part of | Agency shall provide, as part of | Director of the Agency |
| the Council, the Commission and the Court | the annual activity report | the annual activity report | shall provide, without |
| of Auditors, detailed and substantiated | delivered to the European | delivered to the European | delay as part of the |
| information on the costs to be covered by | Parliament, the Council, the | Parliament, the Council, the | annual activity report |
| fees and charges that are within the scope of | Commission and the Court of | Commission and the Court of | delivered to the |
| this Regulation. That information shall | Auditors, detailed and | Auditors, detailed and | European Parliament, |
| include the performance information set out | substantiated information on the | substantiated information on the | the Council, the |
| in Annex VI and a cost breakdown related | costs to be covered by fees and | costs to be covered by fees and | Commission and the |
| to the previous calendar year and to a | charges that are within the scope | charges that are within the scope | Court of Auditors, |
| forecast for the following calendar year. The | of this Regulation. That | of this Regulation. That | detailed and |
| Agency shall also publish an overview of | information shall include the | information shall include the | substantiated |
| that information in its annual report. | performance information set out | performance information set out | information on the costs |
| | in Annex VI and other relevant | in Annex VI and a cost | to be covered by fees |
| | information, in particular on the | breakdown related to the | and charges that are |
| | practical aspects of carrying out | previous calendar year and to a | within the scope of this |
| | the activities for which the | forecast for the following | Regulation. That |
| | Agency collects fees or charges, | calendar year. The Agency shall | information shall |
| | and a cost breakdown related to | also publish an overview of that | include the performance |
| | the previous calendar year and to | information in its annual report. | information set out in |

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| | | | | proposals and |
| | | | 0 | comments |
| | | a forecast for the following | | Annex VI and other |
| | | calendar year. The Agency shall | (C.) | relevant information, in |
| | | also publish without delay, an | | particular on the |
| | | overview of that information in | | practical aspects of |
| | | its annual report. | | carrying out the |
| | | | | activities for which the |
| | | | | Agency collects fees or |
| | | | | charges, and a cost |
| | | | | breakdown related to the |
| | | | | previous calendar year |
| | | | | and to a forecast for the |
| | | | | following calendar year. |
| | | | | The Agency shall also |
| | | | | publish without delay, |
| | | | | an overview of that |
| | | | | information in its annual |
| | | | | report. |
| 93a | | 2a. All fees received, | | |
| | | including those where reductions | | |

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| | | | 0/ | comments |
| | | and waivers have been granted, | | |
| | | and fees which are due but not | | |
| | | yet received by the Agency shall | | |
| | | be published on the Agency's | | |
| | | website and listed in its annual | | |
| | | report. | | |
| | | The Agency's annual report | | |
| | | shall furthermore list a detailed | | |
| | | breakdown of all remunerated | | |
| | | amounts paid to national | | |
| | | authorities for their work. | | |
| 94 | 3. Evidence of significant changes in | | 3. Evidence of significant | 3. Evidence of |
| | the costs of services provided to the | | changes in the costs of services | significant changes in |
| | Agency, excluding any effect of inflationary | | provided to the Agency, | the costs of services |
| | adjustments and any costs for activities that | | excluding any effect of | provided to the Agency, |
| | do not constitute a service to the Agency, | | inflationary adjustments and any | excluding any effect of |
| | may be provided by competent authorities | | costs for activities that do not | inflationary adjustments |
| | of the Member States responsible for | | constitute a service to the | and any costs for |
| | medicinal products or by experts contracted | | Agency, may be provided by | activities that do not |

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| | | | comments |
| for the procedures of the expert panels on | | competent authorities of the | constitute a service to |
| medical devices to the Agency. Such | | Member States responsible for | the Agency, may be |
| information may be provided once per | | medicinal products or by experts | provided by competent |
| calendar year or less frequently, as a | | contracted for the procedures of | authorities of the |
| complement to the information provided i | n | the expert panels on medical | Member States |
| accordance with Annex VI. Such evidence | e | devices to the Agency. Such | responsible for |
| shall be based on duly justified and specif | ic | information may be provided | medicinal products or by |
| official financial information on the natur | e | once per calendar year or less | experts contracted for |
| and the extent of the financial impact on | | frequently, as a complement to | the procedures of the |
| costs for services to the Agency. To that | | the information provided in | expert panels on medical |
| end, the Agency may provide a common | | accordance with Annex VI. | devices to the Agency. |
| format facilitating comparison and | | Such evidence shall be based on | Such information may |
| consolidation. The competent authorities | of | duly justified and specific | be provided once per |
| the Member States and the experts | | official financial information on | calendar year or less |
| contracted for the procedures of the exper | t | the nature and the extent of the | frequently, as a |
| panels on medical devices to the Agency | | financial impact on costs for | complement to the |
| shall provide such information in the form | nat | services to the Agency. To that | information provided in |
| provided by the Agency, together with an | y | end, the Agency may provide | accordance with Annex |
| supporting information allowing to verify | | the a common format | VI. Such evidence shall |

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| | | | proposals and |
| | | 0/ | comments |
| the correctness of the amounts submitted. | | facilitating comparison and | be based on duly |
| The Agency shall review and aggregate that | | consolidation, established in | justified and specific |
| information and shall use it, in accordance | | accordance with Article 8 shall | official financial |
| with paragraph 6, as a source for the special | | be used . The competent | information on the |
| report provided for in that paragraph. | | authorities of the Member States | nature and the extent of |
| | | and the experts contracted to the | the financial impact on |
| | | Agency for the procedures of | costs for services to the |
| | | the expert panels on medical | Agency. To that end, the |
| | | devices to the Agency shall | Agency may provide the |
| | | provide such information in the | a common format |
| | | format provided by the Agency, | facilitating comparison |
| | | together with any supporting | and consolidation, |
| | | information allowing to verify | established in |
| | | the correctness of the amounts | accordance with |
| | | submitted. The Agency shall | Article 8 shall be used. |
| | | review and aggregate that | The competent |
| | | information and shall use it, in | authorities of the |
| | | accordance with paragraph 6, as | Member States and the |
| | | | experts contracted to the |

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| | | | proposals and |
| | | | comments |
| | | a source for the special report | Agency for the |
| | | provided for in that paragraph. | procedures of the expert |
| | | | panels on medical |
| | | | devices to the Agency |
| | | | shall provide such |
| | | | information in the |
| | | | format provided by the |
| | | | Agency, together with |
| | | | any supporting |
| | | | information allowing to |
| | | | verify the correctness of |
| | | | the amounts submitted. |
| | | | The Agency shall |
| | | | review and aggregate |
| | | | that information and |
| | | | shall use it, in |
| | | | accordance with |
| | | | paragraph 6, as a source |
| | | | for the special report |

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| | | | | proposals and |
| | | | 0 | comments |
| | | | | provided for in that |
| | | | | paragraph. |
| 95 | 4. Article 257 of Regulation (EU, | | 4. Article 257 of | 4. Article 257 of |
| | Euratom) 2018/1046 shall apply to the | | Regulation (EU, Euratom) | Regulation (EU, |
| | information provided to the Agency in | | 2018/1046 shall apply to the | Euratom) 2018/1046 |
| | accordance with paragraph 3 of this Article | | information provided to the | shall apply to the |
| | and Annex VI to this Regulation. | | Agency in accordance with | information provided to |
| | | | paragraph 3 of this Article and | the Agency in |
| | | | Annex VI to this Regulation. | accordance with |
| | | | | paragraph 3 of this |
| | | | | Article and Annex VI to |
| | | | | this Regulation. |
| 96 | 5. The Commission shall monitor the | 5. The Commission shall | 5. The Commission shall | 5. The Commission |
| | inflation rate, measured by means of the | monitor the inflation rate, | monitor the inflation rate, | shall monitor the |
| | Harmonised Index of Consumer Prices | measured by means of the | measured by means of the | inflation rate, measured |
| | published by Eurostat pursuant to | Harmonised Index of Consumer | Harmonised Index of Consumer | by means of the |
| | Regulation (EU) No 2016/792, in relation to | Prices published by Eurostat | Prices published by Eurostat | Harmonised Index of |
| | the amounts of fees, charges and | pursuant to Regulation (EU) No | pursuant to Regulation (EU) | Consumer Prices |
| | remuneration set out in the Annexes to this | 2016/792, in relation to the | No 2016/792, in relation to the | published by Eurostat |

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| | | | proposals and |
| | | 0 | comments |
| Regulation. The monitoring exercise shall | amounts of fees, charges and | amounts of fees, charges and | pursuant to Regulation |
| take place no earlier than [OP: please insert | remuneration set out in the | remuneration set out in the | (EU) No 2016/792, in |
| date one year after the date of application | Annexes to this Regulation. The | Annexes to this Regulation. The | relation to the amounts |
| of this Regulation], and thereafter on an | monitoring exercise shall take | monitoring exercise shall take | of fees, charges and |
| annual basis. Any adjustment, in line with | place no earlier than [OP: please | place no earlier than start at the | remuneration set out in |
| inflation, to fees, charges and remuneration | insert date one year after the date | date [OP: please insert date one | the Annexes to this |
| established in accordance with this | of application of this Regulation], | year after the date of application | Regulation. The |
| regulation shall become applicable, at the | and thereafter on an annual basis. | of this Regulation <u></u> 1, shall cover | monitoring exercise |
| earliest, on 1 January of the calendar year | On the basis of this exercise, the | the period since the last | shall take place no |
| following the calendar year in which the | Commission shall draw up a | inflation adjustment and shall | earlier than start at the |
| monitoring exercise took place. | report and submit it to the | thereafter take place and | date [OP: please insert |
| | European Parliament and to the | thereafter on an annual basis. | date one year after the |
| | Council. Any adjustment, in line | Any adjustment, in line with | date-of application of |
| | with inflation and following the | inflation, to fees, charges and | this Regulation <u>I, shall</u> |
| | annual activity report referred to | remuneration established in | cover the period since |
| | in Article 10(2), to fees, charges | accordance with this regulation | the last inflation |
| | and remuneration established in | shall become applicable, at the | adjustment and shall |
| | accordance with this regulation | earliest, on 1 January of the | thereafter take place |
| | shall become applicable, at the | calendar year following the | and thereafter on an |

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| | | | | proposals and |
| | | | 0 | comments |
| | | earliest, on 1 January of the | calendar year in which the | annual basis. Any |
| | | calendar year following the | monitoring exercise took place. | adjustment, in line with |
| | | calendar year in which the | | inflation, to fees, |
| | | monitoring exercise took place. | | charges and |
| | | | | remuneration |
| | | | | established in |
| | | | | accordance with this |
| | | | | regulation shall become |
| | | | | applicable, at the |
| | | | | earliest, on 1 January of |
| | | | | the calendar year |
| | | | | following the calendar |
| | | | | year in which the |
| | | | | monitoring exercise took |
| | | | | place. |
| 97 | 6. At the earliest on [OP: please insert | 6. At the earliest on [OP: | 6. At the earliest on [<i>OP</i> : | MB discussion |
| | date 3 years after the date of application] | please insert date 3 years after the | please insert date 3 years 9 | Transparency discussion |
| | and at three-year intervals thereafter, the | date of application] and at three- | months after the date of | |
| | Executive Director of the Agency may, | year intervals thereafter, the | application] and at three-year | |

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| | | | | proposals and |
| | | | 0 | comments |
| | where considered relevant in view of Article | Executive Director of the Agency | intervals thereafter, the | |
| | 11(2), and after consultation of the | shall, where considered relevant | Executive Director of the | |
| | Management Board of the Agency, provide | in view of Article 11(2), and after | Agency may shall, where | |
| | the Commission with a special report | consultation of the Management | considered relevant in view of | |
| | outlining, in an objective, fact-based and | Board of the Agency, provide the | Article 11(2), and after | |
| | sufficiently detailed manner, justified | Commission with a special report | consultation of the Management | |
| | recommendations: | . The Agency shall publish the | Board of the Agency, provide | |
| | | special report without delay and | the Commission with a special | |
| | | shall set out in an objective, | report adopted by the | |
| | | justified, fact-based and | Management Board of the | |
| | | sufficiently detailed manner, the | Agency outlining, in an | |
| | | following recommendations: | objective, fact-based and | |
| | | | sufficiently detailed manner, | |
| | | | justified recommendations to : | |
| 98 | (a) to increase or decrease the amount | | (a) to-increase or decrease | (a) to-increase or |
| | of any fee, charge or remuneration, | | the amount of any fee, charge or | decrease the amount of |
| | following a significant change in the | | remuneration, following a | any fee, charge or |
| | respective costs as identified, documented | | significant change in the | remuneration, following |
| | and justified in the report; | | respective costs as identified, | a significant change in |

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| | | | | proposals and |
| | | | | comments |
| | | | documented and justified in the | the respective costs as |
| | | | report; | identified, documented |
| | | | | and justified in the |
| | | | | report; |
| 98a | | (aa) to adapt any fee, charge | | deleted |
| | | or remuneration, or introduce a | | |
| | | new fee, charge or remuneration | | |
| | | following a change in the | | |
| | | statutory tasks of the Agency | | |
| | | resulting in a significant change | | |
| | | in the respective costs; | | |
| 99 | (b) to amend any other element of the | | (b) to amend any other | (b) to amend any |
| | Annexes pertaining to the levying of fees | | element of the Annexes | other element of the |
| | and charges, including additional fees and | | pertaining to the levying of fees | Annexes pertaining to |
| | charges referred to in Article 4. | | and charges, including | the levying of fees and |
| | | | additional fees and charges | charges, including |
| | | | referred to in Article 4; | additional fees and |
| | | | | charges referred to in |
| | | | | Article 4; |

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| | | | | proposals and |
| | | | | comments |
| 99a | | | (c) adapt the specification | (c) adapt the |
| | | | of activities for which the | specification of |
| | | | Agency collects fees or charges | activities for which the |
| | | | to changing conditions and | Agency collects fees or |
| | | | requirements. | charges to changing |
| | | | | conditions and |
| | | | | requirements. |
| 99b | | | (d) increase, decrease or | (d) increase, |
| | | | introduce any fee, charge or | decrease or introduce |
| | | | remuneration following a | any fee, charge or |
| | | | change in the statutory tasks | <u>remuneration</u> |
| | | | of the Agency leading to a | following a change in |
| | | | significant change in its costs; | the statutory tasks of |
| | | | | the Agency leading to a |
| | | | | significant change in |
| | | | | its costs; |
| 99c | | The special report shall be | | |
| | | submitted to the European | | |

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| | | | | proposals and |
| | | | 0 | comments |
| | | Parliament and to the Council | | |
| | | for information. | | |
| 99d | | 6a. With a view to supporting | | |
| | | the Agency reach its conclusions | | |
| | | in an efficient and effective | | |
| | | manner, during the preparation | | |
| | | of a report, the Agency shall | | |
| | | organise consultations with | | |
| | | stakeholders in order to receive | | |
| | | input on the structure and level | | |
| | | of fees, charges and | | |
| | | remuneration, including the | | |
| | | reasons for any change thereto. | | |
| 99e | | 6b. The special report shall | | 6b. The special |
| | | be made publicly available | | report shall be made |
| | | without delay on the Agency's | | publicly available |
| | | website. The special report shall | | without delay on the |
| | | include information on the | | Agency's website. |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | 0 | comments |
| | | stakeholders consulted in the | | |
| | | preparation of that report. | | |
| 100 | 7. The special report referred to in | | 7. The special report | 7. The special |
| | paragraph 6 and the recommendations it | | referred to in paragraph 6 and | report referred to in |
| | contains shall be based on the following: | | the recommendations it contains | paragraph 6 and the |
| | | | shall be based on the following: | recommendations it |
| | | | | contains shall be based |
| | | | | on the following: |
| 101 | (a) continuous monitoring of the | | (a) continuous monitoring of | (a) continuous |
| | information referred to in paragraphs 2 and | | the information referred to in | monitoring of the |
| | 3 and of the cost of the activities necessary | | paragraphs 2 and 3 and of the | information referred to |
| | for the fulfilment of the statutory tasks of | | cost of the activities necessary | in paragraphs 2 and 3 |
| | the Agency, aimed at identifying significant | | for the fulfilment of the statutory | and of the cost of the |
| | changes to the cost base of services and | | tasks of the Agency, aimed at | activities necessary for |
| | activities of the Agency; | | identifying significant changes | the fulfilment of the |
| | | | to the cost base of services and | statutory tasks of the |
| | | | activities of the Agency; | Agency, aimed at |
| | | | | identifying significant |
| | | | | changes to the cost base |

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| | | | | proposals and |
| | | | 0 | comments |
| | | | | of services and activities |
| | | | | of the Agency; |
| 102 | (b) objective and verifiable information | | (b) objective and verifiable | (b) objective and |
| | and quantification that directly supports the | | information, and including | verifiable information, |
| | relevance of the recommended adjustments. | | quantification, that directly | and including |
| | | | supports the relevance of the | quantification, that |
| | | | recommended adjustments. | directly supports the |
| | | | | relevance of the |
| | | | | recommended |
| | | | | adjustments. |
| 103 | 8. The Commission may request any | 8. The Commission, <i>the</i> | 8. The Commission may | Transparency |
| | clarification or further substantiation of the | European Parliament or the | request any clarification or | |
| | report and its recommendations, if | Council may request any | further substantiation of the | |
| | considered necessary. Following such a | clarification or further | report and its recommendations, | |
| | request, the Agency shall without undue | substantiation of the report and its | if considered necessary. | |
| | delay provide the Commission with an | recommendations, if considered | Following such a request, the | |
| | updated version of the report which | necessary. Following such a | Executive Director of the | |
| | addresses any comments made and | request, the Agency shall without | Agency shall without undue | |
| | questions raised by the Commission. | undue delay provide the | delay provide the Commission | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | | Commission, the European | with an updated version of the | |
| | | Parliament and the Council with | report adopted in accordance | |
| | | an updated version of the report | with paragraph 6 which | |
| | | which addresses any comments | addresses any comments made | |
| | | made and questions raised by the | and questions raised by the | |
| | | respective institution. | Commission. | |
| 104 | 9. The reporting time interval referred | 9. The time interval for the | 9. The <u>time interval to the</u> | 9. The time |
| | to in paragraph 6 may be shortened in any | first special report as well as the | first special report as well as | interval for the first |
| | of the following situations: | reporting time interval referred to | <u>the</u> reporting time interval | special report as well as |
| | | in paragraph 6 may be shortened | referred to in paragraph 6 may | the reporting time |
| | | in any of the following situations: | be shortened in any of the | interval referred to in |
| | | | following situations: | paragraph 6 may be |
| | | | | shortened in any of the |
| | | | | following situations: |
| 105 | (a) in the case of a public health | | (a) in the case of a public | (a) in the-case of a |
| | emergency; | | health emergency; | public health |
| | | | | emergency; |

| | Commission proposal | EP amendments voted on 12 July 2023 | Text agreed by the Council on 13 June 2023 | Tentatively agreed text, compromise proposals and |
|------|--|--------------------------------------|---|--|
| 106 | | | | comments |
| 106 | (b) in the case of a change of the legal mandate of the Agency; | | (b) in the case of a change of the legal mandate in the statutory tasks of the Agency; | (b) in the case of a change of the legal mandate in the statutory tasks of the Agency; |
| 107 | (c) in the case there is clear and compelling evidence of significant changes in the costs or the cost-revenue balance of the Agency, including costs for cost-based remuneration to competent authorities of the Member States. | | (c) in the case there is clear and compelling evidence of significant changes in the costs or the cost-revenue balance of the Agency: | (c) in the case there is elear and compelling evidence of significant changes in the costs or the cost-revenue balance of the Agency; |
| 107a | | | of significant changes in the costs including costs for cost- based remuneration to competent authorities of the Member States; | evidence of significant changes in the costs including costs for cost- based remuneration to competent authorities of the Member States; |

| 107b | Commission proposal | EP amendments voted on 12 July 2023 | Text agreed by the Council on 13 June 2023 (de) upon request of the Management Board of the | Tentatively agreed text, compromise proposals and comments MB discussion |
|------|---|---|--|---|
| 108 | Article 11 | | Article 11 | Article 11 |
| | Revision | | Revision | Revision |
| 108a | | -1. By [four months before the date of application of this Regulation], the Commission shall adopt, notwithstanding Article 10(5), a delegated act in accordance with Article 13, to amend Annexes I, II, III and IV, in order to adjust the amounts set out therein to the inflation rate published four months before [the date of application of this Regulation]. | | |
| 109 | 1. The Commission is empowered to | | 1. The Commission is | 1. The Commission |
| | adopt delegated acts in accordance with | | empowered to adopt delegated | is empowered to adopt |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | comments |
| | Article 13 to amend the Annexes where | | acts in accordance with Article | delegated acts in |
| | justified in view of any of the following: | | 13 to amend the Annexes where | accordance with Article |
| | | | justified in view of any of the | 13 to amend the |
| | | | following: | Annexes where justified |
| | | | | in view of any of the |
| | | | | following: |
| 110 | (a) a special report received by the | | (a) a special report received | (a) a special report |
| | Commission in accordance with Article | | by the Commission in | received by the |
| | 10(6); | | accordance with Article 10(6); | Commission in |
| | | | | accordance with Article |
| | | | | 10(6); |
| 111 | (b) the findings from the monitoring of | | (b) the findings from the | (b) the findings from |
| | the inflation rate referred to in Article 10(5); | | monitoring of the inflation rate | the monitoring of the |
| | | | referred to in Article 10(5); | inflation rate referred to |
| | | | | in Article 10(5); |
| 112 | (c) a change in the statutory tasks of the | deleted | (c) a change in the statutory | deleted |
| | Agency leading to a significant change in its | | tasks of the Agency leading to a | |
| | costs; | | significant change in its costs; | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | 0 | comments |
| 113 | (d) the budgetary reporting of the | | (d) the budgetary reporting | (d) the budgetary |
| | Agency; | | of the Agency; | reporting of the Agency; |
| 114 | (e) other relevant information, in | deleted | (e) other relevant | deleted |
| | particular on practical aspects for the | | information, in particular on | |
| | execution of activities for which the Agency | | practical aspects for the | |
| | collects fees or charges. | | execution of activities for which | |
| | | | the Agency collects fees or | |
| | | | charges. | |
| 115 | 2. Any revision of the fees and charges | | 2. Any revision of the fees | |
| | and of the remuneration paid to competent | | and charges and of the | |
| | authorities of the Member States provided | | remuneration paid to competent | |
| | for in this Regulation shall be based on the | | authorities of the Member States | |
| | Commission's evaluation of the Agency's | | provided for in this Regulation | |
| | costs and revenues and of the relevant costs | | shall be based on the | |
| | of the services provided to the Agency by | | Commission's evaluation of the | |
| | the competent authorities of the Member | | Agency's costs and revenues | |
| | States. | | and of the relevant full costs of | |
| | | | the services provided to the | |
| | | | Agency in the scope of this | |

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| | | | | proposals and |
| | | | | comments |
| | | | Regulation by the competent | |
| | | | authorities of the Member | |
| | | | States, taking into account also | |
| | | | the sustainability of the Union | |
| | | | regulatory network including | |
| | | | a fair and objective allocation | |
| | | | of fees, charges and | |
| | | | remuneration. | |
| 115a | | By way of derogation from the | | |
| | | first subparagraph, the | | |
| | | Commission may take into | | |
| | | account other factors that could | | |
| | | have a substantive impact on the | | |
| | | Agency's budget, including but | | |
| | | not limited to its workload and | | |
| | | potential risks related to | | |
| | | fluctuations in its fee revenues. | | |
| | | The level of fees shall be set at a | | |
| | | level which ensures that the | | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | 0 | comments |
| | | revenue derived from them, | | |
| | | when combined with other | | |
| | | sources of revenue of | | |
| | | the Agency, is sufficient to cover | | |
| | | the costs of the services delivered | | |
| | | in accordance with the key | | |
| | | performance indicators and | | |
| | | transparency principles set out in | | |
| | | Annex VI. | | |
| 115b | | | 3. <u>In any revision of the</u> | 3. <u>In any revision</u> |
| | | | Annexes, the amounts of | of the Annexes, the |
| | | | remuneration paid to | amounts of |
| | | | competent authorities of the | remuneration paid to |
| | | | Member States provided for in | competent authorities |
| | | | this Regulation shall be | of the Member States |
| | | | maintained as a single | provided for in this |
| | | | amounts of remuneration | Regulation shall be |
| | | | irrespective of the Member | maintained as a single |
| | | | | amounts of |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | 0 | comments |
| | | | State of the competent | <u>remuneration</u> |
| | | | authority concerned. | <u>irrespective of the</u> |
| | | | | Member State of the |
| | | | | competent authority |
| | | | | concerned. |
| 116 | Article 12 | | Article 12 | Article 12 |
| | Estimate of the Agency's budget | | Estimate of the Agency's | Estimate of the |
| | | | budget | Agency's budget |
| 117 | The Agency shall, when producing an | | The Agency shall, when | The Agency shall, when |
| | estimate of revenue and expenditure for the | | producing an estimate of | producing an estimate of |
| | following financial year in accordance with | | revenue and expenditure for the | revenue and expenditure |
| | Article 67(6) of Regulation (EC) | | following financial year in | for the following |
| | No 726/2004, include detailed information | | accordance with Article 67(6) of | financial year in |
| | on income from each type of fees and | | Regulation (EC) No 726/2004, | accordance with |
| | charges and respective remuneration. In | | include detailed information on | Article 67(6) of |
| | accordance with the typology of fees and | | income from each type of fees | Regulation (EC) |
| | charges set out in Article 3 of this | | and charges and respective | No 726/2004, include |
| | Regulation, that information shall | | remuneration. In accordance | detailed information on |
| | | | with the typology of fees and | income from each type |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| | distinguish, respectively, between the | | charges set out in Article 3 of | of fees and charges and |
| | following: | | this Regulation, that information | respective remuneration. |
| | | | shall distinguish, respectively, | In accordance with the |
| | | | between the following: | typology of fees and |
| | | | | charges set out in |
| | | | | Article 3 of this |
| | | | | Regulation, that |
| | | | | information shall |
| | | | | distinguish, respectively, |
| | | | | between the following: |
| 118 | (a) medicinal products for human use | | (a) medicinal products for | (a) medicinal |
| | and consultations on medical devices; | | human use and consultations on | products for human use |
| | | | medical devices; | and consultations on |
| | | | | medical devices; |
| 119 | (b) veterinary medicinal products; | | (b) veterinary medicinal | (b) veterinary |
| | | | products; | medicinal products; |
| 120 | (c) annual fees, by type; | | (c) annual fees, by type; | (c) annual fees, by |
| | | | | type; |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
|-----|--|---------------------------|--------------------------------|---------------------------|
| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| 121 | (d) other fees and charges, by type. | | (d) other fees and charges, | (d) other fees and |
| | | | by type. | charges, by type. |
| 122 | A breakdown by type of procedure may be | | A breakdown by type of | A breakdown by type of |
| | provided by the Agency in an annex to the | | procedure may be provided by | procedure may be |
| | single programming document produced in | | the Agency in an annex to the | provided by the Agency |
| | accordance with Article 32(1) of Delegated | | single programming document | in an annex to the single |
| | Regulation (EU) 2019/715. | | produced in accordance with | programming document |
| | | | Article 32(1) of Delegated | produced in accordance |
| | | | Regulation (EU) 2019/715. | with Article 32(1) of |
| | | | | Delegated Regulation |
| | | | | (EU) 2019/715. |
| 123 | Article 13 | | Article 13 | Article 13 |
| | Exercise of the delegation | | Exercise of the delegation | Exercise of the |
| | | | | delegation |
| 124 | 1. The power to adopt delegated acts is | | 1. The power to adopt | 1. The power to |
| | conferred on the Commission subject to the | | delegated acts is conferred on | adopt delegated acts is |
| | conditions laid down in this Article. | | the Commission subject to the | conferred on the |
| | | | conditions laid down in this | Commission subject to |
| | | | Article. | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
|-----|--|---------------------------|-----------------------------------|---------------------------|
| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | 0 | comments |
| | | | | the conditions laid down |
| | | | | in this Article. |
| 125 | 2. The power to adopt delegated acts | | 2. The power to adopt | 2. The power to |
| | referred to in Article 11(1) shall be | | delegated acts referred to in | adopt delegated acts |
| | conferred on the Commission for a period | | Article 11(1) shall be conferred | referred to in |
| | of 5 years from [tbc] 20[xx]. The | | on the Commission for a period | Article 11(1) shall be |
| | Commission shall draw up a report in | | of 5 years from [tbc] 20[xx]. | conferred on the |
| | respect of the delegation of power not later | | The Commission shall draw up | Commission for a period |
| | than 6 months before the end of the 5-year | | a report in respect of the | of 5 years from [tbc] |
| | period. The delegation of power shall be | | delegation of power not later | <i>20[xx]</i> . The |
| | tacitly extended for periods of an identical | | than 6 9 months before the end | Commission shall draw |
| | duration, unless the European Parliament or | | of the 5-year period. The | up a report in respect of |
| | the Council opposes such extension not later | | delegation of power shall be | the delegation of power |
| | than 3 months before the end of each | | tacitly extended for periods of | not later than 6 9 months |
| | period. | | an identical duration, unless the | before the end of the 5- |
| | | | European Parliament or the | year period. The |
| | | | Council opposes such extension | delegation of power |
| | | | not later than 3 months before | shall be tacitly extended |
| | | | the end of each period. | for periods of an |

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| | | | | proposals and |
| | | | 0 | comments |
| | | | | identical duration, |
| | | | | unless the European |
| | | | | Parliament or the |
| | | | | Council opposes such |
| | | | | extension not later than |
| | | | | 3 months before the end |
| | | | | of each period. |
| | | | | |
| | | | | Commission to double- |
| | | | | <u>check</u> |
| 126 | 3. The delegation of power referred to | | 3. The delegation of power | 3. The delegation |
| | in Article 11(1) may be revoked at any time | | referred to in Article 11(1) may | of power referred to in |
| | by the European Parliament or by the | | be revoked at any time by the | Article 11(1) may be |
| | Council. A decision to revoke shall put an | | European Parliament or by the | revoked at any time by |
| | end to the delegation of the power specified | | Council. A decision to revoke | the European Parliament |
| | in that decision. It shall take effect the day | | shall put an end to the | or by the Council. A |
| | following the publication of the decision in | | delegation of the power | decision to revoke shall |
| | the Official Journal of the European | | specified in that decision. It | put an end to the |
| | <i>Union</i> or at a later date specified therein. It | | shall take effect the day | delegation of the power |

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| | | | 0 | comments |
| | shall not affect the validity of any delegated | | following the publication of the | specified in that |
| | acts already in force. | | decision in the Official Journal | decision. It shall take |
| | | | of the European Union or at a | effect the day following |
| | | | later date specified therein. It | the publication of the |
| | | | shall not affect the validity of | decision in the Official |
| | | | any delegated acts already in | Journal of the European |
| | | | force. | Union or at a later date |
| | | | | specified therein. It shall |
| | | | | not affect the validity of |
| | | | | any delegated acts |
| | | | | already in force. |
| 127 | 4. Before adopting a delegated act, the | 4. Before adopting a | 4. Before adopting a | 4. Before adopting |
| | Commission shall consult experts | delegated act, the Commission | delegated act, the Commission | a delegated act, the |
| | designated by each Member State in | shall take into account any | shall consult experts designated | Commission shall |
| | accordance with the principles laid down in | opinions delivered by experts | by each Member State in | consult experts |
| | the Interinstitutional Agreement of 13 April | designated by each Member State | accordance with the principles | designated by each |
| | 2016 on Better Law-Making. | in accordance with the principles | laid down in the | Member State in |
| | | laid down in the Interinstitutional | Interinstitutional Agreement of | accordance with the |
| | | | | principles laid down in |

