

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
1	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		REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 <u>and (EU) 2022/123</u> of the European Parliament and of	

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	(EU) 658/2014 of the European Parliament and of the Council		the Council and repealing 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 COUNCIL OF THE EUROPEAN UNION,		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	
3	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), points (b) and (c), thereof,		Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), points (b) and (c), thereof,	
4	Having regard to the proposal from the European Commission,		Having regard to the proposal from the European Commission,	
5	After transmission of the draft legislative act to the national parliaments,		After transmission of the draft legislative act to the national parliaments,	

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

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

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	and charges to be levied by the Agency, as well as cost-based remuneration to competent authorities of the Member States for the services they provide for the completion of the Agency's statutory tasks. 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.		<u>medicinal products for human use and veterinary medicinal products and to ensuring high level of protection of public and animal health, by</u> providing a sound financial basis for the operations of the Agency. It by establishes <u>cost-based fees and charges to be levied by the Agency, as well as cost-based remuneration to competent authorities of the Member States for the services 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,</u>	

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			<u>regardless of the Member State of origin of the competent authority.</u> 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			<u>(2a) This Regulation should only regulate fees and charges which are to be levied by the</u>	

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			<u>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.</u>	
12	(3) The fees payable to the Agency should be proportionate to the work carried out in relation to obtaining and maintaining a Union authorisation, and should be based on an evaluation of the Agency's estimations and forecasts as regards the workload and related costs for that work, as well as on an evaluation of the costs of the services provided to the Agency by the competent authorities of Member States that	(3) The fees payable to the Agency should be proportionate to the work carried out in relation to obtaining and maintaining a Union authorisation, and should be based on <i>a transparent</i> evaluation of the Agency's estimations and forecasts as regards the workload and related costs for that work, as well as on	(3) The fees payable to the Agency should be proportionate to the work carried out in relation to obtaining and maintaining a Union authorisation, and should be based on an evaluation of the Agency's estimations and forecasts as regards the workload and related costs for	

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	are responsible for regulating medicinal products, which act as rapporteurs and, where applicable, co-rapporteurs appointed by the scientific committees of the Agency.	an evaluation of the costs of the services provided to the Agency by the competent authorities of Member States that are responsible for regulating medicinal products, which act as rapporteurs and, where applicable, co-rapporteurs appointed by the scientific committees of the Agency. <i>The fees and fee structure should 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.</i>	that work, as well as on an evaluation of the costs of the services provided to the Agency by the competent authorities of Member States that are responsible for regulating medicinal products, which act as rapporteurs and, where applicable, co-rapporteurs appointed by the scientific committees of the Agency.	

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13	(4) Pursuant to Article 67(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council⁵, the revenue of the Agency consists of a contribution from the Union, a contribution from third countries participating in the work of the Agency with which the Union has concluded international agreements for this purpose, fees paid by undertakings for obtaining and maintaining Union marketing authorisations and for services provided by the coordination group as regards the fulfilment of its tasks in accordance with Articles 107c, 107e, 107g, 107k and 107q of Directive 2001/83/EC of the European Parliament and of the Council⁶, charges for other services provided by the Agency, and Union funding in the form of grants for participation in research and assistance		(4) Pursuant to Article 67(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council⁷, the revenue of the Agency consists of a contribution from the Union, a contribution from third countries participating in the work of the Agency with which the Union has concluded international agreements for this purpose, fees paid by undertakings for obtaining and maintaining Union marketing authorisations and for services provided by the coordination group as regards the fulfilment of its tasks in accordance with Articles 107c, 107e, 107g, 107k	

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	projects, in accordance with the Agency's financial rules and with the provisions of the relevant instruments supporting the policies of the Union. ⁵ 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 veterinary use and establishing a European Medicines Agency, (OJ L 136 30.4.2004, p. 1). ⁶ 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).		and 107q of Directive 2001/83/EC of the European Parliament and of the Council⁸, charges for other services provided by the Agency, and Union funding in the form of grants for participation in research and assistance projects, in accordance with the Agency's financial rules and with the provisions of the relevant instruments supporting the policies of the Union. 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		<i>(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</i>		

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		<i>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.</i> <i>^{1a} 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).</i>		
13b		<i>(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</i>		

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		<i>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.</i>		
13c		<i>(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</i>		

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		<i>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.</i>		
14	(5) Fees and charges should cover the cost of statutory services and activities of the Agency that is not already covered by the contributions to its revenue from other sources. All relevant Union legislation governing the Agency's activities and fees should be taken into account when establishing the fees and charges, including	(5) Fees and charges should cover the cost of statutory services and activities of the Agency that is not already covered by the contributions to its revenue from other sources. All relevant Union legislation governing the Agency's activities	(5) Fees and charges should cover the cost of statutory services and activities of the Agency that is not already covered by the contributions to its revenue from other sources. All relevant Union legislation governing the Agency's	

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

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	⁹ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43). ¹⁰ Regulation (EC) No 1901/2006 of the European 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 (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1). ¹¹ 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 Regulation (EC) No 1394/2007 of 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).	Parliament and of the Council²⁷, Regulation (EC) No 470/2009 of the European Parliament and of the Council²⁸, <i>Regulation (EU) 2022/123</i>, Commission Regulation (EU) 2018/782²⁹, Commission Implementing Regulation (EU) 2021/1281³⁰ and Commission Regulation (EC) No 2141/96³¹. ²¹ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43). ²² Regulation (EC) No 1901/2006 of the European 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	1234/2008²⁵, Regulation (EU) 2017/745 of the European Parliament and of the Council²⁶, <u>Regulation (EU) 2017/746 of the European Parliament and of the Council²⁷</u>, Regulation (EC) No 470/2009 of the European Parliament and of the Council²⁸, Commission Regulation (EU) 2018/782²⁹, Commission Implementing Regulation (EU) 2021/1281³⁰ and Commission Regulation (EC) No 2141/96³¹. ²⁰ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and	

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	¹³ 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). ¹⁴ Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning 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). ¹⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). ¹⁶ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying	(EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1). ²³ 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). ²⁴ Regulation (EC) No 1394/2007 of 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). ²⁵ 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). ²⁶ Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning 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). ²⁷ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,	repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43). ²¹ Regulation (EC) No 1901/2006 of the European 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 (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1). ²² 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). ²³ Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC	

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	down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11). ¹⁷ 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). ¹⁸ Commission Implementing Regulation (EU) 2021/1281 of 2 August 2021 laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products (OJ L 279, 3.8.2021, p. 15).	amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). 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 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 pharmacovigilance practice and on the format, content and summary of the pharmacovigilance system master file	and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121). ²⁴ 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). ²⁵ Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning 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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	¹⁹ Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorization for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93 (OJ L 286, 8.11.1996, p. 6).	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 (EC) No 2309/93 (OJ L 286, 8.11.1996, p. 6).	²⁶ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). <u>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)</u> 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 practice and on the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products (OJ L 279, 3.8.2021, p. 15). 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 (EEC) No 2309/93 (OJ L 286, 8.11.1996, p. 6).	
15	(6) Pursuant to Article 6(1) of Regulation (EC) No 726/2004, each application for the authorisation of a medicinal product for human use is to be accompanied by the fee payable to the Agency for the examination of that application. Pursuant to Article 43(1) of Regulation (EU) 2019/6, an application for a		(6) Pursuant to Article 6(1) of Regulation (EC) No 726/2004, each application for the authorisation of a medicinal product for human use is to be accompanied by the fee payable to the Agency for the examination of that	

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

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

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	be auditable in accordance with Article 257 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council³². 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 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).	Agency by the competent authorities of Member States, which act as rapporteurs and, where applicable, co-rapporteurs and by experts contracted by the Agency for the procedures of the expert panels on medical devices. Cost information relating to services remunerated by the Agency should be auditable in accordance with Article 257 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council³². 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	remuneration of services provided to the Agency by the competent authorities of Member States, which act as rapporteurs and, where applicable, co-rapporteurs and by experts contracted by the Agency for the procedures of the expert panels on medical devices. Cost information relating to services remunerated by the Agency should be auditable in accordance with Article 257 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council³³.	

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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).	³³ 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 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).	
17	(8) Fees should be levied on marketing authorisation applicants and holders on a fair basis whereby the fee charged is proportionate to the assessment work. Therefore, for the purpose of charging some post-authorisation fees where products authorised by the Member States are included in the assessment performed by the Agency, a chargeable unit should be established, irrespective not only of the procedure under which the product has been		(8) Fees should be levied on marketing authorisation applicants and holders on a fair basis whereby the fee charged is proportionate to the assessment work. Therefore, for the purpose of charging some post-authorisation fees where products authorised by the Member States are included in the assessment performed by the	

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

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	the chargeable unit in respect of homeopathic medicinal products or herbal medicinal products. For veterinary medicinal products, the same objective of 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) 2021/16³⁴, as well as the Permanent Identifier referred to under Data Field ID 3.1 in Annex III to that Implementing Regulation. _____		by establishing the chargeable unit on the basis of the active substances and the pharmaceutical form of the products that are subject to the obligation to be registered in the database referred to in Article 57(1), second subparagraph , point (l), of Regulation (EC) No 726/2004, based on information from the list of all medicinal products for human use authorised in the Union referred to in Article 57(2), second subparagraph, of that Regulation. The active substances should not be taken into account when establishing the chargeable unit in respect of	

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	³⁴ 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).		homeopathic medicinal products or herbal medicinal products. For veterinary medicinal products, the same objective of 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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			2021/16³⁵, 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 marketing authorisations of medicinal products granted to marketing authorisation holders, the number of chargeable units corresponding to those authorisations should take into account the number of		(9) In order to take into account all the marketing authorisations of medicinal products granted to marketing authorisation holders, the number of chargeable units corresponding to those	

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

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

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	maintenance of marketing authorisation dossiers and of the various databases managed by the Agency, and activities contributing to a continuous follow-up of the risk-benefit balance of authorised medicinal products. They also comprise access to and analysis of Union-wide health data to support better decision-making throughout the product lifecycle on medicines 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.		Those activities include the recording of the actual marketing of medicinal products authorised in accordance with Union procedures, the maintenance of marketing authorisation dossiers and of the various databases managed by the Agency, <u>minor variations of Type I and renewals</u> and activities contributing to a continuous follow-up of the risk-benefit balance of authorised medicinal products. They also comprise access to and analysis of Union-wide 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 charged for medicinal products authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by the Member States in accordance with Regulation (EU) 2019/6 specifically for the pharmacovigilance activities carried out by the Agency that		(12) A specific annual fee should be charged for medicinal products authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by the Member States in accordance with Regulation	

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	benefit marketing authorisation holders overall. Those activities relate to information technology, in particular maintenance of the EudraVigilance database referred to in Article 24(1) of Regulation (EC) No 726/2004, the Union product database referred to in Article 55(1) of Regulation (EU) 2019/6 and the Union pharmacovigilance database referred to in Article 74(1) of that Regulation, the monitoring of selected medical literature and the timely access to and analysis of Union-wide health data to support decision-making throughout the product lifecycle on medicines with valid and reliable real-world evidence.		(EU) 2019/6 specifically for the pharmacovigilance activities carried out by the Agency that benefit marketing authorisation holders overall. Those activities relate to information technology, in particular maintenance of the EudraVigilance database referred to in Article 24(1) of Regulation (EC) No 726/2004, the Union product database referred to in Article 55(1) of Regulation (EU) 2019/6 and the Union pharmacovigilance database referred to in 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 activities and services of an administrative nature, such as issuing certificates, that are not covered by a fee provided for in this Regulation, whereas fees levied by the Agency should correspond to services of a scientific nature provided by the Agency under its mandate, which contribute to the assessment relating to medicinal products and the maintenance of authorised products, including a continuous monitoring of the risk-benefit balance.		(13) Charges should <u>can</u> be levied for activities and services of an administrative nature, such as issuing certificates, that are not covered by a fee provided for in this Regulation, whereas fees levied by the Agency should correspond to services of a scientific nature provided by the Agency under its mandate, which contribute to the assessment relating to medicinal products and the maintenance of authorised products, including a	

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

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

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			products <u>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 2022.</u>	
26	(17) The Management Board of the Agency should be empowered to provide further fee reductions for justified reasons of protection of public and animal health. A favourable opinion from the Commission should be mandatory before granting further	(17) The Management Board of the Agency should be empowered to provide further fee reductions for duly justified reasons of protection of public and animal health. A favourable	(17) The Management Board of the Agency should be empowered to provide further fee <u>or charge</u> reductions for justified reasons of protection of public and animal health <u>or for</u>	

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

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		Agency to reduce certain types of fees on the basis of a critical examination of the situation specific to each case. <i>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.</i>		
27	(18) In order to provide flexibility, in particular to adapt to developments in science, the Management Board of the Agency should be enabled to specify working arrangements to facilitate the application of this Regulation, on a duly justified proposal from the Executive Director. In particular, the Management Board should be able to establish due dates	(18) In order to provide flexibility, in particular to adapt to developments in science and to address unforeseen circumstances and medical needs , the Management Board of the Agency should be enabled to specify working arrangements to facilitate the application of this	(18) In order to provide flexibility, in particular to adapt to developments in science, the Management Board of the Agency should be enabled to specify working arrangements to facilitate the application of this Regulation, on a duly justified proposal from the Executive	