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| | | | | proposals and |
| | | | 0 | comments |
| | | Agreement of 13 April 2016 on | 13 April 2016 on Better Law- | the Interinstitutional |
| | | Better Law-Making. | Making. | Agreement of 13 April |
| | | | | 2016 on Better Law- |
| | | | | Making. |
| 128 | 5. As soon as it adopts a delegated act, | | 5. As soon as it adopts a | 5. As soon as it |
| | the Commission shall notify it | | delegated act, the Commission | adopts a delegated act, |
| | simultaneously to the European Parliament | | shall notify it simultaneously to | the Commission shall |
| | and to the Council. | | the European Parliament and to | notify it simultaneously |
| | | | the Council. | to the European |
| | | | | Parliament and to the |
| | | | | Council. |
| 129 | 6. A delegated act adopted pursuant to | | 6. A delegated act adopted | 6. A delegated act |
| | Article 11(1) shall enter into force only if no | | pursuant to Article 11(1) shall | adopted pursuant to |
| | objection has been expressed either by the | | enter into force only if no | Article 11(1) shall enter |
| | European Parliament or the Council within | | objection has been expressed | into force only if no |
| | a period of 2 months of notification of that | | either by the European | objection has been |
| | act to the European Parliament and the | | Parliament or the Council within | expressed either by the |
| | Council or if, before the expiry of that | | a period of 2 months of | European Parliament or |
| | period, the European Parliament and the | | notification of that act to the | the Council within a |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | Council have both informed the | | European Parliament and the | period of 2 months of |
| | Commission that they will not object. That | | Council or if, before the expiry | notification of that act to |
| | period shall be extended by 2 months at the | | of that period, the European | the European Parliament |
| | initiative of the European Parliament or of | | Parliament and the Council have | and the Council or if, |
| | the Council. | | both informed the Commission | before the expiry of that |
| | | | that they will not object. That | period, the European |
| | | | period shall be extended by 2 | Parliament and the |
| | | | months at the initiative of the | Council have both |
| | | | European Parliament or of the | informed the |
| | | | Council. | Commission that they |
| | | | | will not object. That |
| | | | | period shall be extended |
| | | | | by 2 months at the |
| | | | | initiative of the |
| | | | | European Parliament or |
| | | | | of the Council. |
| 130 | Article 14 | | Article 14 | Article 14 |
| | Amendment to Regulation (EU) | | Amendment to Regulation | |
| | No 2017/745 | | (EU) No 2017/745 | |

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| | | | | comments |
| | | | | Amendment to |
| | | | | Regulation (EU) |
| | | | | No 2017/745 |
| 131 | Article 106 of Regulation (EU) | | Article 106 of Regulation (EU) | Article 106 of |
| | No 2017/745, paragraph 14 is replaced by | | No 2017/745, paragraph 14 is | Regulation (EU) |
| | the following: | | replaced by the following: | No 2017/745, paragraph |
| | | | | 14 is replaced by the |
| | | | | following: |
| 132 | '14. The fees payable to EMA in | | '14. The fees <u>established</u> | '14. The fees |
| | accordance with the procedure under | | payable to EMA in accordance | established payable to |
| | paragraph 13 of this Article related to the | | with the procedure under | EMA-in accordance |
| | advice provided by expert panels for which | | paragraph 13 of this Article | with the procedure |
| | EMA provides the secretariat in accordance | | related to the advice provided by | under paragraph 13 of |
| | with Article 30 of Regulation (EU) 2022/123 | | expert panels for which EMA | this Article related to the |
| | of the European Parliament and of the | | provides the secretariat in | advice provided by |
| | Council ⁵⁰ shall be set in a transparent manner | | accordance with Article 30 of | expert panels for which |
| | and on the basis of the costs for the services | | Regulation (EU) 2022/123 of | EMA provides the |
| | provided. The fees payable shall be reduced | | the European Parliament and of | secretariat in accordance |
| | in the case of a clinical evaluation | | the Council ⁵¹ -shall be set in a | with Article 30 of |

| Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
|--|---------------------------|---|----------------------------------|
| | July 2023 | 13 June 2023 | text, compromise |
| | | | proposals and |
| | | 0 | comments |
| consultation procedure initiated in | | transparent manner and on the | Regulation (EU) |
| accordance with section 5.1, point (c), of | | basis of the costs for the services | 2022/123 of the |
| Annex IX to this Regulation involving a | | provided. The fees payable shall | European Parliament |
| manufacturer who is a micro, small or | | be reduced in the case of a | and of the Council ⁵¹ |
| medium-sized enterprise within the meaning | | clinical evaluation consultation | shall be set in a |
| of Recommendation 2003/361/EC.'. | | procedure initiated in | transparent manner and |
| | | accordance with section 5.1, | on the basis of the costs |
| ⁵⁰ Regulation (EU) 2022/123 of the European | | point (c), of Section 5.1 of | for the services |
| Parliament and of the Council of 25 January 2022 on | | Annex IX to this Regulation | provided. The fees |
| a reinforced role for the European Medicines Agency | | involving a manufacturer who is | payable shall be reduced |
| in crisis preparedness and management for medicinal | | a micro, small or medium-sized | in the case of a clinical |
| products and medical devices (OJ L 20, 31.1.2022, p. 1). | | enterprise within the meaning of | evaluation consultation |
| | | Recommendation 2003/361/EC. | procedure initiated in |
| | | | accordance with section |
| | | 51 Regulation (EU) 2022/123 of the | 5.1, point (c), of Section |
| | | European Parliament and of the | 5.1 of Annex IX to this |
| | | Council of 25 January 2022 on a | Regulation-involving a |
| | | reinforced role for the European | manufacturer who is a |
| | | Medicines Agency in crisis preparedness and management for | micro, small or medium- |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| | | | medicinal products and medical | sized enterprise within |
| | | | devices (OJ L 20, 31.1.2022, p. 1). | the meaning of |
| | | | | Recommendation |
| | | | | 2003/361/EC. |
| | | | | |
| | | | | ⁵¹ Regulation (EU) 2022/123 |
| | | | | of the European Parliament |
| | | | | and of the Council of 25 |
| | | | | January 2022 on a reinforced |
| | | | | role for the European |
| | | | | Medicines Agency in crisis |
| | | | | preparedness and |
| | | | | management for medicinal |
| | | | | products and medical devices |
| | | | | (OJ L 20, 31.1.2022, p. 1). |
| 132a | | | The fees related to the advice | The fees related to the |
| | | | provided by expert panels are | advice provided by |
| | | | payable to EMA pursuant to | expert panels are |
| | | | Article 30, point (f) of | payable to EMA |
| | | | Regulation (EU) 2022/123 of | pursuant to Article 30, |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | | | the European Parliament and | point (f) of Regulation |
| | | | of the Council. ⁵² | (EU) 2022/123 of the |
| | | | | European Parliament |
| | | | 52 Regulation (EU) 2022/123 of | and of the Council.52 |
| | | | the European Parliament and of | |
| | | | the Council of 25 January 2022 | 52 Regulation (EU) |
| | | | on a reinforced role for the | 2022/123 of the |
| | | | European Medicines Agency in | European Parliament |
| | | | crisis preparedness and | and of the Council of 25 |
| | | | management for medicinal | January 2022 on a |
| | | | products and medical devices | reinforced role for the |
| | | | (OJ L 20, 31.1.2022, p. 1). | European Medicines |
| | | | | Agency in crisis |
| | | | | preparedness and |
| | | | | management for |
| | | | | medicinal products and |
| | | | | medical devices (OJ L |
| | | | | 20, 31.1.2022, p. 1). |
| 132b | | | The fees related to the advice | The fees related to the |
| | | | provided by expert | advice provided by |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
|------|---------------------|---------------------------|---------------------------------|---------------------------------|
| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| | | | laboratories are payable to the | expert laboratories are |
| | | | Commission.'. | payable to the |
| | | | | Commission.'. |
| 132c | | | Article 14a | Article 14a |
| | | | Amendment to Regulation | Amendment to |
| | | | (EU) 2022/123 | Regulation (EU) |
| | | | | <u>2022/123</u> |
| 132d | | | Article 30, point (f) of | Article 30, point (f) of |
| | | | Regulation (EU) 2022/123, is | Regulation (EU) |
| | | | replaced by the following: | 2022/123, is replaced by |
| | | | '(f) charge fees in | the following: |
| | | | accordance with Article | '(f) charge fees in |
| | | | 106(14) of Regulation | accordance with |
| | | | (EU) 2017/745 and | <u>Article 106(14) of</u> |
| | | | ensure that | Regulation (EU) |
| | | | remuneration and | 2017/745 and ensure |
| | | | expenses are provided to | that remuneration and |
| | | | experts in accordance | expenses are provided |
| | | | with implementing acts | to experts in |

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| | | | adopted by the | accordance with |
| | | | Commission pursuant to | implementing acts |
| | | | <u>Article 106(1) of</u> | adopted by the |
| | | | Regulation (EU) | Commission pursuant |
| | | | <u>2017/745.'.</u> | to Article 106(1) of |
| | | | | Regulation (EU) |
| | | | | <u>2017/745.'.</u> |
| 133 | Article 15 | | Article 15 | Article 15 |
| | Repeal | | Repeal | Repeal |
| 134 | Regulations (EC) No 297/95 and (EU) | | Regulations (EC) No 297/95 and | Regulations (EC) |
| | No 658/2014 are repealed. | | (EU) No 658/2014 are repealed | No 297/95 and (EU) |
| | | | as of [OP: please insert date of | No 658/2014 are |
| | | | application of this Regulation]. | repealed as of [OP: |
| | | | | please insert date of |
| | | | | application of this |
| | | | | <u>Regulation</u>]. |
| 135 | References to Regulation (EC) No 297/95 | | References to Regulation (EC) | References to |
| | shall be construed as references to this | | No 297/95 shall be construed as | Regulation (EC) |
| | Regulation and read in accordance with the | | references to this Regulation and | No 297/95 shall be |

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| | correlation table in Annex VII to this | | read in accordance with the | construed as references |
| | Regulation. | | correlation table in Annex VII to | to this Regulation and |
| | | | this Regulation. | read in accordance with |
| | | | | the correlation table in |
| | | | | Annex VII to this |
| | | | | Regulation. |
| 136 | Article 16 | | Article 16 | Article 16 |
| | Transitional provisions | | Transitional provisions | Transitional provisions |
| 137 | 1. This Regulation shall not apply to | | 1. This Regulation shall not | 1. This Regulation |
| | procedures and services for which the | | apply to annual fees, | shall not apply to |
| | payable amount became due before [OP: | | procedures and services for | annual fees, procedures |
| | please insert date of application]. | | which the payable amount | and services for which |
| | | | became due <u>pursuant to</u> | the payable amount |
| | | | Regulation (EC) No 297/95 or | became due <u>pursuant to</u> |
| | | | Regulation (EU) No 658/2014 | Regulation (EC) No |
| | | | before [OP: please insert date | 297/95 or Regulation |
| | | | of application]. | (EU) No 658/2014 |
| | | | | before [OP: please |

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| | | | 0 | comments |
| | | | | insert date of |
| | | | | application]. |
| 138 | 2. With regard to annual fees set out in | | 2. With regard to annual | deleted |
| | Annex III, this Regulation shall not apply to | | fees set out in Annex III, this | |
| | products for which an annual fee has | | Regulation shall not apply to | |
| | become due pursuant to Regulation (EC) No | | products for which an annual fee | |
| | 297/95 or Regulation (EU) No 658/2014 in | | has become due pursuant to | |
| | the year [OP: please insert calendar year of | | Regulation (EC) No 297/95 or | |
| | application]. | | Regulation (EU) No 658/2014 in | |
| | | | the year [OP: please insert | |
| | | | calendar year of application]. | |
| 139 | Article 17 | | Article 17 | Article 17 |
| | Entry into force and date of application | | Entry into force and date of | Entry into force and |
| | | | application | date of application |
| 140 | This Regulation shall enter into force on the | | This Regulation shall enter into | This Regulation shall |
| | twentieth day following that of its | | force on the twentieth-day | enter into force on the |
| | publication in the Official Journal of the | | following that of its publication | twentieth day following |
| | European Union. | | in the Official Journal of the | that of its publication in |
| | | | European Union. | |

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| | | | | proposals and |
| | | | 0 | comments |
| | | | | the Official Journal of |
| | | | | the European Union. |
| 141 | It shall apply from [OP: please insert date | | It shall apply from [OP: please | It shall apply from [OP: |
| | of first day of the month following | | insert date of 1 January of the | please insert date of <u>1</u> |
| | expiration of 6 months after entry into | | calendar year following the | January of the |
| | force]. | | year of entry into force of this | <u>calendar year</u> |
| | | | Regulation if it enters into | following the year of |
| | | | force by 1 July. In case the | entry into force of this |
| | | | Regulation enters into force | Regulation if it enters |
| | | | after 1 July, please insert date | into force by 1 July. In |
| | | | of 1 January of the calendar | case the Regulation |
| | | | <u>year</u> first day of the month | enters into force after 1 |
| | | | following expiration of 6-9 | July, please insert date |
| | | | months after entry into force]. | of 1 January of the |
| | | | | <u>calendar year</u> first day |
| | | | | of the month-following |
| | | | | expiration of 6-9 months |
| | | | | after entry into force]. |

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| | | | | comments |
| 141a | | The delegated act referred to in | | To be taken out if no DA |
| | | Article 11(-1) shall apply from | (C.) | on initial inflation |
| | | [OP: please insert date of first | | adjustment |
| | | day of the month following | | |
| | | expiration of 6 months after | | |
| | | entry into force]. | | |
| 142 | This Regulation shall be binding in its | | This Regulation shall be binding | This Regulation shall be |
| | entirety and directly applicable in all | | in its entirety and directly | binding in its entirety |
| | Member States. | | applicable in all Member States. | and directly applicable |
| | | | | in all Member States. |
| 143 | Done at Brussels, | | Done at Brussels, | Done at Brussels, |
| 144 | For the European Parliament | | For the European Parliament | For the European |
| | | | | Parliament |
| 145 | The President | | The President | The President |
| 146 | For the Council | | For the Council | For the Council |
| 147 | The President | | The President | The President |
| | | | | |

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| | | | 0 | comments |
| 148 | ANNEX I Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use | | ANNEX I Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use | ANNEX I Fees, charges and remuneration for assessment procedures and services relating to medicinal products for |
| 149 | 1. Scientific advice provided by the Agency in accordance with Article 57(1)(n) of | | Scientific advice provided by the Agency in | human use 1. Scientific advice provided by the Agency |
| | Regulation (EC) No 726/2004 | | accordance with Article 57(1)(n) of Regulation (EC) No 726/2004 | in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004 |
| 150 | 1.1 A fee of EUR 55 200 shall apply to any | 1.1 A fee of EUR 94 000 shall | 1.1 A fee of EUR 55 200 <u>79</u> | 1.1 A fee of EUR 94 |
| | of the following requests: | apply to any of the following | 400 shall apply to any of the | 000 shall apply to any of |
| | | requests: | following requests: | the following requests: |
| 151 | (a) a request on quality, non-clinical and | | (a) a request on quality, non- | (a) a request on quality, |
| | clinical development; | | clinical and clinical | non-clinical and clinical |
| | | | development; | development; |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| 152 | (b) a request on quality and clinical | | (b) a request on quality and | (b) a request on quality |
| | development; | | clinical development; | and clinical |
| | | | | development; |
| 153 | (c) a request on non-clinical and clinical | | (c) a request on non-clinical and | (c) a request on non- |
| | development; | | clinical development; | clinical and clinical |
| | | | | development; |
| 154 | (d) a request on qualification of novel | | (d) a request on qualification of | (d) a request on |
| | methodologies. | | novel methodologies. | qualification of novel |
| | | | | methodologies. |
| 155 | The remuneration shall be EUR 10 400 for | The remuneration shall be EUR | The remuneration shall be EUR | The remuneration shall |
| | each of the two scientific advice co- | 23 500 for each of the two | 10 400 20 200 for each of the | be EUR <i>23 500</i> for each |
| | ordinators. | scientific advice co-ordinators. | two scientific advice co- | of the two scientific |
| | | | ordinators. | advice co-ordinators. |
| 156 | 1.2. A fee of EUR 44 700 shall apply to any | 1.2 A fee of EUR 70 600 shall | 1.2 A fee of EUR 44-700 <u>62</u> | 1.2 A fee of EUR 70 |
| | of the following requests: | apply to any of the following | 900 shall apply to any of the | 600 shall apply to any of |
| | | requests: | following requests: | the following requests: |
| 157 | (a) a request on clinical development; | | (a) a request on clinical | (a) a request on clinical |
| | | | development; | development; |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
|-----|---|--------------------------------------|---|---------------------------------|
| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| 158 | (b) a request on quality and non-clinical | | (b) a request on quality and non- | (b) a request on quality |
| | development; | | clinical development; | and non-clinical |
| | | | | development; |
| 159 | (c) a request on quality and bioequivalence | | (c) a request on quality | (c) a request on quality |
| | studies for generic medicinal products as | | development and | development and |
| | defined in Article 10(2), point (b) of | | bioequivalence studies for | bioequivalence studies |
| | Directive 2001/83/EC. | | generic medicinal products as | for generic medicinal |
| | | | defined in Article 10(2), point | products as defined in |
| | | | (b) of Directive 2001/83/EC. | Article 10(2), point (b) |
| | | | | of Directive |
| | | | | 2001/83/EC. |
| 160 | The remuneration shall be EUR 6 500 for | The remuneration shall be EUR | The remuneration shall be EUR | The remuneration shall |
| | each of the two scientific advice co- | <i>17 650</i> for each of the two | 6 500 13 400 for each of the two | be EUR <i>17 650</i> for each |
| | ordinators. | scientific advice co-ordinators. | scientific advice co-ordinators. | of the two scientific |
| | | | | advice co-ordinators. |
| 161 | 1.3. A fee of EUR 37 200 shall apply to any | 1.3 A fee of EUR 46 900 shall | 1.3. A fee of EUR 37 200 <u>49</u> | 1.3. A fee of EUR 37 |
| | of the following requests: | apply to any of the following | 600 shall apply to any of the | 200 49 600 shall apply |
| | | requests: | following requests: | to any of the following |
| | | | | requests: |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| 162 | a) a request on quality development; | | a) a request on quality | a) a request on quality |
| | | | development; | development; |
| 163 | b) a request on non-clinical development; | | b) a request on non-clinical | b) a request on non- |
| | | | development; | clinical development; |
| 164 | c) a request on bioequivalence studies for | | c) a request on bioequivalence | c) a request on |
| | generic medicinal products as defined in | | studies for generic medicinal | bioequivalence studies |
| | Article 10(2), point (b), of Directive | | products as defined in Article | for generic medicinal |
| | 2001/83/EC. | | 10(2), point (b), of Directive | products as defined in |
| | | | 2001/83/EC. | Article 10(2), point (b), |
| | | | | of Directive |
| | | | | 2001/83/EC. |
| 165 | The remuneration shall be EUR 5 300 for | The remuneration shall be EUR | The remuneration shall be EUR | The remuneration shall |
| | each of the two scientific advice co- | 11 730 for each of the two | 5 300 9 700 for each of the two | be EUR <i>11 730</i> for each |
| | ordinators. | scientific advice co-ordinators. | scientific advice co-ordinators. | of the two scientific |
| | | | | advice co-ordinators |
| 166 | 2. Scientific opinions and assessments | | 2. Scientific opinions and | 2. Scientific |
| | prior to potential submission of an | | assessments prior to potential | opinions and |
| | application for a marketing authorisation | | | assessments prior to |
| | | | | potential submission of |

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| | | | | proposals and |
| | | | | comments |
| | | | submission of an application for | an application for a |
| | | | a marketing authorisation | marketing authorisation |
| 167 | 2.1. A fee of EUR 549 800 shall apply to any | | 2.1. A fee of EUR 549 800 828 | Suggestion to Separate |
| | of the following: | | 100 shall apply to any of the | rolling reviews from |
| | | | following: | compassionate use |
| 168 | (a) an opinion on a medicinal product for | | (a) an opinion on a medicinal | (a) an opinion on a |
| | compassionate use pursuant to Article 83 of | | product for compassionate use | medicinal product for |
| | Regulation (EC) No 726/2004; | | pursuant to Article 83 of | compassionate use |
| | | | Regulation (EC) No 726/2004; | pursuant to Article 83 of |
| | | | | Regulation (EC) No |
| | | | | 726/2004; |
| 169 | (b) an assessment on an on-going basis of | | (b) an assessment on an on- | (b) an assessment on an |
| | data packages of particulars and documents | | going basis of data packages of | on-going basis of data |
| | submitted to the Agency by a prospective | | particulars and documents | packages of particulars |
| | applicant prior to a formal submission of an | | submitted to the Agency by a | and documents |
| | application for a marketing authorisation | | prospective applicant prior to a | submitted to the Agency |
| | falling within the scope of Regulation (EC) | | formal submission of an | by a prospective |
| | No 726/2004. | | application for a marketing | applicant prior to a |

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| | | | | proposals and |
| | | | | comments |
| | | | authorisation falling within the | formal submission of an |
| | | | scope of Regulation (EC) No | application for a |
| | | | 726/2004. | marketing authorisation |
| | | | | falling within the scope |
| | | | | of Regulation (EC) No |
| | | | | 726/2004. |
| 170 | That fee shall cover all strengths, all | | That fee shall cover all strengths, | |
| | pharmaceutical forms and all presentations | | all pharmaceutical forms and all | |
| | submitted in the same application. The | | presentations submitted in the | |
| | remuneration shall be EUR 153 000 for the | | same application. The | |
| | rapporteur and EUR 143 300 for the co- | | remuneration shall be EUR 153 | |
| | rapporteur. | | 000 <u>260 800</u> for the rapporteur | |
| | | | and, EUR 143 300 227 200 for | |
| | | | the co-rapporteur and 24 400 for | |
| | | | the PRAC-rapporteur. | |
| 170a | | | 2.1a(new) An additional fee of | |
| | | | EUR 124 200 shall apply to the | |
| | | | assessment set out in point | |
| | | | 2.1(b). The remuneration shall | |

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| | | | 0/ | comments |
| | | | be EUR 39 100 for the | |
| | | | rapporteur, EUR 34 100 for | |
| | | | the co-rapporteur and EUR | |
| | | | 3 700 for the PRAC- | |
| | | | rapporteur. | |
| 171 | 2.2. In the event of multiple submissions of | | 2.2. In the event of multiple | |
| | data packages submitted by the same | | submissions of data packages | |
| | prospective applicant for the same product, | | submitted by the same | |
| | the fee set out in point 2.1 (b) shall only be | | prospective applicant for the | |
| | charged once. | | same product, the fee set out in | |
| | | | point 2.1 (b) and 2.1a(new) | |
| | | | shall only be charged once. | |
| 172 | 2.3. The amounts set out in point 2.1 shall | | 2.3. The amounts set out in point | 2.3. The amounts set out |
| | be deducted from the respective fee and | | 2.1 shall be deducted from the | in point 2.1 shall be |
| | from the remuneration to competent | | respective fee and from the | deducted from the |
| | authorities of the Member States payable for | | remuneration to competent | respective fee and from |
| | a marketing authorisation application for the | | authorities of the Member States | the remuneration to |
| | same product, where such application is | | payable for a marketing | competent authorities of |
| | submitted by the same applicant. | | authorisation application for the | the Member States |

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| | | | | proposals and |
| | | | 0 | comments |
| | | | same product, where such | payable for a marketing |
| | | | application is submitted by the | authorisation application |
| | | | same applicant. | for the same product, |
| | | | | where such application |
| | | | | is submitted by the same |
| | | | | applicant. |
| 173 | 3. Authorisation to market a medicinal | | 3. Authorisation to market a | 3. Authorisation to |
| | product falling within the scope of | | medicinal product falling within | market a medicinal |
| | Regulation (EC) No 726/2004 | | the scope of Regulation (EC) No | product falling within |
| | | | 726/2004 | the scope of Regulation |
| | | | | (EC) No 726/2004 |
| 174 | 3.1. A fee of EUR 684 900 shall apply to an | | 3.1. A fee of EUR 684 900 | |
| | application for a marketing authorisation for | | 828 100 shall apply to an | |
| | a medicinal product pursuant to Article 8(3) | | application for a marketing | |
| | of Directive 2001/83/EC when the applicant | | authorisation for a medicinal | |
| | claims a new active substance. That fee | | product pursuant to Article 8(3) | |
| | shall cover all strengths, all pharmaceutical | | of Directive 2001/83/EC when | |
| | forms and all presentations submitted in the | | the applicant claims a new active | |
| | same application. The remuneration shall be | | substance. That fee shall cover | |

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| | | | | proposals and |
| | | | 0/ | comments |
| | EUR 217 300 for the rapporteur and EUR | | all strengths, all pharmaceutical | |
| | 189 300 for the co-rapporteur. | | forms and all presentations | |
| | | | submitted in the same | |
| | | | application. The remuneration | |
| | | | shall be EUR 217 300 260 800 | |
| | | | for the rapporteur ₂ and EUR 189 | |
| | | | 300 <u>227 200</u> for the co- | |
| | | | rapporteur and EUR 24 400 for | |
| | | | the PRAC-rapporteur. | |
| 175 | 3.2. A fee of EUR 549 800 shall apply to an | | 3.2. A fee of EUR 549 800 | |
| | application for a marketing authorisation for | | 661 000 shall apply to an | |
| | a medicinal product pursuant to Article 8(3) | | application for a marketing | |
| | of Directive 2001/83/EC when the applicant | | authorisation for a medicinal | |
| | claims a known active substance. That fee | | product pursuant to Article 8(3) | |
| | shall cover all strengths, all pharmaceutical | | of Directive 2001/83/EC when | |
| | forms and all presentations submitted in the | | the applicant claims a known | |
| | same application. The remuneration shall be | | active substance. That fee shall | |
| | EUR 153 000 for the rapporteur and EUR | | cover all strengths, all | |
| | 143 300 for the co-rapporteur. | | pharmaceutical forms and all | |

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| | | | | proposals and |
| | | | 0/ | comments |
| | | | presentations submitted in the | |
| | | | same application. The | |
| | | | remuneration shall be EUR 153 | |
| | | | 000 <u>183 600</u> for the rapporteur | |
| | | | and, EUR 143 300 172 000 for | |
| | | | the co-rapporteur and EUR | |
| | | | 17 800 for the PRAC- | |
| | | | rapporteur. | |
| 176 | 3.3 A fee of EUR 456 800 shall apply to an | | 3.3 A fee of EUR 456 | |
| | application for a fixed combination | | 800 <u>546 500</u> shall apply to an | |
| | medicinal product pursuant to Article 10b of | | application for a fixed | |
| | Directive 2001/83/EC. That fee shall cover | | combination medicinal product | |
| | all strengths, all pharmaceutical forms and | | pursuant to Article 10b of | |
| | all presentations submitted in the same | | Directive 2001/83/EC. That fee | |
| | application. The remuneration shall be EUR | | shall cover all strengths, all | |
| | 141 500 for the rapporteur and EUR 83 000 | | pharmaceutical forms and all | |
| | for the co-rapporteur. | | presentations submitted in the | |
| | | | same application. The | |
| | | | remuneration shall be EUR 141 | |

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| | | | 0 | comments |
| | | | 500 169 800 for the rapporteur. | |
| | | | and EUR 83 000 <u>99 600</u> for the | |
| | | | co-rapporteur and EUR 13 500 | |
| | | | for the PRAC-rapporteur. | |
| 177 | 3.4 A fee of EUR 575 000 shall apply to an | | 3.4. A fee of EUR 575 000 | |
| | application for a biological medicinal | | 701 100 shall apply to an | |
| | product which is similar to a reference | | application for a biological | |
| | biological product pursuant to Article 10(4) | | medicinal product which is | |
| | of Directive 2001/83/EC. That fee shall | | similar to a reference biological | |
| | cover all strengths, all pharmaceutical forms | | product pursuant to Article 10(4) | |
| | and all presentations submitted in the same | | of Directive 2001/83/EC. That | |
| | application. The remuneration shall be EUR | | fee shall cover all strengths, all | |
| | 236 500 for the rapporteur and EUR 151 | | pharmaceutical forms and all | |
| | 700 for the co-rapporteur. | | presentations submitted in the | |
| | | | same application. The | |
| | | | remuneration shall be EUR 236 | |
| | | | 500 <u>283 800</u> for the rapporteur | |
| | | | and, EUR 151 700 182 000 for | |
| | | | the co-rapporteur and EUR | |

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| | | | 0 | comments |
| | | | 23 500 for the PRAC- | |
| | | | rapporteur. | |
| 178 | 3.5. A fee of EUR 624 300 shall apply to an | | 3.5. A fee of EUR 624 300 | |
| | application for a marketing authorisation for | | 747 300 shall apply to an | |
| | a medicinal product pursuant to Article 10a | | application for a marketing | |
| | of Directive 2001/83/EC. That fee shall | | authorisation for a medicinal | |
| | cover all strengths, all pharmaceutical forms | | product pursuant to Article 10a | |
| | and all presentations submitted in the same | | of Directive 2001/83/EC. That | |
| | application. The remuneration shall be EUR | | fee shall cover all strengths, all | |
| | 160 600 for the rapporteur and EUR 149 | | pharmaceutical forms and all | |
| | 400 for the co-rapporteur. | | presentations submitted in the | |
| | | | same application. The | |
| | | | remuneration shall be | |
| | | | EUR 160 600 192 700 for the | |
| | | | rapporteur and EUR 149 | |
| | | | 400 <u>179 300</u> for the co- | |
| | | | rapporteur and EUR 18 600 for | |
| | | | the PRAC-rapporteur. | |

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| | | | | proposals and |
| | | | 0 | comments |
| 179 | 3.6. A fee of EUR 141 200 shall apply to | | 3.6. A fee of EUR 141 200 <u>239</u> | Generics discussion |
| | any of the following: | | 500 shall apply to any of the | + pharmacovigilance |
| | | | following: | annual fee |
| 180 | (a) an application for a marketing | | (a) an application for a | |
| | authorisation for a generic medicinal | | marketing authorisation for a | |
| | product pursuant to Article 10(1) of | | generic medicinal product | |
| | Directive 2001/83/EC, | | pursuant to Article 10(1) of | |
| | | | Directive 2001/83/EC, | |
| 181 | (b) an application based on informed | | (b) an application based on | |
| | consent for a marketing authorisation for a | | informed consent for a | |
| | medicinal product pursuant to Article 10c of | | marketing authorisation for a | |
| | Directive 2001/83/EC. | | medicinal product pursuant to | |
| | | | Article 10c of Directive | |
| | | | 2001/83/EC. | |
| 182 | That fee shall cover all strengths, all | | That fee shall cover all strengths, | |
| | pharmaceutical forms and all presentations | | all pharmaceutical forms and all | |
| | submitted in the same application. The | | presentations submitted in the | |
| | remuneration shall be EUR 40 200 for the | | same application. The | |
| | rapporteur. | | арричины тис | |