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

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			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 and co-rapporteurs and the other roles considered as equivalent for the purposes of this regulation in scientific advice and inspections rely on the scientific evaluations and resources of the competent authorities of Member States, while it is the responsibility of the Agency to coordinate the existing scientific resources put at its disposal by the Member States, in accordance with Article 55 of Regulation (EC) No 726/2004. In light of that, and to ensure appropriate resources for the	(19) For their assessments, rapporteurs and co-rapporteurs and the other roles considered as equivalent for the purposes of this regulation in scientific advice and inspections rely on the scientific evaluations and resources of the competent authorities of Member States, while it is the responsibility of the Agency to coordinate the existing scientific resources put at its disposal by the Member States, in accordance	(19) For their assessments, rapporteurs and co-rapporteurs and the other roles considered as equivalent for the purposes of this regulation in scientific advice and inspections rely on the scientific evaluations and resources of the competent authorities of Member States, while it is the responsibility of the Agency to coordinate the existing scientific resources put at its disposal by the Member	

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

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		services provided by those rapporteurs and co-rapporteurs should be based on estimations of the workload involved and should be taken into account in setting the level of the fees charged by the Agency. <i>Based on a specific public interest benefitting both 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.</i>	amount of remuneration for the services provided by those rapporteurs and co-rapporteurs should be based on estimations of the workload involved and should be taken into account in setting the level of the fees charged by the Agency.	
29	(20) In line with the policy of the Union to support SMEs within the meaning of Commission Recommendation 2003/361/EC ³⁶ , fee reductions should apply		(20) In line with the policy of the Union to support SMEs as defined in within the meaning of Commission	

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	to them. Such reductions should be established on a basis that takes due account of the ability of SMEs to pay. In order to ensure that the current framework for support to SMEs remains unchanged until a possible revision of Commission Regulation (EC) No 2049/2005³⁷, current post-authorisation fee reduction rates should be granted to SMEs. Furthermore, microenterprises should be exempted from all post-authorisation fees. ³⁶ Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (2003/361/EC) (OJ L 124, 20.5.2003, p. 36). ³⁷ 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		Recommendation 2003/361/EC³⁸, fee reductions should apply to them. Such reductions should be <u>beare to be</u> established on a basis that takes due account of the ability of SMEs to pay. In order to ensure <u>consistency of</u> that the current framework for support to SMEs <u>with</u> remains unchanged until a possible revision of Commission Regulation (EC) No 2049/2005³⁹, current post-authorisation fee reduction rates should be granted to SMEs. Furthermore, microenterprises should be exempted from all post-authorisation fees.	

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	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).		³⁸ Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized 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 human use and generic veterinary medicinal products, medicinal products for human use and veterinary medicinal products authorised under the provisions relating to		(21) Generic medicinal products for human use and generic veterinary medicinal products, medicinal products for human use and veterinary	

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	well-established medicinal use, homeopathic medicinal products for human use and homeopathic veterinary medicinal products, as well as herbal medicinal products for human use should be subject to a reduced annual pharmacovigilance fee, as those medicinal products generally have a well-established safety 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 charged in view of the work involved.		medicinal products authorised under the provisions relating to well-established medicinal use, homeopathic medicinal products for human use and homeopathic veterinary medicinal products, as well as herbal medicinal products for human use should be subject to a reduced annual pharmacovigilance fee, as those medicinal products generally have a well-established safety 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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			charged in view of the work involved.	
31	(22) In order to avoid a disproportionate administrative workload for the Agency, fee reductions and fee exemptions should be applied on the basis of a declaration of the marketing authorisation holder or applicant claiming to be entitled to such a measure. The submission of incorrect information in that respect should be discouraged by means of the application of a specific charge if the Agency establishes that such incorrect information has been submitted.		(22) In order to avoid a disproportionate administrative workload for the Agency, fee reductions and fee exemptions should be applied on the basis of a declaration of the marketing authorisation holder or applicant claiming to be entitled to such a measure. The submission of incorrect information in that 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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32	(23) For reasons of predictability and clarity, the amounts of the fees, charges and remuneration should be set in euro.		(23) For reasons of predictability and clarity, the amounts of the fees, charges and remuneration should be <u>are</u> set in euro.	
33	(24) The amounts of the fees and charges and the remuneration to competent authorities of the Member States should be adjusted, where appropriate, to take account of significant changes in costs, detected through cost monitoring, and to take account of inflation. For the purpose of taking into account the impact of inflation, the Harmonised Index of Consumer Prices published by Eurostat pursuant to Regulation (EU) No 2016/792 of the European Parliament and of the Council ⁴⁰ should be used. 		(24) The amounts of the fees and charges and the remuneration to competent authorities of the Member States should be adjusted, where appropriate, to take account of significant changes in costs, detected through cost monitoring, and to take account of inflation. For the purpose of taking into account the impact of inflation, the Harmonised Index of Consumer Prices published by Eurostat pursuant	

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	⁴⁰ 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).		to Regulation (EU) No 2016/792 of the European Parliament and of the Council⁴¹ should be used. <u>The first 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.</u> 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).	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
34	(25) In order to ensure swift adjustment of the structure and amounts of fees, charges and remuneration to competent authorities of the Member States to significant changes of costs or processes, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the relevant amounts and the activities subject to fees and charges and remuneration, on the basis of objective information related to costs or changes to the regulatory framework. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional		(25) In order to ensure swift adjustment of the structure and amounts of fees, charges and remuneration to competent authorities of the Member States to significant changes of costs or processes, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the relevant amounts and the activities subject to fees and charges and remuneration, on the basis of objective information related to costs or changes to the regulatory framework. <u>This information is</u>	

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	Agreement of 13 April 2016 on Better Law-Making⁴². 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. ⁴² Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12.5.2016, p. 1).		<u>provided mainly via a special report adopted by the Management Board of the Agency, which contains justified recommendations to increase or decrease the amount of any fee, charge or remuneration, amend the Annexes, including on the basis of changes in the statutory tasks of the Agency, add fees and adapt the specification of activities.</u> It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in	

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			accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁴³. 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. <u>If a change of the fees were to result in an increased share on the side of the Agency, special consideration should be given</u>	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			<u>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.</u> ⁴³ Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12.5.2016, p. 1).	
35	(26) In order to ensure cost recovery, the Agency should provide services by virtue of the tasks entrusted to it only after the corresponding fee or charge has been paid in its entirety. However, in accordance with Article 71, fourth subparagraph, of Commission Delegated Regulation (EU)		(26) In order to ensure cost recovery, the Agency should provide services by virtue of the tasks entrusted to it only after the corresponding fee or charge has been paid in its entirety. However, in accordance with	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	2019/715⁴⁴, in exceptional circumstances, a service may be provided without prior payment of the corresponding fee or charge. ⁴⁴ Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 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).		Article 71, fourth subparagraph, of Commission Delegated Regulation (EU) 2019/715⁴⁵, in exceptional circumstances, a service may be provided without prior payment of the corresponding fee or charge. ⁴⁵ Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 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		<i>(26a) Member States should ensure that adequate financial resources are available to</i>		

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
		<i>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.</i>		
35b		<i>(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</i>		

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
		<i>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</i>		

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
		<i>months before the date of application of this Regulation.</i>		
36	(27) In accordance with Article 30 of Regulation (EU) 2022/123⁴⁶, the Agency provides, on behalf of the Commission, the secretariat for the expert panels designated in accordance with Regulation (EU) 2017/745. The provision in Article 106 of Regulation (EU) 2017/745 concerning the payment of fees for advice provided by expert panels should therefore be amended in order to allow the Agency to receive those fees, once such fees are established by the Commission in accordance with that Regulation. _____ ⁴⁶ 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		(27) In accordance with Article 30 of Regulation (EU) 2022/123⁴⁷, the Agency provides, on behalf of the Commission, the secretariat for the expert panels designated in accordance with Regulation (EU) 2017/745. The provision in Article 106 of Regulation (EU) 2017/745 concerning the payment of fees for advice provided by expert panels should therefore be amended in order to allow the Agency to receive charge those fees, once such fees are established by the	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).		Commission in accordance with that Regulation. 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 Regulation, namely to ensure appropriate funding of Agency activities carried out at Union level, cannot sufficiently be achieved by the Member States but can rather, by reason of the scale of the measure, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in		(28) Since the objective of this Regulation, namely to ensure appropriate funding of Agency activities carried out at Union level, cannot sufficiently be achieved by the Member States but can rather, by reason of the scale of the measure, be better achieved at Union level,	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	Article 5 of the Treaty on 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,		the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on 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			<u>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.</u>	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
38	HAVE ADOPTED THIS REGULATION:		HAVE ADOPTED THIS REGULATION:	
39	<i>Article 1</i> Subject matter		<i>Article 1</i> Subject matter <u>and scope</u>	
40	This Regulation lays down the following:		<u>L.</u> This Regulation lays down the following:	<u>L.</u> This Regulation lays down the following:
41	(a) the amounts of the fees and charges established on cost-based evaluation and levied by the European Medicines Agency (the ‘Agency’) for assessment activities relating to obtaining and maintaining a Union authorisation to market medicinal products for human use and veterinary medicinal 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;		(a) the amounts of the fees and charges established on cost-based evaluation and levied by the European Medicines Agency (the ‘Agency’) for assessment activities relating to obtaining and maintaining a Union authorisation to market medicinal products for human use and veterinary medicinal products and for other services provided or tasks carried out by the Agency, as provided for in	(a) the amounts of the fees and charges established on cost-based evaluation and levied by the European Medicines Agency (the ‘Agency’) for assessment activities relating to obtaining and maintaining a Union authorisation to market medicinal products for human use and

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			Regulations (EC) 726/2004 and (EU) 2019/6;	veterinary medicinal 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 remuneration established on cost-based evaluation and payable by the Agency to the competent authorities of the Member States for the services provided by rapporteurs and, where applicable, co-rapporteurs from competent authorities of 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		(b) the corresponding amounts of remuneration established on cost-based evaluation and payable by the Agency to the competent authorities of the Member States for the services provided by rapporteurs and, where applicable, co-rapporteurs from competent authorities of the Member States, or by other roles	(b) the corresponding amounts of remuneration established on cost-based evaluation and payable by the Agency to the competent authorities of the Member States for the services provided by rapporteurs and, where

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			considered as equivalent for the purposes of this regulation, as referred to in the Annexes to this Regulation; and	applicable, co-rapporteurs from competent authorities of 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 and services provided by the Agency and of costs for remuneration referred to in point (b).		(c) the monitoring of costs of activities and services provided by the Agency and of costs for remuneration referred to in point (b).	(c) the monitoring of costs of activities and services provided by the Agency and of costs for remuneration referred to in point (b).
43a			<u>2. Medicinal products for human use which are</u>	<u>2. Medicinal products for human use which are</u>

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			<u>authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC shall not be subject to the fees for pharmacovigilance activities set out in the Annexes to this Regulation.</u>	<u>authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC shall not be subject to the fees for pharmacovigilance activities set out in the Annexes to this Regulation.</u>
44	<i>Article 2</i> Definitions		<i>Article 2</i> Definitions	
45	For the purposes of this Regulation, the following definitions shall apply:		For the purposes of this Regulation, the following definitions shall apply:	For the purposes of this Regulation, the following definitions shall apply:
46	(1) ‘chargeable unit in relation to medicinal products for human use’		(1) ‘chargeable unit in relation to medicinal products	(1) ‘chargeable unit in relation to medicinal

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	(‘chargeable unit - human’) means a unit defined by a unique combination of the following dataset derived from information on all medicinal products authorised in the Union held by the Agency, and consistent with the obligation of marketing authorisation holders referred to in Article 57(2), points (b) and (c), of Regulation (EC) No 726/2004 to submit such information to the database referred to in Article 57(1), second subparagraph, point (l), of that Regulation:		for human use’ (‘chargeable unit - human’) means a unit defined by a unique combination of the following dataset derived from information on all medicinal products authorised in the Union held by the Agency, and consistent with the obligation of marketing authorisation holders referred to in Article 57(2), points (b) and (c), of Regulation (EC) No 726/2004 to submit such information to the database referred to in Article 57(1), second subparagraph, point (l), of that Regulation:	products for human use’ (‘chargeable unit - human’) means a unit defined by a unique combination of the following dataset derived from information on all medicinal products authorised in the Union held by the Agency, and consistent with the obligation of marketing authorisation holders referred to in Article 57(2), points (b) and (c), of Regulation (EC) No 726/2004 to submit such information

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
				to the database referred to in Article 57(1), second subparagraph, point (l), of that Regulation:
47	(a) name of the medicinal product, as defined in Article 1, point (20), of Directive 2001/83/EC;		(a) name of the medicinal product, as defined in Article 1, point (20), of Directive 2001/83/EC;	(a) name of the medicinal product, as defined in Article 1, point (20), of Directive 2001/83/EC;
48	(b) marketing authorisation holder;		(b) marketing authorisation holder;	(b) marketing authorisation holder;
49	(c) the Member State in which the marketing authorisation is valid;		(c) the Member State in which the marketing authorisation is valid;	(c) the Member State in which the marketing authorisation is valid;
50	(d) active substance or a combination of active substances, except in the case of homeopathic medicinal products or herbal		(d) active substance or a combination of active substances, except in the case of	(d) active substance or a combination of active substances,

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	medicinal products, as defined in Article 1, points 5 and 30, respectively, of Directive 2001/83/EC;		homeopathic medicinal products or herbal medicinal products, as defined in Article 1, points 5 and 30, respectively, of Directive 2001/83/EC;	except in the case of homeopathic medicinal products or herbal medicinal products, as 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 veterinary medicinal products’ (‘chargeable unit - veterinary’) means a unit defined by the unique combination of the following data fields contained in the Union product database established pursuant to Article 55(1) of Regulation (EU) 2019/6:		(2) ‘chargeable unit in relation to veterinary medicinal products’ (‘chargeable unit - veterinary’) means a unit defined by the unique combination of the following data fields contained in the Union product database established pursuant to	(2) ‘chargeable unit in relation to veterinary medicinal products’ (‘chargeable unit - veterinary’) means a unit defined by the unique combination of the following data fields contained in the Union

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			Article 55(1) of Regulation (EU) 2019/6:	product database established pursuant to Article 55(1) of Regulation (EU) 2019/6:
53	(a) the Permanent Identifier referred to under Data Field ID 3.1 in Annex III to Implementing Regulation (EU) 2021/16;		(a) the Permanent Identifier referred to under Data Field ID 3.1 in Annex III to Implementing Regulation (EU) 2021/16;	(a) the Permanent Identifier referred to under Data Field ID 3.1 in Annex III to Implementing Regulation (EU) 2021/16;
54	(b) the Product Identifier referred to under Data Field ID 3.2 in Annex III to Implementing Regulation (EU) 2021/16;		(b) the Product Identifier referred to under Data Field ID 3.2 in Annex III to Implementing Regulation (EU) 2021/16;	(b) the Product Identifier referred to under Data Field ID 3.2 in Annex III to Implementing Regulation (EU) 2021/16;

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
55	(3) 'medium-sized enterprise' means a medium-sized enterprise within the meaning of Recommendation 2003/361/EC;		(3) 'medium-sized enterprise' means a medium-sized enterprise within the meaning of Recommendation 2003/361/EC;	(3) 'medium-sized enterprise' means a medium-sized enterprise within the meaning of Recommendation 2003/361/EC;
56	(4) 'small enterprise' means a small enterprise within the meaning of Recommendation 2003/361/EC;		(4) 'small enterprise' means a small enterprise within the meaning of Recommendation 2003/361/EC;	(4) 'small enterprise' means a small enterprise within the meaning of Recommendation 2003/361/EC;
57	(5) 'microenterprise' means a microenterprise within the meaning of Recommendation 2003/361/EC;		(5) 'microenterprise' means a microenterprise within the meaning of Recommendation 2003/361/EC;	(5) 'microenterprise' means a microenterprise within the meaning of Recommendation 2003/361/EC;
57a		<i>(5a) 'Academia' or 'academic sector' means public or private</i>		

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
		<i>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;</i>		
57b		<i>(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;</i>		
57c		<i>(5c) ‘International European interest organisation’ means an international organisation, the majority of whose members are</i>		

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
		<i>Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in the Union;</i>		
58	(6) ‘public health emergency’ means a situation of public health emergency recognised by the Commission in accordance with Article 12(1) of Decision No 1082/2013/EU of the European Parliament and of the Council⁴⁸. ⁴⁸ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).	(6) ‘public health emergency’ means a situation of public health emergency recognised by the Commission in accordance with Article 23 of Regulation (EU) 2022/2371 of the European Parliament and of the Council⁴⁰. ⁴⁰ 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, p. 26).	(6) ‘public health emergency’ means a situation of public health emergency recognised by the Commission in accordance with Article <u>23(1) of Regulation (EU) 2022/2371 of the European Parliament and of the Council</u> 12(1) of Decision No 1082/2013/EU of the European Parliament and of the Council⁴⁸.	(6) ‘public health emergency’ means a situation of public health emergency recognised by the Commission in accordance with Article <u>23(1) of Regulation (EU) 2022/2371 of the European Parliament and of the Council</u> 12(1) of Decision

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			⁴⁹ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1). <u>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, p. 26–63</u>	No 1082/2013/EU of the European Parliament and of the Council⁴⁸.
59	<i>Article 3</i> Types of fees and charges		<i>Article 3</i> Types of fees and charges	<i>Article 3</i> Types of fees and charges
60	The Agency may levy the following types of fees or charges:		The Agency may levy the following types of fees or charges:	The Agency may levy the following types of fees or charges:

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
61	(a) fees and charges for assessment procedures and services relating to medicinal products for human use, set out in Annex I;		(a) fees and charges for assessment procedures and services relating to medicinal products for human use, set out in Annex I;	(a) fees and charges for assessment procedures and services relating to medicinal products for human use, set out in Annex I;
62	(b) fees for and charges for assessment procedures and services relating to veterinary medicinal products, set out in Annex II;		(b) fees for and charges for assessment procedures and services relating to veterinary medicinal products, set out in Annex II;	(b) fees for and charges for assessment procedures and services relating to veterinary medicinal products, set out in Annex II;
63	(c) annual fees for authorised medicinal products for human use and for authorised veterinary medicinal products, set out in Annex III;		(c) annual fees for authorised medicinal products for human use and for authorised veterinary medicinal products, set out in Annex III;	(c) annual fees for authorised medicinal products for human use and for authorised veterinary medicinal products, set out in Annex III;

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
64	(d) other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices, set out in Annex IV.		(d) other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices, set out in Annex IV.	(d) other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices, set out in Annex IV.
65	<i>Article 4</i> Additional fees and charges		<i>Article 4</i> Additional fees and charges	<i>Article 4</i> Additional fees and charges
66	1. The Agency may levy a scientific service fee for scientific services it provides if these services are not covered by another fee or charge provided for in this Regulation. The amount of the scientific service fee shall take into account the workload involved. Its minimum and maximum amount and, where relevant, the corresponding remuneration to		1. The Agency may levy a scientific service fee for scientific services it provides if these services are not covered by another fee or charge provided for in this Regulation. The amount of the scientific service fee shall take into account the	1. The Agency may levy a scientific service fee for scientific services it provides if these services are not covered by another fee or charge provided for in this Regulation. The

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	the rapporteurs and, where relevant, co-rapporteurs, are set out in point 5 of Annex IV.		workload involved. Its minimum and maximum amount and, where relevant, the corresponding remuneration to the rapporteurs and, where relevant, co-rapporteurs, are set out in point 5 of Annex IV.	amount of the scientific service fee shall take into account the workload involved. Its minimum and maximum amount and, where 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 administrative services it provides, at the request of a third party, if these services are not covered by another fee or charge provided for in this Regulation. The amount of the charge for administrative services shall		2. The Agency may levy a charge for administrative services it provides, at the request of a third party, if these services are not covered by another fee or charge provided	2. The Agency may levy a charge for administrative services it provides, at the request of a third party, if these services are not covered

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	take into account the workload involved. Its minimum and maximum amount are set out in point 6.4 of Annex IV.		for in this Regulation. The amount of the charge for administrative services shall take into account the workload involved. Its minimum and maximum amount are set out in point 6.4 of Annex IV.	by another fee or charge provided for in this Regulation. The amount of the charge for administrative services shall take into account 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 paragraphs 1 and 2 shall be set by the Management Board of the Agency following a favourable opinion by the Commission, in accordance with the procedure established under Article 8. The applicable amounts shall be published on the website of the Agency.		3. Fees and charges levied pursuant to paragraphs 1 and 2 shall be set by the Management Board of the Agency following a favourable opinion by the Commission, in accordance with the procedure established under Article 8. The applicable	3. Fees and charges levied pursuant to paragraphs 1 and 2 shall be set by the Management Board of the Agency following a favourable opinion by the Commission, in

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			amounts shall be published on the website of the Agency.	accordance with the procedure established under Article 8. The applicable amounts shall be published on the website of the Agency.
69	4. The Commission shall take into account any fees and charges levied in accordance with this Article in any revision of this Regulation.		4. The Commission shall take into account any fees and charges levied in accordance with this Article in any revision of this Regulation.	4. The Commission shall take into account any fees and charges levied in accordance with this Article in any revision of this Regulation.

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
70	<i>Article 5</i> Payment of remuneration to competent authorities of the Member States for the provision of services to the Agency		<i>Article 5</i> Payment of remuneration to competent authorities of the Member States for the provision of services to the Agency	<i>Article 5</i> Payment of remuneration to competent authorities of the Member States for the provision of services to the Agency
71	1. The Agency shall pay the remuneration referred to in Article 1(b) in accordance with the amounts of remuneration provided for in this Regulation.		1. The Agency shall pay the remuneration referred to in Article 1(b) in accordance with the amounts of remuneration provided for in this Regulation.	1. The Agency shall pay the remuneration referred to in Article 1(b) in accordance with the amounts of remuneration provided for in this Regulation.
72	2. Unless otherwise provided for in this Regulation, where fee reductions apply, the remuneration to competent authorities of the	2. Unless otherwise provided for in this Regulation, where <i>less than total</i> fee reductions apply, the remuneration to competent	2. Unless otherwise provided for in this Regulation, where fee reductions <u>or waivers</u> apply, the remuneration to	<i>Linked with discussion on annexes</i>

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

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	by the Management Board of the Agency, in accordance with Article 8 of this Regulation.		of such remuneration shall be borne by the Agency. 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.	No 726/2004. The remuneration shall be paid in euro. Any bank charges related to the payment of such remuneration shall be borne by the Agency. 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	<i>Article 6</i> Reductions of fees and charges		<i>Article 6</i> Reductions of fees and charges	<i>Article 6</i> Reductions of fees and charges

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75	1. The Agency shall apply the reductions set out in Annex V.		1. The Agency shall apply the reductions set out in Annex V.	1. The Agency shall apply the reductions set out in Annex V.
76	2. Where an assessment, an opinion or a service of the Agency is requested either by a Member State or by a Union institution, the Agency shall waive the respective fee or charge, as applicable, in full.		2. Where an assessment, an opinion or a service of the Agency is requested either by a Member State or by a Union institution, the Agency shall <u>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.</u> waive the respective fee or charge, as applicable, in full.	
77	3. Where the applicant or marketing authorisation holder may also benefit from		3. <u>Without prejudice to Article 5(2),</u> W where the	<u>Without prejudice to Article 5(2),</u> W where

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	another reduction provided for in Union legislation, only the reduction that is the most favourable to the applicant or marketing authorisation holder shall apply.		applicant or marketing authorisation holder may also benefit from another reduction provided for in Union legislation, only the reduction that is the most favourable to the applicant or marketing authorisation holder shall apply.	the applicant or marketing authorisation holder may also benefit from another reduction provided for in Union legislation, only the reduction that is the most favourable to the applicant or marketing authorisation holder shall apply.
78	4. On a duly justified proposal from the Executive Director of the Agency, in particular for the protection of public or animal health or for the support of specific types of products or applicants, selected for duly justified reasons, the Management Board of the Agency may grant, following a favourable opinion from the Commission, a	4. On a duly justified proposal from the Executive Director of the Agency, in particular for the protection of public or animal health or for the support of specific types of products or <i>types of</i> applicants, selected for duly justified reasons,	4. On a duly justified proposal from the Executive Director of the Agency, in particular for the protection of public or animal health or for the support of specific types of products or applicants, selected for duly justified reasons, the	

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

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	point 3 of Annex III. Any decision taken pursuant to this Article shall state the reasons on which it is based.	II, III and IV, with the exception of the fees set out in points 6, 15 and 16 of Annex I, points 7 and 10 of Annex II and point 3 of Annex III. Any decision taken pursuant to this Article shall state the reasons on which it is based. <i>The Agency shall make information on such decisions by the Executive Director, including the reasons for the reduction, publicly available on the Agency's website.</i>	and IV, with the exception of the fees set out in points 6, 14 ⁵ and 15 ⁶ of Annex I, points 7 and 10 of Annex II and point 3 of Annex III. Any decision taken pursuant to this Article shall state the reasons on which it is based.	
80	<i>Article 7</i> Payment of fees and charges		<i>Article 7</i> Payment of fees and charges	<i>Article 7</i> Payment of fees and charges
81	1. Fees and charges due under this Regulation shall be paid in euro.		1. Fees and charges due under this Regulation shall be paid in euro.	1. Fees and charges due under this