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| | | | remuneration shall be EUR 40 | |
| | | | 200 <u>118 900</u> for the rapporteur | |
| | | | and EUR 5 900 for the PRAC- | |
| | | | rapporteur. | |
| 183 | | | 3.6a A fee of EUR 141 200 165 | |
| | | | 300 shall apply to any of the | |
| | | | following: | |
| 184 | | | (c) an application for a | |
| | | | marketing authorisation for a | |
| | | | generic medicinal product | |
| | | | pursuant to Article 10(1) of | |
| | | | Directive 2001/83/EC, | |
| 185 | | | (d) an application based on | |
| | | | informed consent for a | |
| | | | marketing authorisation for a | |
| | | | medicinal product pursuant to | |
| | | | Article 10c of Directive | |
| | | | 2001/83/EC. | |

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| | | | 0 | comments |
| 186 | | | That fee shall cover all | |
| | | | strengths, all pharmaceutical | |
| | | | forms and all presentations | |
| | | | submitted in the same | |
| | | | application. The remuneration | |
| | | | shall be EUR 40 <u>48</u> 200 for the | |
| | | | rapporteur and EUR 2 400 for | |
| | | | the PRAC-rapporteur. | |
| 187 | 3.7. A fee of EUR 339 700 shall apply to an | | 3.7. A fee of EUR 339 | |
| | application for a marketing authorisation for | | 700 407 800 shall apply to an | |
| | a medicinal product pursuant to Article | | application for a marketing | |
| | 10(3) of Directive 2001/83/EC. That fee | | authorisation for a medicinal | |
| | shall cover all strengths, all pharmaceutical | | product pursuant to Article | |
| | forms and all presentations submitted in the | | 10(3) of Directive 2001/83/EC. | |
| | same application. The remuneration shall be | | That fee shall cover all | |
| | EUR 89 100 for the rapporteur and EUR 89 | | strengths, all pharmaceutical | |
| | 100 for the co-rapporteur. | | forms and all presentations | |
| | | | submitted in the same | |

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| | | | | proposals and |
| | | | 0 | comments |
| | | | application. The remuneration | |
| | | | shall be EUR 89 100 <u>106 900</u> | |
| | | | for the rapporteur-and, EUR 89 | |
| | | | 100 106 900 for the co- | |
| | | | rapporteur and EUR 10 700 for | |
| | | | the PRAC-rapporteur. | |
| 188 | 3.8. A fee of EUR 27 600 shall apply to the | | 3.8. A fee of EUR 27 600 <u>31</u> | |
| | second and to each subsequent application | | 800 shall apply to the second and | |
| | for a marketing authorisation submitted | | to each subsequent application | |
| | pursuant to Article 10(1), (3) or (4) of | | for a marketing authorisation | |
| | Directive 2001/83/EC on usage patent | | submitted pursuant to Article | |
| | grounds where the reference medicinal | | 10(1), (3) or (4) of Directive | |
| | product is subject to a usage patent. That fee | | 2001/83/EC on usage patent | |
| | shall cover all strengths, all pharmaceutical | | grounds where the reference | |
| | forms and all presentations submitted in the | | medicinal product is subject to a | |
| | same application. The remuneration shall be | | usage patent. That fee shall cover | |
| | EUR 6 800 for the rapporteur and EUR 1 | | all strengths, all pharmaceutical | |
| | 000 for the co-rapporteur. | | forms and all presentations | |
| | | | submitted in the same | |

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| | | | | proposals and |
| | | | | comments |
| | | | application. The remuneration | |
| | | | shall be EUR 6-800 <u>8 200</u> for the | |
| | | | rapporteur and EUR 1 000 <u>1 200</u> | |
| | | | for the co-rapporteur. | |
| 189 | 4. Extension of a marketing | | 4. Extension of a marketing | 4. Extension of a |
| | authorisation within the meaning of Annex I | | authorisation within the meaning | marketing authorisation |
| | to Commission Regulation (EC) No | | of Annex I to Commission Regulation (EC) No 1234/2008 ⁵⁴ | within the meaning of Annex I to Commission |
| | 1234/2008 ⁵³ | | 105 110 125 1/2000 | Regulation (EC) No |
| | | | 54 Commission Regulation (EC) No | 1234/2008 ⁵⁴ |
| | ⁵³ Commission Regulation (EC) No 1234/2008 of 24 | | 1234/2008 of 24 November 2008 | |
| | November 2008 concerning the examination of | | concerning the examination of variations to the terms of marketing | ⁵⁴ Commission Regulation |
| | variations to the terms of marketing authorisations | | authorisations for medicinal products for human use and veterinary medicinal | (EC) No 1234/2008 of 24 |
| | for medicinal products for human use and veterinary | | products (OJ L 334, 12.12.2008, p. 7). | November 2008 concerning |
| | medicinal products (OJ L 334, 12.12.2008, p. 7). | | | 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) |

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| | | | | comments |
| 190 | 4.1 A fee of EUR 138 000 shall apply to an | | 4.1. A fee of EUR 138 000 | |
| | application for an extension of a marketing | | 161 300 shall apply to an | |
| | authorisation requiring only chemical, | | application for an extension of a | |
| | pharmaceutical or biological documentation | | marketing authorisation | |
| | and for which no clinical or non-clinical | | requiring only chemical, | |
| | data are submitted. That fee shall cover a | | pharmaceutical or biological | |
| | single pharmaceutical form and a single | | documentation and for which no | |
| | associated strength. The remuneration shall | | clinical or non-clinical data are | |
| | be EUR 45 300 for the rapporteur and EUR | | submitted. That fee shall cover a | |
| | 26 600 for the co-rapporteur. | | single pharmaceutical form and a | |
| | | | single associated strength. The | |
| | | | remuneration shall be EUR 45 | |
| | | | 300 <u>54 400</u> for the rapporteur | |
| | | | and EUR 26 600 <u>31 900</u> for the | |
| | | | co-rapporteur. | |
| 191 | 4.2. A fee of EUR 161 000 shall apply to an | | 4.2. A fee of EUR 161 000 <u>188</u> | |
| | application for an extension of a marketing | | 300 shall apply to an application | |
| | authorisation not covered by point 4.1. That | | for an extension of a marketing | |
| | fee shall cover a single pharmaceutical form | | authorisation not covered by | |

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| | | | | comments |
| | and a single associated strength. The | | point 4.1. That fee shall cover a | |
| | remuneration shall be EUR 55 300 for the | | single pharmaceutical form and a | |
| | rapporteur and EUR 31 200 for the co- | | single associated strength. The | |
| | rapporteur. | | remuneration shall be EUR 55 | |
| | | | 300 <u>66 400</u> for the rapporteur | |
| | | | and EUR 31 200 37 400 for the | |
| | | | co-rapporteur. | |
| 192 | 4.3 Without prejudice to points 4.1 and 4.2, | | 4.3. Without prejudice to | |
| | a fee of EUR 27 600 shall apply to each | | points 4.1 and 4.2, a fee of EUR | |
| | application for extension of a marketing | | 27 600 31 800 shall apply to | |
| | authorisation on the basis of an application | | each application for extension of | |
| | submitted under Article 10(1), (3) or (4) of | | a marketing authorisation on the | |
| | Directive 2001/83/EC on usage patent | | basis of an application submitted | |
| | grounds as referred to in point 3.8 of this | | under Article 10(1), (3) or (4) of | |
| | Annex. The remuneration shall be EUR 6 | | Directive 2001/83/EC on usage | |
| | 800 for the rapporteur and EUR 1 000 for | | patent grounds as referred to in | |
| | the co-rapporteur. | | point 3.8 of this Annex. The | |
| | | | remuneration shall be EUR 6 | |
| | | | 800 <u>8 200</u> for the rapporteur and | |

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| | | | | proposals and |
| | | | 0 | comments |
| | | | EUR 1-000 1 200 for the corapporteur. | |
| 193 | 5. Major variation of type II to the terms of a marketing authorisation in accordance with Commission Regulation (EC) No 1234/2008 | | 5. Major variation of type II to the terms of a marketing authorisation in accordance with Commission Regulation (EC) No 1234/2008 | 5. Major variation of type II to the terms of a marketing authorisation in accordance with |
| | | | | Commission Regulation (EC) No 1234/2008 |
| 194 | 5.1. A fee of EUR 99 800 shall apply to an | | 5.1. A fee of EUR 99 800 | |
| | application for a major variation of type II | | 175 300 shall apply to an | |
| | as defined in Article 2(3) of Regulation | | application for a major variation | |
| | (EC) No 1234/2008 ('major variation of | | of type II as defined in Article | |
| | type II') for an addition of a new therapeutic | | 2(3) of Regulation (EC) No | |
| | indication or modification of an approved | | 1234/2008 ('major variation of | |
| | indication. The remuneration shall be EUR | | type II') for an addition of a new | |
| | 29 400 for the rapporteur and EUR 29 400 | | therapeutic indication or | |
| | for the co-rapporteur. | | modification of an approved indication. The remuneration | |

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| | | | | proposals and |
| | | | 0 | comments |
| | | | shall be EUR 29 400 64 400 for | |
| | | | the rapporteur and EUR 29 | |
| | | | 40064 400 for the co-rapporteur. | |
| 195 | 5.2. A fee of EUR 13 000 shall apply to an | | 5.2. A fee of EUR 13 000 28 500 | |
| | application for a major variation of type II | | shall apply to an application for | |
| | not covered by point 5.1. The remuneration | | a major variation of type II not | |
| | shall be EUR 6 800 for the rapporteur. | | covered by point 5.1. The | |
| | | | remuneration shall be EUR 6 800 | |
| | | | 21 500 for the rapporteur. | |
| 196 | 5.3. For each application for a major | | 5.3. For each application for a | 5.3. For each |
| | variation of type II that is grouped in a | | major variation of type II that is | application for a major |
| | single application pursuant to Article 7 of | | grouped in a single application | variation of type II that |
| | Regulation (EC) No 1234/2008, the | | pursuant to Article 7 of | is grouped in a single |
| | corresponding fee shall be charged as set | | Regulation (EC) No 1234/2008, | application pursuant to |
| | out in points 5.1 and 5.2. Remuneration | | the corresponding fee shall be | Article 7 of Regulation |
| | shall be paid in accordance with those | | charged as set out in points 5.1 | (EC) No 1234/2008, the |
| | points. | | and 5.2. Remuneration shall be | corresponding fee shall |
| | | | paid in accordance with those | be charged as set out in |
| | | | points. | points 5.1 and 5.2. |

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| | | | | proposals and |
| | | | 0 | comments |
| | | | | Remuneration shall be |
| | | | | paid in accordance with |
| | | | | those points. |
| 197 | 5.4 Where a work-sharing application | | 5.4. Where a work-sharing | |
| | pursuant to Article 20 of Regulation (EC) | | application pursuant to Article | |
| | No 1234/2008 includes more than one | | 20 of Regulation (EC) No | |
| | centrally authorised product, the fees and | | 1234/2008 includes more than | |
| | remuneration specified in points 5.1 and 5.2 | | one centrally authorised product, | |
| | of this Annex shall apply to each variation | | the fees and remuneration | |
| | of the first centrally authorised product, | | specified in points 5.1 and 5.2 of | |
| | whereas a charge of EUR 800 shall apply to | | this Annex shall apply to each | |
| | each variation of the second and subsequent | | variation of the first centrally | |
| | centrally authorised product included in the | | authorised product, whereas a | |
| | application. | | charge of EUR 800-900 shall | |
| | | | apply to each variation of the | |
| | | | second and subsequent centrally | |
| | | | authorised product included in | |
| | | | the application. | |

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| | | | 0 | comments |
| 198 | 6. Referrals and scientific opinions | | 6. Referrals and scientific | 6. Referrals and |
| | pursuant to Article 5(3) of Regulation (EC) | | opinions pursuant to Article 5(3) | scientific opinions |
| | No 726/2004 | | of Regulation (EC) No 726/2004 | pursuant to Article 5(3) |
| | | | | of Regulation (EC) No |
| | | | | 726/2004 |
| 199 | 6.1. A fee of EUR 136 700 shall apply to | 6.1. A fee of EUR 136 700 | 6.1. A fee of EUR <u>136 700</u> <u>156</u> | |
| | the assessment carried out in the context of | shall apply to the assessment | 700 shall apply to the assessment | |
| | a procedure initiated under Article 5(3) of | carried out in the context of a | carried out in the context of a | |
| | Regulation (EC) No 726/2004. Such fee | procedure initiated under Article | procedure initiated under Article | |
| | shall be waived in full. The remuneration | 5(3) of Regulation (EC) No | 5(3) of Regulation (EC) No | |
| | shall be EUR 12 400 for the rapporteur and | 726/2004. Such fee shall be | 726/2004. Such fee shall be | |
| | EUR 12 400 for the co-rapporteur. | waived in full. The remuneration | waived in full. The remuneration | |
| | | shall be EUR 6 200 for the | shall be EUR 12 400 14 900 for | |
| | | rapporteur and EUR 6 200 for the | the rapporteur and EUR 12 | |
| | | co-rapporteur. | 400 <u>14 900</u> for the co-rapporteur. | |
| 200 | 6.2. A fee of EUR 262 400 shall apply to | 6.2. A fee of EUR 262 400 | 6.2. A fee of EUR 262 400 299 | |
| | the assessment carried out in the context of | shall apply to the assessment | 800 shall apply to the assessment | |
| | a procedure initiated under Article 13 of | carried out in the context of a | carried out in the context of a | |
| | Regulation (EC) No 1234/2008. Such fee | procedure initiated under Article | procedure initiated under Article | |

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| | | | | comments |
| | shall be waived in full. The remuneration | 13 of Regulation (EC) No | 13 of Regulation (EC) No | |
| | shall be EUR 15 300 for the rapporteur and | 1234/2008. Such fee shall be | 1234/2008. Such fee shall be | |
| | EUR 15 300 for the co-rapporteur. | waived in full. The remuneration | waived in full. The remuneration | |
| | | shall be EUR 7 650 for the | shall be EUR 15 300 18 400 for | |
| | | rapporteur and EUR 7 650 for the | the rapporteur and EUR 15 | |
| | | co-rapporteur. | 300 <u>18 400</u> for the co-rapporteur. | |
| 201 | 6.3. A fee of EUR 83 000 shall apply to the | 6.3. A fee of EUR 83 000 shall | 6.3. A fee of EUR 83 000 94 | |
| | assessment carried out in the context of a | apply to the assessment carried | 600 shall apply to the | |
| | procedure initiated under Article 29(4) of | out in the context of a procedure | assessment carried out in the | |
| | Directive 2001/83/EC. Such fee shall be | initiated under Article 29(4) of | context of a procedure initiated | |
| | waived in full. The remuneration shall be | Directive 2001/83/EC. Such fee | under Article 29(4) of Directive | |
| | EUR 2 800 for the rapporteur and EUR 2 | shall be waived in full. The | 2001/83/EC. Such fee shall be | |
| | 800 for the co-rapporteur. | remuneration shall be EUR 1 400 | waived in full. The | |
| | | for the rapporteur and EUR 1 400 | remuneration shall be EUR 2 | |
| | | for the co-rapporteur. | 8003 400 for the rapporteur and | |
| | | | EUR 2 8003 400 for the co- | |
| | | | rapporteur. | |
| 202 | 6.4. A fee of EUR 128 200 shall apply to | | 6.4. A fee of EUR 128 200 146 | |
| | the assessment carried out in the context of | | 400 shall apply to the | |

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| | | | 0/ | comments |
| | a procedure initiated under Article 30 of | | assessment carried out in the | |
| | Directive 2001/83/EC. The remuneration | | context of a procedure initiated | |
| | shall be EUR 6 800 for the rapporteur and | | under Article 30 of Directive | |
| | EUR 6 800 for the co-rapporteur. | | 2001/83/EC. The remuneration | |
| | | | shall be EUR 6 800 200 for the | |
| | | | rapporteur and EUR 6 800 8 200 | |
| | | | for the co-rapporteur. | |
| 203 | 6.5. A fee of EUR 180 700 shall apply to | | 6.5. A fee of EUR 180 700206 | |
| | the assessment carried out in the context of | | 700 shall apply to the assessment | |
| | a procedure initiated under Article 31 of | | carried out in the context of a | |
| | Directive 2001/83/EC where the procedure | | procedure initiated under Article | |
| | is initiated as a result of the evaluation of | | 31 of Directive 2001/83/EC | |
| | data other than data relating to | | where the procedure is initiated | |
| | pharmacovigilance. The remuneration shall | | as a result of the evaluation of | |
| | be EUR 12 400 for the rapporteur and EUR | | data other than data relating to | |
| | 12 400 for the co-rapporteur. | | pharmacovigilance. The | |
| | | | remuneration shall be EUR 12 | |
| | | | 400 <u>14 900</u> for the rapporteur and | |

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| | | | 0 | comments |
| | | | EUR 12 40014 900 for the co- | |
| | | | rapporteur. | |
| 204 | 6.6. A fee of EUR 172 100 shall apply to | | 6.6. A fee of EUR 172 100 197 | |
| | the assessment carried out in accordance | | 600 shall apply to the assessment | |
| | with a procedure initiated under Article 20 | | carried out in accordance with a | |
| | of Regulation (EC) No 726/2004 where that | | procedure initiated under Article | |
| | procedure is initiated as a result of the | | 20 of Regulation (EC) No | |
| | evaluation of data other than data relating to | | 726/2004 where that procedure | |
| | pharmacovigilance. The remuneration shall | | is initiated as a result of the | |
| | be EUR 17 500 for the rapporteur and EUR | | evaluation of data other than data | |
| | 17 500 for the co-rapporteur. | | relating to pharmacovigilance. | |
| | | | The remuneration shall be EUR | |
| | | | 17 500 21 000 for the rapporteur | |
| | | | and EUR 17 50021 000 for the | |
| | | | co-rapporteur. | |
| 205 | 6.7. For an assessment carried out in the | | 6.7. For an | 6.7. For an |
| | context of a procedure initiated as a result of | | assessment carried out in the | assessment carried out |
| | the evaluation of pharmacovigilance data | | context of a procedure initiated | in the context of a |
| | under Article 31(1), second subparagraph, | | as a result of the evaluation of | procedure initiated as a |

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| | | | 0 | comments |
| | Article 31(2) and Articles 107i, 107j | | pharmacovigilance data under | result of the evaluation |
| | and107k of Directive 2001/83/EC or under | | Article 31(1), second | of pharmacovigilance |
| | Article 20(8) of Regulation (EC) No | | subparagraph, Article 31(2) and | data under Article 31(1), |
| | 726/2004, the following fees shall apply: | | Articles 107i, 107j and 107k of | second subparagraph, |
| | | | Directive 2001/83/EC or under | Article 31(2) and |
| | | | Article 20(8) of Regulation (EC) | Articles 107i, 107j |
| | | | No 726/2004, the following fees | and 107k of Directive |
| | | | shall apply: | 2001/83/EC or under |
| | | | | Article 20(8) of |
| | | | | Regulation (EC) No |
| | | | | 726/2004, the following |
| | | | | fees shall apply: |
| 206 | 6.7.1. a fee of EUR 172 100 where one | | 6.7.1. a fee of EUR 172 100210 | |
| | active substance or combination of active | | 200 where one active substance | |
| | substances and one marketing authorisation | | or combination of active | |
| | holder are included in the assessment. The | | substances and one marketing | |
| | remuneration shall be EUR 17 500 for the | | authorisation holder are included | |
| | rapporteur and EUR 17 500 for the co- | | in the assessment. The | |
| | rapporteur; | | remuneration shall be EUR 17 | |

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| | | | 0/ | comments |
| | | | 50027300 for the rapporteur and | |
| | | | EUR <u>17-500</u> 27 300 for the co- | |
| | | | rapporteur; | |
| 207 | 6.7.2. a fee of EUR 258 200 where two or | | 6.7.2. a fee of EUR 258 200 296 | |
| | more active substances or combinations of | | 400 where two or more active | |
| | active substances and one marketing | | substances or combinations of | |
| | authorisation holder are included in the | | active substances and one | |
| | assessment. The remuneration shall be EUR | | marketing authorisation holder | |
| | 26 300 for the rapporteur and EUR 26 300 | | are included in the assessment. | |
| | for the co-rapporteur; | | The remuneration shall be EUR | |
| | | | 26 300 31 600 for the rapporteur | |
| | | | and EUR 26 30031 600 for the | |
| | | | co-rapporteur; | |
| 208 | 6.7.3. a fee of EUR 314 100 where one or | | 6.7.3. a fee of EUR 314 100 <u>360</u> | |
| | two active substances or combinations of | | 600 where one or two active | |
| | active substances and two or more | | substances or combinations of | |
| | marketing authorisation holders are | | active substances and two or | |
| | included in the assessment. The | | more marketing authorisation | |
| | remuneration shall be EUR 32 000 for the | | holders are included in the | |

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| | | | 0 | comments |
| | rapporteur and EUR 32 000 for the co- | | assessment. The remuneration | |
| | rapporteur; | | shall be EUR 32 00038 400 for | |
| | | | the rapporteur and EUR 32 | |
| | | | 00038 400 for the co-rapporteur; | |
| 209 | 6.7.4. a fee of EUR 426 100 where more | | 6.7.4. a fee of EUR 426 100489 | |
| | than two active substances or combinations | | 200 where more than two active | |
| | of active substances and two or more | | substances or combinations of | |
| | marketing authorisation holders are | | active substances and two or | |
| | included in the assessment. The | | more marketing authorisation | |
| | remuneration shall be EUR 43 400 for the | | holders are included in the | |
| | rapporteur and EUR 43 400 for the co- | | assessment. The remuneration | |
| | rapporteur. | | shall be EUR 43-400 <u>52 100</u> for | |
| | | | the rapporteur and EUR 43 | |
| | | | 400 <u>52 100</u> for the co-rapporteur. | |
| 210 | 6.8. Where two or more marketing | | 6.8. Where two or more | 6.8. Where two or |
| | authorisation holders are involved in the | | marketing authorisation holders | more marketing |
| | procedures referred to in points 6.4, 6.5, 6.6 | | are involved in the procedures | authorisation holders are |
| | and 6.7, the amount payable by each | | referred to in points 6.4, 6.5, 6.6 | involved in the |
| | marketing authorisation holder shall be | | and 6.7, the amount payable by | procedures referred to in |

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| | calculated by the Agency in two steps, as | | each marketing authorisation | points 6.4, 6.5, 6.6 and |
| | follows: | | holder shall be calculated by the | 6.7, the amount payable |
| | | | Agency in two steps, as follows: | by each marketing |
| | | | | authorisation holder |
| | | | | shall be calculated by |
| | | | | the Agency in two steps, |
| | | | | as follows: |
| 211 | (a) by dividing the total amount of the fee | | (a) by dividing the total | by dividing the total |
| | among the marketing authorisation holders | | amount of the fee among the | amount of the fee among |
| | proportionally to the number of chargeable | | marketing authorisation holders | the marketing |
| | units-human corresponding to products | | proportionally to the number of | authorisation holders |
| | included in the procedure which are held by | | chargeable units-human | proportionally to the |
| | each of those marketing authorisation | | corresponding to products | number of chargeable |
| | holders; | | included in the procedure which | units-human |
| | | | are held by each of those | corresponding to |
| | | | marketing authorisation holders; | products included in the |
| | | | | procedure which are |
| | | | | held by each of those |

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| | | | 0 | comments |
| | | | | marketing authorisation |
| | | | | holders; |
| 212 | (b) by subsequently applying, where | | (b) by subsequently applying, | (b) by subsequently |
| | relevant, the fee reduction laid down in | | where relevant, the fee reduction | applying, where |
| | Annex V. | | laid down in Annex V. | relevant, the fee |
| | | | | reduction laid down in |
| | | | | Annex V. |
| 213 | 7. Evaluation of traditional herbal | | 7. Evaluation of traditional | 7. Evaluation of |
| | medicinal products in accordance with | | herbal medicinal products in | traditional herbal |
| | Article 57(1)(n) of Regulation (EC) No | | accordance with Article 57(1)(n) | medicinal products in |
| | 726/2004 | | of Regulation (EC) No 726/2004 | accordance with Article |
| | | | | 57(1)(n) of Regulation |
| | | | | (EC) No 726/2004 |
| 214 | A fee of EUR 29 700 shall apply to a | | A fee of EUR 29 700 <u>34 000</u> | |
| | request for scientific advice from the | | shall apply to a request for | |
| | Committee on Herbal Medicinal Products | | scientific advice from the | |
| | related to traditional herbal medicinal | | Committee on Herbal Medicinal | |
| | products. The remuneration shall be EUR 4 | | Products related to traditional | |
| | 100 for the rapporteur. | | herbal medicinal products. The | |

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| | | | | proposals and |
| | | | 0 | comments |
| | | | remuneration shall be EUR 4 | |
| | | | <u>9</u> 100 for the rapporteur. | |
| 215 | 8. Certification of compliance with | | 8. Certification of | 8. Certification of |
| | Union legislation for a plasma master file | | compliance with Union | compliance with Union |
| | (PMF) in accordance with Part III of Annex | | legislation for a plasma master | legislation for a plasma |
| | I of Directive 2001/83/EC | | file (PMF) in accordance with | master file (PMF) in |
| | | | Part III of Annex I of Directive | accordance with Part III |
| | | | 2001/83/EC | of Annex I of Directive |
| | | | | 2001/83/EC |
| 216 | 8.1. A fee of EUR 57 200 shall apply to an | | 8.1. A fee of EUR 57 20066 000 | |
| | application for review of a PMF and its | | shall apply to an application for | |
| | initial certification pursuant to Part III, | | review of a PMF and its initial | |
| | point 1.1 of Annex I to Directive | | certification pursuant to Part III, | |
| | 2001/83/EC. The remuneration shall be | | point 1.1 of Annex I to Directive | |
| | EUR 8 600 for the rapporteur and EUR 8 | | 2001/83/EC. The remuneration | |
| | 600 for the co-rapporteur. | | shall be EUR <u>8 600</u> 10 300 for the | |
| | | | rapporteur and EUR <u>8 600</u> 10 300 | |
| | | | for the co-rapporteur. | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| 217 | 8.2. A charge of EUR 5 800 shall apply to | | 8.2. A charge of EUR 5 800 <u>6</u> | |
| | the issuing of an initial PMF certification | | 600 shall apply to the issuing of | |
| | where it is submitted simultaneously with | | an initial PMF certification | |
| | an application for a marketing authorisation | | where it is submitted | |
| | for a medicinal product under the | | simultaneously with an | |
| | centralised procedure. The PMF | | application for a marketing | |
| | documentation shall be evaluated within the | | authorisation for a medicinal | |
| | centralised marketing authorisation | | product under the centralised | |
| | application. | | procedure. The PMF | |
| | | | documentation shall be | |
| | | | evaluated within the centralised | |
| | | | marketing authorisation | |
| | | | application. | |
| 218 | 8.3. A fee of EUR 10 600 shall apply to an | | 8.3. A fee of EUR 10 600 <u>12</u> | |
| | application for review and certification of a | | 200 shall apply to an application | |
| | major variation of type II to the PMF | | for review and certification of a | |
| | pursuant to Regulation (EC) No 1234/2008. | | major variation of type II to the | |
| | The remuneration shall be EUR 1 600 for | | PMF pursuant to Regulation | |
| | | | (EC) No 1234/2008. The | |

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| | | | | comments |
| | the rapporteur and EUR 1 600 for the co- | | remuneration shall be EUR 4 | |
| | rapporteur. | | 6001 900 for the rapporteur and | |
| | | | EUR 1 <u>96</u> 00 for the co- | |
| | | | rapporteur. | |
| 219 | For two or more major variations of type II | | For two or more major variations | |
| | grouped in a single application pursuant to | | of type II grouped in a single | |
| | Regulation (EC) No 1234/2008, the fee and | | application pursuant to | |
| | remuneration laid down in point 9.4 of this | | Regulation (EC) No 1234/2008, | |
| | Annex shall apply. | | the fee and remuneration laid | |
| | | | down in point 98.4 of this Annex | |
| | | | shall apply. | |
| 220 | 8.4. A fee of EUR 17 000 shall apply for an | | 8.4. A fee of EUR 17 000 19 | |
| | application for review and annual re- | | 500 shall apply for an | |
| | certification of a PMF which may include | | application for review and | |
| | any variation pursuant to Regulation (EC) | | annual re-certification of a PMF | |
| | No 1234/2008 submitted simultaneously | | which may include any variation | |
| | with the application for a PMF annual re- | | pursuant to Regulation (EC) No | |
| | certification. The remuneration shall be | | 1234/2008 submitted | |
| | | | simultaneously with the | |

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| | | | 0 | comments |
| | EUR 1 900 for the rapporteur and EUR 1 | | application for a PMF annual re- | |
| | 900 for the co-rapporteur. | | certification. The remuneration | |
| | | | shall be EUR <u>1 900</u> 2 300 for the | |
| | | | rapporteur and EUR <u>1-900</u> 2 300 | |
| | | | for the co-rapporteur. | |
| 221 | 9. Certification of compliance with | | 9. Certification of | 9. Certification of |
| | Union legislation for a vaccine antigen | | compliance with Union | compliance with Union |
| | master file (VAMF) in accordance with Part | | legislation for a vaccine antigen | legislation for a vaccine |
| | III of Annex I of Directive 2001/83/EC | | master file (VAMF) in | antigen master file |
| | | | accordance with Part III of | (VAMF) in accordance |
| | | | Annex I of Directive | with Part III of Annex I |
| | | | 2001/83/EC | of Directive 2001/83/EC |
| 222 | 9.1. A fee of EUR 57 200 shall apply for an | | 9.1. A fee of EUR <u>57 200</u> 66 | |
| | application for review of a VAMF and its | | <u>000</u> shall apply for an application | |
| | initial certification not submitted | | for review of a VAMF and its | |
| | simultaneously with a new application for | | initial certification not submitted | |
| | marketing authorisation under the | | simultaneously with a new | |
| | centralised procedure pursuant to Part III, | | application for marketing | |
| | point 1.2 of Annex I to Directive | | authorisation under the | |

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| | | | | comments |
| | 2001/83/EC. The remuneration shall be | | centralised procedure pursuant to | |
| | EUR 8 600 for the rapporteur and EUR 8 | | Part III, point 1.2 of Annex I to | |
| | 600 for the co-rapporteur. | | Directive 2001/83/EC. The | |
| | | | remuneration shall be EUR 8 | |
| | | | 600 <u>10 300</u> for the rapporteur and | |
| | | | EUR 8 60010 300 for the co- | |
| | | | rapporteur. | |
| 223 | 9.2. In the case of a group of antigens aimed | | 9.2. In the case of a group of | |
| | at preventing a single infectious disease, a | | antigens aimed at preventing a | |
| | fee shall be charged for the VAMF | | single infectious disease, a fee | |
| | application for one antigen and | | shall be charged for the VAMF | |
| | remuneration shall be paid pursuant to point | | application for one antigen and | |
| | 10.1. The second and subsequent VAMF | | remuneration shall be paid | |
| | applications submitted simultaneously for | | pursuant to point 109.1. The | |
| | antigens as part of the same group shall be | | second and subsequent VAMF | |
| | charged a fee of EUR 7 800 per VAMF. | | applications submitted | |
| | The maximum total amount charged by the | | simultaneously for antigens as | |
| | Agency for VAMF applications submitted | | part of the same group shall be | |
| | simultaneously for antigens as part of the | | charged a fee of EUR 7 800 9 100 | |