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

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

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	from the Commission, establish working arrangements to facilitate the application of this Regulation, including payment methods of the fees and charges levied by the Agency and the mechanism for payment of remuneration to competent authorities of the Member States under this Regulation.		Director and following a favourable opinion from the Commission, establish working arrangements to facilitate the application of this Regulation, including payment methods of the fees and charges levied by the Agency, and the mechanism for payment of remuneration to competent authorities of the Member States under this Regulation, <u>a total or partial reduction in accordance with Article 6(4) and a common format, based on a transparent methodology, to be used by competent authorities of the Member States when providing to the</u>	the Executive Director and following a favourable opinion from the Commission, establish working arrangements to facilitate the application of this Regulation, including payment methods of the fees and charges levied by the Agency, and the mechanism for payment of remuneration to competent authorities of the Member States under this Regulation, <u>a total or partial reduction in</u>

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			<u>Agency the financial information in accordance with Article 10(3).</u>	<u>accordance with Article 6(4) and a 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 Article 10(3).</u>
86a			<u>The Management Board of the Agency shall also define in the working arrangements the scope of a distinct inspection, for each type of inspection.</u>	<u>The Management Board of the Agency shall also define in the working arrangements the scope of a distinct</u>

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			<u>This shall include, where relevant, the medicinal product concerned, the site concerned, the activity concerned and the inspection team concerned.</u>	<u>inspection, for each type of inspection. This shall include, where relevant, the medicinal product concerned, the site concerned, the activity concerned and the inspection team concerned.</u>
87	Those arrangements shall be made publicly available on the Agency's website.		Those arrangements shall be made publicly available on the Agency's website.	Those arrangements shall be made publicly available on the Agency's website.
88	<i>Article 9</i> Due date and measures in case of non-payment		<i>Article 9</i> Due date and measures in case of non-payment	<i>Article 9</i> Due date and measures in case of non-payment
89	1. The due dates of the fees or charges levied in accordance with this Regulation shall be specified in the working		1. <u>By /OP: please insert date of application of this Regulation/</u> The the due dates of the fees or	1. <u>By /OP: please insert date of application of this Regulation/</u> The the

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

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

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			Regulation (EU, Euratom) 2018/1046.	services and procedures 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	<i>Article 10</i> Transparency and monitoring		<i>Article 10</i> Transparency and monitoring	<i>Article 10</i> Transparency and monitoring
92	1. The amounts set out in the annexes shall be published on the website of the Agency.	1. The amounts set out in the annexes shall be published on the website of the Agency <i>and shall be updated to reflect any changes.</i>	1. The amounts set out in the annexes shall be published on the website of the Agency.	1. The amounts set out in the annexes shall be published on the website of the Agency.
93	2. The Agency shall monitor its costs and the Executive Director of the Agency shall provide, as part of the annual activity	2. The Agency shall monitor its costs and the Executive Director of the Agency shall	2. The Agency shall monitor its costs and the Executive Director of the	2. The Agency shall monitor its costs and the Executive

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

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

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		<i>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.</i> <i>The Agency's annual report shall furthermore list a detailed breakdown of all remunerated amounts paid to national authorities for their work.</i>		
94	3. Evidence of significant changes in the costs of services provided to the Agency, excluding any effect of inflationary adjustments and any costs for activities that do not constitute a service to the Agency, may be provided by competent authorities of the Member States responsible for medicinal products or by experts contracted		3. Evidence of significant changes in the costs of services provided to the Agency, excluding any effect of inflationary adjustments and any costs for activities that do not constitute a service to the Agency, may be provided by	3. Evidence of significant changes in the costs of services provided to the Agency, excluding any effect of inflationary adjustments and any costs for activities that do not

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	for the procedures of the expert panels on medical devices to the Agency. Such information may be provided once per calendar year or less frequently, as a complement to the information provided in accordance with Annex VI. Such evidence shall be based on duly justified and specific official financial information on the nature and the extent of the financial impact on costs for services to the Agency. To that end, the Agency may provide a common format facilitating comparison and consolidation. The competent authorities of the Member States and the experts contracted for the 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		competent authorities of the Member States responsible for medicinal products or by experts contracted for the procedures of the expert panels on medical devices to the Agency. Such information may be provided once per calendar year or less frequently, as a complement to the information provided in accordance with Annex VI. Such evidence shall be based on duly justified and specific official financial information on the nature and the extent of the financial impact on costs for services to the Agency. To that end, the Agency may provide <u>the</u> a common format	constitute a service to the Agency, may be provided by competent authorities of the Member States responsible for medicinal products or by experts contracted for the procedures of the expert panels on medical devices to the Agency. Such information may be provided once per calendar year or less frequently, as a complement to the information provided in accordance with Annex VI. Such evidence shall

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	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 provided for in that paragraph.		facilitating comparison and consolidation, <u>established in accordance with Article 8 shall be used</u>. The competent authorities of the Member States and the experts contracted <u>to the Agency</u> for the 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	be based on duly justified <u>and specific</u> official financial information on the nature and the extent of the financial impact on costs for services to the Agency. To that end, the Agency may provide the a common format facilitating comparison and consolidation, <u>established in accordance with Article 8 shall be used</u>. The competent authorities of the Member States and the experts contracted <u>to the</u>

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

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

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

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

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			documented and justified in the report;	the respective costs as identified, documented and justified in the report;
98a		<i>(aa) to adapt any fee, charge 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;</i>		<i>deleted</i>
99	(b) to amend any other element of the Annexes pertaining to the levying of fees and charges, including additional fees and charges referred to in Article 4.		(b) to amend any other element of the Annexes pertaining to the levying of fees and charges, including additional fees and charges referred to in Article 4;	(b) to amend any other element of the Annexes pertaining to the levying of fees and charges, including additional fees and charges referred to in Article 4;

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

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		<i>Parliament and to the Council for information.</i>		
99d		<i>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.</i>		
99e		<i>6b. The special report shall be made publicly available without delay on the Agency's website. The special report shall include information on the</i>		6b. The special report shall be made publicly available without delay on the Agency's website.

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		<i>stakeholders consulted in the preparation of that report.</i>		
100	7. The special report referred to in paragraph 6 and the recommendations it contains shall be based on the following:		7. The special report referred to in paragraph 6 and the recommendations it contains shall be based on the following:	7. The special report referred to in paragraph 6 and the recommendations it contains shall be based on the following:
101	(a) continuous monitoring of the information referred to in paragraphs 2 and 3 and of the cost of the activities necessary for the fulfilment of the statutory tasks of the Agency, aimed at identifying significant changes to the cost base of services and activities of the Agency;		(a) continuous monitoring of the information referred to in paragraphs 2 and 3 and of the cost of the activities necessary for the fulfilment of the statutory tasks of the Agency, aimed at identifying significant changes to the cost base of services and activities of the Agency;	(a) continuous monitoring of the information referred to in paragraphs 2 and 3 and of the cost of the activities necessary for the fulfilment of the statutory tasks of the Agency, aimed at identifying significant changes to the cost base

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
		Commission, <i>the European Parliament and the Council</i> with an updated version of the report which addresses any comments made and questions raised by the <i>respective institution</i> .	with an updated version of the report <u>adopted in accordance with paragraph 6</u> which addresses any comments made and questions raised by the Commission.	
104	9. The reporting time interval referred to in paragraph 6 may be shortened in any of the following situations:	9. <i>The time interval for the first special report as well as</i> the reporting time interval referred to in paragraph 6 may be shortened in any of the following situations:	9. The <u>time interval to the first special report as well as the</u> reporting time interval referred to in paragraph 6 may be shortened in any of the following situations:	9. <i>The time interval for the first special report as well as</i> the reporting time interval referred to in paragraph 6 may be shortened in any of the following situations:
105	(a) in the case of a public health emergency;		(a) in the case of a public health emergency;	(a) in the case of a 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 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 <u>in the statutory tasks</u> of the Agency;	(b) in the case of a change of the legal mandate <u>in the statutory tasks</u> 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 clear and compelling evidence of significant changes in the costs or the cost-revenue balance of the Agency;
107a			<u>(d) in case there is evidence of significant changes in the costs</u> including costs for cost-based remuneration to competent authorities of the Member States;	<u>(d) in case there is evidence of significant changes in the costs</u> including costs for cost-based remuneration to competent authorities of the Member States;

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
107b			(de) <u>upon request of the Management Board of the Agency.</u>	MB discussion
108	Article 11 Revision		Article 11 Revision	Article 11 Revision
108a		<i>-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].</i>		
109	1. The Commission is empowered to adopt delegated acts in accordance with		1. The Commission is empowered to adopt delegated	1. The Commission is empowered to adopt

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	Article 13 to amend the Annexes where justified in view of any of the following:		acts in accordance with Article 13 to amend the Annexes where justified in view of any of the following:	delegated acts in accordance with Article 13 to amend the Annexes where justified in view of any of the following:
110	(a) a special report received by the Commission in accordance with Article 10(6);		(a) a special report received by the Commission in accordance with Article 10(6);	(a) a special report received by the Commission in accordance with Article 10(6);
111	(b) the findings from the monitoring of the inflation rate referred to in Article 10(5);		(b) the findings from the monitoring of the inflation rate referred to in Article 10(5);	(b) the findings from the monitoring of the inflation rate referred to in Article 10(5);
112	(c) a change in the statutory tasks of the Agency leading to a significant change in its costs;	<i>deleted</i>	(c) a change in the statutory tasks of the Agency leading to a significant change in its costs;	<i>deleted</i>

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
113	(d) the budgetary reporting of the Agency;		(d) the budgetary reporting of the Agency;	(d) the budgetary reporting of the Agency;
114	(e) other relevant information, in particular on practical aspects for the execution of activities for which the Agency collects fees or charges.	<i>deleted</i>	(e) — other relevant information, in particular on practical aspects for the execution of activities for which the Agency collects fees or charges.	<i>deleted</i>
115	2. Any revision of the fees and charges and of the remuneration paid to competent authorities of the Member States provided for in this Regulation shall be based on the Commission's evaluation of the Agency's costs and revenues and of the relevant costs of the services provided to the Agency by the competent authorities of the Member States.		2. Any revision of the fees and charges and of the remuneration paid to competent authorities of the Member States provided for in this Regulation shall be based on the Commission's evaluation of the Agency's costs and revenues and of the relevant full costs of the services provided to the Agency <u>in the scope of this</u>	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			<u>Regulation</u> by the competent authorities of the Member States, <u>taking into account also the sustainability of the Union regulatory network including a fair and objective allocation of fees, charges and remuneration.</u>	
115a		<i>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</i>		

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
		<i>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.</i>		
115b			<u>3. In any revision of the Annexes, the amounts of remuneration paid to competent authorities of the Member States provided for in this Regulation shall be maintained as a single amounts of remuneration irrespective of the Member</u>	<u>3. In any revision of the Annexes, the amounts of remuneration paid to competent authorities of the Member States provided for in this Regulation shall be maintained as a single amounts of</u>

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	distinguish, respectively, between the following:		charges set out in Article 3 of this Regulation, that information shall distinguish, respectively, between the following:	of fees and charges and respective remuneration. In accordance with the 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 and consultations on medical devices;		(a) medicinal products for human use and consultations on medical devices;	(a) medicinal products for human use and consultations on medical devices;
119	(b) veterinary medicinal products;		(b) veterinary medicinal products;	(b) veterinary 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 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
121	(d) other fees and charges, by type.		(d) other fees and charges, by type.	(d) other fees and charges, by type.
122	A breakdown by type of procedure may be provided by the Agency in an annex to the single programming document produced in accordance with Article 32(1) of Delegated Regulation (EU) 2019/715.		A breakdown by type of procedure may be provided by the Agency in an annex to the single programming document produced in accordance with Article 32(1) of Delegated Regulation (EU) 2019/715.	A breakdown by type of procedure may be provided by the Agency in an annex to the single programming document produced in accordance with Article 32(1) of Delegated Regulation (EU) 2019/715.
123	<i>Article 13</i> Exercise of the delegation		<i>Article 13</i> Exercise of the delegation	<i>Article 13</i> Exercise of the delegation
124	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
				identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period. <i>Commission to double-check</i>
126	3. The delegation of power referred to in Article 11(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the <i>Official Journal of the European Union</i> or at a later date specified therein. It		3. The delegation of power referred to in Article 11(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day	3. The delegation of power referred to in Article 11(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	shall not affect the validity of any delegated acts already in force.		following the publication of the decision in the <i>Official Journal of the European Union</i> or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	specified in that decision. It shall take effect the day following the publication of the decision in the <i>Official Journal of the European Union</i> 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 Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.	4. Before adopting a delegated act, the Commission shall <i>take into account any opinions delivered by</i> experts designated by each Member State in accordance with the principles laid down in the Interinstitutional	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
		Agreement of 13 April 2016 on Better Law-Making.	13 April 2016 on Better Law-Making.	the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.
128	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
129	6. A delegated act adopted pursuant to Article 11(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the		6. A delegated act adopted pursuant to Article 11(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the	6. A delegated act adopted pursuant to Article 11(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	Council have both informed the 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.		European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the 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.	period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the 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	<i>Article 14</i> Amendment to Regulation (EU) No 2017/745		<i>Article 14</i> Amendment to Regulation (EU) No 2017/745	<i>Article 14</i>