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| | | | 0/ | comments |
| | same group shall not exceed EUR 68 600. | | per VAMF. The maximum total | |
| | In that case, the remuneration per each | | amount charged by the Agency | |
| | second and subsequent VAMF shall be | | for VAMF applications | |
| | EUR 1 900 for the rapporteur and EUR 1 | | submitted simultaneously for | |
| | 900 for the co-rapporteur. | | antigens as part of the same | |
| | | | group shall not exceed EUR 68 | |
| | | | 600 <u>78</u> 000. In that case, the | |
| | | | remuneration per each second | |
| | | | and subsequent VAMF shall be | |
| | | | EUR <u>1 900</u> 2 300 for the | |
| | | | rapporteur and EUR 1-9002 300 | |
| | | | for the co-rapporteur. | |
| 224 | 9.3. A charge of EUR 5 800 shall apply to | | 9.3. A charge of EUR <u>5 8006 600</u> | |
| | an application for issuing each VAMF | | shall apply to an application for | |
| | certification where it is submitted | | issuing each VAMF certification | |
| | simultaneously with a new application for | | where it is submitted | |
| | marketing authorisation under the | | simultaneously with a new | |
| | centralised procedure. | | application for marketing | |

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| | | | | proposals and |
| | | | 0 | comments |
| | | | authorisation under the | |
| | | | centralised procedure. | |
| 225 | 9.4. A fee of EUR 10 600 shall apply to an | | 9.4. A fee of EUR 10 600 <u>12</u> | |
| | application for review and certification of a | | 200 shall apply to an application | |
| | major variation of type II to the VAMF | | for review and certification of a | |
| | pursuant to Regulation (EC) No 1234/2008. | | major variation of type II to the | |
| | The remuneration shall be EUR 1 500 for | | VAMF pursuant to Regulation | |
| | the rapporteur and EUR 1 500 for the co- | | (EC) No 1234/2008. The | |
| | rapporteur. | | remuneration shall be EUR 1 500 | |
| | For each major variation of type II that is | | 800 for the rapporteur and EUR | |
| | grouped in a single application made | | 1 <u>500 <u>800</u> for the co-rapporteur.</u> | |
| | pursuant to Regulation (EC) No 1234/2008 | | For each major variation of type | |
| | a fee shall be charged as set out in the first | | II that is grouped in a single | |
| | subparagraph of this point. | | application made pursuant to | |
| | | | Regulation (EC) No 1234/2008 a | |
| | | | fee shall be charged as set out in | |
| | | | the first subparagraph of this | |
| | | | point. | |

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| | | | | proposals and |
| | | | 0 | comments |
| 226 | 10. Certification of quality and non- | | 10. Certification of quality | 10. Certification of |
| | clinical data relating to advanced therapy | | and non-clinical data relating to | quality and non-clinical |
| | medicinal products (ATMPs) developed by | | advanced therapy medicinal | data relating to |
| | small and medium-sized enterprises (SMEs) | | products (ATMPs) developed by | advanced therapy |
| | in accordance with Regulation (EC) No | | small and medium-sized | medicinal products |
| | 1394/2007 of the European Parliament and | | enterprises (SMEs) in | (ATMPs) developed by |
| | of the Council | | accordance with Regulation | small and medium-sized |
| | | | (EC) No 1394/2007 of the | enterprises (SMEs) in |
| | | | European Parliament and of the | accordance with |
| | | | Council | Regulation (EC) No |
| | | | | 1394/2007 of the |
| | | | | European Parliament |
| | | | | and of the Council |
| 227 | 10.1. A fee of EUR 143 200 shall apply to | 10.1. A fee of EUR 143 200 | 10.1 A fee of EUR 143 | |
| | an application for evaluating and certifying | shall apply to an application for | 200 <u>165 600</u> shall apply to an | |
| | the quality and non-clinical data pursuant to | evaluating and certifying the | application for evaluating and | |
| | Article 18 of Regulation (EC) No | quality and non-clinical data | certifying the quality and non- | |
| | 1394/2007 of the European Parliament and | pursuant to Article 18 of | clinical data pursuant to Article | |
| | of the Council ⁵⁵ . Such fee shall be waived | Regulation (EC) No 1394/2007 of | 18 of Regulation (EC) No | |

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| | | | 0 | comments |
| | in full. The remuneration shall be EUR 47 | the European Parliament and of | 1394/2007 of the European | |
| | 400 for the rapporteur. | the Council ⁴³ . Such fee shall be | Parliament and of the Council ⁵⁶ . | |
| | | waived in full. The remuneration | Such fee shall be waived in full. | |
| | ⁵⁵ Regulation (EC) No 1394/2007 of the European | shall be EUR 23 700 for the | The remuneration shall be EUR | |
| | Parliament and of the Council of 13 November 2007 | rapporteur. | 47-400 <u>56 900</u> for the rapporteur. | |
| | on advanced therapy medicinal products and | | | |
| | amending Directive 2001/83/EC and Regulation | | ⁵⁶ Regulation (EC) No 1394/2007 of | |
| | (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121). | | 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). | |
| 228 | 10.2. A fee of EUR 95 200 shall apply to an | 10.2. A fee of EUR 95 200 shall | 10.2. A fee of EUR 95 200 <u>110</u> | |
| | application for evaluating and certifying | apply to an application for | 100 shall apply to an application | |
| | only the quality data pursuant to Article 18 | evaluating and certifying only the | for evaluating and certifying | |
| | of Regulation (EC) No 1394/2007. Such fee | quality data pursuant to Article 18 | only the quality data pursuant to | |
| | shall be waived in full. The remuneration | of Regulation (EC) No | Article 18 of Regulation (EC) No | |
| | shall be EUR 31 500 for the rapporteur. | 1394/2007. Such fee shall be | 1394/2007. Such fee shall be | |
| | | waived in full. The remuneration | waived in full. The remuneration | |

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| | | | | comments |
| | | shall be EUR 15 750 for the | shall be EUR 31 50037 800 for | |
| | | rapporteur. | the rapporteur. | |
| 229 | 11. Paediatric applications in accordance | | 11. Paediatric applications in | 11. Paediatric |
| | with Regulation (EC) No 1901/2006 of the | | accordance with Regulation (EC) | applications in |
| | European Parliament and of the Council ⁵⁷ | | No 1901/2006 of the European | accordance with |
| | | | Parliament and of the Council ⁵⁸ | Regulation (EC) No |
| | ⁵⁷ Regulation (EC) No 1901/2006 of the European | | | 1901/2006 of the |
| | 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 | | 58 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and | European Parliament and of the Council ⁵⁸ |
| | (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1). | | amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation | ⁵⁸ Regulation (EC) No |
| | | | (EC) No 726/2004 (OJ L 378, | 1901/2006 of the European |
| | | | 27.12.2006, p. 1). | 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 |
| | | | | 2001/20/EC, Directive 2001/83/EC and Regulation |

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| | | | 0 | comments |
| | | | | (EC) No 726/2004 (OJ L 378, |
| | | | | 27.12.2006, p. 1). |
| 230 | 11.1. A fee of EUR 31 700 shall apply to an | 11.1. A fee of EUR 31 700 shall | 11.1. A fee of EUR 31 70036 | |
| | application for agreement of a paediatric | apply to an application for | 400 shall apply to an application | |
| | investigation plan requested pursuant to | agreement of a paediatric | for agreement of a paediatric | |
| | Article 15 of Regulation (EC) No | investigation plan requested | investigation plan requested | |
| | 1901/2006. Such fee shall be waived in full. | pursuant to Article 15 of | pursuant to Article 15 of | |
| | The remuneration shall be EUR 6 700 for | Regulation (EC) No 1901/2006. | Regulation (EC) No 1901/2006. | |
| | the rapporteur. | Such fee shall be waived in full. | Such fee shall be waived in full. | |
| | | The remuneration shall be EUR 3 | The remuneration shall be EUR | |
| | | 350 for the rapporteur. | 6 700 8 000 for the rapporteur. | |
| 231 | 11.2. A fee of EUR 17 600 shall apply to an | 11.2. A fee of EUR 17 600 shall | 11.2. A fee of EUR 17 600 20 | |
| | application for a modification of an agreed | apply to an application for a | 400 shall apply to an application | |
| | paediatric investigation plan pursuant to | modification of an agreed | for a modification of an agreed | |
| | Article 22 of Regulation (EC) No | paediatric investigation plan | paediatric investigation plan | |
| | 1901/2006. Such fee shall be waived in full. | pursuant to Article 22 of | pursuant to Article 22 of | |
| | The remuneration shall be EUR 6 400 for | Regulation (EC) No 1901/2006. | Regulation (EC) No 1901/2006. | |
| | the rapporteur. | Such fee shall be waived in full. | Such fee shall be waived in full. | |

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| | | | 0 | comments |
| | | The remuneration shall be EUR 3 | The remuneration shall be EUR | |
| | | 200 for the rapporteur. | 6 400 7 700 for the rapporteur. | |
| 232 | 11.3. A fee of EUR 12 000 shall apply to an | 11.3. A fee of EUR 12 000 shall | 11.3. A fee of EUR 12 000 <u>13</u> | |
| | application for a product-specific waiver | apply to an application for a | 700 shall apply to an application | |
| | pursuant to Article 13 of Regulation (EC) | product-specific waiver pursuant | for a product-specific waiver | |
| | No 1901/2006. Such fee shall be waived in | to Article 13 of Regulation (EC) | pursuant to Article 13 of | |
| | full. The remuneration shall be EUR 1 800 | No 1901/2006. Such fee shall be | Regulation (EC) No 1901/2006. | |
| | for the rapporteur. | waived in full. The remuneration | Such fee shall be waived in full. | |
| | | shall be EUR 900 for the | The remuneration shall be EUR 1 | |
| | | rapporteur. | 800 <u>2 200</u> for the rapporteur. | |
| 233 | 11.4. A fee of EUR 8 000 shall apply to a | 11.4. A fee of EUR 8 000 shall | 11.4. A fee of EUR <u>8 0009</u> | |
| | request for compliance check with the | apply to a request for compliance | 100 shall apply to a request for | |
| | paediatric investigation plan pursuant to | check with the paediatric | compliance check with the | |
| | Article 23 of Regulation (EC) No | investigation plan pursuant to | paediatric investigation plan | |
| | 1901/2006. Such fee shall be waived in full. | Article 23 of Regulation (EC) No | pursuant to Article 23 of | |
| | The remuneration shall be EUR 1 000 for | 1901/2006. Such fee shall be | Regulation (EC) No 1901/2006. | |
| | the rapporteur. | waived in full. The remuneration | Such fee shall be waived in full. | |
| | | shall be EUR 500 for the | The remuneration shall be EUR | |
| | | rapporteur. | 1 000 1 200 for the rapporteur. | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| 234 | 12. Orphan designation in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council ⁵⁹ 59 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). | | 12. Orphan designation in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council 60 60 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). | designation in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council 60 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). |
| 235 | A fee of EUR 16 800 shall apply to an application for the designation of an orphan | A fee of EUR 16 800 shall apply to an application for the | A fee of EUR 16 800 19 200 shall apply to an application for or | |
| | medicinal product pursuant to Regulation (EC) No 141/2000. Such fee shall be | designation of an orphan medicinal product pursuant to Regulation (EC) No 141/2000. | reassessment of the designation of an orphan medicinal product pursuant to Regulation (EC) No | |

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| | | | 0 | comments |
| | waived in full. The remuneration shall be | Such fee shall be waived in full. | 141/2000. Such fee shall be | |
| | EUR 1 500 for the rapporteur. | The remuneration shall be EUR | waived in full. The remuneration | |
| | | 750 for the rapporteur. | shall be EUR <u>1-500</u> 1 800 for the | |
| | | | rapporteur. | |
| 236 | 13. Scientific opinion on the evaluation | | 13. Scientific opinion on the | 13. Scientific |
| | of medicinal product intended exclusively | | evaluation of medicinal product | opinion on the |
| | for markets outside the Union | | intended exclusively for markets | evaluation of medicinal |
| | | | outside the Union | product intended |
| | | | | exclusively for markets |
| | | | | outside the Union |
| 237 | A fee and corresponding remuneration as | | A fee and corresponding | A fee and corresponding |
| | specified in points 1 to 5 of this Annex and | | remuneration as specified in | remuneration as |
| | sections 1, 3, 4 and 5 of Annex IV and | | points 1 to 5 of this Annex and | specified in points 1 to 5 |
| | points 6.1, 6.2 and 6.4 thereof shall apply | | sections 1, 3, 4 and 5 of Annex | of this Annex and |
| | for an application for a scientific opinion | | IV and points 6.1, 6.2 and 6.4 | sections 1, 3, 4 and 5 of |
| | following the evaluation of a medicinal | | thereof shall apply for an | Annex IV and points |
| | product intended exclusively for markets | | application for a scientific | 6.1, 6.2 and 6.4 thereof |
| | outside the Union pursuant to Article 58 of | | opinion following the evaluation | shall apply for an |
| | Regulation (EC) No 726/2004. | | of a medicinal product intended | application for a |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | comments |
| | | | exclusively for markets outside | scientific opinion |
| | | | the Union pursuant to Article 58 | following the evaluation |
| | | | of Regulation (EC) No | of a medicinal product |
| | | | 726/2004. | intended exclusively for |
| | | | | markets outside the |
| | | | | Union pursuant to |
| | | | | Article 58 of Regulation |
| | | | | (EC) No 726/2004. |
| 238 | 14. Periodic safety update reports | | 14. Periodic safety update | 14. Periodic safety |
| | | | reports | update reports |
| 239 | 14.1 A fee of EUR 27 000 shall apply per | | 14.1 A fee of EUR 27 000 <u>32</u> | |
| | procedure for the assessment of periodic | | 600 shall apply per procedure | |
| | safety update reports referred to in Articles | | for the assessment of periodic | |
| | 107e and 107g of Directive 2001/83/EC and | | safety update reports referred to | |
| | in Article 28 of Regulation (EC) No | | in Articles 107e and 107g of | |
| | 726/2004. The remuneration shall be EUR | | Directive 2001/83/EC and in | |
| | 12 900 for the rapporteur. | | Article 28 of Regulation (EC) | |
| | | | No 726/2004. The remuneration | |

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| | | | | proposals and |
| | | | | comments |
| | | | shall be EUR 12 900 16 600 for | |
| | | | the rapporteur. | |
| 240 | 14.2. Where two or more marketing | | 14.2. Where two or more | 14.2. Where two or |
| | authorisation holders are subject to the | | marketing authorisation holders | more marketing |
| | obligation to submit periodic safety update | | are subject to the obligation to | authorisation holders are |
| | reports in the context of the procedures | | submit periodic safety update | subject to the obligation |
| | referred to in point 14.1, the amount | | reports in the context of the | to submit periodic safety |
| | payable by each marketing authorisation | | procedures referred to in point | update reports in the |
| | holder shall be calculated by the Agency in | | 14.1, the amount payable by | context of the |
| | two steps, as follows: | | each marketing authorisation | procedures referred to in |
| | | | holder shall be calculated by the | point 14.1, the amount |
| | | | Agency in two steps, as follows: | payable by each |
| | | | | marketing authorisation |
| | | | | holder shall be |
| | | | | calculated by the |
| | | | | Agency in two steps, as |
| | | | | follows: |
| 241 | (a) by dividing the total amount of the fee | | (a) by dividing the total amount | (a) by dividing the total |
| | among the marketing authorisation holders | | of the fee among the marketing | amount of the fee among |

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| | | | | proposals and |
| | | | | comments |
| | proportionally to the number of chargeable | | authorisation holders | the marketing |
| | units-human corresponding to products | | proportionally to the number of | authorisation holders |
| | included in the procedure which are held by | | chargeable units-human | proportionally to the |
| | each of those marketing authorisation | | corresponding to products | number of chargeable |
| | holders; | | included in the procedure which | units-human |
| | | | are held by each of those | corresponding to |
| | | | marketing authorisation holders; | products included in the |
| | | | | procedure which are |
| | | | | held by each of those |
| | | | | marketing authorisation |
| | | | | holders; |
| 242 | (b) by subsequently applying, where | | (b) by subsequently applying, | (b) by subsequently |
| | relevant, the fee reduction laid down in | | where relevant, the fee reduction | applying, where |
| | point 1 of Annex V. | | laid down in point 1 of Annex | relevant, the fee |
| | | | V. | reduction laid down in |
| | | | | point 1 of Annex V. |
| 243 | 15. Post-authorisation safety studies | | 15. Post-authorisation | 15. Post- |
| | | | safety studies | authorisation safety |
| | | | | studies |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| 244 | 15.1 A fee of EUR 88 200 shall apply to an | | 15.1. A fee of EUR 88 | |
| | assessment carried out under Articles 107n | | 200 102 400 shall apply to an | |
| | to 107q of Directive 2001/83/EC and | | assessment carried out under | |
| | Article 28b of Regulation (EC) No | | Articles 107n to 107q of | |
| | 726/2004 of post-authorisation safety | | Directive 2001/83/EC and | |
| | studies as referred to in Article 21a, point | | Article 28b of Regulation (EC) | |
| | (b), or Article 22a(1), point (a), of Directive | | No 726/2004 of post- | |
| | 2001/83/EC, or in Article 9(4), point (cb), | | authorisation safety studies as | |
| | or Article 10a(1), point (a), of Regulation | | referred to in Article 21a, point | |
| | (EC) No 726/2004, that are conducted in | | (b), or Article 22a(1), point (a), | |
| | more than one Member State. | | 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. | |
| 245 | 15.2 The fee shall be charged in two | | 15.2 The fee shall be charged | 15.2 The fee shall be |
| | instalments, as follows: | | in two instalments, as follows: | charged in two |
| | | | | instalments, as follows: |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | 0 | comments |
| 246 | 15.2.1. EUR 44 100 shall be due on the date | | 15.2.1. EUR 44-100 <u>51 200</u> shall | |
| | of the start of the procedure for the | | be due on the date of the start of | |
| | assessment of the draft protocol referred to | | the procedure for the assessment | |
| | in Article 107n of Directive 2001/83/EC; | | of the draft protocol referred to | |
| | the remuneration shall be EUR 17 800 for | | in Article 107n of Directive | |
| | the rapporteur. | | 2001/83/EC; the remuneration | |
| | | | shall be EUR <u>17 800</u> 21 400 for | |
| | | | the rapporteur. | |
| 247 | 15.2.2. EUR 44 100 shall be due at the date | | 15.2.2 EUR 44 100 <u>51 200</u> shall | |
| | of the start of the procedure for the | | be due at the date of the start of | |
| | assessment of the final study report, as | | the procedure for the assessment | |
| | referred to in Article 107p of Directive | | of the final study report, as | |
| | 2001/83/EC, by the Pharmacovigilance Risk | | referred to in Article 107p of | |
| | Assessment Committee; the remuneration | | Directive 2001/83/EC, by the | |
| | shall be EUR 17 800 for the rapporteur. | | Pharmacovigilance Risk | |
| | | | Assessment Committee; the | |
| | | | remuneration shall be EUR 17 | |
| | | | 800 <u>21 400</u> for the rapporteur. | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | 0 | comments |
| 248 | 15.3. Where the obligation to conduct a | | 15.3. Where the obligation to | 15.3. Where the |
| | post-authorisation safety study is imposed | | conduct a post-authorisation | obligation to conduct a |
| | by the Commission on more than one | | safety study is imposed by the | post-authorisation safety |
| | marketing authorisation holder, the same | | Commission on more than one | study is imposed by the |
| | concerns apply to more than one medicinal | | marketing authorisation holder, | Commission on more |
| | product and the marketing authorisation | | the same concerns apply to more | than one marketing |
| | holders concerned conduct a joint post- | | than one medicinal product and | authorisation holder, the |
| | authorisation safety study, the Agency shall | | the marketing authorisation | same concerns apply to |
| | calculate the amount payable by each | | holders concerned conduct a | more than one medicinal |
| | marketing authorisation holder in two | | joint post-authorisation safety | product and the |
| | steps, as follows: | | study, the Agency shall calculate | marketing authorisation |
| | | | the amount payable by each | holders concerned |
| | | | marketing authorisation holder | conduct a joint post- |
| | | | in two steps, as follows: | authorisation safety |
| | | | | study, the Agency shall |
| | | | | calculate the amount |
| | | | | payable by each |
| | | | | marketing authorisation |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | | | | holder in two steps, as |
| | | | /C-/ | follows: |
| 249 | (a) by evenly dividing the total amount of | | (a) by evenly dividing the total | (a) by evenly dividing |
| | the fee among those marketing authorisation | | amount of the fee among those | the total amount of the |
| | holders; | | marketing authorisation holders; | fee among those |
| | | | | marketing authorisation |
| | | | | holders; |
| 250 | (b) by subsequently applying the fee | | (b) by subsequently applying the | (b) by subsequently |
| | reduction as set out in point 1 of Annex V, | | fee reduction as set out in point | applying the fee |
| | where relevant. | | 1 of Annex V, where relevant. | reduction as set out in |
| | | | | point 1 of Annex V, |
| | | | | where relevant. |
| 250a | | | 15.4 Marketing | |
| | | | authorisation holders who are | |
| | | | charged the fee under this | |
| | | | point shall be exempted from | |
| | | | the payment of any other fee | |
| | | | charged by the Agency or | |
| | | | competent authorities of the | |

| | Commission proposal | EP amendments voted on 12 July 2023 | Text agreed by the Council on 13 June 2023 Member State for the submission of the studies referred to in paragraph 15.1. | Tentatively agreed text, compromise proposals and comments |
|-----|--|--------------------------------------|---|--|
| 251 | ANNEX II Fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products | | ANNEX II Fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products | ANNEX II Fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products |
| 252 | Scientific advice in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004 A fee of EUR 33 100 shall apply to | | Scientific advice in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004 1.1. A fee of EUR 33 100 34 | 1. Scientific advice in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004 |
| | any of the following requests: | | 900 shall apply to any of the following requests: | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| 254 | (a) a request on quality, safety and clinical | | (a) a request on quality, safety | (a) a request on quality, |
| | development; | | and clinical development; | safety and clinical |
| | | | | development; |
| 255 | (b) a request on quality and clinical | | (b) a request on quality and | (b) a request on quality |
| | development; | | clinical development; | and clinical |
| | | | | development; |
| 256 | (c) a request on safety and clinical | | (c) a request on safety and | (c) a request on safety |
| | development; | | clinical development; | and clinical |
| | | | | development; |
| 257 | The remuneration shall be EUR 15 800 for | | The remuneration shall be | |
| | the scientific advice co-ordinator. | | EUR 15 800 16 700 for the | |
| | | | scientific advice co-ordinator. | |
| 258 | 1.2. A fee of EUR 24 300 shall apply to any | | 1.2. A fee of EUR 24 300 | |
| | of the following requests: | | 25 600 shall apply to any of the | |
| | | | following requests: | |
| 259 | (a) a request on clinical development; | | (a) a request on clinical | (a) a request on clinical |
| | | | development; | development; |
| 260 | (b) a request on quality and safety | | (b) a request on quality and | (b) a request on quality |
| | development; | | safety development; | and safety development; |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| 261 | (c) a request on quality and bioequivalence | | (c) a request on quality | (c) a request on quality |
| | studies for generic veterinary medicinal | | development and | development and |
| | products as defined in Article 4(9) of (EU) | | bioequivalence studies for | bioequivalence studies |
| | 2019/6. | | generic veterinary medicinal | for generic veterinary |
| | | | products as defined in Article | medicinal products as |
| | | | 4(9) of Regulation (EU) 2019/6. | defined in Article 4(9) |
| | | | | of Regulation (EU) |
| | | | | 2019/6 |
| | | | | 12/09 As already |
| | | | | agreed on 159 |
| 262 | The remuneration shall be EUR 10 100 for | | The remuneration shall be EUR | |
| | the scientific advice co-ordinator. | | 10 100 10 600 for the scientific | |
| | | | advice co-ordinator. | |
| 263 | 1.3. A fee of EUR 21 300 shall apply to a | | 1.3. A fee of EUR 21 300 22 | |
| | request related to any of the following: | | 500 shall apply to a request | |
| | | | related to any of the following: | |
| 264 | (a) a request on quality development; | | (a) a request on quality | (a) a request on quality |
| | | | development; | development; |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | 0 | comments |
| 265 | (b) a request on safety development; | | (b) a request on safety | (b) a request on safety |
| | | | development; | development; |
| 266 | (c) a request on bioequivalence studies for | | (c) a request on bioequivalence | (c) a request on |
| | generic veterinary medicinal products as | | studies for generic veterinary | bioequivalence studies |
| | defined in Article 4(9) of (EU) 2019/6; | | medicinal products as defined in | for generic veterinary |
| | | | Article 4(9) of Regulation (EU) | medicinal products as |
| | | | 2019/6; | defined in Article 4(9) |
| | | | | of Regulation (EU) |
| | | | | 2019/6; |
| 267 | (d) a request for preliminary risk profile; | | (d) a request for preliminary risk | (d) a request for |
| | | | profile; | preliminary risk profile; |
| 268 | (e) a request related to setting a new | | (e) a request related to setting a | (e) a request related to |
| | maximum residue limit. | | new maximum residue limit. | setting a new maximum |
| | | | | residue limit. |
| 269 | The remuneration shall be EUR 6 100 for | | The remuneration shall be EUR | |
| | the scientific advice co-ordinator. | | 6 100 <u>6 400</u> for the scientific | |
| | | | advice co-ordinator. | |
| 270 | 2. Request for classification of a | | 2. Request for classification | 2. Request for |
| | veterinary medicinal product as intended for | | of a veterinary medicinal | classification of a |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | 0 | comments |
| | a limited market as defined in Article 4, | | product as intended for a limited | veterinary medicinal |
| | point (29), of Regulation (EU) 2019/6 and | | market as defined in Article 4, | product as intended for a |
| | for consideration for eligibility for | | point (29), of Regulation (EU) | limited market as |
| | authorisation in accordance with Article 23 | | 2019/6 and for consideration for | defined in Article 4, |
| | of that Regulation | | eligibility for authorisation in | point (29), of Regulation |
| | | | accordance with Article 23 of | (EU) 2019/6 and for |
| | | | that Regulation | consideration for |
| | | | | eligibility for |
| | | | | authorisation in |
| | | | | accordance with Article |
| | | | | 23 of that Regulation |
| 271 | A charge of EUR 5 200 shall apply to a | | A charge of EUR 5 200 5 500 | |
| | request for classification of a veterinary | | shall apply to a request for | |
| | medicinal product as intended for a limited | | classification of a veterinary | |
| | market within the meaning of Article 4(29) | | medicinal product as intended | |
| | of Regulation (EU) 2019/6 and for | | for a limited market within the | |
| | consideration for eligibility for authorisation | | meaning of Article 4(29) of | |
| | pursuant to Article 23 of Regulation (EU) | | Regulation (EU) 2019/6 and for | |
| | 2019/6. | | consideration for eligibility for | |

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| | | | | proposals and |
| | | | | comments |
| | | | authorisation pursuant to Article | |
| | | | 23 of Regulation (EU) 2019/6. | |
| 272 | 3. Establishment, modification or | | 3. Establishment, | 3. Establishment, |
| | extension of a maximum residue limit | | modification or extension of a | modification or |
| | (MRL) in accordance with the procedure | | maximum residue limit (MRL) | extension of a maximum |
| | laid down in Regulation (EC) No 470/2009 | | in accordance with the | residue limit (MRL) in |
| | of the European Parliament and of the | | procedure laid down in | accordance with the |
| | Council ⁶¹ | | Regulation (EC) No 470/2009 of | procedure laid down in |
| | | | the European Parliament and of | Regulation (EC) No |
| | 61 Regulation (EC) No 470/2009 of the European | | the Council ⁶² | 470/2009 of the |
| | Parliament and of the Council of 6 May 2009 laying | | | European Parliament |
| | down Community procedures for the establishment | | 62 Regulation (EC) No 470/2009 of the | and of the Council ⁶² |
| | of residue limits of pharmacologically active | | European Parliament and of the | |
| | substances in foodstuffs of animal origin, repealing | | Council of 6 May 2009 laying down | 62 Regulation (EC) No |
| | Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European | | Community procedures for the | 470/2009 of the European |
| | Parliament and of the Council and Regulation (EC) | | establishment of residue limits of | Parliament and of the Council |
| | No 726/2004 of the European Parliament and of the | | pharmacologically active substances in | of 6 May 2009 laying down |
| | Council (OJ L 152, 16.6.2009, p. 11). | | foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 | Community procedures for |
| | | | and amending Directive 2001/82/EC of | the establishment of residue |
| | | | and amending Directive 2001/02/DC 01 | limits of pharmacologically |