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
				Amendment to Regulation (EU) No 2017/745
131	Article 106 of Regulation (EU) No 2017/745, paragraph 14 is replaced by the following:		Article 106 of Regulation (EU) No 2017/745, paragraph 14 is replaced by the following:	Article 106 of Regulation (EU) No 2017/745, paragraph 14 is replaced by the following:
132	‘14. The fees payable to EMA in accordance with the procedure under paragraph 13 of this Article related to the advice provided by expert panels for which EMA provides the secretariat in accordance with Article 30 of Regulation (EU) 2022/123 of the European Parliament and of the Council ⁵⁰ shall be set in a transparent manner and on the basis of the costs for the services provided. The fees payable shall be reduced in the case of a clinical evaluation		‘14. The fees established payable to EMA in accordance with the procedure under paragraph 13 of this Article related to the advice provided by expert panels for which EMA provides the secretariat in accordance with Article 30 of Regulation (EU) 2022/123 of the European Parliament and of the Council⁵¹ shall be set in a	‘14. The fees established payable to EMA in accordance with the procedure under paragraph 13 of this Article related to the advice provided by expert panels for which EMA provides the secretariat in accordance with Article 30 of

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	consultation procedure initiated in accordance with section 5.1, point (c), of Annex IX to this Regulation involving a manufacturer who is a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC.’. ⁵⁰ 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).		transparent manner and on the basis of the costs for the services provided. The fees payable shall be reduced in the case of a clinical evaluation consultation procedure initiated in accordance with section 5.1, point (c), of <u>Section 5.1 of</u> Annex IX to this Regulation involving a manufacturer who is a micro, small or medium-sized enterprise within 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	Regulation (EU) 2022/123 of the European Parliament and of the Council⁵¹ shall be set in a transparent manner and on the basis of the costs for the services provided. The fees payable shall be reduced in the case of a clinical evaluation consultation procedure initiated in accordance with section 5.1, point (c), of <u>Section 5.1 of</u> Annex IX to this Regulation involving a manufacturer who is a micro, small or medium-

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).	sized enterprise within 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			<u>The fees related to the advice provided by expert panels are payable to EMA pursuant to Article 30, point (f) of Regulation (EU) 2022/123 of</u>	<u>The fees related to the advice provided by expert panels are payable to EMA pursuant to Article 30,</u>

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			<u>the European Parliament and of the Council.</u>⁵² ⁵² <u>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).</u>	<u>point (f) of Regulation (EU) 2022/123 of the European Parliament and of the Council.</u>⁵² ⁵² <u>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).</u>
132b			<u>The fees related to the advice provided by expert</u>	<u>The fees related to the advice provided by</u>

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			<u>adopted by the Commission pursuant to Article 106(1) of Regulation (EU) 2017/745.</u>	<u>accordance with implementing acts adopted by the Commission pursuant to Article 106(1) of Regulation (EU) 2017/745.</u>
133	<i>Article 15</i> Repeal		<i>Article 15</i> Repeal	<i>Article 15</i> Repeal
134	Regulations (EC) No 297/95 and (EU) No 658/2014 are repealed.		Regulations (EC) No 297/95 and (EU) No 658/2014 are repealed <u>as of [OP: please insert date of application of this Regulation].</u>	Regulations (EC) No 297/95 and (EU) No 658/2014 are repealed <u>as of [OP: please insert date of application of this Regulation].</u>
135	References to Regulation (EC) No 297/95 shall be construed as references to this Regulation and read in accordance with the		References to Regulation (EC) No 297/95 shall be construed as references to this Regulation and	References to Regulation (EC) No 297/95 shall be

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	correlation table in Annex VII to this Regulation.		read in accordance with the correlation table in Annex VII to this Regulation.	construed as references to this Regulation and read in accordance with the correlation table in Annex VII to this Regulation.
136	<i>Article 16</i> Transitional provisions		<i>Article 16</i> Transitional provisions	<i>Article 16</i> Transitional provisions
137	1. This Regulation shall not apply to procedures and services for which the payable amount became due before [OP: <i>please insert date of application</i>].		1. This Regulation shall not apply to <u>annual fees,</u> procedures and services for which the payable amount became due <u>pursuant to Regulation (EC) No 297/95 or Regulation (EU) No 658/2014</u> before [OP: <i>please insert date of application</i>].	1. This Regulation shall not apply to <u>annual fees,</u> procedures and services for which the payable amount became due <u>pursuant to Regulation (EC) No 297/95 or Regulation (EU) No 658/2014</u> before [OP: <i>please</i>

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
				<i>insert date of application</i>].
138	2. With regard to annual fees set out in Annex III, this Regulation shall not apply to products for which an annual fee has become due pursuant to Regulation (EC) No 297/95 or Regulation (EU) No 658/2014 in the year <i>[OP: please insert calendar year of application]</i> .		2. With regard to annual fees set out in Annex III, this Regulation shall not apply to products for which an annual fee has become due pursuant to Regulation (EC) No 297/95 or Regulation (EU) No 658/2014 in the year <i>[OP: please insert calendar year of application]</i>.	<i>deleted</i>
139	<i>Article 17</i> Entry into force and date of application		<i>Article 17</i> Entry into force and date of application	<i>Article 17</i> Entry into force and date of application
140	This Regulation shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i> .		This Regulation shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i> .	This Regulation shall enter into force on the twentieth day following that of its publication in

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
				the <i>Official Journal of the European Union</i> .
141	It shall apply from [<i>OP: please insert date of first day of the month following expiration of 6 months after entry into force</i>].		It shall apply from [<i>OP: please insert date of 1 January of the calendar year following the year of entry into force of this Regulation if it enters into force by 1 July. In case the Regulation enters into force after 1 July, please insert date of 1 January of the calendar year first day of the month following expiration of 6-9 months after entry into force</i>].	It shall apply from [<i>OP: please insert date of 1 January of the calendar year following the year of entry into force of this Regulation if it enters into force by 1 July. In case the Regulation enters into force after 1 July, please insert date of 1 January of the calendar year first day of the month following expiration of 6-9 months after entry into force</i>].

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
141a		<i>The delegated act referred to in Article 11(-1) shall apply from ... [OP: please insert date of first day of the month following expiration of 6 months after entry into force].</i>		<i>To be taken out if no DA on initial inflation adjustment</i>
142	This Regulation shall be binding in its entirety and directly applicable in all Member States.		This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety 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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and 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 human use
149	1. Scientific advice provided by the Agency in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004		1. Scientific advice provided by the Agency in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004	1. Scientific advice provided by the Agency 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 of the following requests:	1.1 A fee of EUR 94 000 shall apply to any of the following requests:	1.1 A fee of EUR 55 200 79 400 shall apply to any of the following requests:	1.1 A fee of EUR 94 000 shall apply to any of the following requests:
151	(a) a request on quality, non-clinical and clinical development;		(a) a request on quality, non-clinical and clinical development;	(a) a request on quality, non-clinical and clinical development;

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

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

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			submission of an application for a marketing authorisation	an application for a marketing authorisation
167	2.1. A fee of EUR 549 800 shall apply to any of the following:		2.1. A fee of EUR 549 800 828 100 shall apply to any of the following:	<i>Suggestion to Separate rolling reviews from compassionate use</i>
168	(a) an opinion on a medicinal product for compassionate use pursuant to Article 83 of Regulation (EC) No 726/2004;		(a) an opinion on a medicinal product for compassionate use pursuant to Article 83 of Regulation (EC) No 726/2004;	(a) an opinion on a medicinal product for compassionate use pursuant to Article 83 of Regulation (EC) No 726/2004;
169	(b) an assessment on an on-going basis of data packages of particulars and documents submitted to the Agency by a prospective applicant prior to a formal submission of an application for a marketing authorisation falling within the scope of Regulation (EC) No 726/2004.		(b) an assessment on an on-going basis of data packages of particulars and documents submitted to the Agency by a prospective applicant prior to a formal submission of an application for a marketing	(b) an assessment on an on-going basis of data packages of particulars and documents submitted to the Agency by a prospective applicant prior to a

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			authorisation falling within the scope of Regulation (EC) No 726/2004.	formal submission of an application for a marketing authorisation falling within the scope of Regulation (EC) No 726/2004.
170	That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 153 000 for the rapporteur and EUR 143 300 for the co-rapporteur.		That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 153 000 <u>260 800</u> for the rapporteur and, EUR 143 300 <u>227 200</u> for the co-rapporteur <u>and 24 400 for the PRAC-rapporteur.</u>	
170a			<u>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</u>	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			<u>be EUR 39 100 for the rapporteur, EUR 34 100 for the co-rapporteur and EUR 3 700 for the PRAC-rapporteur.</u>	
171	2.2. In the event of multiple submissions of data packages submitted by the same prospective applicant for the same product, the fee set out in point 2.1 (b) shall only be charged once.		2.2. In the event of multiple submissions of data packages submitted by the same prospective applicant for the same product, the fee set out in point 2.1 (b) <u>and 2.1a(new)</u> shall only be charged once.	
172	2.3. The amounts set out in point 2.1 shall be deducted from the respective fee and from the remuneration to competent authorities of the Member States payable for a marketing authorisation application for the same product, where such application is submitted by the same applicant.		2.3. The amounts set out in point 2.1 shall be deducted from the respective fee and from the remuneration to competent authorities of the Member States payable for a marketing authorisation application for the	2.3. The amounts set out in point 2.1 shall be deducted from the respective fee and from the remuneration to competent authorities of the Member States

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			same product, where such application is submitted by the same applicant.	payable for a marketing authorisation application for the same product, where such application is submitted by the same applicant.
173	3. Authorisation to market a medicinal product falling within the scope of Regulation (EC) No 726/2004		3. Authorisation to market a medicinal product falling within the scope of Regulation (EC) No 726/2004	3. Authorisation to market a medicinal product falling within the scope of Regulation (EC) No 726/2004
174	3.1. A fee of EUR 684 900 shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 8(3) of Directive 2001/83/EC when the applicant claims a new active substance. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be		3.1. A fee of EUR 684 900 828 100 shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 8(3) of Directive 2001/83/EC when the applicant claims a new active substance. That fee shall cover	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	EUR 217 300 for the rapporteur and EUR 189 300 for the co-rapporteur.		all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 217 300 <u>260 800</u> for the rapporteur, and EUR 189 300 <u>227 200</u> for the co-rapporteur <u>and EUR 24 400 for the PRAC-rapporteur.</u>	
175	3.2. A fee of EUR 549 800 shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 8(3) of Directive 2001/83/EC when the applicant claims a known active substance. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 153 000 for the rapporteur and EUR 143 300 for the co-rapporteur.		3.2. A fee of EUR 549 800 <u>661 000</u> shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 8(3) of Directive 2001/83/EC when the applicant claims a known active substance. That fee shall cover all strengths, all pharmaceutical forms and all	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			presentations submitted in the same application. The remuneration shall be EUR 453 000 <u>183 600</u> for the rapporteur and, EUR 443 300 <u>172 000</u> for the co-rapporteur <u>and EUR 17 800 for the PRAC-rapporteur.</u>	
176	3.3 A fee of EUR 456 800 shall apply to an application for a fixed combination medicinal product pursuant to Article 10b of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 141 500 for the rapporteur and EUR 83 000 for the co-rapporteur.		3.3 A fee of EUR 456 800 <u>546 500</u> shall apply to an application for a fixed combination medicinal product pursuant to Article 10b of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 141	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			500 169 800 for the rapporteur, and EUR 83 000 <u>99 600</u> for the co-rapporteur <u>and EUR 13 500</u> <u>for the PRAC-rapporteur.</u>	
177	3.4 A fee of EUR 575 000 shall apply to an application for a biological medicinal product which is similar to a reference biological product pursuant to Article 10(4) of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 236 500 for the rapporteur and EUR 151 700 for the co-rapporteur.		3.4. A fee of EUR 575 000 <u>701 100</u> shall apply to an application for a biological medicinal product which is similar to a reference biological product pursuant to Article 10(4) of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 236 500 <u>283 800</u> for the rapporteur and, EUR 151 700 <u>182 000</u> for the co-rapporteur <u>and EUR</u>	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			<u>23 500 for the PRAC-rapporteur.</u>	
178	3.5. A fee of EUR 624 300 shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 10a of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 160 600 for the rapporteur and EUR 149 400 for the co-rapporteur.		3.5. A fee of EUR 624 300 <u>747 300</u> shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 10a of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 160 600 <u>192 700</u> for the rapporteur and, EUR 149 400 <u>179 300</u> for the co-rapporteur <u>and EUR 18 600 for the PRAC-rapporteur.</u>	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
179	3.6. A fee of EUR 141 200 shall apply to any of the following:		3.6. A fee of EUR 141 200 239 500 shall apply to any of the following .	<i>Generics discussion + pharmacovigilance annual fee</i>
180	(a) an application for a marketing authorisation for a generic medicinal product pursuant to Article 10(1) of Directive 2001/83/EC,		(a) an application for a marketing authorisation for a generic medicinal product pursuant to Article 10(1) of Directive 2001/83/EC,	
181	(b) an application based on informed consent for a marketing authorisation for a medicinal product pursuant to Article 10c of Directive 2001/83/EC.		(b) — an application based on informed consent for a marketing authorisation for a medicinal product pursuant to Article 10c of Directive 2001/83/EC.	
182	That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 40 200 for the rapporteur.		That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			remuneration shall be EUR 40 200 <u>118 900</u> for the rapporteur <u>and EUR 5 900 for the PRAC-rapporteur.</u>	
183			<u>3.6a</u> A fee of EUR 441 200 <u>165 300</u> 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.	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and 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 48 200 for the rapporteur <u>and EUR 2 400 for the PRAC-rapporteur.</u>	
187	3.7. A fee of EUR 339 700 shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 10(3) of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 89 100 for the rapporteur and EUR 89 100 for the co-rapporteur.		3.7. A fee of EUR 339 700 <u>407 800</u> shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 10(3) of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			application. The remuneration shall be EUR 89 100 <u>106 900</u> for the rapporteur and , EUR 89 100 <u>106 900</u> for the co-rapporteur <u>and EUR 10 700 for the PRAC-rapporteur.</u>	
188	3.8. A fee of EUR 27 600 shall apply to the second and to each subsequent application for a marketing authorisation submitted pursuant to Article 10(1), (3) or (4) of Directive 2001/83/EC on usage patent grounds where the reference medicinal product is subject to a usage patent. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 6 800 for the rapporteur and EUR 1 000 for the co-rapporteur.		3.8. A fee of EUR 27 600 <u>31 800</u> shall apply to the second and to each subsequent application for a marketing authorisation submitted pursuant to Article 10(1), (3) or (4) of Directive 2001/83/EC on usage patent grounds where the reference medicinal product is subject to a usage patent. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			application. The remuneration shall be EUR 6 800 8 200 for the rapporteur and EUR 4 000 1 200 for the co-rapporteur.	
189	4. Extension of a marketing authorisation within the meaning of Annex I to Commission Regulation (EC) No 1234/2008⁵³ ⁵³ Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning 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).		4. Extension of a marketing authorisation within the meaning of Annex I to Commission Regulation (EC) No 1234/2008⁵⁴ ⁵⁴ Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning 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).	4. Extension of a marketing authorisation within the meaning of Annex I to Commission Regulation (EC) No 1234/2008⁵⁴ ⁵⁴ Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning 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)

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
190	4.1 A fee of EUR 138 000 shall apply to an application for an extension of a marketing authorisation requiring only chemical, pharmaceutical or biological documentation and for which no clinical or non-clinical data are submitted. That fee shall cover a single pharmaceutical form and a single associated strength. The remuneration shall be EUR 45 300 for the rapporteur and EUR 26 600 for the co-rapporteur.		4.1. A fee of EUR 138 000 <u>161 300</u> shall apply to an application for an extension of a marketing authorisation requiring only chemical, pharmaceutical or biological documentation and for which no clinical or non-clinical data are submitted. That fee shall cover a single pharmaceutical form and a single associated strength. The remuneration shall be EUR 45 300 54 400 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 application for an extension of a marketing authorisation not covered by point 4.1. That fee shall cover a single pharmaceutical form		4.2. A fee of EUR 161 000 <u>188 300</u> shall apply to an application for an extension of a marketing authorisation not covered by	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	and a single associated strength. The remuneration shall be EUR 55 300 for the rapporteur and EUR 31 200 for the co-rapporteur.		point 4.1. That fee shall cover a single pharmaceutical form and a single associated strength. The remuneration shall be EUR 55 300 66 400 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, a fee of EUR 27 600 shall apply to each application for extension of a marketing authorisation on the basis of an application submitted under Article 10(1), (3) or (4) of Directive 2001/83/EC on usage patent grounds as referred to in point 3.8 of this Annex. The remuneration shall be EUR 6 800 for the rapporteur and EUR 1 000 for the co-rapporteur.		4.3. Without prejudice to points 4.1 and 4.2, a fee of EUR 27 600 31 800 shall apply to each application for extension of a marketing authorisation on the basis of an application submitted under Article 10(1), (3) or (4) of Directive 2001/83/EC on usage patent grounds as referred to in point 3.8 of this Annex. The remuneration shall be EUR 6 800 8 200 for the rapporteur and	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			EUR 1 000 1 200 for the co-rapporteur.	
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 application for a major variation of type II as defined in Article 2(3) of Regulation (EC) No 1234/2008 ('major variation of type II') for an addition of a new therapeutic indication or modification of an approved indication. The remuneration shall be EUR 29 400 for the rapporteur and EUR 29 400 for the co-rapporteur.		5.1. A fee of EUR 99 800 175 300 shall apply to an application for a major variation of type II as defined in Article 2(3) of Regulation (EC) No 1234/2008 ('major variation of type II') for an addition of a new therapeutic indication or modification of an approved indication. The remuneration	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			shall be EUR 29 400 64 400 for the rapporteur and EUR 29 400 64 400 for the co-rapporteur.	
195	5.2. A fee of EUR 13 000 shall apply to an application for a major variation of type II not covered by point 5.1. The remuneration shall be EUR 6 800 for the rapporteur.		5.2. A fee of EUR 13 000 28 500 shall apply to an application for a major variation of type II not 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 variation of type II that is grouped in a single application pursuant to Article 7 of Regulation (EC) No 1234/2008, the corresponding fee shall be charged as set out in points 5.1 and 5.2. Remuneration shall be paid in accordance with those points.		5.3. For each application for a major variation of type II that is grouped in a single application pursuant to Article 7 of Regulation (EC) No 1234/2008, the corresponding fee shall be charged as set out in points 5.1 and 5.2. Remuneration shall be paid in accordance with those points.	5.3. For each application for a major variation of type II that is grouped in a single application pursuant to Article 7 of Regulation (EC) No 1234/2008, the corresponding fee shall be charged as set out in points 5.1 and 5.2.

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
				Remuneration shall be paid in accordance with those points.
197	5.4 Where a work-sharing application pursuant to Article 20 of Regulation (EC) No 1234/2008 includes more than one centrally authorised product, the fees and remuneration specified in points 5.1 and 5.2 of this Annex shall apply to each variation of the first centrally authorised product, whereas a charge of EUR 800 shall apply to each variation of the second and subsequent centrally authorised product included in the application.		5.4. Where a work-sharing application pursuant to Article 20 of Regulation (EC) No 1234/2008 includes more than one centrally authorised product, the fees and remuneration specified in points 5.1 and 5.2 of this Annex shall apply to each variation of the first centrally authorised product, whereas a charge of EUR 800— <u>900</u> shall apply to each variation of the second and subsequent centrally authorised product included in the application.	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
198	6. Referrals and scientific opinions pursuant to Article 5(3) of Regulation (EC) No 726/2004		6. Referrals and scientific opinions pursuant to Article 5(3) of Regulation (EC) No 726/2004	6. Referrals and scientific opinions pursuant to Article 5(3) of Regulation (EC) No 726/2004
199	6.1. A fee of EUR 136 700 shall apply to the assessment carried out in the context of a procedure initiated under Article 5(3) of Regulation (EC) No 726/2004. Such fee shall be waived in full. The remuneration shall be EUR 12 400 for the rapporteur and EUR 12 400 for the co-rapporteur.	6.1. A fee of EUR 136 700 shall apply to the assessment carried out in the context of a procedure initiated under Article 5(3) of Regulation (EC) No 726/2004. Such fee shall be waived in full. The remuneration shall be EUR 6 200 for the rapporteur and EUR 6 200 for the co-rapporteur.	6.1. A fee of EUR 136 700 156 700 shall apply to the assessment carried out in the context of a procedure initiated under Article 5(3) of Regulation (EC) No 726/2004. Such fee shall be waived in full. The remuneration shall be EUR 12 400 14 900 for the rapporteur and EUR 12 400 14 900 for the co-rapporteur.	
200	6.2. A fee of EUR 262 400 shall apply to the assessment carried out in the context of a procedure initiated under Article 13 of Regulation (EC) No 1234/2008. Such fee	6.2. A fee of EUR 262 400 shall apply to the assessment carried out in the context of a procedure initiated under Article	6.2. A fee of EUR 262 400 299 800 shall apply to the assessment carried out in the context of a procedure initiated under Article	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	shall be waived in full. The remuneration shall be EUR 15 300 for the rapporteur and EUR 15 300 for the co-rapporteur.	13 of Regulation (EC) No 1234/2008. Such fee shall be waived in full. The remuneration shall be EUR 7 650 for the rapporteur and EUR 7 650 for the co-rapporteur.	13 of Regulation (EC) No 1234/2008. Such fee shall be waived in full. The remuneration shall be EUR 15 300 <u>18 400</u> for the rapporteur and EUR 15 300 <u>18 400</u> for the co-rapporteur.	
201	6.3. A fee of EUR 83 000 shall apply to the assessment carried out in the context of a procedure initiated under Article 29(4) of Directive 2001/83/EC. Such fee shall be waived in full. The remuneration shall be EUR 2 800 for the rapporteur and EUR 2 800 for the co-rapporteur.	6.3. A fee of EUR 83 000 shall apply to the assessment carried out in the context of a procedure initiated under Article 29(4) of Directive 2001/83/EC. Such fee shall be waived in full. The remuneration shall be EUR 1 400 for the rapporteur and EUR 1 400 for the co-rapporteur.	6.3. A fee of EUR 83 000 <u>94 600</u> shall apply to the assessment carried out in the context of a procedure initiated under Article 29(4) of Directive 2001/83/EC. Such fee shall be waived in full. The remuneration shall be EUR 2 800 <u>3 400</u> for the rapporteur and EUR 2 800 <u>3 400</u> for the co-rapporteur.	
202	6.4. A fee of EUR 128 200 shall apply to the assessment carried out in the context of		6.4. A fee of EUR 128 200 <u>146 400</u> shall apply to the	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	a procedure initiated under Article 30 of Directive 2001/83/EC. The remuneration shall be EUR 6 800 for the rapporteur and EUR 6 800 for the co-rapporteur.		assessment carried out in the context of a procedure initiated under Article 30 of Directive 2001/83/EC. The remuneration shall be EUR 6 800 <u>8 200</u> for the rapporteur and EUR 6 800 <u>8 200</u> for the co-rapporteur.	
203	6.5. A fee of EUR 180 700 shall apply to the assessment carried out in the context of a procedure initiated under Article 31 of Directive 2001/83/EC where the procedure is initiated as a result of the evaluation of data other than data relating to pharmacovigilance. The remuneration shall be EUR 12 400 for the rapporteur and EUR 12 400 for the co-rapporteur.		6.5. A fee of EUR 180 700 <u>206 700</u> shall apply to the assessment carried out in the context of a procedure initiated under Article 31 of Directive 2001/83/EC where the procedure is initiated as a result of the evaluation of data other than data relating to pharmacovigilance. The remuneration shall be EUR 12 400 <u>14 900</u> for the rapporteur and	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			EUR 12 400 <u>14 900</u> for the co-rapporteur.	
204	6.6. A fee of EUR 172 100 shall apply to the assessment carried out in accordance with a procedure initiated under Article 20 of Regulation (EC) No 726/2004 where that procedure is initiated as a result of the evaluation of data other than data relating to pharmacovigilance. The remuneration shall be EUR 17 500 for the rapporteur and EUR 17 500 for the co-rapporteur.		6.6. A fee of EUR 172 100 <u>197 600</u> shall apply to the assessment carried out in accordance with a procedure initiated under Article 20 of Regulation (EC) No 726/2004 where that procedure is initiated as a result of the evaluation of data other than data relating to pharmacovigilance. The remuneration shall be EUR 17 500 <u>21 000</u> for the rapporteur and EUR 17 500 <u>21 000</u> for the co-rapporteur.	
205	6.7. For an assessment carried out in the context of a procedure initiated as a result of the evaluation of pharmacovigilance data under Article 31(1), second subparagraph,		6.7. For an assessment carried out in the context of a procedure initiated as a result of the evaluation of	6.7. For an assessment carried out in the context of a procedure initiated as a