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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| | | | the European Parliament and of the | active substances in |
| | | | Council and Regulation (EC) No | foodstuffs of animal origin, |
| | | | 726/2004 of the European Parliament | repealing Council Regulation |
| | | | and of the Council (OJ L 152, | (EEC) No 2377/90 and |
| | | | 16.6.2009, p. 11). | 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). |
| 273 | 3.1. A fee of EUR 84 700 shall apply to an | | 3.1. A fee of EUR 84 700 89 | |
| | application to set an initial MRL for a given | | 300 shall apply to an application | |
| | substance. The remuneration shall be EUR | | to set an initial MRL for a given | |
| | 21 400 for the rapporteur and EUR 10 300 | | substance. The remuneration | |
| | for the co-rapporteur. | | shall be EUR 21 400 22 600 for | |
| | | | the rapporteur and EUR 10 300 | |
| | | | 10 900 for the co-rapporteur. | |
| 274 | 3.2. A fee of EUR 53 000 shall apply to | | 3.2. A fee of EUR 53 000 | |
| | each application to modify or to extend an | | 55 900 shall apply to each | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | 0 | comments |
| | existing MRL. The remuneration shall be | | application to modify or to | |
| | EUR 10 600 for the rapporteur and EUR 9 | | extend an existing MRL. The | |
| | 700 for the co-rapporteur. | | remuneration shall be EUR 10 | |
| | | | 600-11 200 for the rapporteur | |
| | | | and EUR 9-700-10 200 for the | |
| | | | co-rapporteur. | |
| 275 | 3.3. A fee of EUR 24 300 shall apply to the | | 3.3. A fee of EUR 24 300 <u>25</u> | |
| | assessment to determine whether a | | 600 shall apply to the | |
| | chemical-unlike biological substance | | assessment to determine whether | |
| | requires a full MRL evaluation or not | | a chemical-unlike biological | |
| | pursuant to Annex I, Section 1.7, to | | substance requires a full MRL | |
| | Commission Regulation (EU) 2018/782 ⁶³ . | | evaluation or not pursuant to | |
| | The remuneration shall be EUR 10 100 for | | Annex I, Section <u>I</u> 4.7, to | |
| | the rapporteur. | | Commission Regulation (EU) | |
| | | | 2018/782 ⁶⁴ . The remuneration | |
| | ⁶³ Commission Regulation (EU) 2018/782 of 29 | | shall be EUR 10 100 10 600 for | |
| | May 2018 establishing the methodological principles | | the rapporteur. | |
| | for the risk assessment and risk management | | ⁶⁴ Commission Regulation (EU) | |
| | | | 2018/782 of 29 May 2018 establishing | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | recommendations referred to in Regulation (EC) No | | the methodological principles for the | |
| | 470/2009 (OJ L 132, 30.5.2018, p. 5). | | risk assessment and risk management | |
| | | | recommendations referred to in | |
| | | | Regulation (EC) No 470/2009 (OJ L | |
| | | | 132, 30.5.2018, p. 5). | |
| 276 | 4. Authorisation to market veterinary | | 4. Authorisation to market | 4. Authorisation to |
| | medicinal products falling within the scope | | veterinary medicinal products | market veterinary |
| | of the centralised marketing authorisation | | falling within the scope of the | medicinal products |
| | procedure pursuant to Article 42 of | | centralised marketing | falling within the scope |
| | Regulation (EU) 2019/6 | | authorisation procedure pursuant | of the centralised |
| | | | to Article 42 of Regulation (EU) | marketing authorisation |
| | | | 2019/6 | procedure pursuant to |
| | | | | Article 42 of Regulation |
| | | | | (EU) 2019/6 |
| 277 | 4.1. A fee of EUR 295 500 shall apply to an | | 4.1. A fee of EUR 295 500 | |
| | application for a marketing authorisation for | | 311 500 shall apply to an | |
| | a veterinary medicinal product pursuant to | | application for a marketing | |
| | Articles 8, 23 or Article 25 of Regulation | | authorisation for a veterinary | |
| | (EU) 2019/6 where the applicant claims a | | medicinal product pursuant to | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
|-----|---|---------------------------|---|--------------------|
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| | | | | proposals and |
| | | | 0 | comments |
| | new active substance. That fee shall cover | | Articles 8, 23 or Article 25 of | |
| | all strengths, all pharmaceutical forms and | | Regulation (EU) 2019/6 where | |
| | all presentations submitted in the same | | the applicant claims a new | |
| | application, irrespective of the number of | | active substance. That fee shall | |
| | target species. The remuneration shall be | | cover all strengths, all | |
| | EUR 107 000 for the rapporteur and EUR | | pharmaceutical forms and all | |
| | 38 100 for the co-rapporteur. | | presentations submitted in the | |
| | | | same application, irrespective of | |
| | | | the number of target species. | |
| | | | The remuneration shall be EUR | |
| | | | 107 000 <u>112 800</u> for the | |
| | | | rapporteur and EUR 38 100 40 | |
| | | | 200 for the co-rapporteur. | |
| 278 | 4.2. A fee of EUR 267 700 shall apply to an | | 4.2. A fee of EUR 267 700 | |
| | application for a marketing authorisation for | | 282 200 shall apply to an | |
| | a veterinary medicinal product pursuant to | | application for a marketing | |
| | Articles 8, 20, 22, 23 or Article 25 of | | authorisation for a veterinary | |
| | Regulation (EU) 2019/6 where the applicant | | medicinal product pursuant to | |
| | claims a known active substance. That fee | | Articles 8, 20, 22, 23 or Article | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | shall cover all strengths, all pharmaceutical | | 25 of Regulation (EU) 2019/6 | |
| | forms and all presentations submitted in the | | where the applicant claims a | |
| | same application, irrespective of the number | | known active substance. That | |
| | of target species. The remuneration shall be | | fee shall cover all strengths, all | |
| | EUR 82 100 for the rapporteur and EUR 35 | | pharmaceutical forms and all | |
| | 300 for the co-rapporteur. | | presentations submitted in the | |
| | | | same application, irrespective of | |
| | | | the number of target species. | |
| | | | The remuneration shall be EUR | |
| | | | 82 100 86 500 for the rapporteur | |
| | | | and EUR 35 300 37 200 for the | |
| | | | co-rapporteur. | |
| 279 | 4.3. A fee of EUR 136 800 shall apply for | | 4.3. A fee of EUR 136 800 | |
| | any of the following applications: | | 144 200 shall apply for any of | |
| | | | the following applications: | |
| 280 | (a) an application for a marketing | | (a) an application for a | (a) an application for a |
| | authorisation for a generic veterinary | | marketing authorisation for a | marketing authorisation |
| | medicinal product pursuant to Article 18 of | | generic veterinary medicinal | for a generic veterinary |
| | Regulation (EU) 2019/6; | | | medicinal product |

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| | | | | proposals and |
| | | | | comments |
| | | | product pursuant to Article 18 of | pursuant to Article 18 of |
| | | | Regulation (EU) 2019/6; | Regulation (EU) 2019/6; |
| 281 | (b) an application for a marketing | | (b) an application for a | (b) an application for a |
| | authorisation for a hybrid veterinary | | marketing authorisation for a | marketing authorisation |
| | medicinal product pursuant to Article 19 of | | hybrid veterinary medicinal | for a hybrid veterinary |
| | Regulation (EU) 2019/6; | | product pursuant to Article 19 of | medicinal product |
| | | | Regulation (EU) 2019/6; | pursuant to Article 19 of |
| | | | | Regulation (EU) 2019/6; |
| 282 | (c) an application based on informed | | (c) an application based on | (c) an application based |
| | consent for a marketing authorisation for a | | informed consent for a | on informed consent for |
| | veterinary medicinal product pursuant to | | marketing authorisation for a | a marketing |
| | Article 21 of Regulation (EU) 2019/6. | | veterinary medicinal product | authorisation for a |
| | | | pursuant to Article 21 of | veterinary medicinal |
| | | | Regulation (EU) 2019/6. | product pursuant to |
| | | | | Article 21 of Regulation |
| | | | | (EU) 2019/6. |
| 283 | That fee shall cover all strengths, all | | That fee shall cover all | |
| | pharmaceutical forms and all presentations | | strengths, all pharmaceutical | |
| | submitted in the same application, | | forms and all presentations | |

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| | | | | proposals and |
| | | | | comments |
| | irrespective of the number of target species. | | submitted in the same | |
| | The remuneration shall be EUR 30 800 for | | application, irrespective of the | |
| | the rapporteur and EUR 17 900 for the co- | | number of target species. The | |
| | rapporteur. | | remuneration shall be EUR 30 | |
| | | | 800-32 500 for the rapporteur | |
| | | | and EUR 17 900 18 900 for the | |
| | | | co-rapporteur. | |
| 284 | 5. Re-examination of a marketing | | 5. Re-examination of a | 5. Re-examination |
| | authorisation for limited markets | | marketing authorisation for | of a marketing |
| | | | limited markets | authorisation for limited |
| | | | | markets |
| 285 | A fee of EUR 19 000 shall apply to an | | A fee of EUR 19 000 20 000 | |
| | application for a re-examination of a | | shall apply to an application for | |
| | marketing authorisation for a limited market | | a re-examination of a marketing | |
| | pursuant to Article 24(3) of Regulation | | authorisation for a limited | |
| | (EU) 2019/6. The remuneration shall be | | market pursuant to Article 24(3) | |
| | EUR 3 100 for the rapporteur and EUR 2 | | of Regulation (EU) 2019/6. The | |
| | 400 for the co-rapporteur. | | remuneration shall be EUR 3 | |
| | | | 100-3 300 for the rapporteur and | |

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| | | | | proposals and |
| | | | | comments |
| | | | EUR 2-400-2 500 for the co- | |
| | | | rapporteur. | |
| 286 | 6. Variations to the terms of a | | 6. Variations to the terms | 6. Variations to the |
| | marketing authorisation, requiring | | of a marketing authorisation, | terms of a marketing |
| | assessment in accordance with Articles 64, | | requiring assessment in | authorisation, requiring |
| | 65 and 66 of Regulation (EU) 2019/6 | | accordance with Articles 64, 65 | assessment in |
| | | | and 66 of Regulation (EU) | accordance with Articles |
| | | | 2019/6 | 64, 65 and 66 of |
| | | | | Regulation (EU) 2019/6 |
| 287 | 6.1. A fee of EUR 87 800 shall apply to a | | 6.1. A fee of EUR 87 800 <u>92</u> | |
| | variation requiring assessment introducing | | 600 shall apply to a variation | |
| | changes of active substance(s), strength, | | requiring assessment | |
| | pharmaceutical form, route of | | introducing changes of active | |
| | administration or food-producing target | | substance(s), strength, | |
| | species, which are to be assessed within 90 | | pharmaceutical form, route of | |
| | days in accordance with Article 66(3) of | | administration or food- | |
| | Regulation (EU) 2019/6. That fee shall be | | producing target species, which | |
| | charged for each single pharmaceutical form | | are to be assessed within 90 | |
| | or each single associated strength/potency. | | days in accordance with Article | |

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| | | | | proposals and |
| | | | | comments |
| | The remuneration shall be EUR 28 600 for | | 66(3) of Regulation (EU) | |
| | the rapporteur and EUR 8 600 for the co- | | 2019/6. That fee shall be | |
| | rapporteur. | | charged for each single | |
| | | | pharmaceutical form or each | |
| | | | single associated | |
| | | | strength/potency. The | |
| | | | remuneration shall be EUR 28 | |
| | | | 600-30 100 for the rapporteur | |
| | | | and EUR <u>8 600 9 100</u> for the co- | |
| | | | rapporteur. | |
| 288 | 6.2. A fee of EUR 47 500 shall apply to | | 6.2. A fee of EUR 47 500 <u>50</u> | |
| | variations requiring assessment that | | 100 shall apply to variations | |
| | introduce changes to safety, efficacy or | | requiring assessment that | |
| | pharmacovigilance, which are to be | | introduce changes to safety, | |
| | assessed within 60 or 90 days, as the case | | efficacy or pharmacovigilance, | |
| | may be, in accordance with Article 66(3) of | | which are to be assessed within | |
| | Regulation (EU) 2019/6. The remuneration | | 60 or 90 days, as the case may | |
| | shall be EUR 9 800 for the rapporteur and | | be, in accordance with Article | |
| | EUR 7 600 for the co-rapporteur. | | 66(3) of Regulation (EU) | |

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| | | | | proposals and |
| | | | 0 | comments |
| | | | 2019/6. The remuneration shall | |
| | | | be EUR 9 800- <u>10 300</u> for the | |
| | | | rapporteur and EUR 7 600 8 000 | |
| | | | for the co-rapporteur. | |
| 289 | 6.3. A fee of EUR 23 900 shall apply to | | 6.3. A fee of EUR 23 900 25 | |
| | variations requiring assessment introducing | | 200 shall apply to variations | |
| | quality changes only, which are to be | | requiring assessment | |
| | assessed within 60 days in accordance with | | introducing quality changes | |
| | Article 66(3) of Regulation (EU) 2019/6. | | only, which are to be assessed | |
| | The remuneration shall be EUR 3 600 for | | within 60 days in accordance | |
| | the rapporteur and EUR 3 600 for the co- | | with Article 66(3) of Regulation | |
| | rapporteur. | | (EU) 2019/6. The remuneration | |
| | | | shall be EUR <u>3-600-3 800</u> for | |
| | | | the rapporteur and EUR 3-600 | |
| | | | 3 800 for the co-rapporteur. | |
| 290 | 6.4. Where several variations requiring | | 6.4. Where several variations | |
| | assessment are grouped in a single | | requiring assessment are | |
| | application under Article 64 of Regulation | | grouped in a single application | |
| | (EU) 2019/6, the corresponding fee as set | | under Article 64 of Regulation | |

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| | | | | comments |
| | out in points 6.1, 6.2 and 6.3 of this Annex | | (EU) 2019/6, the corresponding | |
| | shall apply to each of the first two | | fee as set out in points 6.1, 6.2 | |
| | variations. Remuneration shall be paid in | | and 6.3 of this Annex shall | |
| | accordance with those points. For the third | | apply to each of the first two | |
| | and subsequent variations, the fee shall be | | variations. Remuneration shall | |
| | EUR 12 000 per variation and the | | be paid in accordance with those | |
| | remuneration shall be EUR 1 800 per | | points. For the third and | |
| | variation for the rapporteur and EUR 1 800 | | subsequent variations, the fee | |
| | for the co-rapporteur. | | shall be EUR <u>12 000 12 600</u> per | |
| | | | variation and the remuneration | |
| | | | shall be EUR <u>1 800 1 900</u> per | |
| | | | variation for the rapporteur and | |
| | | | EUR <u>1 800 <u>1</u> 900 for the co-</u> | |
| | | | rapporteur. | |
| 291 | 6.5. Where a work-sharing application | | 6.5. Where a work-sharing | 6.5. Where a work- |
| | pursuant to Article 65 of Regulation (EU) | | application pursuant to Article | sharing application |
| | 2019/6 includes more than one centrally | | 65 of Regulation (EU) 2019/6 | pursuant to Article 65 of |
| | authorised product, the fees and | | includes more than one centrally | Regulation (EU) 2019/6 |
| | remuneration specified in points 6.1, 6.2 | | authorised product, the fees and | includes more than one |

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| | | | | comments |
| _ | and 6.3 of this Annex shall apply for each | | remuneration specified in points | centrally authorised |
| | variation to the first centrally authorised | | 6.1, 6.2 and 6.3 of this Annex | product, the fees and |
| | product, whereas a charge of EUR 800 shall | | shall apply for each variation to | remuneration specified |
| | apply for each variation to the second and | | the first centrally authorised | in points 6.1, 6.2 and 6.3 |
| | subsequent centrally authorised product | | product, whereas a charge of | of this Annex shall |
| | included in the same application. | | EUR 800 shall apply for each | apply for each variation |
| | | | variation to the second and | to the first centrally |
| | | | subsequent centrally authorised | authorised product, |
| | | | product included in the same | whereas a charge of |
| | | | application. | EUR 800 shall apply for |
| | | | | each variation to the |
| | | | | second and subsequent |
| | | | | centrally authorised |
| | | | | product included in the |
| | | | | same application. |
| 292 | 7. Referrals and arbitration procedures | | 7. Referrals and arbitration | 7. Referrals and |
| | | | procedures | arbitration procedures |
| 293 | 7.1. A fee of EUR 152 700 shall apply to an | 7.1. A fee of EUR 152 700 | 7.1. A fee of EUR 152 | |
| | assessment carried out in the context of a | shall apply to an assessment | 700 161 000 shall apply to an | |

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| | | | | proposals and |
| | | | 0 | comments |
| | procedure initiated under Article 54(8) of | carried out in the context of a | assessment carried out in the | |
| | Regulation (EU) 2019/6. Such fee shall be | procedure initiated under Article | context of a procedure initiated | |
| | waived in full. The remuneration shall be | 54(8) of Regulation (EU) 2019/6. | under Article 54(8) of | |
| | EUR 21 100 for the rapporteur and EUR 9 | Such fee shall be waived in full. | Regulation (EU) 2019/6. Such | |
| | 600 for the co-rapporteur. | The remuneration shall be EUR | fee shall be waived in full. The | |
| | | 10 550 for the rapporteur and | remuneration shall be EUR 21 | |
| | | EUR 4 800 for the co-rapporteur. | 100-22 200 for the rapporteur | |
| | | | and EUR 9-600-10 100 for the | |
| | | | co-rapporteur. | |
| 294 | 7.2. A fee of EUR 209 300 shall apply to | 7.2. A fee of EUR 209 300 | 7.2. A fee of EUR 209 300 | |
| | the assessment carried out in the context of | shall apply to the assessment | 220 600 shall apply to the | |
| | a procedure initiated under Article 70(11) of | carried out in the context of a | assessment carried out in the | |
| | Regulation (EU) 2019/6. Such fee shall be | procedure initiated under Article | context of a procedure initiated | |
| | waived in full. The remuneration shall be | 70(11) of Regulation (EU) | under Article 70(11) of | |
| | EUR 29 200 for the rapporteur and EUR 12 | 2019/6. Such fee shall be waived | Regulation (EU) 2019/6. Such | |
| | 900 for the co-rapporteur. | in full. The remuneration shall be | fee shall be waived in full. The | |
| | | EUR 14 600 for the rapporteur | remuneration shall be EUR 29 | |
| | | and EUR 6 450 for the co- | 200-30 800 for the rapporteur | |
| | | rapporteur. | | |

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| | | | | proposals and |
| | | | 0/ | comments |
| | | | and EUR 12 900 13 600 for the | |
| | | | co-rapporteur. | |
| 295 | 7.3. A fee of EUR 147 200 shall apply to | 7.3. A fee of EUR 147 200 | 7.3. A fee of EUR 147 200 | |
| | the assessment carried out pursuant to | shall apply to the assessment | <u>155 200</u> shall apply to the | |
| | Article 141(1), points (c) and (e), of | carried out pursuant to Article | assessment carried out pursuant | |
| | Regulation (EU) 2019/6. Such fee shall be | 141(1), points (c) and (e), of | to Article 141(1), points (c) and | |
| | waived in full. The remuneration shall be | Regulation (EU) 2019/6. Such fee | (e), of Regulation (EU) 2019/6. | |
| | EUR 17 500 for the rapporteur and EUR 7 | shall be waived in full. The | Such fee shall be waived in full. | |
| | 700 for the co-rapporteur. | remuneration shall be EUR 8 750 | The remuneration shall be EUR | |
| | | for the rapporteur and EUR 3 850 | 17 500 18 400 for the rapporteur | |
| | | for the co-rapporteur. | and EUR 7 700 <u>8</u> 100 for the co- | |
| | | | rapporteur. | |
| 296 | 7.4. A fee of EUR 209 300 shall apply to | | 7.4. A fee of EUR 209 300 | |
| | the assessment carried out in the context of | | 220 600 shall apply to the | |
| | a procedure initiated under Article 82 of | | assessment carried out in the | |
| | Regulation (EU) 2019/6. The remuneration | | context of a procedure initiated | |
| | shall be EUR 29 200 for the rapporteur and | | under Article 82 of Regulation | |
| | EUR 12 900 for the co-rapporteur. | | (EU) 2019/6. The remuneration | |
| | | | shall be EUR 29 200 - <u>30 800</u> for | |

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| | | | | proposals and |
| | | | | comments |
| | | | the rapporteur and EUR 12 900 | |
| | | | 13 600 for the co-rapporteur. | |
| 297 | 7.5. A fee of EUR 147 200 shall apply for | | 7.5. A fee of EUR 147 200 | |
| | the assessment carried out in the context of | | 155 200 shall apply for the | |
| | a procedure initiated under Article 129(3) or | | assessment carried out in the | |
| | Article 130(4) of Regulation (EU) 2019/6. | | context of a procedure initiated | |
| | The remuneration shall be EUR 17 500 for | | under Article 129(3) or Article | |
| | the rapporteur and EUR 7 700 for the co- | | 130(4) of Regulation (EU) | |
| | rapporteur. | | 2019/6. The remuneration shall | |
| | | | be EUR 17 500 18 400 for the | |
| | | | rapporteur and EUR 7-700-<u>8 100</u> | |
| | | | for the co-rapporteur. | |
| 298 | 7.6. Where two or more marketing | | 7.6. Where two or more | 7.6. Where two or |
| | authorisation holders are involved in the | | marketing authorisation holders | more marketing |
| | procedures referred to in points 7.4 or 7.5, | | are involved in the procedures | authorisation holders are |
| | the amount payable by each marketing | | referred to in points 7.4 or 7.5, | involved in the |
| | authorisation holder shall be calculated by | | the amount payable by each | procedures referred to in |
| | the Agency in two steps, as follows: | | marketing authorisation holder | points 7.4 or 7.5, the |
| | | | | amount payable by each |

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| | | | | proposals and |
| | | | | comments |
| | | | shall be calculated by the | marketing authorisation |
| | | | Agency in two steps, as follows: | holder shall be |
| | | | | calculated by the |
| | | | | Agency in two steps, as |
| | | | | follows: |
| 299 | (a) by dividing the total amount of the fee | | (a) by dividing the total amount | (a) by dividing the total |
| | among the marketing authorisation holders | | of the fee among the marketing | amount of the fee among |
| | proportionally to the number of chargeable | | authorisation holders | the marketing |
| | units – veterinary corresponding to products | | proportionally to the number of | authorisation holders |
| | included in the procedure which are held by | | chargeable units – veterinary | proportionally to the |
| | each of those marketing authorisation | | corresponding to products | number of chargeable |
| | holders; | | included in the procedure which | units – veterinary |
| | | | are held by each of those | corresponding to |
| | | | marketing authorisation holders; | products included in the |
| | | | | procedure which are |
| | | | | held by each of those |
| | | | | marketing authorisation |
| | | | | holders; |

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| | | | | proposals and |
| | | | 0 | comments |
| 300 | (b) by subsequently applying the fee | | (b) by subsequently applying the | (b) by subsequently |
| | reduction laid down in point 1 of Annex V, | | fee reduction laid down in point | applying the fee |
| | where relevant. | | 1 of Annex V, where relevant. | reduction laid down in |
| | | | | point 1 of Annex V, |
| | | | | where relevant. |
| 301 | 8. Certification of compliance with | | 8. Certification of | 8. Certification of |
| | Union legislation for vaccine antigen master | | compliance with Union | compliance with Union |
| | files (VAMF) | | legislation for vaccine antigen | legislation for vaccine |
| | | | master files (VAMF) | antigen master files |
| | | | | (VAMF) |
| 302 | 8.1. A fee of EUR 23 900 shall apply to an | | 8.1. A fee of EUR 23 900 | |
| | application for review of a VAMF and its | | 25 200 shall apply to an | |
| | certification pursuant to point V.2 of Annex | | application for review of a | |
| | II to Regulation (EU) 2019/6 when it is | | VAMF and its certification | |
| | submitted simultaneously with an initial | | pursuant to point V.2 of Annex | |
| | application for marketing authorisation for a | | II to Regulation (EU) 2019/6 | |
| | veterinary medicinal product under the | | when it is submitted | |
| | centralised procedure containing the named | | simultaneously with an initial | |
| | antigen. The remuneration shall be EUR 3 | | application for marketing | |

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| | | | 0 | comments |
| | 600 for the rapporteur and EUR 3 600 for | | authorisation for a veterinary | |
| | the co-rapporteur. | | medicinal product under the | |
| | | | centralised procedure containing | |
| | | | the named antigen. The | |
| | | | remuneration shall be EUR 3 | |
| | | | 600-3 800 for the rapporteur and | |
| | | | EUR 3-600-3 800 for the co- | |
| | | | rapporteur. | |
| 303 | 8.2. For multiple VAMF applications | | 8.2. For multiple VAMF | |
| | submitted simultaneously in the context of | | applications submitted | |
| | the same initial marketing authorisation | | simultaneously in the context of | |
| | application, a fee of EUR 23 900 shall apply | | the same initial marketing | |
| | per VAMF. The maximum total amount | | authorisation application, a fee of | |
| | charged by the Agency shall not exceed | | EUR 23 900 25 200 shall apply | |
| | EUR 71 700. The remuneration shall be | | per VAMF. The maximum total | |
| | EUR 3 600 for the rapporteur and EUR 3 | | amount charged by the Agency | |
| | 600 for the co-rapporteur. For multiple | | shall not exceed EUR 71 700 <u>74</u> | |
| | VAMF applications submitted | | 800 . The remuneration shall be | |
| | simultaneously in the context of the same | | EUR <u>3 600 3</u> 800 for the | |

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| | | | | proposals and |
| | | | 0 | comments |
| | initial marketing authorisation application, | | rapporteur and EUR 3 600 3 800 | |
| | the remuneration shall not exceed EUR 10 | | for the co-rapporteur. For | |
| | 800 for the rapporteur and EUR 10 800 for | | multiple VAMF applications | |
| | the co-rapporteur. | | submitted simultaneously in the | |
| | | | context of the same initial | |
| | | | marketing authorisation | |
| | | | application, the remuneration | |
| | | | shall not exceed EUR 10 800-11 | |
| | | | 400 for the rapporteur and EUR | |
| | | | 10 800 <u>11 400</u> for the co- | |
| | | | rapporteur. | |
| 304 | 8.3. A fee of EUR 33 100 shall apply to an | | 8.3. A fee of EUR 33 100 <u>34</u> | |
| | application for the review of a VAMF and | | 900 shall apply to an application | |
| | its certification when submitted as a | | for the review of a VAMF and | |
| | separate application for an antigen in | | its certification when submitted | |
| | vaccine(s) already authorised under the | | as a separate application for an | |
| | centralised, decentralised or mutual | | antigen in vaccine(s) already | |
| | recognition procedure. The remuneration | | authorised under the centralised, | |
| | | | decentralised or mutual | |

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| | | | | proposals and |
| | | | | comments |
| | shall be EUR 5 000 for the rapporteur and | | recognition procedure. The | |
| | EUR 5 000 for the co-rapporteur. | | remuneration shall be EUR 5 | |
| | | | 000-5 300 for the rapporteur and | |
| | | | EUR <u>5 000 <u>5</u> 300 for the co-</u> | |
| | | | rapporteur. | |
| 305 | 8.4. Section 6 [of this Annex] shall apply by | | 8.4. Section 6 [of this Annex] | 8.4. Section 6 fof this |
| | analogy to variations to a certified VAMF. | | shall apply by analogy to | Annex} shall apply by |
| | | | variations to a certified VAMF. | analogy to variations to |
| | | | | a certified VAMF. |
| 306 | 9. Certification of compliance with | | 9. Certification of | 9. Certification of |
| | Union legislation for vaccine platform | | compliance with Union | compliance with Union |
| | technology master files (vPTMF) | | legislation for vaccine platform | legislation for vaccine |
| | | | technology master files | platform technology |
| | | | (vPTMF) | master files (vPTMF) |
| 307 | 9.1. A fee of EUR 23 900 shall apply to an | | 9.1. A fee of EUR 23 900 <u>25</u> | |
| | application for review of a vPTMF and its | | 200 shall apply to an application | |
| | certification pursuant to point V.4 of Annex | | for review of a vPTMF and its | |
| | II to Regulation (EU) 2019/6 when | | certification pursuant to point | |
| | submitted simultaneously with an initial | | V.4 of Annex II to Regulation | |

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| | | | | proposals and |
| | | | 0 | comments |
| | application for marketing authorisation for a | | (EU) 2019/6 when submitted | |
| | veterinary medicinal product under the | | simultaneously with an initial | |
| | centralised procedure containing the named | | application for marketing | |
| | platform. The remuneration shall be EUR 3 | | authorisation for a veterinary | |
| | 600 for the rapporteur and EUR 3 600 for | | medicinal product under the | |
| | the co-rapporteur. | | centralised procedure containing | |
| | | | the named platform. The | |
| | | | remuneration shall be EUR 3 | |
| | | | 600-3 800 for the rapporteur and | |
| | | | EUR 3 600 3 800 for the co- | |
| | | | rapporteur. | |
| 308 | 9.2. A fee of EUR 33 100 shall apply to an | | 9.2. A fee of EUR 33 100 <u>34</u> | |
| | application for review of a vPTMF and its | | 900 shall apply to an application | |
| | certification when submitted as a separate | | for review of a vPTMF and its | |
| | application for a platform in vaccines | | certification when submitted as | |
| | already authorised under the centralised, | | a separate application for a | |
| | decentralised or mutual recognition | | platform in vaccines already | |
| | procedure. The remuneration shall be EUR | | authorised under the centralised, | |
| | | | decentralised or mutual | |

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| | | | | proposals and |
| | | | | comments |
| | 5 000 for the rapporteur and EUR 5 000 for | | recognition procedure. The | |
| | the co-rapporteur. | | remuneration shall be EUR 5 | |
| | | | 000-5 300 for the rapporteur and | |
| | | | EUR <u>5 000 5 300</u> for the co- | |
| | | | rapporteur. | |
| 309 | 9.3. Section 6 of this Annex shall apply | | 9.3. Section 6 of this Annex | 9.3. Section 6 of this |
| | by analogy to variations to a certified | | shall apply by analogy to | Annex shall apply by |
| | vPTMF. | | variations to a certified vPTMF. | analogy to variations to |
| | | | | a certified vPTMF. |
| 310 | 10. Assessment of post-marketing | | 10. Assessment of post- | 10. Assessment of |
| | surveillance studies | | marketing surveillance studies | post-marketing |
| | | | | surveillance studies |
| 311 | 10.1. A fee of EUR 37 800 shall apply to | | 10.1. A fee of EUR 37 800 | |
| | the assessment of post-marketing | | 39 800 shall apply to the | |
| | surveillance studies pursuant to Article | | assessment of post-marketing | |
| | 76(3) of Regulation (EU) 2019/6 that are | | surveillance studies pursuant to | |
| | conducted in more than one Member States. | | Article 76(3) of Regulation (EU) | |
| | | | 2019/6 that are conducted in | |
| | | | more than one Member States. | |