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	Article 31(2) and Articles 107i, 107j and 107k of Directive 2001/83/EC or under Article 20(8) of Regulation (EC) No 726/2004, the following fees shall apply:		pharmacovigilance data under Article 31(1), second subparagraph, Article 31(2) and Articles 107i, 107j and 107k of Directive 2001/83/EC or under Article 20(8) of Regulation (EC) No 726/2004, the following fees shall apply:	result of the evaluation of pharmacovigilance data under Article 31(1), second subparagraph, Article 31(2) and Articles 107i, 107j and 107k of Directive 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 active substance or combination of active substances and one marketing authorisation holder are included in the assessment. The remuneration shall be EUR 17 500 for the rapporteur and EUR 17 500 for the co-rapporteur;		6.7.1. a fee of EUR 172 100 210 200 where one active substance or combination of active substances and one marketing authorisation holder are included in the assessment. The remuneration shall be EUR 17 500 for the rapporteur and EUR 17 500 for the co-rapporteur;	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			500 27 300 for the rapporteur and EUR 17 500 27 300 for the co-rapporteur;	
207	6.7.2. a fee of EUR 258 200 where two or more active substances or combinations of active substances and one marketing authorisation holder are included in the assessment. The remuneration shall be EUR 26 300 for the rapporteur and EUR 26 300 for the co-rapporteur;		6.7.2. a fee of EUR 258 200 296 400 where two or more active substances or combinations of active substances and one marketing authorisation holder are included in the assessment. The remuneration shall be EUR 26 300 31 600 for the rapporteur and EUR 26 300 31 600 for the co-rapporteur;	
208	6.7.3. a fee of EUR 314 100 where one or two active substances or combinations of active substances and two or more marketing authorisation holders are included in the assessment. The remuneration shall be EUR 32 000 for the		6.7.3. a fee of EUR 314 100 360 600 where one or two active substances or combinations of active substances and two or more marketing authorisation holders are included in the	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	rapporteur and EUR 32 000 for the co-rapporteur;		assessment. The remuneration shall be EUR 32 000 38 400 for the rapporteur and EUR 32 000 38 400 for the co-rapporteur;	
209	6.7.4. a fee of EUR 426 100 where more than two active substances or combinations of active substances and two or more marketing authorisation holders are included in the assessment. The remuneration shall be EUR 43 400 for the rapporteur and EUR 43 400 for the co-rapporteur.		6.7.4. a fee of EUR 426 100 489 200 where more than two active substances or combinations of active substances and two or more marketing authorisation holders are included in the assessment. The remuneration shall be EUR 43 400 52 100 for the rapporteur and EUR 43 400 52 100 for the co-rapporteur.	
210	6.8. Where two or more marketing authorisation holders are involved in the procedures referred to in points 6.4, 6.5, 6.6 and 6.7, the amount payable by each marketing authorisation holder shall be		6.8. Where two or more marketing authorisation holders are involved in the procedures referred to in points 6.4, 6.5, 6.6 and 6.7, the amount payable by	6.8. Where two or more marketing authorisation holders are involved in the procedures referred to in

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	calculated by the Agency in two steps, as follows:		each marketing authorisation holder shall be calculated by the Agency in two steps, as follows:	points 6.4, 6.5, 6.6 and 6.7, the amount payable 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 among the marketing authorisation holders proportionally to the number of chargeable units-human corresponding to products included in the procedure which are held by each of those marketing authorisation holders;		(a) by dividing the total amount of the fee among the marketing authorisation holders proportionally to the number of chargeable units-human corresponding to products included in the procedure which are held by each of those marketing authorisation holders;	by dividing the total amount of the fee among the marketing authorisation holders proportionally to the number of chargeable units-human corresponding to products included in the procedure which are held by each of those

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			remuneration shall be EUR 4 2 100 for the rapporteur.	
215	8. Certification of compliance with Union legislation for a plasma master file (PMF) in accordance with Part III of Annex I of Directive 2001/83/EC		8. Certification of compliance with Union legislation for a plasma master file (PMF) in accordance with Part III of Annex I of Directive 2001/83/EC	8. Certification of compliance with Union legislation for a plasma master file (PMF) in accordance with Part III of Annex I of Directive 2001/83/EC
216	8.1. A fee of EUR 57 200 shall apply to an application for review of a PMF and its initial certification pursuant to Part III, point 1.1 of Annex I to Directive 2001/83/EC. The remuneration shall be EUR 8 600 for the rapporteur and EUR 8 600 for the co-rapporteur.		8.1. A fee of EUR 57 200 66 000 shall apply to an application for review of a PMF and its initial certification pursuant to Part III, point 1.1 of Annex I to Directive 2001/83/EC. The remuneration shall be EUR 8 600 10 300 for the rapporteur and EUR 8 600 10 300 for the co-rapporteur.	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
217	8.2. A charge of EUR 5 800 shall apply to the issuing of an initial PMF certification where it is submitted simultaneously with an application for a marketing authorisation for a medicinal product under the centralised procedure. The PMF documentation shall be evaluated within the centralised marketing authorisation application.		8.2. A charge of EUR 5 800 <u>600</u> shall apply to the issuing of an initial PMF certification where it is submitted simultaneously with an application for a marketing authorisation for a medicinal product under the centralised 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 application for review and certification of a major variation of type II to the PMF pursuant to Regulation (EC) No 1234/2008. The remuneration shall be EUR 1 600 for		8.3. A fee of EUR 10 600 <u>12 200</u> shall apply to an application for review and certification of a major variation of type II to the PMF pursuant to Regulation (EC) No 1234/2008. The	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	the rapporteur and EUR 1 600 for the co-rapporteur.		remuneration shall be EUR 4 600 <u>1 900</u> for the rapporteur and EUR 1 2 600 for the co-rapporteur.	
219	For two or more major variations of type II grouped in a single application pursuant to Regulation (EC) No 1234/2008, the fee and remuneration laid down in point 9.4 of this Annex shall apply.		For two or more major variations of type II grouped in a single application pursuant to Regulation (EC) No 1234/2008, the fee and remuneration laid down in point 9 <u>8</u> .4 of this Annex shall apply.	
220	8.4. A fee of EUR 17 000 shall apply for an application for review and annual re-certification of a PMF which may include any variation pursuant to Regulation (EC) No 1234/2008 submitted simultaneously with the application for a PMF annual re-certification. The remuneration shall be		8.4. A fee of EUR 17 000 <u>19 500</u> shall apply for an application for review and annual re-certification of a PMF which may include any variation pursuant to Regulation (EC) No 1234/2008 submitted simultaneously with the	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	EUR 1 900 for the rapporteur and EUR 1 900 for the co-rapporteur.		application for a PMF annual re-certification. The remuneration shall be EUR 1 900 2 300 for the rapporteur and EUR 1 900 2 300 for the co-rapporteur.	
221	9. Certification of compliance with Union legislation for a vaccine antigen master file (VAMF) in accordance with Part III of Annex I of Directive 2001/83/EC		9. Certification of compliance with Union legislation for a vaccine antigen master file (VAMF) in accordance with Part III of Annex I of Directive 2001/83/EC	9. Certification of compliance with Union legislation for a vaccine antigen master file (VAMF) in accordance with Part III of Annex I of Directive 2001/83/EC
222	9.1. A fee of EUR 57 200 shall apply for an application for review of a VAMF and its initial certification not submitted simultaneously with a new application for marketing authorisation under the centralised procedure pursuant to Part III, point 1.2 of Annex I to Directive		9.1. A fee of EUR 57 200 66 000 shall apply for an application for review of a VAMF and its initial certification not submitted simultaneously with a new application for marketing authorisation under the	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	2001/83/EC. The remuneration shall be EUR 8 600 for the rapporteur and EUR 8 600 for the co-rapporteur.		centralised procedure pursuant to Part III, point 1.2 of Annex I to Directive 2001/83/EC. The remuneration shall be EUR 8 600 10 300 for the rapporteur and EUR 8 600 10 300 for the co-rapporteur.	
223	9.2. In the case of a group of antigens aimed at preventing a single infectious disease, a fee shall be charged for the VAMF application for one antigen and remuneration shall be paid pursuant to point 10.1. The second and subsequent VAMF applications submitted simultaneously for antigens as part of the same group shall be charged a fee of EUR 7 800 per VAMF. The maximum total amount charged by the Agency for VAMF applications submitted simultaneously for antigens as part of the		9.2. In the case of a group of antigens aimed at preventing a single infectious disease, a fee shall be charged for the VAMF application for one antigen and remuneration shall be paid pursuant to point 10 9 .1. The second and subsequent VAMF applications submitted simultaneously for antigens as part of the same group shall be charged a fee of EUR 7 800 9 100	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	same group shall not exceed EUR 68 600. In that case, the remuneration per each second and subsequent VAMF shall be EUR 1 900 for the rapporteur and EUR 1 900 for the co-rapporteur.		per VAMF. The maximum total amount charged by the Agency for VAMF applications submitted simultaneously for antigens as part of the same group shall not exceed EUR 68 600 <u>78 000</u> . In that case, the remuneration per each second and subsequent VAMF shall be EUR 1 900 <u>2 300</u> for the rapporteur and EUR 1 900 <u>2 300</u> for the co-rapporteur.	
224	9.3. A charge of EUR 5 800 shall apply to an application for issuing each VAMF certification where it is submitted simultaneously with a new application for marketing authorisation under the centralised procedure.		9.3. A charge of EUR 5 800 <u>6 600</u> shall apply to an application for issuing each VAMF certification where it is submitted simultaneously with a new application for marketing	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			authorisation under the centralised procedure.	
225	9.4. A fee of EUR 10 600 shall apply to an application for review and certification of a major variation of type II to the VAMF pursuant to Regulation (EC) No 1234/2008. The remuneration shall be EUR 1 500 for the rapporteur and EUR 1 500 for the co-rapporteur. For each major variation of type II that is grouped in a single application made pursuant to Regulation (EC) No 1234/2008 a fee shall be charged as set out in the first subparagraph of this point.		9.4. A fee of EUR 10 60012 200 shall apply to an application for review and certification of a major variation of type II to the VAMF pursuant to Regulation (EC) No 1234/2008. The remuneration shall be EUR 1 500 800 for the rapporteur and EUR 1 500 800 for the co-rapporteur. For each major variation of type II that is grouped in a single application made pursuant to Regulation (EC) No 1234/2008 a fee shall be charged as set out in the first subparagraph of this point.	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
226	10. Certification of quality and non-clinical data relating to advanced therapy medicinal products (ATMPs) developed by small and medium-sized enterprises (SMEs) in accordance with Regulation (EC) No 1394/2007 of the European Parliament and of the Council		10. Certification of quality and non-clinical data relating to advanced therapy medicinal products (ATMPs) developed by small and medium-sized enterprises (SMEs) in accordance with Regulation (EC) No 1394/2007 of the European Parliament and of the Council	10. Certification of quality and non-clinical data relating to advanced therapy medicinal products (ATMPs) developed by small and medium-sized enterprises (SMEs) in accordance with 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 an application for evaluating and certifying the quality and non-clinical data pursuant to Article 18 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council ⁵⁵ . Such fee shall be waived	10.1. A fee of EUR 143 200 shall apply to an application for evaluating and certifying the quality and non-clinical data pursuant to Article 18 of Regulation (EC) No 1394/2007 of	10.1 A fee of EUR 143 200 165 600 shall apply to an application for evaluating and certifying the quality and non-clinical data pursuant to Article 18 of Regulation (EC) No	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	in full. The remuneration shall be EUR 47 400 for the rapporteur. ⁵⁵ Regulation (EC) No 1394/2007 of 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).	the European Parliament and of the Council⁴³. Such fee shall be waived in full. The remuneration shall be EUR 23 700 for the rapporteur.	1394/2007 of the European Parliament and of the Council⁵⁶. Such fee shall be waived in full. The remuneration shall be EUR 47 40056 900 for the rapporteur. ⁵⁶ Regulation (EC) No 1394/2007 of 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 application for evaluating and certifying only the quality data pursuant to Article 18 of Regulation (EC) No 1394/2007. Such fee shall be waived in full. The remuneration shall be EUR 31 500 for the rapporteur.	10.2. A fee of EUR 95 200 shall apply to an application for evaluating and certifying only the quality data pursuant to Article 18 of Regulation (EC) No 1394/2007. Such fee shall be waived in full. The remuneration	10.2. A fee of EUR 95 200110 100 shall apply to an application for evaluating and certifying only the quality data pursuant to Article 18 of Regulation (EC) No 1394/2007. Such fee shall be waived in full. The remuneration	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
		shall be EUR 15 750 for the rapporteur.	shall be EUR 31 500 37 800 for the rapporteur.	
229	11. Paediatric applications in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council⁵⁷ ⁵⁷ Regulation (EC) No 1901/2006 of the European 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 (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).		11. Paediatric applications in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council⁵⁸ 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 amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).	11. Paediatric applications in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council⁵⁸ 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 amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and 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 application for agreement of a paediatric investigation plan requested pursuant to Article 15 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 6 700 for the rapporteur.	11.1. A fee of EUR 31 700 shall apply to an application for agreement of a paediatric investigation plan requested pursuant to Article 15 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 3 350 for the rapporteur.	11.1. A fee of EUR 31 700 36 400 shall apply to an application for agreement of a paediatric investigation plan requested pursuant to Article 15 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 6 700 8 000 for the rapporteur.	
231	11.2. A fee of EUR 17 600 shall apply to an application for a modification of an agreed paediatric investigation plan pursuant to Article 22 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 6 400 for the rapporteur.	11.2. A fee of EUR 17 600 shall apply to an application for a modification of an agreed paediatric investigation plan pursuant to Article 22 of Regulation (EC) No 1901/2006. Such fee shall be waived in full.	11.2. A fee of EUR 17 600 20 400 shall apply to an application for a modification of an agreed paediatric investigation plan pursuant to Article 22 of Regulation (EC) No 1901/2006. Such fee shall be waived in full.	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
		The remuneration shall be EUR 3 200 for the rapporteur.	The remuneration shall be EUR 6 400 <u>7 700</u> for the rapporteur.	
232	11.3. A fee of EUR 12 000 shall apply to an application for a product-specific waiver pursuant to Article 13 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 1 800 for the rapporteur.	11.3. A fee of EUR 12 000 shall apply to an application for a product-specific waiver pursuant to Article 13 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 900 for the rapporteur.	11.3. A fee of EUR 12 000 13 700 shall apply to an application for a product-specific waiver pursuant to Article 13 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 1 800 2 200 for the rapporteur.	
233	11.4. A fee of EUR 8 000 shall apply to a request for compliance check with the paediatric investigation plan pursuant to Article 23 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 1 000 for the rapporteur.	11.4. A fee of EUR 8 000 shall apply to a request for compliance check with the paediatric investigation plan pursuant to Article 23 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 500 for the rapporteur.	11.4. A fee of EUR 8 000 100 shall apply to a request for compliance check with the paediatric investigation plan pursuant to Article 23 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 1 000 1 200 for the rapporteur.	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
234	12. Orphan designation in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council⁵⁹ 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 Council⁶⁰ 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).	12. Orphan designation in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council⁶⁰ 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 medicinal product pursuant to Regulation (EC) No 141/2000. Such fee shall be	A fee of EUR 16 800 shall apply to an application for the designation of an orphan medicinal product pursuant to Regulation (EC) No 141/2000.	A fee of EUR 16 800 19 200 shall apply to an application for <u>or reassessment of</u> the designation of an orphan medicinal product pursuant to Regulation (EC) No	