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| | | | | proposals and |
| | | | | comments |
| 312 | 10.2. The fee shall be charged as follows: | | 10.2. The fee shall be charged | 10.2. The fee shall be |
| | | | as follows: | charged as follows: |
| 313 | (a) EUR 18 900 shall be due at the date of | | (a) EUR 18 900 19 900 shall | |
| | the start of the procedure for the approval of | | be due at the date of the start of | |
| | the draft study protocol as referred to in | | the procedure for the approval of | |
| | Article 15(3) of Commission Implementing | | the draft study protocol as | |
| | Regulation (EU) 2021/1281 ⁶⁵ . The | | referred to in Article 15(3) of | |
| | remuneration shall be EUR 7 700 for the | | Commission Implementing | |
| | rapporteur; | | Regulation (EU) 2021/1281 ⁶⁶ . | |
| | | | The remuneration shall be EUR | |
| | 65 Commission Implementing Regulation (EU) | | 7 700 <u>8 100</u> for the rapporteur; | |
| | 2021/1281 of 2 August 2021 laying down rules for | | | |
| | the application of Regulation (EU) 2019/6 of the | | ⁶⁶ Commission Implementing | |
| | European Parliament and of the Council as regards | | Regulation (EU) 2021/1281 of 2 | |
| | good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance | | August 2021 laying down rules for the | |
| | system master file for veterinary medicinal products | | application of Regulation (EU) 2019/6 | |
| | (OJ L 279, 3.8.2021, p. 15). | | of the European Parliament and of the | |
| | (O3 E 277, 3.0.2021, p. 13). | | Council as regards good | |
| | | | pharmacovigilance practice and on the | |
| | | | format, content and summary of the | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | | | pharmacovigilance system master file | |
| | | | for veterinary medicinal products (OJ | |
| | | | L 279, 3.8.2021, p. 15). | |
| 314 | (b) EUR 18 900 shall be due at the date of | | (b) EUR 18 900 <u>19 900</u> shall | |
| | the start of the procedure for the assessment | | be due at the date of the start of | |
| | of the final study report as referred to in | | the procedure for the assessment | |
| | Article 15(5) of Implementing Regulation | | of the final study report as | |
| | (EU) 2021/1281. The remuneration shall be | | referred to in Article 15(5) of | |
| | EUR 7 700 for the rapporteur. | | Implementing Regulation (EU) | |
| | | | 2021/1281. The remuneration | |
| | | | shall be EUR 7 700 <u>8 100</u> for | |
| | | | the rapporteur. | |
| 315 | 10.3. Where the obligation to conduct a | | 10.3. Where the obligation to | 10.3. Where the |
| | post-authorisation surveillance study is | | conduct a post-authorisation | obligation to conduct a |
| | imposed on more than one marketing | | marketing surveillance study is | post-authorisation |
| | authorisation holder and the marketing | | imposed on more than one | marketing surveillance |
| | authorisation holders concerned conduct a | | marketing authorisation holder | study is imposed on |
| | joint post-authorisation safety study, the | | and the marketing authorisation | more than one |
| | | | holders concerned conduct a | marketing authorisation |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | 0 | comments |
| | Agency shall calculate the fee to be charged | | joint post-authorisation safety | holder and the |
| | in two steps, as follows: | | marketing surveillance study, | marketing authorisation |
| | | | the Agency shall calculate the | holders concerned |
| | | | fee to be charged in two steps, | conduct a joint post- |
| | | | as follows: | authorisation safety |
| | | | | marketing surveillance |
| | | | | study, the Agency shall |
| | | | | calculate the fee to be |
| | | | | charged in two steps, as |
| | | | | follows: |
| | | | | 12/09 to match the |
| | | | | section title |
| 316 | (a) by evenly dividing the total amount | | (a) by evenly dividing the | (a) by evenly |
| | of the fee among those marketing | | total amount of the fee among | dividing the total |
| | authorisation holders; | | those marketing authorisation | amount of the fee among |
| | | | holders; | those marketing |
| | | | | authorisation holders; |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | 0 | comments |
| 317 | (b) by subsequently applying the fee | | (b) by subsequently | (b) by subsequently |
| | reduction as set out in Annex V, point 1, | | applying the fee reduction as set | applying the fee |
| | where relevant. | | out in Annex V, point 1, where | reduction as set out in |
| | | | relevant. | Annex V, point 1, where |
| | | | | relevant. |
| 318 | 11. Scientific opinions in the context of | | 11. Scientific opinions in the | 11. Scientific |
| | cooperation with international organisations | | context of cooperation with | opinions in the context |
| | for animal health for the evaluation of | | international organisations for | of cooperation with |
| | veterinary medicinal products intended | | animal health for the evaluation | international |
| | exclusively for markets outside the Union | | of veterinary medicinal products | organisations for animal |
| | | | intended exclusively for markets | health for the evaluation |
| | | | outside the Union | of veterinary medicinal |
| | | | | products intended |
| | | | | exclusively for markets |
| | | | | outside the Union |
| 319 | A fee and corresponding remuneration as | | A fee and corresponding | A fee and corresponding |
| | specified in points 1, 3, 4 and 6 of this | | remuneration as specified in | remuneration as |
| | Annex and in points 1, 3, 4 and 5 of Annex | | points 1, 3, 4 and 6 of this | specified in points 1, 3, |
| | IV and points 6.1, 6.2 and 6.4 of that Annex | | Annex and in points 1, 3, 4 and | 4 and 6 of this Annex |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | to this Regulation shall apply for an | | 5 of Annex IV and points 6.1, | and in points 1, 3, 4 and |
| | application for a scientific opinion for the | | 6.2 and 6.4 of that Annex to this | 5 of Annex IV and |
| | evaluation of veterinary medicinal products | | Regulation shall apply for an | points 6.1, 6.2 and 6.4 of |
| | intended exclusively for markets outside the | | application for a scientific | that Annex to this |
| | Union pursuant to Article 138 of Regulation | | opinion for the evaluation of | Regulation shall apply |
| | (EU) 2019/6. | | veterinary medicinal products | for an application for a |
| | | | intended exclusively for markets | scientific opinion for the |
| | | | outside the Union pursuant to | evaluation of veterinary |
| | | | Article 138 of Regulation (EU) | medicinal products |
| | | | 2019/6. | intended exclusively for |
| | | | | markets outside the |
| | | | | Union pursuant to |
| | | | | Article 138 of |
| | | | | Regulation (EU) 2019/6. |
| 320 | ANNEX III | | ANNEX III | ANNEX III |
| | Annual fees and remuneration | | Annual fees and remuneration | Annual fees and |
| | | | | remuneration |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| 321 | 1. Annual fee for medicinal products | | 1. Annual fee for medicinal | 1. Annual fee for |
| | for human use authorised in accordance | | products for human use | medicinal products for |
| | with Regulation (EC) No 726/2004 | | authorised in accordance with | human use authorised in |
| | | | Regulation (EC) No 726/2004 | accordance with |
| | | | | Regulation (EC) No |
| | | | | 726/2004 |
| 322 | 1.1. An annual fee of EUR 48 900 shall | | 1.1. An annual fee of EUR 48 | |
| | apply to each marketing authorisation of a | | 900 57 700 shall apply to each | |
| | medicinal product for human use authorised | | marketing authorisation of a | |
| | on the basis of an application submitted | | medicinal product for human | |
| | under Article 10(1) and (3) and Article 10c | | use authorised on the basis of an | |
| | of Directive 2001/83/EC. The remuneration | | application submitted under | |
| | shall be EUR 6 400 for the rapporteur and | | Article 10(1) and (3) and Article | |
| | EUR 5 600 for the co-rapporteur. | | 10c of Directive 2001/83/EC. | |
| | | | The remuneration shall be EUR | |
| | | | 6 400 7 700 for the rapporteur | |
| | | | and, EUR 5 600 6 700 for the | |
| | | | co-rapporteur and EUR 1 400 | |
| | | | for the PRAC-rapporteur. | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
|-----|--|---------------------------|--|--------------------|
| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | 0 | comments |
| 323 | 1.2. An annual fee of EUR 95 600 shall | | 1.2. An annual fee of EUR 95 | |
| | apply to each marketing authorisation of a | | 600 113 000 shall apply to each | |
| | medicinal product for human use authorised | | marketing authorisation of a | |
| | on the basis of an application submitted | | medicinal product for human | |
| | under Article 10(4) of Directive | | use authorised on the basis of an | |
| | 2001/83/EC. The remuneration shall be | | application submitted under | |
| | EUR 12 900 for the rapporteur and EUR 11 | | Article 10(4) of Directive | |
| | 400 for the co-rapporteur. | | 2001/83/EC. The remuneration | |
| | | | shall be EUR <u>12 900 <u>15 500</u> for</u> | |
| | | | the rapporteur and EUR 11 400 | |
| | | | 13 700 for the co-rapporteur and | |
| | | | EUR 2 900 for the PRAC- | |
| | | | rapporteur. | |
| 324 | 1.3. An annual fee of EUR 188 000 shall | | 1.3. An annual fee of EUR | |
| | apply to each marketing authorisation of a | | 188 000 222 300 shall apply to | |
| | medicinal product for human use not | | each marketing authorisation of | |
| | covered by point 1.1 or 1.2. The | | a medicinal product for human | |
| | remuneration shall be EUR 25 700 for the | | use not covered by point 1.1 or | |
| | | | 1.2. The remuneration shall be | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| | rapporteur and EUR 22 700 for the co- | | EUR 25 700-30 800 for the | |
| | rapporteur. | | rapporteur and EUR 22 700 | |
| | | | 27 200 for the co-rapporteur and | |
| | | | EUR 5 800 for the PRAC- | |
| | | | rapporteur. | |
| 324a | | | 1.3a. The annual fees as | |
| | | | specified in points 1.1, 1.2 and | |
| | | | 1.3 shall relate to the | |
| | | | preceding year. | |
| 325 | 2. Annual fee for veterinary medicinal | | 2. Annual fee for veterinary | 2. Annual fee for |
| | products authorised through the centralised | | medicinal products authorised | veterinary medicinal |
| | procedure in accordance with Regulation | | through the centralised | products authorised |
| | (EU) 2019/6 | | procedure in accordance with | through the centralised |
| | | | Regulation (EU) 2019/6 | procedure in accordance |
| | | | | with Regulation (EU) |
| | | | | 2019/6 |
| 326 | 2.1. An annual fee of EUR 21 500 for shall | | 2.1. An annual fee of EUR 21 | |
| | apply for each marketing authorisation of a | | 500 <u>25 000</u> for shall apply for | |
| | veterinary medicinal product authorised | | each marketing authorisation of | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| | pursuant to Article 18, 19 or 21 of | | a veterinary medicinal product | |
| | Regulation (EU) 2019/6. The remuneration | | authorised pursuant to Article | |
| | shall be EUR 5 000 for the rapporteur and | | 18, 19 or 21 of Regulation (EU) | |
| | EUR 4 600 for the co-rapporteur. | | 2019/6. The remuneration shall | |
| | | | be EUR 5 0006 000 for the | |
| | | | rapporteur and EUR 4-600 <u>5 500</u> | |
| | | | for the co-rapporteur. | |
| 327 | 2.2. An annual fee of EUR 87 500 shall | | 2.2 An annual fee of EUR 87 | |
| | apply to each marketing authorisation not | | 500 <u>101 800</u> shall apply to each | |
| | covered by point 2.1. The remuneration | | marketing authorisation not | |
| | shall be EUR 20 400 for the rapporteur and | | covered by point 2.1. The | |
| | EUR 18 800 for the co-rapporteur. | | remuneration shall be EUR 20 | |
| | | | 400 <u>24 500</u> for the rapporteur | |
| | | | and EUR 18 80022 600 for the | |
| | | | co-rapporteur. | |
| 327a | | | 2.2a. The annual fees as | |
| | | | specified in points 2.1 and 2.2 | |
| | | | shall relate to the preceding | |
| | | | <u>vear.</u> | |

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| | | | | proposals and |
| | | | | comments |
| 328 | 3. Annual pharmacovigilance fee for | | 3. Annual | 3. Annual |
| | medicinal products for human use | | pharmacovigilance fee for | pharmacovigilance fee |
| | authorised in accordance with Directive | | medicinal products for human | for medicinal products |
| | 2001/83/EC and for veterinary medicinal | | use authorised in accordance | for human use |
| | products authorised by competent | | with Directive 2001/83/EC and | authorised in accordance |
| | authorities of the Member States in | | for veterinary medicinal | with Directive |
| | accordance with Regulation (EU) 2019/6 | | products authorised by | 2001/83/EC and for |
| | | | competent authorities of the | veterinary medicinal |
| | | | Member States in accordance | products authorised by |
| | | | with Regulation (EU) 2019/6 | competent authorities of |
| | | | | the Member States in |
| | | | | accordance with |
| | | | | Regulation (EU) 2019/6 |
| 329 | 3.1. For medicinal products for human use | | 3.1. For medicinal products | |
| | authorised in accordance with Directive | | for human use authorised in | |
| | 2001/83/EC, a fee of EUR 190 per | | accordance with Directive | |
| | chargeable unit-human, shall apply once per | | 2001/83/EC, a fee of EUR 190 | |
| | year for the Agency's pharmacovigilance | | 220 per chargeable unit-human, | |
| | activities including analysis of Union-wide | | shall apply once per year for the | |

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| | | | | proposals and |
| | | | | comments |
| | health data to support better decision- | | Agency's pharmacovigilance | |
| | making with real world evidence. The | | activities including analysis of | |
| | Agency shall retain the fee revenue from the | | Union-wide health data to | |
| | annual pharmacovigilance fee. | | support better decision-making | |
| | | | with real world evidence. The | |
| | | | Agency shall retain the fee | |
| | | | revenue from the annual | |
| | | | pharmacovigilance fee. | |
| 330 | 3.2. For veterinary medicinal products | | 3.2 For veterinary medicinal | |
| | authorised by competent authorities of the | | products authorised by | |
| | Member States in accordance with Chapter | | competent authorities of the | |
| | III, Sections 2 to 5 of Regulation (EU) | | Member States in accordance | |
| | 2019/6, a fee of EUR 80 per chargeable | | with Chapter III, Sections 2 to 5 | |
| | unit-veterinary shall apply once per year for | | of Regulation (EU) 2019/6, a fee | |
| | the Agency's pharmacovigilance activities. | | of EUR 80-90 per chargeable | |
| | The Agency shall retain the fee revenue | | unit-veterinary shall apply once | |
| | from the annual pharmacovigilance fee. | | per year for the Agency's | |
| | | | pharmacovigilance activities. | |
| | | | The Agency shall retain the fee | |

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| | | | | proposals and |
| | | | | comments |
| | | | revenue from the annual | |
| | | | pharmacovigilance fee. | |
| 331 | 3.3 The total payable amount of the | | 3.3 The total payable amount | 3.3 The total payable |
| | annual fees referred to in points 3.1 and 3.2 | | of the annual fees referred to in | amount of the annual |
| | for each marketing authorisation holder | | points 3.1 and 3.2 for each | fees referred to in points |
| | shall be calculated by the Agency on the | | marketing authorisation holder | 3.1 and 3.2 for each |
| | basis of the number of chargeable units- | | shall be calculated by the | marketing authorisation |
| | human and chargeable units-veterinary, | | Agency on the basis of the | holder shall be |
| | respectively, which correspond to the | | number of chargeable units- | calculated by the |
| | information recorded on 1 July of each year. | | human and chargeable units- | Agency on the basis of |
| | | | veterinary, respectively, which | the number of |
| | | | correspond to the information | chargeable units-human |
| | | | recorded on 1 July of each year. | and chargeable units- |
| | | | | veterinary, respectively, |
| | | | | which correspond to the |
| | | | | information recorded on |
| | | | | 1 July of each year. |
| 332 | 3.4. The annual fees referred to in points | | 3.4. The annual fees referred | 3.4. The annual fees |
| | 3.1 and 3.2 shall be due on 1 July of every | | to in points 3.1 and 3.2 shall be | referred to in points 3.1 |

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| | | | | proposals and |
| | | | | comments |
| | year and shall cover the period from 1 | | due on 1 July of every year and | and 3.2 shall be due on 1 |
| | January to 31 December of that calendar | | shall cover the period from 1 | July of every year and |
| | year. | | January to 31 December of that | shall cover the period |
| | | | calendar year. | from 1 January to 31 |
| | | | | December of that |
| | | | | calendar year. |
| 333 | ANNEX IV | | ANNEX IV | ANNEX IV |
| | Other fees and charges for medicinal | | Other fees and charges for | Other fees and charges |
| | products for human use, veterinary | | medicinal products for human | for medicinal products |
| | medicinal products and consultations on | | use, veterinary medicinal | for human use, |
| | medical devices | | products and consultations on | veterinary medicinal |
| | | | medical devices | products and |
| | | | | consultations on medical |
| | | | | devices |
| 334 | 1. Inspections pursuant to Article 8(2), 19 | | 1. Inspections pursuant to | |
| | and Article 57(1), point (i) of Regulation | | Article 8(2), 19 and Article | |
| | (EC) No 726/2004 | | 57(1), point (i) of Regulation | |
| | | | (EC) No 726/2004 and Article | |
| | | | 126(2) of Regulation No 2019/6 | |

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| | | | | proposals and |
| | | | | comments |
| 335 | 1.1. Inspections in relation to medicinal | | 1.1. Inspections in relation to | 1.1. Inspections in |
| | products for human use and veterinary | | medicinal products for human | relation to medicinal |
| | medicinal products | | use and veterinary medicinal | products for human use |
| | | | products | and veterinary medicinal |
| | | | | products |
| 336 | 1.1.1. For any distinct Good Manufacturing | | 1.1.1. For any distinct Good | |
| | Practice inspection within the Union a fee | | Manufacturing Practice | |
| | of EUR 24 800 shall apply. The | | inspection within the Union a | |
| | remuneration shall be EUR 8 600 for the | | fee of EUR 24-80029 000 shall | |
| | leading supervisory authority and EUR 5 | | apply. The remuneration shall be | |
| | 200 for the supporting supervisory | | EUR <u>8 600</u> 10 300 for the | |
| | authority. | | leading supervisory authority | |
| | | | and EUR <u>5 2006 200</u> for the | |
| | | | supporting supervisory | |
| | | | authority. | |
| 337 | 1.1.2. For any distinct Good Manufacturing | | 1.1.2. For any distinct Good | |
| | Practice inspection outside the Union a fee | | Manufacturing Practice | |
| | of EUR 37 800 shall apply. The | | inspection outside the Union a | |
| | remuneration shall be EUR 15 600 for the | | fee of EUR 37_800-56 000 shall | |

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| | | | | proposals and |
| | | | 0 | comments |
| | leading supervisory authority and EUR 9 | | apply. The remuneration shall be | |
| | 400 for the supporting supervisory | | EUR 15_600_24 800 for the | |
| | authority. | | leading supervisory authority | |
| | | | and EUR 9_400_16 700 for the | |
| | | | supporting supervisory | |
| | | | authority. | |
| 338 | 1.1.3. For any distinct Good Clinical | | 1.1.3. For any distinct Good | |
| | Practice inspection within the Union a fee | | Clinical Practice inspection | |
| | of EUR 37 100 shall apply. The | | within the Union a fee of EUR | |
| | remuneration shall be EUR 14 700 for the | | 37 100 <u>43 700</u> shall apply. The | |
| | leading supervisory authority and EUR 9 | | remuneration shall be EUR 14 | |
| | 100 for the supporting supervisory | | 700 <u>17 600</u> for the leading | |
| | authority. | | supervisory authority and EUR | |
| | | | 9 100 10 900 for the supporting | |
| | | | supervisory authority. | |
| 339 | 1.1.4. For any distinct Good Clinical | | 1.1.4. For any distinct Good | |
| | Practice inspection outside the Union a fee | | Clinical Practice inspection | |
| | of EUR 44 200 shall apply. The | | outside the Union a fee of EUR | |
| | remuneration shall be EUR 19 600 for the | | 44 200 <u>56 600</u> shall apply. The | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | 0 | comments |
| | leading supervisory authority and EUR 10 | | remuneration shall be EUR 19 | |
| | 400 for the supporting supervisory | | 600-25 800 for the leading | |
| | authority. | | supervisory-authority and EUR | |
| | | | 10 400 14 700 for the | |
| | | | supporting supervisory | |
| | | | authority. | |
| 340 | 1.1.5. For any distinct Plasma Master File | | 1.1.5. For any distinct Plasma | |
| | inspection within or outside the Union a fee | | Master File inspection within or | |
| | of EUR 36 100 shall apply. The | | outside the Union a fee of EUR | |
| | remuneration shall be EUR 13 400 for the | | 36 100 47 300 shall apply. The | |
| | leading supervisory authority and EUR 8 | | remuneration shall be EUR-13 | |
| | 200 for the supporting supervisory | | 400 <u>16 700</u> for the leading | |
| | authority. | | supervisory authority and EUR | |
| | | | 8 200 <u>14 100</u> for the supporting | |
| | | | supervisory authority. | |
| 341 | 1.1.6. For any consecutive Plasma Master | | 1.1.6. For any consecutive | |
| | File inspection within or outside the Union | | Plasma Master File inspection | |
| | a fee of EUR 36 100 shall apply. The | | within or outside the Union a fee | |
| | remuneration shall be EUR 13 400 for the | | of EUR 36 100 42 400 shall | |

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| | leading supervisory authority and EUR 8 | | apply. The remuneration shall be | |
| | 200 for the supporting supervisory | | EUR 13_400_16 100 for the | |
| | authority. | | leading supervisory authority | |
| | | | and EUR 8 <u>200-9 800</u> for the | |
| | | | supporting supervisory | |
| | | | authority. | |
| 342 | 1.1.7. For any distinct Good Laboratory | | 1.1.7. For any distinct Good | |
| | Practice inspection within or outside the | | Laboratory Practice inspection | |
| | Union a fee of EUR 34 900 shall apply. The | | within or outside the Union a fee | |
| | remuneration shall be EUR 13 200 for the | | of EUR 34 900 <u>41 000</u> shall | |
| | leading supervisory authority and EUR 8 | | apply. The remuneration shall be | |
| | 700 for the supporting supervisory | | EUR 13 200 15 800 for the | |
| | authority. | | leading supervisory authority | |
| | | | and EUR 8 70010 400 for the | |
| | | | supporting supervisory | |
| | | | authority. | |
| 343 | 1.1.8. For any distinct pharmacovigilance | | 1.1.8. For any distinct | |
| | inspection within or outside the Union a fee | | pharmacovigilance inspection | |
| | of EUR 52 700 shall apply. The | | within or outside the Union a fee | |

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| | remuneration shall be EUR 16 200 for the | | of EUR 52 70061 500 shall | |
| | leading supervisory authority and EUR 10 | | apply. The remuneration shall be | |
| | 100 for the supporting supervisory | | EUR 16 200 19 400 for the | |
| | authority. | | leading supervisory authority | |
| | | | and EUR 10 100 12 100 for the | |
| | | | supporting supervisory | |
| | | | authority. | |
| 344 | 1.2. If a scheduled inspection is | | 1.2. If a scheduled inspection | 1.2. If a scheduled |
| | cancelled 30 calendar days or less before the | | is cancelled 30 calendar days or | inspection is cancelled |
| | first day of the inspection for reasons | | less before the first day of the | 30 calendar days or less |
| | attributable to the applicant, the applicable | | inspection for reasons | before the first day of |
| | fee referred to in point 1.1 shall apply. | | attributable to the applicant, the | the inspection for |
| | | | applicable fee referred to in | reasons attributable to |
| | | | point 1.1 shall apply. | the applicant, the |
| | | | | applicable fee referred |
| | | | | to in point 1.1 shall |
| | | | | apply. |
| 345 | 1.3. If a scheduled inspection is cancelled | | 1.3. If a scheduled inspection | |
| | more than 30 calendar days before the first | | is cancelled more than 30 | |

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| | day of the inspection, a charge of EUR 840 | | calendar days before the first | |
| | shall apply. | | day of the inspection for | |
| | | | reasons attributable to the | |
| | | | applicant, a charge of EUR 840 | |
| | | | <u>1 000</u> shall apply. | |
| 346 | 1.4. The supervisory authorities shall | | 1.4. The supervisory | 1.4. The supervisory |
| | charge the applicant the travel expenses | | authorities shall charge the | authorities shall charge |
| | separately from the fee specified in this | | applicant the travel expenses | the applicant the travel |
| | Annex, based on actual cost. In case of a | | separately from the fee specified | expenses separately |
| | cancelled inspection as per points 1.2 or 1.3, | | in this Annex, based on actual | from the fee specified in |
| | the applicant shall be charged for any travel | | cost. In case of a cancelled | this Annex, based on |
| | expenses already incurred by the inspecting | | inspection as per points 1.2 or | actual cost. In case of a |
| | authority on the date of cancellation for | | 1.3, the applicant shall be | cancelled inspection as |
| | which that authority is not able to obtain | | charged for any travel expenses | per points 1.2 or 1.3, the |
| | reimbursement. | | already incurred by the | applicant shall be |
| | | | inspecting authority on the date | charged for any travel |
| | | | of cancellation for which that | expenses already |
| | | | authority is not able to obtain | incurred by the |
| | | | reimbursement. | inspecting authority on |

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| | | | | comments |
| | | | | the date of cancellation |
| | | | (C.) | for which that authority |
| | | | | is not able to obtain |
| | | | | reimbursement. |
| 347 | 2. Transfer of a marketing | | 2. Transfer of a marketing | 2. Transfer of a |
| | authorisation | | authorisation | marketing authorisation |
| 348 | A charge of EUR 3 700 shall apply to an | | A charge of EUR 3 7004 200 | |
| | application for the transfer of a marketing | | shall apply to an application for | |
| | authorisation pursuant to Article 3 of | | the transfer of a marketing | |
| | Commission Regulation (EC) No 2141/96 ⁶⁷ . | | authorisation pursuant to Article | |
| | This covers all authorised presentations of a | | 3 of Commission Regulation | |
| | given medicinal product. | | (EC) No 2141/96 ⁶⁸ . This covers | |
| | | | all authorised presentations of a | |
| | ⁶⁷ Commission Regulation (EC) No 2141/96 of 7 | | given medicinal product. | |
| | November 1996 concerning the examination of an | | | |
| | application for the transfer of a marketing | | ⁶⁸ Commission Regulation (EC) No | |
| | authorization for a medicinal product falling within | | 2141/96 of 7 November 1996 | |
| | the scope of Council Regulation (EC) No 2309/93 (OJ L 286, 8.11.1996, p. 6). | | concerning the examination of an | |
| | (O3 L 260, 6.11.1770, p. 0). | | application for the transfer of a | |

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| | | | | comments |
| | | | marketing authorization for a | |
| | | | medicinal product falling within the | |
| | | | scope of Council Regulation (EEC) No | |
| 240 | The shares shall be levied to the manustine | | 2309/93 (OJ L 286, 8.11.1996, p. 6). | The above about he |
| 349 | The charge shall be levied to the marketing | | The charge shall be levied to the | The charge shall be |
| | authorisation holder that requested the | | marketing authorisation holder | levied to the marketing |
| | transfer, according to the application | | that requested the transfer, | authorisation holder that |
| | submitted to the Agency. | | according to the application | requested the transfer, |
| | | | submitted to the Agency. | according to the |
| | | | | application submitted to |
| | | | | the Agency. |
| 350 | 3. Pre-submission requests by a | | 3. Pre-submission requests | 3. Pre-submission |
| | prospective applicant prior to a potential | | by a prospective applicant prior | requests by a |
| | submission of an application for a | | to a potential submission of an | prospective applicant |
| | marketing authorisation falling within the | | application for a marketing | prior to a potential |
| | scope of the centralised procedure | | authorisation falling within the | submission of an |
| | | | scope of the centralised | application for a |
| | | | procedure | marketing authorisation |
| | | | | falling within the scope |

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| | | | | proposals and |
| | | | 0/ | comments |
| | | | | of the centralised |
| | | | | procedure |
| 351 | 3.1. A fee of EUR 7 100 shall apply to each | | 3.1. A fee of EUR 7-100 8 | |
| | eligibility request submitted with a | | 200 shall apply to each | |
| | notification of intention to submit an | | eligibility request submitted | |
| | application for a marketing authorisation | | with a notification of intention | |
| | falling within the scope of Regulation (EC) | | to submit an application for a | |
| | No 726/2004 or the scope of the centralised | | marketing authorisation falling | |
| | marketing authorisation procedure pursuant | | within the scope of Regulation | |
| | to Article 42 of Regulation (EU) 2019/6. | | (EC) No 726/2004 or the scope | |
| | The fee shall cover any costs related to pre- | | of the centralised marketing | |
| | submission activities up until the potential | | authorisation procedure pursuant | |
| | submission of the marketing authorisation | | to Article 42 of Regulation (EU) | |
| | application. The fee shall apply irrespective | | 2019/6. The fee shall cover any | |
| | of whether or not a marketing authorisation | | costs related to pre-submission | |
| | application for the concerned product is | | activities up until the potential | |
| | subsequently submitted. If an eligibility | | submission of the marketing | |
| | request has not been submitted, the fee shall | | authorisation application. The | |
| | | | fee shall apply irrespective of | |

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| | | | | comments |
| | apply in addition to the applicable | | whether or not a marketing | |
| | authorisation fee. | | 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. | |
| 352 | The remuneration of the national competent | | The remuneration of the national | |
| | authority, where applicable, shall be EUR 1 | | competent authority, where | |
| | 300 for the rapporteur and EUR 1 300 for | | applicable, shall be EUR 1 3001 | |
| | the co-rapporteur. | | 600 for the rapporteur and EUR | |
| | | | 1 300 <u>1 600</u> for the co- | |
| | | | rapporteur. | |
| 353 | 3.2. Where the applicant changes the | | 3.2. Where the applicant | |
| | intended submission date by more than 60 | | changes the intended submission | |
| | days, an additional fee of EUR 3 500 shall | | date by more than 60 days, an | |
| | apply. The additional remuneration of the | | additional fee of EUR 3 5004 | |
| | national competent authority, where | | <u>000</u> shall apply. The additional | |

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| | | | | comments |
| | applicable, shall be EUR 600 for the | | remuneration of the national | |
| | rapporteur and EUR 600 for the co- | | competent authority, where | |
| | rapporteur. | | applicable, shall be EUR 600 | |
| | | | 700 for the rapporteur and EUR | |
| | | | 600-700 for the co-rapporteur. | |
| 354 | 4. Re-examination of an opinion of the | | 4. Re-examination of an | 4. Re-examination |
| | Committees referred to in Article 56(1) of | | opinion of the Committees | of an opinion of the |
| | Regulation (EC) No 726/2004 and in | | referred to in Article 56(1) of | Committees referred to |
| | Article 139(1) of Regulation (EU) 2019/6 | | Regulation (EC) No 726/2004 | in Article 56(1) of |
| | | | and in Article 139(1) of | Regulation (EC) |
| | | | Regulation (EU) 2019/6 | No 726/2004 and in |
| | | | | Article 139(1) of |
| | | | | Regulation (EU) 2019/6 |
| 355 | The fee for the re-examination of an opinion | | The fee for the re-examination | The fee for the re- |
| | of any of the committees referred to in | | of an opinion of any of the | examination of an |
| | Article 56(1) of Regulation (EC) | | committees referred to in Article | opinion of any of the |
| | No 726/2004 and in Article 139(1) of | | 56(1) of Regulation (EC) | committees referred to |
| | Regulation (EU) 2019/6 shall be 30% of the | | No 726/2004 and in | in Article 56(1) of |
| | fee applicable to the initial opinion in | | Article 139(1) of Regulation | Regulation (EC) |

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| | | | | proposals and |
| | | | 0 | comments |
| | accordance with points 3, 4, 5 and 6 of | | (EU) 2019/6 shall be 30% of the | No 726/2004 and in |
| | Annex I and points 3, 4, 6 and 7 of Annex II | | fee applicable to the initial | Article 139(1) of |
| | to this Regulation. The remuneration to the | | opinion in accordance with | Regulation (EU) 2019/6 |
| | rapporteur and the co-rapporteur shall be | | points 3, 4, 5 and 6 of Annex I | shall be 30% of the fee |
| | calculated based on the same proportion of | | and points 3, 4, 6 and 7 of | applicable to the initial |
| | the respective remuneration. | | Annex II to this Regulation. The | opinion in accordance |
| | | | remuneration to the rapporteur | with points 3, 4, 5 and 6 |
| | | | and the co-rapporteur shall be | of Annex I and points 3, |
| | | | calculated based on the same | 4, 6 and 7 of Annex II to |
| | | | proportion of the respective | this Regulation. The |
| | | | remuneration. | remuneration to the |
| | | | | rapporteur and the co- |
| | | | | rapporteur shall be |
| | | | | calculated based on the |
| | | | | same proportion of the |
| | | | | respective remuneration. |
| 356 | 5. Scientific services referred to in | | 5. Scientific services | 5. Scientific |
| | Article 4(1) | | referred to in Article 4(1) | services referred to in |
| | | | | Article 4(1) |

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| | | | | comments |
| 357 | The range for fees for scientific services | | The range for fees for scientific | |
| | referred to in Article 4(1) shall be EUR 4 | | services referred to in Article | |
| | 100 to EUR 684 500. The range for the | | 4(1) shall be EUR 4 1004 800 to | |
| | remuneration shall be EUR 1 000 to EUR | | EUR 684 500805 100. The | |
| | 217 300 for the rapporteur and the co- | | range for the remuneration shall | |
| | rapporteur. The applicable amounts of the | | be EUR <u>1 000</u> 1 200 to EUR 217 | |
| | fee and the remuneration within the above | | 300 <u>261 000</u> for the rapporteur | |
| | ranges shall be determined in accordance | | and the co-rapporteur. The | |
| | with Article 8. | | applicable amounts of the fee | |
| | | | and the remuneration within the | |
| | | | above ranges shall be | |
| | | | determined in accordance with | |
| | | | Article 8. | |
| 358 | 6. Administrative services | | 6. Administrative services | 6. Administrative |
| | | | | services |
| 359 | 6.1. Administrative charge | | 6.1. Administrative charge | 6.1. Administrative |
| | | | | charge |
| 360 | A charge of EUR 3 700 shall apply for | | A charge of EUR 3 7004 200 | |
| | applications subject to a fee set out in | | shall apply for applications | |

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| | | | | comments |
| | Annex I or II in any of the following | | subject to a fee set out in Annex | |
| | situations: | | I or II in any of the following | |
| | | | situations: | |
| 361 | (a) the application is withdrawn after 24 | | (a) the application is withdrawn | (a) the application is |
| | hours of its submission and prior to | | after 24 hours of its submission | withdrawn after 24 |
| | completion of the administrative validation; | | and prior to completion of the | hours of its submission |
| | | | administrative validation; | and prior to completion |
| | | | | of the administrative |
| | | | | validation; |
| 362 | (b) the application has been rejected | | (b) the application has been | (b) the application has |
| | following the conclusion of the | | rejected following the | been rejected following |
| | administrative validation. | | conclusion of the administrative | the conclusion of the |
| | | | validation. | administrative |
| | | | | validation. |
| 363 | In the cases referred to in the previous | | In the cases referred to in the | In the cases referred to |
| | subparagraph, the corresponding fee shall | | previous subparagraph, the | in the previous |
| | not be levied. | | corresponding fee shall not be | subparagraph, the |
| | | | levied. | corresponding fee shall |
| | | | | not be levied. |

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| 364 | In addition to the applicable fee or charge | | In addition to the applicable fee | |
| | set out in Annexes I, II or Annex III, a | | or charge set out in Annexes I, II | |
| | charge of EUR 3 700 shall also apply to | | or Annex III, a charge of EUR 3 | |
| | applications where a marketing | | 700 <u>4</u> 200 shall also apply to | |
| | authorisation holder or an applicant | | applications where a marketing | |
| | claiming, or having claimed, to be entitled | | authorisation holder or an | |
| | to a fee reduction, fails to demonstrate that | | applicant claiming, or having | |
| | it is entitled to such a reduction. | | claimed, to be entitled to a fee | |
| | | | reduction, fails to demonstrate | |
| | | | that it is entitled to such a | |
| | | | reduction. | |
| 365 | 6.2. Certificates of medicinal products as | | 6.2. Certificates of medicinal | 6.2. Certificates of |
| | referred to in Article 127 of Directive | | products as referred to in Article | medicinal products as |
| | 2001/83/EC and in Article 98 of Regulation | | 127 of Directive 2001/83/EC | referred to in Article 127 |
| | (EU) 2019/6 | | and in Article 98 of Regulation | of Directive 2001/83/EC |
| | | | (EU) 2019/6 | and in Article 98 of |
| | | | | Regulation (EU) 2019/6 |
| 366 | 6.2.1. A charge of EUR 140 shall apply to | | 6.2.1 A charge of EUR 140 | |
| | each request for a set of certificates issued | | 160 shall apply to each request | |

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| | | | | comments |
| | by the Agency for a medicinal product, | | for a set of certificates issued by | |
| | using the standard procedure for issuing the | | the Agency for a medicinal | |
| | certificate. | | product, using the standard | |
| | | | procedure for issuing the | |
| | | | certificate. | |
| 367 | 6.2.2. A charge of EUR 420 shall apply to | | 6.2.2. A charge of EUR 420 | |
| | each request for a set of certificates issued | | 480 shall apply to each request | |
| | by the Agency for a medicinal product, | | for a set of certificates issued by | |
| | using the urgent procedure for issuing the | | the Agency for a medicinal | |
| | certificate. | | product, using the urgent | |
| | | | procedure for issuing the | |
| | | | certificate. | |
| 368 | 6.3. Notification of parallel distribution | | 6.3. Notification of parallel | 6.3. Notification of |
| | in accordance with Article 57(1), point (o), | | distribution in accordance with | parallel distribution in |
| | of Regulation (EC) No 726/2004 | | Article 57(1), point (o), | accordance with Article |
| | | | of Regulation (EC) No 726/2004 | 57(1), point (o), |
| | | | | of Regulation (EC) No |
| | | | | 726/2004 |

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| | | | | comments |
| 369 | 6.3.1. A charge of EUR 1 200 shall apply to | | 6.3.1. A charge of EUR <u>1 2001</u> | |
| | each initial notification for each | | 400 shall apply to each initial | |
| | presentation of a medicinal product, for one | | notification for each | |
| | Member State of destination having one or | | presentation of a medicinal | |
| | more official languages or for several | | product, for one Member State | |
| | Member States of destination having the | | of destination having one or | |
| | same official language. That charge shall | | more official languages or for | |
| | cover any subsequent safety update | | several Member States of | |
| | notification relating to the initial | | destination having the same | |
| | notification. | | official language. That charge | |
| | | | shall cover any subsequent | |
| | | | safety update notification | |
| | | | relating to the initial | |
| | | | notification. | |
| 370 | 6.3.2. A charge of EUR 350 shall apply to | | 6.3.2. A charge of EUR 350 | |
| | each notification of a bulk change. That | | 400 shall apply to each | |
| | charge shall cover all initial notifications | | notification of a bulk change. | |
| | approved by the date of submission of the | | That charge shall cover all initial | |
| | notification of bulk changes. | | notifications approved by the | |

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| | | | | comments |
| | | | date of submission of the | |
| | | | notification of bulk changes. | |
| 371 | 6.3.3. A charge of EUR 350 shall apply to | | 6.3.3. A charge of EUR 350 | |
| | each annual update notification. That charge | | 400 shall apply to each annual | |
| | shall cover all the presentations belonging | | update notification. That charge | |
| | to the same pharmaceutical form of the | | shall cover all the presentations | |
| | same medicinal product for one Member | | belonging to the same | |
| | State of destination having one or more | | pharmaceutical form of the same | |
| | official languages, or for several Member | | medicinal product for one | |
| | States of destination having the same | | Member State of destination | |
| | official language. No charge shall apply if | | having one or more official | |
| | there have been no regulatory updates in the | | languages, or for several | |
| | past twelve months or if the product was | | Member States of destination | |
| | dormant. | | 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. | |

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| | | | | comments |
| 372 | 6.4. Administrative services referred to | | 6.4. Administrative services | 6.4. Administrative |
| | in Article 4(2) | | referred to in Article 4(2) | services referred to in |
| | | | | Article 4(2) |
| 373 | The range of charges for other | | The range of charges for other | |
| | administrative services referred to in Article | | administrative services referred | |
| | 4(2) shall be from EUR 100 to EUR 10 000. | | to in Article 4(2) shall be from | |
| | The applicable amounts of the charge within | | EUR 100 <u>110</u> to EUR 10 000 <u>11</u> | |
| | the above range shall be determined in | | <u>300</u> . The applicable amounts of | |
| | accordance with Article 8. | | the charge within the above | |
| | | | range shall be determined in | |
| | | | accordance with Article 8. | |
| 374 | 7. Consultation on medical devices | | 7. Consultation on medical | 7. Consultation on |
| | | | devices | medical devices |
| 375 | 7.1. Ancillary substances incorporated in | | 7.1. Ancillary substances | 7.1. Ancillary |
| | medical devices | | incorporated in medical devices | substances incorporated |
| | | | | in medical devices |
| 376 | 7.1.1. A fee of EUR 94 000 shall apply to a | | 7.1.1. A fee of EUR 94-000 <u>109</u> | |
| | consultation on one or more ancillary | | 700 shall apply to a consultation | |
| | medicinal substances pursuant to section 5.2 | | on one or more ancillary | |

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| | | 0 | comments |
| of Annex IX to Regulation (EU) 2017/7 | 745, | medicinal substances pursuant to | |
| where the medicinal substance(s) from | the | section 5.2 of Annex IX to | |
| specified manufacturer has not been | | Regulation (EU) 2017/745, | |
| evaluated by the Agency or a competen | ıt e | where the medicinal | |
| authority designated by the Member Sta | ates | substance(s) from the specified | |
| in accordance with Directive 2001/83/E | EC | manufacturer has not been | |
| (hereafter 'medicinal products authority | y') in | evaluated by the Agency or a | |
| connection with a previous marketing | | competent authority designated | |
| authorisation or through a previous | | by the Member States in | |
| consultation by a notified body. One | | accordance with Directive | |
| application may include a range of stream | ngth | 2001/83/EC (hereafter | |
| or concentrations of the ancillary | | 'medicinal products authority') | |
| substance(s) or a range of similar devic | es | in connection with a previous | |
| from the same medical device manufac | turer | marketing authorisation or | |
| incorporating the same substance(s) or | both. | through a previous consultation | |
| The remuneration shall be EUR 23 500 | for | by a notified body. One | |
| the rapporteur and EUR 23 500 for the | co- | application may include a range | |
| rapporteur. | | of strength or concentrations of | |
| | | the ancillary substance(s) or a | |

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| | | | range of similar devices from | |
| | | | the same medical device | |
| | | | manufacturer incorporating the | |
| | | | same substance(s) or both. The | |
| | | | remuneration shall be EUR 23 | |
| | | | 500 <u>28 200</u> for the rapporteur | |
| | | | and EUR 23 500 28 200 for the | |
| | | | co-rapporteur. | |
| 377 | 7.1.2. A fee of EUR 46 900 shall apply to a | | 7.1.2. A fee of EUR 46 900 <u>54</u> | |
| | consultation on one or more ancillary | | 700 shall apply to a consultation | |
| | medicinal substance(s) pursuant to section | | on one or more ancillary | |
| | 5.2 of Annex IX to Regulation (EU) | | medicinal substance(s) pursuant | |
| | 2017/745, where the medicinal substance(s) | | to section 5.2 of Annex IX to | |
| | from the specified manufacturer has been | | Regulation (EU) 2017/745, | |
| | evaluated by a medicinal products authority | | where the medicinal | |
| | in connection with a previous marketing | | substance(s) from the specified | |
| | authorisation or through a previous | | manufacturer has been evaluated | |
| | consultation by a notified body. One | | by a medicinal products | |
| | application may include a range of strengths | | authority in connection with a | |

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| | or concentrations of the ancillary | | previous marketing | |
| | substance(s) or a range of similar devices | | authorisation or through a | |
| | from the same medical device manufacturer | | previous consultation by a | |
| | incorporating the same substance(s) or both. | | notified body. One application | |
| | The remuneration shall be EUR 11 500 for | | may include a range of strengths | |
| | the rapporteur and EUR 11 500 for the co- | | or concentrations of the | |
| | rapporteur. | | 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 <u>13 800</u> for the rapporteur | |
| | | | and EUR 11 500 13 800 for the | |
| | | | co-rapporteur. | |
| 378 | 7.1.3. For the purpose of 7.1.1. and 7.1.2., a | | 7.1.3. For the purpose of 7.1.1. | |
| | fee of EUR 4 100 shall apply to a | | and 7.1.2., a fee of EUR 4 1004 | |
| | consultation, pursuant to section 5.2, point | | 700 shall apply to a | |
| | (f), of Annex IX to Regulation (EU) | | consultation, pursuant to section | |

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| | 2017/745, regarding a change with respect | | 5.2, point (f), of Annex IX to | |
| | to an ancillary medicinal substance | | Regulation (EU) 2017/745, | |
| | incorporated in a device. The remuneration | | regarding a change with respect | |
| | shall be EUR 1 400 for the rapporteur. | | to an ancillary medicinal | |
| | | | substance incorporated in a | |
| | | | device. The remuneration shall | |
| | | | be EUR <u>1-400</u> 1 for the | |
| | | | rapporteur. | |
| 379 | 7.2. Medical devices composed of a | | 7.2. Medical devices | 7.2. Medical devices |
| | substance or a combination of substances | | composed of a substance or a | composed of a substance |
| | that are systemically absorbed to achieve | | combination of substances that | or a combination of |
| | their intended purpose. | | are systemically absorbed to | substances that are |
| | | | achieve their intended purpose. | systemically absorbed to |
| | | | | achieve their intended |
| | | | | purpose. |
| 380 | A fee of EUR 70 600 shall apply to a | | A fee of EUR 70 600 82 400 | |
| | consultation on a medical device or a range | | shall apply to a consultation on a | |
| | of similar devices composed of a substance | | medical device or a range of | |
| | or a combination of substances that are | | similar devices composed of a | |

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| | absorbed by or locally dispersed in the | | substance or a combination of | |
| | human body, pursuant to section 5.4 of | | substances that are absorbed by | |
| | Annex IX, to Regulation (EU) 2017/745. | | or locally dispersed in the | |
| | The remuneration shall be EUR 17 500 for | | human body, pursuant to section | |
| | the rapporteur and EUR 17 500 for the co- | | 5.4 of Annex IX, to Regulation | |
| | rapporteur. | | (EU) 2017/745. The | |
| | | | remuneration shall be EUR 17 | |
| | | | 500 <u>21 000</u> for the rapporteur | |
| | | | and EUR 17 500 21 000 for the | |
| | | | co-rapporteur. | |
| 381 | 7.3. Companion diagnostic | | 7.3. Companion diagnostic | 7.3. Companion |
| | | | | diagnostic |
| 382 | 7.3.1. A fee of EUR 46 900 shall apply to a | | 7.3.1. A fee of EUR 46 900 <u>54</u> | |
| | consultation on the suitability of a | | <u>000</u> shall apply to a consultation | |
| | companion diagnostic in relation to a | | on the suitability of a companion | |
| | concerned medicinal product, pursuant to | | diagnostic in relation to a | |
| | Article 48(3) or (4), of Regulation (EU) | | concerned medicinal product, | |
| | 2017/746, and section 5.2 of Annex IX, or | | pursuant to Article 48(3) or (4), | |
| | section 3, point (k), of Annex X to that | | of Regulation (EU) 2017/746, | |

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| | Regulation. The remuneration shall be EUR | | and section 5.2 of Annex IX, or | |
| | 11 800 for the rapporteur. | | section 3, point (k), of Annex X | |
| | | | to that Regulation. The | |
| | | | remuneration shall be EUR 11 | |
| | | | 800 <u>14 200</u> for the rapporteur. | |
| 383 | A fee of EUR 4 100 shall apply to a | | A fee of EUR 4 1004 700 shall | |
| | consultation on a change affecting the | | apply to a consultation on a | |
| | suitability of the companion diagnostic in | | change affecting the suitability | |
| | relation to the medicinal product concerned, | | of the companion diagnostic in | |
| | pursuant to section 5.2, point (f), of Annex | | relation to the medicinal product | |
| | IX to Regulation (EU) 2017/746. The | | concerned, pursuant to section | |
| | remuneration shall be EUR 1 400 for the | | 5.2, point (f), of Annex IX to | |
| | rapporteur. | | Regulation (EU) 2017/746. The | |
| | | | remuneration shall be EUR 4 | |
| | | | 400 <u>1 700</u> for the rapporteur. | |
| 384 | 7.4. The fees set out in points 7.1, 7.2 | | 7.4. The fees set out in points | 7.4. The fees set out |
| | and 7.3 shall be charged to the medical | | 7.1, 7.2 and 7.3 shall be charged | in points 7.1, 7.2 and 7.3 |
| | device manufacturer that, according to the | | to the medical device | shall be charged to the |
| | application form submitted to the Agency, | | manufacturer that, according to | medical device |

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| | requested the assessment of conformity of | | the application form submitted | manufacturer that, |
| | the medical device for which the notified | | to the Agency, requested the | according to the |
| | body is consulting the Agency. | | assessment of conformity of the | application form |
| | | | medical device for which the | submitted to the |
| | | | notified body is consulting the | Agency, requested the |
| | | | Agency. | assessment of |
| | | | | conformity of the |
| | | | | medical device for |
| | | | | which the notified body |
| | | | | is consulting the |
| | | | | Agency. |
| 385 | ANNEX V | | ANNEX V | ANNEX V |
| | Fee reductions | | Fee reductions | Fee reductions |
| 386 | 1. Fee reductions granted to micro, small- | | 1. Fee reductions granted to | Fee reductions granted |
| | and medium-sized enterprises | | micro, small- and medium-sized | to micro, small- and |
| | | | enterprises | medium-sized |
| | | | | enterprises |
| 387 | 1.1. The following total or partial reductions | | 1.1. The following total or | 1.1. The following total |
| | to the fees laid down in this Regulation shall | | partial reductions to the fees laid | or partial reductions to |

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| | | | | comments |
| | be granted to micro, small and medium- | | down in this Regulation shall be | the fees laid down in |
| | sized enterprises: | | granted to micro, small and | this Regulation shall be |
| | | | medium-sized enterprises: | granted to micro, small |
| | | | | and medium-sized |
| | | | | enterprises: |
| 388 | 1.1.1 for a small or medium-sized | | 1.1.1 for a small or medium- | 1.1.1 for a small or |
| | enterprise, a fee reduction of 40 % of the | | sized enterprise, a fee reduction | medium-sized |
| | applicable amount shall apply to the | | of 40 % of the applicable | enterprise, a fee |
| | following fees: | | amount shall apply to the | reduction of 40 % of the |
| | | | following fees: | applicable amount shall |
| | | | | apply to the following |
| | | | | fees: |
| 389 | (a) extension of a marketing authorisation | | (a) extension of a marketing | (a) extension of a |
| | for medicinal products for human use | | authorisation for medicinal | marketing authorisation |
| | pursuant to section 4 of Annex I; | | products for human use pursuant | for medicinal products |
| | | | to section 4 of Annex I; | for human use pursuant |
| | | | | to section 4 of Annex I; |
| 390 | (b) major type-II variations for medicinal | | (b) major type-II variations for | (b) major type-II |
| | products for human use pursuant to section | | medicinal products for human | variations for medicinal |

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| | | | | comments |
| | 5 of Annex I, excluding point 5.4 of that | | use pursuant to section 5 of | products for human use |
| | section; | | Annex I, excluding point 5.4 of | pursuant to section 5 of |
| | | | that section; | Annex I, excluding point |
| | | | | 5.4 of that section; |
| 391 | (c) referral procedures for medicinal | | (c) referral procedures for | (c) referral procedures |
| | products for human use pursuant to points | | medicinal products for human | for medicinal products |
| | 6.4 to 6.7 of Annex I; | | use pursuant to points 6.4 to 6.7 | for human use pursuant |
| | | | of Annex I; | to points 6.4 to 6.7 of |
| | | | | Annex I; |
| 392 | (d) request for scientific support and advice | | (d) request for scientific support | |
| | by the Committee on Herbal Medicinal | | and advice by the Committee on | |
| | Products related to traditional herbal | | Herbal Medicinal Products | |
| | medicinal products pursuant to section 7 of | | related to traditional herbal | |
| | Annex I; | | medicinal products pursuant to | |
| | | | section 7 of Annex I; | |
| 393 | (e) certification of compliance with Union | | (e) certification of compliance | |
| | legislation for plasma master files pursuant | | with Union legislation for | |
| | to section 9 of Annex I; | | plasma master files pursuant to | |
| | | | section 98 of Annex I; | |

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| | | | | comments |
| 394 | (f) certification of compliance with Union | | (f) certification of compliance | |
| | legislation regarding vaccine antigen master | | with Union legislation regarding | |
| | files (VAMF) pursuant to section 10 of | | vaccine antigen master files | |
| | Annex I; | | (VAMF) pursuant to section 109 | |
| | | | of Annex I; | |
| 395 | (g) assessment of periodic safety update | | (g) assessment of periodic safety | |
| | reports for medicinal products for human | | update reports for medicinal | |
| | use pursuant to section 15 of Annex I; | | products for human use pursuant | |
| | | | to section 45-14 of Annex I; | |
| 396 | (h) assessment of post-authorisation safety | | (h) assessment of post- | |
| | studies for medicinal products for human | | authorisation safety studies for | |
| | use pursuant to section 16 of Annex I; | | medicinal products for human | |
| | | | use pursuant to section 16-15 of | |
| | | | Annex I; | |
| 397 | (i) variations requiring assessment pursuant | | (i) variations requiring | (i) variations requiring |
| | to section 6 of Annex II, excluding point 6.5 | | assessment pursuant to section 6 | assessment pursuant to |
| | of that section; | | of Annex II, excluding point 6.5 | section 6 of Annex II, |
| | | | of that section; | excluding point 6.5 of |
| | | | | that section; |

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| 398 | (j) referral procedures for veterinary | | (j) referral procedures for | |
| | medicinal products pursuant to points 7.4 to | | veterinary medicinal products | |
| | 7.7 of Annex II; | | pursuant to points 7.4 to 7. <u>5</u> 7 of | |
| | | | Annex II; | |
| 399 | (k) certification of compliance with Union | | (k) certification of compliance | (k) certification of |
| | legislation regarding VAMF pursuant to | | with Union legislation regarding | compliance with Union |
| | section 8 of Annex II; | | VAMF pursuant to section 8 of | legislation regarding |
| | | | Annex II; | VAMF pursuant to |
| | | | | section 8 of Annex II; |
| 400 | (l) certification of compliance with Union | | (l) certification of compliance | (1) certification of |
| | legislation regarding vaccine platform | | with Union legislation regarding | compliance with Union |
| | technology master files (vPTMF) pursuant | | vaccine platform technology | legislation regarding |
| | to section 9 of Annex II; | | master files (vPTMF) pursuant | vaccine platform |
| | | | to section 9 of Annex II; | technology master files |
| | | | | (vPTMF) pursuant to |
| | | | | section 9 of Annex II; |
| 401 | (m) assessment of post-marketing | | (m) assessment of post- | (m) assessment of post- |
| | surveillance studies for veterinary medicinal | | marketing surveillance studies | marketing surveillance |
| | products pursuant to section 10 of Annex II; | | for veterinary medicinal | studies for veterinary |

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| | | | products pursuant to section 10 | medicinal products |
| | | | of Annex II; | pursuant to section 10 of |
| | | | | Annex II; |
| 402 | (n) annual fee, for medicinal products for | | (n) annual fee, for medicinal | (n) annual fee, for |
| | human use or for veterinary medicinal | | products for human use or for | medicinal products for |
| | products, or both, pursuant to section 1 or 2, | | veterinary medicinal products, | human use or for |
| | respectively, of Annex III; | | or both, pursuant to section 1 or | veterinary medicinal |
| | | | 2, respectively, of Annex III; | products, or both, |
| | | | | pursuant to section 1 or |
| | | | | 2, respectively, of |
| | | | | Annex III; |
| 403 | (o) pharmacovigilance annual fee, for | | (o) pharmacovigilance annual | (o) pharmacovigilance |
| | medicinal products for human use or | | fee, for medicinal products for | annual fee, for medicinal |
| | veterinary medicinal products pursuant to | | human use or veterinary | products for human use |
| | Annex III; | | medicinal products pursuant to | or veterinary medicinal |
| | | | Annex III; | products pursuant to |
| | | | | Annex III; |
| 404 | (p) transfer of a marketing authorisation to | | (p) transfer of a marketing | (p) transfer of a |
| | another micro-, small- or medium-sized | | authorisation to another micro-, | marketing authorisation |

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| | enterprise, both for medicinal products for | | small- or medium-sized | to another micro-, small- |
| | human use and veterinary medicinal | | enterprise, both for medicinal | or medium-sized |
| | products pursuant to section 2, point 2 of | | products for human use and | enterprise, both for |
| | Annex IV; | | veterinary medicinal products | medicinal products for |
| | | | pursuant to section 2 , point 2 of | human use and |
| | | | Annex IV; | veterinary medicinal |
| | | | | products pursuant to |
| | | | | section 2 , point 2 of |
| | | | | Annex IV; |
| | | | | 12/09 typo |
| 405 | 1.1.1. for a small or medium-sized | | 1.1.1. for a small or medium- | 1.1.1. for a small or |
| | enterprise, a fee reduction of 90 % of the | | sized enterprise, a fee reduction | medium-sized |
| | applicable amount shall apply to a | | of 90 % of the applicable | enterprise, a fee |
| | consultation on medical devices pursuant to | | amount shall apply to a | reduction of 90 % of the |
| | section 7 of Annex IV, where the medical | | consultation on medical devices | applicable amount shall |
| | device manufacturer has been assigned the | | pursuant to section 7 of Annex | apply to a consultation |
| | small and medium-sized enterprise status by | | IV, where the medical device | on medical devices |
| | the Agency; | | manufacturer has been assigned | pursuant to section 7 of |
| | | | | Annex IV, where the |

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| | | | the small and medium-sized | medical device |
| | | | enterprise status by the Agency; | manufacturer has been |
| | | | | assigned the small and |
| | | | | medium-sized enterprise |
| | | | | status by the Agency; |
| 406 | 1.1.2. for a micro enterprise, a reduction of | | 1.1.2. for a micro enterprise, a | 1.1.2. for a micro |
| | 100 % shall apply to the fees set out in | | reduction of 100 % shall apply | enterprise, a reduction of |
| | points 1.1.1. and 1.1.2. | | to the fees set out in points | 100 % shall apply to the |
| | | | 1.1.1. and 1.1.2. | fees set out in points |
| | | | | 1.1.1. and 1.1.2. |
| 407 | 1.2. The fee reductions set out in point 1.1.1 | | 1.2. The fee reductions set out in | 1.2. The fee reductions |
| | shall apply in addition to fee reductions and | | point 1.1.1 shall apply in | set out in point 1.1.1 |
| | incentives provided for in Regulation (EC) | | addition to fee reductions and | shall apply in addition to |
| | No 2049/2005 or in the Union | | incentives provided for in | fee reductions and |
| | pharmaceutical legislation. | | Regulation (EC) No 2049/2005 | incentives provided for |
| | | | or in the Union pharmaceutical | in Regulation (EC) No |
| | | | legislation. | 2049/2005 or in the |
| | | | | Union pharmaceutical |
| | | | | legislation. |

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| 408 | 1.3. The reductions set out in point 1.1 | | 1.3. The reductions set out in | 1.3. The reductions |
| | shall not be granted to SMEs acting as | | point 1.1 shall not be granted to | set out in point 1.1 shall |
| | applicant or marketing authorisation holder | | SMEs acting as applicant or | not be granted to SMEs |
| | for the relevant medicinal product by virtue | | marketing authorisation holder | acting as applicant or |
| | of a contractual arrangement with a non- | | for the relevant medicinal | marketing authorisation |
| | SME legal entity. Such contractual | | product by virtue of a | holder for the relevant |
| | arrangements shall be declared to the | | contractual arrangement with a | medicinal product by |
| | Agency ahead of any service listed under | | non-SME legal entity. Such | virtue of a contractual |
| | point 1.1.1. | | contractual arrangements shall | arrangement with a non- |
| | | | be declared to the Agency ahead | SME legal entity. Such |
| | | | of any service listed under point | contractual |
| | | | 1.1.1. | arrangements shall be |
| | | | | declared to the Agency |
| | | | | ahead of any service |
| | | | | listed under point 1.1.1. |
| 408a | | 1a. Fee reductions granted to | | |
| | | academia and the non-profit | | |
| | | research sector | | |

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| | 1. A total reduction to the fee for | | |
| | protocol assistance and scientific | | |
| | advice requests on medicinal | | |
| | products shall be granted to | | |
| | applicants from academia or the | | |
| | academic sector. | | |
| | 2. Applicants from academia or | | |
| | the academic sector which are | | |
| | not financed or managed by | | |
| | private profit organisations in | | |
| | the pharmaceutical sector | | |
| | (PPO), or have not concluded | | |
| | any operating agreements with | | |
| | any PPO concerning their | | |
| | sponsorship or participation to | | |
| | the specific research project for | | |
| | which a fee exemption is sought | | |
| | shall provide the following: | | |

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| | (a) the Legal Entity Form (LEF) | | |
| | and the "founding document" | | |
| | (or any other suitable document | | |
| | provided during the application | | |
| | process); | | |
| | (b) evidence of the place of | | |
| | establishment, which may be the | | |
| | founding document or any other | | |
| | suitable document proving that | | |
| | the entity's seat is located in the | | |
| | Union, Iceland, Liechtenstein or | | |
| | Norway; | | |
| | (c) proof that the applicant is not | | |
| | under direct or indirect control | | |
| | of any PPO. | | |
| | For the purposes of paragraph 2, | | |
| | point (c), control may, in | | |
| | particular, take either of the | | |
| | following forms: | | |

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| | (i) the direct or indirect holding | | |
| | of more than 50 % of the | | |
| | nominal value of the issued | | |
| | share capital in the applicant, or | | |
| | of a majority of the voting rights | | |
| | of the shareholders or associates | | |
| | of that applicant, or | | |
| | (ii) the direct or indirect holding, | | |
| | in fact or in law, of decision- | | |
| | making powers in the applicant. | | |
| | Upon receipt of a scientific | | |
| | advice request, the Agency shall | | |
| | check the applicant's declaration | | |
| | of eligibility and the acceptability | | |
| | of the declaration based on | | |
| | defined template as well as the | | |
| | supporting documents. | | |
| | The Agency shall reserve its | | |
| | right to conduct an ex-post check | | |

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| | | and to request evidence | | |
| | | confirming that the criteria for | (C) | |
| | | the fee exemption are fulfilled at | | |
| | | any time before the adoption of | | |
| | | the final advice letter. | | |
| | | 3. Where reductions apply | | |
| | | pursuant to point 1a, no | | |
| | | remuneration shall be paid to the | | |
| | | national competent authorities in | | |
| | | Member States. | | |
| | | | | |
| 409 | 2. Applications relating to core dossier | | 2. Applications relating to core | 2. Applications relating |
| | medicinal products to be used in a human | | dossier medicinal products to be | to core dossier |
| | pandemic situation | | used in a human pandemic | medicinal products to be |
| | | | situation | used in a human |
| | | | | pandemic situation |
| 410 | 2.1. The payment of the fee for an | | 2.1. The payment of the fee | 2.1. The payment of |
| | application for a marketing authorisation of | | for an application for a | the fee for an application |
| | a medicinal product to be used in a human | | marketing authorisation of a | for a marketing |

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| | pandemic situation shall be deferred until | | medicinal product to be used in | authorisation of a |
| | the pandemic situation is duly recognised, | | a human pandemic situation | medicinal product to be |
| | either by the World Health Organisation or | | shall be deferred until the | used in a human |
| | by the Union in accordance with Decision | | pandemic situation is duly | pandemic situation shall |
| | No 1082/2013/EU. | | recognised, either by the World | be deferred until the |
| | | | Health Organisation or by the | pandemic situation is |
| | | | Union Commission in | duly recognised, either |
| | | | accordance with Article 23(1) | by the World Health |
| | | | of Regulation (EU) 2022/2371 | Organisation or by the |
| | | | on serious cross-border | Union Commission in |
| | | | threats to health and repealing | accordance with Article |
| | | | Decision No 1082/2013/EU. | 23(1) of Regulation |
| | | | | (EU) 2022/2371 on |
| | | | | serious cross-border |
| | | | | threats to health and |
| | | | | repealing Decision |
| | | | | No 1082/2013/EU. |
| 411 | Such deferral shall not exceed 5 years. | | Such deferral shall not exceed 5 | Such deferral shall not |
| | | | years. | exceed 5 years. |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | 0 | comments |
| 412 | 2.2. In addition to the deferral provided for | | 2.2. In addition to the | 2.2. In addition to the |
| | in point 2.1, for regulatory activities within | | deferral provided for in point | deferral provided for in |
| | the framework of the submission of a core | | 2.1, for regulatory activities | point 2.1, for regulatory |
| | dossier for a pandemic influenza vaccine | | within the framework of the | activities within the |
| | and the follow-up submission of a pandemic | | submission of a core dossier for | framework of the |
| | variation, a fee reduction of 100 % shall | | a pandemic influenza vaccine | submission of a core |
| | apply in the following cases: | | and the follow-up submission of | dossier for a pandemic |
| | | | a pandemic variation, a fee | influenza vaccine and |
| | | | reduction of 100 % shall apply | the follow-up |
| | | | in the following cases: | submission of a |
| | | | | pandemic variation, a |
| | | | | fee reduction of 100 % |
| | | | | shall apply in the |
| | | | | following cases: |
| 413 | (a) pre-submission activities pursuant to | | (a) pre-submission activities | |
| | section 9 of Annex IV; | | pursuant to section <u>39</u> of Annex | |
| | | | IV; | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | comments |
| 414 | (b) scientific advice pursuant to section 1 of | | (b) scientific advice pursuant to | (b) scientific advice |
| | Annex I; | | section 1 of Annex I; | pursuant to section 1 of |
| | | | | Annex I; |
| 415 | (c) extension of marketing authorisation | | (c) extension of marketing | (c) extension of |
| | pursuant to section 4 of Annex I; | | authorisation pursuant to section | marketing authorisation |
| | | | 4 of Annex I; | pursuant to section 4 of |
| | | | | Annex I; |
| 416 | (d) major type-II variation pursuant to | | (d) major type-II variation | (d) major type-II |
| | section 5 of Annex I; | | pursuant to section 5 of Annex I; | variation pursuant to |
| | | | | section 5 of Annex I; |
| 417 | (e) annual fee pursuant to section 1 of Annex III. | | (e) annual fee pursuant to section 1 of Annex III. | (e) annual fee pursuant to section 1 of Annex III. |
| | Those reductions shall apply until the | | Those reductions shall apply | Those reductions shall |
| | human pandemic situation is duly | | until the human pandemic | apply until the human |
| | recognised. | | situation is duly recognised. | pandemic situation is |
| | | | | duly recognised. |
| 418 | 2.3. Where reductions apply pursuant to | | 2.3. Where reductions apply | 2.3. Where |
| | point 2.2, no remuneration shall be paid to | | pursuant to point 2.2, no | reductions apply |
| | | | remuneration shall be paid to the | pursuant to point 2.2, no |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | the national competent authorities for the | | national competent authorities | remuneration shall be |
| | annual fees referred to in point 2.2(e). | | for the annual fees referred to in | paid to the national |
| | | | point 2.2(e). | competent authorities |
| | | | | for the annual fees |
| | | | | referred to in point |
| | | | | 2.2(e). |
| 419 | 3. Applications submitted under | | 3. Applications submitted | 3. Applications |
| | Article 30 of Regulation (EC) No | | under Article 30 of Regulation | submitted under Article |
| | 1901/2006 | | (EC) No 1901/2006 | 30 of Regulation (EC) |
| | | | | No 1901/2006 |
| 420 | A 50 % fee reduction shall apply to | | A 50 % fee reduction shall apply | A 50 % fee reduction |
| | paediatric use marketing authorisation | | to paediatric use marketing | shall apply to paediatric |
| | applications submitted under Article 30 of | | authorisation applications | use marketing |
| | Regulation (EC) No 1901/2006 for the | | submitted under Article 30 of | authorisation |
| | following services: | | Regulation (EC) No 1901/2006 | applications submitted |
| | | | for the following services: | under Article 30 of |
| | | | | Regulation (EC) No |
| | | | | 1901/2006 for the |
| | | | | following services: |

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| | | | | proposals and |
| | | | 0 | comments |
| 421 | (a) initial marketing authorisation | | (a) initial marketing | (a) initial marketing |
| | application pursuant to section 3 of Annex I, | | authorisation application | authorisation application |
| | to this Regulation; | | pursuant to section 3 of Annex I, | pursuant to section 3 of |
| | | | to this Regulation; | Annex I, to this |
| | | | | Regulation; |
| 422 | (b) pre-authorisation inspection pursuant to | | (b) pre-authorisation inspection | (b) pre-authorisation |
| | section 1 of Annex IV, to this Regulation; | | pursuant to section 1 of Annex | inspection pursuant to |
| | | | IV, to this Regulation; | section 1 of Annex IV, |
| | | | | to this Regulation; |
| 423 | (c) extension of a marketing authorisation | | (c) extension of a marketing | (c) extension of a |
| | pursuant to section 4 of Annex I, to this | | authorisation pursuant to section | marketing authorisation |
| | Regulation, in the first year from granting of | | 4 of Annex I, to this Regulation, | pursuant to section 4 of |
| | the marketing authorisation; | | in the first year from granting of | Annex I, to this |
| | | | the marketing authorisation; | Regulation, in the first |
| | | | | year from granting of |
| | | | | the marketing |
| | | | | authorisation; |
| 424 | (d) major type-II variation pursuant to | | (d) major type-II variation | (d) major type-II |
| | section 5 of Annex I, to this Regulation, in | | pursuant to section 5 of Annex I, | variation pursuant to |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | the first year from granting of a marketing | | to this Regulation, in the first | section 5 of Annex I, to |
| | authorisation; | | year from granting of a | this Regulation, in the |
| | | | marketing authorisation; | first year from granting |
| | | | | of a marketing |
| | | | | authorisation; |
| 425 | (e) annual fee pursuant to section 1 of | | (e) annual fee pursuant to | (e) annual fee pursuant |
| | Annex III, to this Regulation, in the first | | section 1 of Annex III, to this | to section 1 of Annex |
| | year from granting of a marketing | | Regulation, in the first year from | III, to this Regulation, in |
| | authorisation; | | granting of a marketing | the first year from |
| | | | authorisation; | granting of a marketing |
| | | | | authorisation; |
| 426 | (f) post-authorisation inspection pursuant to | | (f) post-authorisation inspection | (f) post-authorisation |
| | section 1 of Annex IV, to this Regulation, in | | pursuant to section 1 of Annex | inspection pursuant to |
| | the first year from granting of a marketing | | IV, to this Regulation, in the | section 1 of Annex IV, |
| | authorisation. | | first year from granting of a | to this Regulation, in the |
| | | | marketing authorisation. | first year from granting |
| | | | | of a marketing |
| | | | | authorisation. |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | 0/ | comments |
| 427 | 4. Immunological veterinary medicinal | | 4. Immunological | 4. Immunological |
| | products | | veterinary medicinal products | veterinary medicinal |
| | | | | products |
| 428 | A fee reduction of 50 % shall apply to | | A fee reduction of 50 % shall | A fee reduction of 50 % |
| | immunological veterinary medicinal | | apply to immunological | shall apply to |
| | products for the following activities: | | veterinary medicinal products | immunological |
| | | | for the following activities: | veterinary medicinal |
| | | | | products for the |
| | | | | following activities: |
| 429 | (a) scientific advice pursuant to section 1 of | | (a) scientific advice pursuant to | (a) scientific advice |
| | Annex II; | | section 1 of Annex II; | pursuant to section 1 of |
| | | | | Annex II; |
| 430 | (b) request for classification of a veterinary | | (b) request for classification of a | (b) request for |
| | medicinal product as intended for a limited | | veterinary medicinal product as | classification of a |
| | market as defined in Article 4, point 29 of | | intended for a limited market as | veterinary medicinal |
| | Regulation (EU) 2019/6 and for | | defined in Article 4, point 29 of | product as intended for a |
| | consideration for eligibility for authorisation | | Regulation (EU) 2019/6 and for | limited market as |
| | according to Article 23 of that Regulation, | | consideration for eligibility for | defined in Article 4, |
| | | | authorisation according to | point 29 of Regulation |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | pursuant to section 2 of Annex II, to this | | Article 23 of that Regulation, | (EU) 2019/6 and for |
| | Regulation; | | pursuant to section 2 of Annex | consideration for |
| | | | II, to this Regulation; | eligibility for |
| | | | | authorisation according |
| | | | | to Article 23 of that |
| | | | | Regulation, pursuant to |
| | | | | section 2 of Annex II, to |
| | | | | this Regulation; |
| 431 | (c) authorisation to market veterinary | | (c) authorisation to market | (c) authorisation to |
| | medicinal products falling within the scope | | veterinary medicinal products | market veterinary |
| | of the centralised marketing authorisation | | falling within the scope of the | medicinal products |
| | procedure pursuant to Article 42 of | | centralised marketing | falling within the scope |
| | Regulation (EU) 2019/6, pursuant to section | | authorisation procedure pursuant | of the centralised |
| | 4 of Annex II, to this Regulation; | | to Article 42 of Regulation (EU) | marketing authorisation |
| | | | 2019/6, pursuant to section 4 of | procedure pursuant to |
| | | | Annex II, to this Regulation; | Article 42 of Regulation |
| | | | | (EU) 2019/6, pursuant to |
| | | | | section 4 of Annex II, to |
| | | | | this Regulation; |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| 432 | (d) variations to the terms of a marketing | | (d) variations to the terms of a | (d) variations to the |
| | authorisation requiring assessment in | | marketing authorisation | terms of a marketing |
| | accordance with Article 66 of Regulation | | requiring assessment in | authorisation requiring |
| | (EU) 2019/6, pursuant to Annex II, section | | accordance with Article 66 of | assessment in |
| | 6, to this Regulation. In the specific case of | | Regulation (EU) 2019/6, | accordance with Article |
| | point 6.5 of Annex II, the reduction shall | | pursuant to Annex II, section 6, | 66 of Regulation (EU) |
| | apply to the variations subject to a fee and | | to this Regulation. In the | 2019/6, pursuant to |
| | shall not apply to the variations subject to a | | specific case of point 6.5 of | Annex II, section 6, to |
| | charge; | | Annex II, the reduction shall | this Regulation. In the |
| | | | apply to the variations subject to | specific case of point 6.5 |
| | | | a fee and shall not apply to the | of Annex II, the |
| | | | variations subject to a charge; | reduction shall apply to |
| | | | | the variations subject to |
| | | | | a fee and shall not apply |
| | | | | to the variations subject |
| | | | | to a charge; |
| 433 | (e) certification of compliance with Union | | (e) certification of compliance | (e) certification of |
| | legislation for VAMF pursuant to section 8 | | with Union legislation for | compliance with Union |
| | of Annex II; | | | legislation for VAMF |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | | | VAMF pursuant to section 8 of | pursuant to section 8 of |
| | | | Annex II; | Annex II; |
| 434 | (f) certification of compliance with Union | | (f) certification of compliance | (f) certification of |
| | legislation for vPTMF pursuant to section 9 | | with Union legislation for | compliance with Union |
| | of Annex II; | | vPTMF pursuant to section 9 of | legislation for vPTMF |
| | | | Annex II; | pursuant to section 9 of |
| | | | | Annex II; |
| 435 | (g) assessment of post-marketing | | (g) assessment of post- | (g) assessment of post- |
| | surveillance studies pursuant to section 10 | | marketing surveillance studies | marketing surveillance |
| | of Annex II; | | pursuant to section 10 of Annex | studies pursuant to |
| | | | II; | section 10 of Annex II; |
| 436 | (h) annual fee pursuant to section 2 of | | (h) annual fee pursuant to section | (h) annual fee pursuant |
| | Annex III; | | 2 of Annex III; | to section 2 of Annex |
| | | | - , | III; |
| 437 | (i) pre-submission services pursuant to | | (i) pre-submission services | (i) pre-submission |
| | section 3 of Annex IV. | | pursuant to section 3 of Annex | services pursuant to |
| | | | IV. | section 3 of Annex IV. |

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| | | ouly 2020 | To dunc 2020 | proposals and comments |
| 438 | 5. Veterinary medicinal products for | | 5. Veterinary medicinal | 5. Veterinary |
| | limited markets | | products for limited markets | medicinal products for |
| | | | | limited markets |
| 439 | 5.1. A fee reduction of 50 % shall apply | | 5.1. A fee reduction of 50 % | 5.1. A fee reduction |
| | to veterinary medicinal products classified | | shall apply to veterinary | of 50 % shall apply to |
| | as intended for a limited market within the | | medicinal products classified as | veterinary medicinal |
| | meaning of Article 4(29) of Regulation | | intended for a limited market | products classified as |
| | (EU) 2019/6 and considered eligible for | | within the meaning of Article | intended for a limited |
| | authorisation or authorised pursuant to | | 4(29) of Regulation (EU) 2019/6 | market within the |
| | Article 23 of that Regulation, for the | | and considered eligible for | meaning of Article 4(29) |
| | following activities: | | authorisation or authorised | of Regulation (EU) |
| | | | pursuant to Article 23 of that | 2019/6 and considered |
| | | | Regulation, for the following | eligible for authorisation |
| | | | activities: | or authorised pursuant to |
| | | | | Article 23 of that |
| | | | | Regulation, for the |
| | | | | following activities: |

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| | | | | proposals and |
| | | | | comments |
| 440 | (a) scientific advice pursuant to section 1 of | | (a) scientific advice pursuant to | (a) scientific advice |
| | Annex II, to this Regulation; | | section 1 of Annex II, to this | pursuant to section 1 of |
| | | | Regulation; | Annex II, to this |
| | | | | Regulation; |
| 441 | (b) applications for establishment, | | (b) applications for | (b) applications for |
| | modification or extension of a maximum | | establishment, modification or | establishment, |
| | residue limit pursuant to section 3 of Annex | | extension of a maximum residue | modification or |
| | II, to this Regulation; | | limit pursuant to section 3 of | extension of a maximum |
| | | | Annex II, to this Regulation; | residue limit pursuant to |
| | | | | section 3 of Annex II, to |
| | | | | this Regulation; |
| 442 | (c) authorisation to market veterinary | | (c) authorisation to market | (c) authorisation to |
| | medicinal products falling within the scope | | veterinary medicinal products | market veterinary |
| | of the centralised marketing authorisation | | falling within the scope of the | medicinal products |
| | procedure pursuant to Article 42 of | | centralised marketing | falling within the scope |
| | Regulation (EU) 2019/6 pursuant to Article | | authorisation procedure pursuant | of the centralised |
| | 23 of that Regulation, pursuant to point 4.1 | | to Article 42 of Regulation (EU) | marketing authorisation |
| | or 4.2 of Annex II, to this Regulation; | | 2019/6 pursuant to Article 23 of | procedure pursuant to |
| | | | that Regulation, pursuant to | Article 42 of Regulation |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | | | point 4.1 or 4.2 of Annex II, to | (EU) 2019/6 pursuant to |
| | | | this Regulation; | Article 23 of that |
| | | | | Regulation, pursuant to |
| | | | | point 4.1 or 4.2 of |
| | | | | Annex II, to this |
| | | | | Regulation; |
| 443 | (d) variations to the terms of a marketing | | (d) variations to the terms of a | (d) variations to the |
| | authorisation requiring assessment in | | marketing authorisation | terms of a marketing |
| | accordance with Article 66 of Regulation | | requiring assessment in | authorisation requiring |
| | (EU) 2019/6, pursuant to section 6 of Annex | | accordance with Article 66 of | assessment in |
| | II. In the specific case of point 6.5 of Annex | | Regulation (EU) 2019/6, | accordance with Article |
| | II, the reduction shall apply to the variations | | pursuant to section 6 of Annex | 66 of Regulation (EU) |
| | subject to a fee and shall not apply to the | | II. In the specific case of point | 2019/6, pursuant to |
| | variations subject to a charge; | | 6.5 of Annex II, the reduction | section 6 of Annex II. In |
| | | | shall apply to the variations | the specific case of point |
| | | | subject to a fee and shall not | 6.5 of Annex II, the |
| | | | apply to the variations subject to | reduction shall apply to |
| | | | a charge; | the variations subject to |
| | | | | a fee and shall not apply |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | | comments |
| | | | | to the variations subject |
| | | | | to a charge; |
| 444 | (e) certification of compliance with Union | | (e) certification of compliance | (e) certification of |
| | legislation for VAMF pursuant to section 8 | | with Union legislation for | compliance with Union |
| | of Annex II to this Regulation; | | VAMF pursuant to section 8 of | legislation for VAMF |
| | | | Annex II to this Regulation; | pursuant to section 8 of |
| | | | | Annex II to this |
| | | | | Regulation; |
| 445 | (f) certification of compliance with Union | | (f) certification of compliance | (f) certification of |
| | legislation for vPTMF pursuant to section 9 | | with Union legislation for | compliance with Union |
| | of Annex II to this Regulation; | | vPTMF pursuant to section 9 of | legislation for vPTMF |
| | | | Annex II to this Regulation; | pursuant to section 9 of |
| | | | | Annex II to this |
| | | | | Regulation; |
| 446 | (g) assessment of post-marketing | | (g) assessment of post- | (g) assessment of post- |
| | surveillance studies pursuant to section 10 | | marketing surveillance studies | marketing surveillance |
| | of Annex II, to this Regulation; | | pursuant to section 10 of Annex | studies pursuant to |
| | | | II, to this Regulation; | section 10 of Annex II, |
| | | | | to this Regulation; |

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| | | | | proposals and |
| | | | | comments |
| 447 | (h) annual fee pursuant to section 2 of | | (h) annual fee pursuant to | (h) annual fee pursuant |
| | Annex III, to this Regulation; | | section 2 of Annex III, to this | to section 2 of Annex |
| | | | Regulation; | III, to this Regulation; |
| 448 | (i) pre-submission services pursuant section | | (i) pre-submission services | (i) pre-submission |
| | 3 to Annex IV, to this Regulation. | | pursuant section 3 to Annex IV, | services pursuant section |
| | | | to this Regulation. | 3 to Annex IV, to this |
| | | | | Regulation. |
| 449 | 5.2. A reduction of 100 % shall apply to | | 5.2. A reduction of 100 % | 5.2. A reduction of |
| | the fee for extension of maximum residues | | shall apply to the fee for | 100 % shall apply to the |
| | limits set out in section 3 of Annex II, when | | extension of maximum residues | fee for extension of |
| | such extension does not require assessment | | limits set out in section 3 of | maximum residues |
| | of data. | | Annex II, when such extension | limits set out in section |
| | | | does not require assessment of | 3 of Annex II, when |
| | | | data. | such extension does not |
| | | | | require assessment of |
| | | | | data. |
| 450 | 6. Veterinary vaccines against certain | | 6. Veterinary vaccines | 6. Veterinary |
| | major epizootic diseases | | against certain major epizootic | vaccines against certain |
| | | | diseases | major epizootic diseases |

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| | | | | proposals and |
| | | | | comments |
| 451 | 6.1. A fee reduction of 100 % shall apply to | | 6.1. A fee reduction of 100 % | |
| | the annual fee for vaccines against | | shall apply to the annual fee for | |
| | bluetongue, pandemic avian influenza, foot | | vaccines against infection with | |
| | and mouth disease and classical swine | | bluetongue virus (serotypes 1- | |
| | fever, where the vaccine is authorised under | | 24), pandemic highly | |
| | normal circumstances and the product has | | pathogenic avian influenza, foot | |
| | not been marketed within the Union at any | | and mouth disease and classical | |
| | time during the totality of the period | | swine fever, where the vaccine | |
| | covered by the fee. | | 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. | |
| 452 | 6.2. Where a reduction applies pursuant | | 6.2. Where a reduction | 6.2. Where a |
| | to point 6.1, no remuneration shall be paid | | applies pursuant to point 6.1, no | reduction applies |
| | to the national competent authorities for the | | remuneration shall be paid to the | pursuant to point 6.1, no |
| | annual fees referred to in point 6.1. | | national competent authorities | remuneration shall be |
| | | | | paid to the national |

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| | | | | proposals and |
| | | | | comments |
| | | | for the annual fees referred to in | competent authorities |
| | | | point 6.1. | for the annual fees |
| | | | | referred to in point 6.1. |
| 453 | 7. Annual fee for veterinary medicinal | | 7. Annual fee for veterinary | 7. Annual fee for |
| | products | | medicinal products | veterinary medicinal |
| | | | | products |
| 454 | A fee reduction of 25 % shall apply to the | | A fee reduction of 25 % shall | A fee reduction of 25 % |
| | annual fee for veterinary medicinal products | | apply to the annual fee for | shall apply to the annual |
| | set out in section 2 of Annex III, with the | | veterinary medicinal products | fee for veterinary |
| | exclusion of those products already listed in | | set out in section 2 of Annex III, | medicinal products set |
| | sections 4 and 5 of this Annex. | | with the exclusion of those | out in section 2 of |
| | | | products already listed in | Annex III, with the |
| | | | sections 4 and 5 of this Annex. | exclusion of those |
| | | | | products already listed |
| | | | | in sections 4 and 5 of |
| | | | | this Annex. |
| 455 | 8. Annual pharmacovigilance fee for | | 8. Annual | 8. Annual |
| | generic, homeopathic and herbal medicinal | | pharmacovigilance fee for | pharmacovigilance fee |
| | products | | | for generic, |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
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| | | | | proposals and |
| | | | 0 | comments |
| | | | generic, homeopathic and herbal | homeopathic and herbal |
| | | | medicinal products | medicinal products |
| 456 | A fee reduction of 20 % shall apply to the | A fee reduction of 30% shall | A fee reduction of 20 % shall | |
| | annual pharmacovigilance fee set out in | apply to the annual | apply to the annual | |
| | section 3 of Annex III for the following | pharmacovigilance fee set out in | pharmacovigilance fee set out in | |
| | medicinal products: | section 3 of Annex III for the | section 3 of Annex III for the | |
| | | following medicinal products: | following medicinal products: | |
| 457 | (a) medicinal products for human use as | | (a) medicinal products for | (a) medicinal products |
| | referred to in Article 10(1) and Article 10a | | human use as referred to in | for human use as |
| | of Directive 2001/83/EC; | | Article 10(1) and Article 10a of | referred to in Article |
| | | | Directive 2001/83/EC; | 10(1) and Article 10a of |
| | | | | Directive 2001/83/EC; |
| 458 | (b) homeopathic medicinal products for | | (b) homeopathic medicinal | (b) homeopathic |
| | human use; | | products for human use; | medicinal products for |
| | | | | human use; |
| 459 | (c) herbal medicinal products for human | | (c) herbal medicinal products for | (c) herbal medicinal |
| | use; | | human use; | products for human use; |

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| | | | | proposals and |
| | | | | comments |
| 460 | (d) veterinary medicinal products as referred | | (d) veterinary medicinal | (d) veterinary medicinal |
| | to in Articles 18 and 22 of Regulation (EU) | | products as referred to in | products as referred to in |
| | 2019/6; | | Articles 18 and 22 of Regulation | Articles 18 and 22 of |
| | | | (EU) 2019/6; | Regulation (EU) 2019/6; |
| 461 | (e) homeopathic veterinary medicinal | | (e) homeopathic veterinary | (e) homeopathic |
| | products; | | medicinal products; | veterinary medicinal |
| | | | | products; |
| 462 | (f) homeopathic veterinary medicinal | | (f) homeopathic veterinary | (f) homeopathic |
| | products registered in accordance with | | medicinal products registered in | veterinary medicinal |
| | Article 87 of Regulation (EU) 2019/6. | | accordance with Article 87 of | products registered in |
| | | | Regulation (EU) 2019/6. | accordance with |
| | | | | Article 87 of Regulation |
| | | | | (EU) 2019/6. |
| 463 | ANNEX VI | | ANNEX VI | ANNEX VI |
| | Performance information | | Performance information | Performance |
| | | | | information |
| 464 | The following information shall relate to | The following information shall | The following information shall | |
| | each calendar year: | relate to each calendar year and | relate to each calendar year: | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
|-----|--|----------------------------------|--------------------------------------|---------------------------|
| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| | | shall be made publicly available | | |
| | | on the Agency's website: | /C./ | |
| 465 | (1) the overall cost and breakdown of | | (1) the overall cost and | |
| | staff and non-staff costs relating to the fees | | breakdown of Agency staff and | |
| | and charges referred to in Article 3; | | non-staff costs relating to the | |
| | | | fees and charges referred to in | |
| | | | Article 3; | |
| 466 | (2) number of Agency staff involved | | (2) number of Agency staff | (2) number of |
| | and the overall costs for obtaining and | | involved and the overall costs | Agency staff involved |
| | maintaining a Union authorisation to market | | for obtaining and maintaining a | and the overall costs for |
| | medicinal products for human use and | | Union authorisation to market | obtaining and |
| | veterinary medicinal products and for other | | medicinal products for human | maintaining a Union |
| | services of the Agency; | | use and veterinary medicinal | authorisation to market |
| | | | products and for other services | medicinal products for |
| | | | of the Agency; | human use and |
| | | | | veterinary medicinal |
| | | | | products and for other |
| | | | | services of the Agency; |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
|------|--|---------------------------------|--|--------------------------|
| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| 467 | (3) number of procedures for obtaining | | (3) number of procedures for | (3) number of |
| | and maintaining a Union authorisation to | | obtaining and maintaining a | procedures for obtaining |
| | market medicinal products for human use | | Union authorisation to market | and maintaining a Union |
| | and veterinary medicinal products and for | | medicinal products for human | authorisation to market |
| | other services of the Agency; | | use and veterinary medicinal | medicinal products for |
| | | | products and for other services | human use and |
| | | | of the Agency; | veterinary medicinal |
| | | | | products and for other |
| | | | | services of the Agency; |
| 468 | (4) number of fee reductions granted per | | (4) number <u>and amount</u> of | |
| | type of fee reduction as set out in Annex V; | | fee reductions or waivers | |
| | | | granted per type of fee reduction | |
| | | | or waiver under Union | |
| | | | Legislation as set out in Annex | |
| | | | V] and number of applicants | |
| | | | or holders concerned; | |
| 468a | | (4a) number of fee reductions | | |
| | | granted as per executive | | |
| | | decisions set out in Article 6; | | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
|-----|--|----------------------------------|----------------------------------|---------------------------|
| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | 0 | comments |
| 469 | (5) attribution of rapporteurs, co- | | (5) attribution of | (5) attribution of |
| | rapporteurs, or roles considered as | | rapporteurs, co-rapporteurs, or | rapporteurs, co- |
| | equivalent for the purposes of this | | roles considered as equivalent | rapporteurs, or roles |
| | regulation as referred to in the Annexes to | | for the purposes of this | considered as equivalent |
| | this regulation, per Member State, per type | | regulation as referred to in the | for the purposes of this |
| | of procedure; | | Annexes to this regulation, per | regulation as referred to |
| | | | Member State, per type of | in the Annexes to this |
| | | | procedure; | regulation, per Member |
| | | | | State, per type of |
| | | | | procedure; |
| 470 | (6) number of working hours spent by the | (6) number of working hours | (6) number of working hours | |
| | rapporteur and the co-rapporteurs and | spent by the rapporteur and the | spent by the rapporteur and the | |
| | experts contracted for the procedures of the | co-rapporteurs, including hours | co-rapporteurs or roles | |
| | expert panels on medical devices per | spent by experts and others | considered as equivalent for | |
| | procedures on the basis of the information | employed by the competent | the purposes of this regulation | |
| | provided to the Agency by the national | authorities of the Member States | as referred to in the Annexes | |
| | competent authorities concerned. The | to assist them, and experts | to this regulation, and experts | |
| | procedures to be included shall be decided | contracted for the procedures of | contracted for the procedures of | |
| | | the expert panels on medical | the expert panels on medical | |

| | Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
|------|------------------------------------|-----------------------------------|---------------------------------|--------------------|
| | | July 2023 | 13 June 2023 | text, compromise |
| | | | | proposals and |
| | | | | comments |
| | by the Management Board based on a | devices per procedures on the | devices per type of procedures | |
| | proposal by the Agency. | basis of the information provided | on the basis of the information | |
| | | to the Agency by the national | provided to the Agency by the | |
| | | competent authorities concerned. | national competent authorities | |
| | | The procedures to be included | concerned. The <u>types of</u> | |
| | | shall be decided by the | procedures to be included shall | |
| | | Management Board based on a | be decided by the Management | |
| | | proposal by the Agency. | Board based on a proposal by | |
| | | | the Agency. | |
| 470a | | (6a) any performance | | |
| | | indicators relevant to scientific | | |
| | | service fees or charges for | | |
| | | administrative services levied in | | |
| | | accordance with Article 4(1) and | | |
| | | (2) of this Regulation; | | |
| 470b | | (6b) any additional relevant | | |
| | | key performance indicators that | | |
| | | impact the evolving workload of | | |
| | | the Agency and national | | |

| Commission proposal | EP amendments voted on 12 | Text agreed by the Council on | Tentatively agreed |
|---------------------|----------------------------------|-------------------------------|--------------------|
| | July 2023 | 13 June 2023 | text, compromise |
| | | | proposals and |
| | | | comments |
| | competent authorities in the | | |
| | Member States in the Union | (C) | |
| | pharmaceutical regulatory | | |
| | framework, including | | |
| | procedures for the authorisation | | |
| | and supervision of medicinal | | |
| | products. | | |

ANNEX VII Correlation table

| Regulation 297/95 | This Regulation |
|-------------------|--|
| Article 8(1) | Annex I, point 1 and Annex II, point 1 |
| Article 3(1) | Annex I, point 3 |
| Article 7 | Annex II, point 3 |
| | |
| | |
| Article 5(1) | Annex II, point 4 |
| Article 3(4) | Annex IV, point 1 |
| | |
| A | A TV : 4 1 |
| Article 5(4) | Annex IV, point 1 |
| Article 8(2) | Annex IV, point 5 |
| Article 8(3) | Annex IV, points 6.1, 6.2 and 6.4 |
| | |



Interinstitutional files: 2022/0417 (COD)

Brussels, 14 September 2023

WK 11431/2023 INIT

LIMITE

PHARM SAN MI COMPET CODEC VETER

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WORKING DOCUMENT

| From: To: | General Secretariat of the Council Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (EMA fees) |
|--------------|---|
| Subject: | 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 |

In preparation for the Working Party on EMA fees on 15 September 2023, the Presidency would like to give delegations the following guidance.

- 1. As regards elements that have been agreed, delegations will find in annex the four-column table which represents the state of negotiations between the co-legislators at the date of 12 September 2023.
 - 2. As regards a possible package for the trilogue, the following elements form part of it:
- Transparency: Rows 78 and 79 (Articles 6.4 and 6.5), Row 93 (Article 10.2), Row 93a (Article 10.2a (new), Row 97 (Article 10.6), Row 99c (Article 10. (6.1) (new), Row 99d and 99e (Article 10.6.a and paragraph 6b(new), Row 103 (Article 10.8), Row 464 (Annex VI)
- Veterinary sector: Annex II figures

- Reduction of annual fee on pharmacovigilance (Annex V)
- Sustainability factor of 7%
- 50% reduction in remuneration for total waivers
- Inclusion of academia in the scope of the Regulation
- Generics: Annex I.3.6 figures
- Variations type II (Annex I, point 5.1 and 5.2) figures
- PRAC rapporteur
- EMA Management Board role
- 3. Some other elements (in yellow) should be outside the package but Commission compromise language has not yet been reviewed in the informal technical meetings (e.g. a recital covering suggestion to include an estimated inflation adjustment for 2023 already in this proposal)

The Presidency will come with further information in the working party after the fourth informal technical meeting on Thursday 14 September. The Presidency will endeavour to come ahead of the working party with more detail on potential options