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			exclusively for markets outside the Union pursuant to Article 58 of Regulation (EC) No 726/2004.	scientific opinion following the evaluation of a medicinal product 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 reports	14. Periodic safety update reports
239	14.1 A fee of EUR 27 000 shall apply per procedure for the assessment of periodic safety update reports referred to in Articles 107e and 107g of Directive 2001/83/EC and in Article 28 of Regulation (EC) No 726/2004. The remuneration shall be EUR 12 900 for the rapporteur.		14.1 A fee of EUR 27 000 ^{32 600} shall apply per procedure for the assessment of periodic safety update reports referred to in Articles 107e and 107g of Directive 2001/83/EC and in Article 28 of Regulation (EC) No 726/2004. The remuneration	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			shall be EUR 42 900 16 600 for the rapporteur.	
240	14.2. Where two or more marketing authorisation holders are subject to the obligation to submit periodic safety update reports in the context of the procedures referred to in point 14.1, the amount payable by each marketing authorisation holder shall be calculated by the Agency in two steps, as follows:		14.2. Where two or more marketing authorisation holders are subject to the obligation to submit periodic safety update reports in the context of the procedures referred to in point 14.1, the amount payable by each marketing authorisation holder shall be calculated by the Agency in two steps, as follows:	14.2. Where two or more marketing authorisation holders are subject to the obligation to submit periodic safety update reports in the context of the procedures referred to in point 14.1, the amount 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 among the marketing authorisation holders		(a) by dividing the total amount of the fee among the marketing	(a) by dividing the total amount of the fee among

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	proportionally to the number of chargeable units-human corresponding to products included in the procedure which are held by each of those marketing authorisation holders;		authorisation holders proportionally to the number of chargeable units-human corresponding to products included in the procedure which are held by each of those marketing authorisation holders;	the marketing authorisation holders proportionally to the number of chargeable units-human corresponding to products included in the procedure which are held by each of those marketing authorisation holders;
242	(b) by subsequently applying, where relevant, the fee reduction laid down in point 1 of Annex V.		(b) by subsequently applying, where relevant, the fee reduction laid down in point 1 of Annex V.	(b) by subsequently applying, where relevant, the fee reduction laid down in point 1 of Annex V.
243	15. Post-authorisation safety studies		15. Post-authorisation safety studies	15. Post-authorisation safety studies

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
244	15.1 A fee of EUR 88 200 shall apply to an assessment carried out under Articles 107n to 107q of Directive 2001/83/EC and Article 28b of Regulation (EC) No 726/2004 of post-authorisation safety studies as referred to in Article 21a, point (b), or Article 22a(1), point (a), of Directive 2001/83/EC, or in Article 9(4), point (cb), or Article 10a(1), point (a), of Regulation (EC) No 726/2004, that are conducted in more than one Member State.		15.1. A fee of EUR 88 200 102 400 shall apply to an assessment carried out under Articles 107n to 107q of Directive 2001/83/EC and Article 28b of Regulation (EC) No 726/2004 of post-authorisation safety studies as referred to in Article 21a, point (b), or Article 22a(1), point (a), of Directive 2001/83/EC, or in Article 9(4), point (cb), or Article 10a(1), point (a), of Regulation (EC) No 726/2004, that are conducted in more than one Member State.	
245	15.2 The fee shall be charged in two instalments, as follows:		15.2 The fee shall be charged in two instalments, as follows:	15.2 The fee shall be charged in two instalments, as follows:

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
246	15.2.1. EUR 44 100 shall be due on the date of the start of the procedure for the assessment of the draft protocol referred to in Article 107n of Directive 2001/83/EC; the remuneration shall be EUR 17 800 for the rapporteur.		15.2.1. EUR 44 100 51 200 shall be due on the date of the start of the procedure for the assessment of the draft protocol referred to in Article 107n of Directive 2001/83/EC; the remuneration shall be EUR 17 800 21 400 for the rapporteur.	
247	15.2.2. EUR 44 100 shall be due at the date of the start of the procedure for the assessment of the final study report, as referred to in Article 107p of Directive 2001/83/EC, by the Pharmacovigilance Risk Assessment Committee; the remuneration shall be EUR 17 800 for the rapporteur.		15.2.2 EUR 44 100 51 200 shall be due at the date of the start of the procedure for the assessment of the final study report, as referred to in Article 107p of Directive 2001/83/EC, by the Pharmacovigilance Risk Assessment Committee; the remuneration shall be EUR 17 800 21 400 for the rapporteur.	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
248	15.3. Where the obligation to conduct a post-authorisation safety study is imposed by the Commission on more than one marketing authorisation holder, the same concerns apply to more than one medicinal product and the marketing authorisation holders concerned conduct a joint post-authorisation safety study, the Agency shall calculate the amount payable by each marketing authorisation holder in two steps, as follows:		15.3. Where the obligation to conduct a post-authorisation safety study is imposed by the Commission on more than one marketing authorisation holder, the same concerns apply to more than one medicinal product and the marketing authorisation holders concerned conduct a joint post-authorisation safety study, the Agency shall calculate the amount payable by each marketing authorisation holder in two steps, as follows:	15.3. Where the obligation to conduct a post-authorisation safety study is imposed by the Commission on more than one marketing authorisation holder, the same concerns apply to more than one medicinal product and the marketing authorisation holders concerned conduct a joint post-authorisation safety study, the Agency shall calculate the amount payable by each marketing authorisation

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
				holder in two steps, as follows:
249	(a) by evenly dividing the total amount of the fee among those marketing authorisation holders;		(a) by evenly dividing the total amount of the fee among those marketing authorisation holders;	(a) by evenly dividing the total amount of the fee among those marketing authorisation holders;
250	(b) by subsequently applying the fee reduction as set out in point 1 of Annex V, where relevant.		(b) by subsequently applying the fee reduction as set out in point 1 of Annex V, where relevant.	(b) by subsequently applying the fee reduction as set out in point 1 of Annex V, where relevant.
250a			<u>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</u>	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			<u>Member State for the submission of the studies referred to in paragraph 15.1.</u>	
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	1. Scientific advice in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004		1. Scientific advice in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004	1. Scientific advice in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004
253	1.1. A fee of EUR 33 100 shall apply to any of the following requests:		1.1. A fee of EUR 33 100 <u>34 900</u> shall apply to any of the following requests:	

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

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
265	(b) a request on safety development;		(b) a request on safety development;	(b) a request on safety development;
266	(c) a request on bioequivalence studies for generic veterinary medicinal products as defined in Article 4(9) of (EU) 2019/6;		(c) a request on bioequivalence studies for generic veterinary medicinal products as defined in Article 4(9) of Regulation (EU) 2019/6;	(c) a request on bioequivalence studies for generic veterinary medicinal products as defined in Article 4(9) of Regulation (EU) 2019/6;
267	(d) a request for preliminary risk profile;		(d) a request for preliminary risk profile;	(d) a request for preliminary risk profile;
268	(e) a request related to setting a new maximum residue limit.		(e) a request related to setting a new maximum residue limit.	(e) a request related to setting a new maximum residue limit.
269	The remuneration shall be EUR 6 100 for the scientific advice co-ordinator.		The remuneration shall be EUR 6 100 6 400 for the scientific advice co-ordinator.	
270	2. Request for classification of a veterinary medicinal product as intended for		2. Request for classification of a veterinary medicinal	2. Request for classification of a

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	a limited market as defined in Article 4, point (29), of Regulation (EU) 2019/6 and for consideration for eligibility for authorisation in accordance with Article 23 of that Regulation		product as intended for a limited market as defined in Article 4, point (29), of Regulation (EU) 2019/6 and for consideration for eligibility for authorisation in accordance with Article 23 of that Regulation	veterinary medicinal product as intended for a limited market as defined in Article 4, point (29), of Regulation (EU) 2019/6 and for consideration for eligibility for authorisation in accordance with Article 23 of that Regulation
271	A charge of EUR 5 200 shall apply to a request for classification of a veterinary medicinal product as intended for a limited market within the meaning of Article 4(29) of Regulation (EU) 2019/6 and for consideration for eligibility for authorisation pursuant to Article 23 of Regulation (EU) 2019/6.		A charge of EUR 5 200 5 500 shall apply to a request for classification of a veterinary medicinal product as intended for a limited market within the meaning of Article 4(29) of Regulation (EU) 2019/6 and for consideration for eligibility for	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			authorisation pursuant to Article 23 of Regulation (EU) 2019/6.	
272	3. Establishment, modification or extension of a maximum residue limit (MRL) in accordance with the procedure laid down in Regulation (EC) No 470/2009 of the European Parliament and of the Council⁶¹ ⁶¹ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).		3. Establishment, modification or extension of a maximum residue limit (MRL) in accordance with the procedure laid down in Regulation (EC) No 470/2009 of the European Parliament and of the Council⁶² ⁶² Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of	3. Establishment, modification or extension of a maximum residue limit (MRL) in accordance with the procedure laid down in Regulation (EC) No 470/2009 of the European Parliament and of the Council⁶² ⁶² Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			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).	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).
273	3.1. A fee of EUR 84 700 shall apply to an application to set an initial MRL for a given substance. The remuneration shall be EUR 21 400 for the rapporteur and EUR 10 300 for the co-rapporteur.		3.1. A fee of EUR 84 700 89 300 shall apply to an application to set an initial MRL for a given substance. The remuneration 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 each application to modify or to extend an		3.2. A fee of EUR 53 000 55 900 shall apply to each	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	existing MRL. The remuneration shall be EUR 10 600 for the rapporteur and EUR 9 700 for the co-rapporteur.		application to modify or to extend an existing MRL. The remuneration shall be EUR 40 600 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 assessment to determine whether a chemical-unlike biological substance requires a full MRL evaluation or not pursuant to Annex I, Section 1.7, to Commission Regulation (EU) 2018/782⁶³. The remuneration shall be EUR 10 100 for the rapporteur. ⁶³ Commission Regulation (EU) 2018/782 of 29 May 2018 establishing the methodological principles for the risk assessment and risk management		3.3. A fee of EUR 24 30025 600 shall apply to the assessment to determine whether a chemical-unlike biological substance requires a full MRL evaluation or not pursuant to Annex I, Section I1.7, to Commission Regulation (EU) 2018/782⁶⁴. The remuneration shall be EUR 40 10010 600 for the rapporteur. ⁶⁴ Commission Regulation (EU) 2018/782 of 29 May 2018 establishing	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	recommendations referred to in Regulation (EC) No 470/2009 (OJ L 132, 30.5.2018, p. 5).		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).	
276	4. Authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6		4. Authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6	4. Authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6
277	4.1. A fee of EUR 295 500 shall apply to an application for a marketing authorisation for a veterinary medicinal product pursuant to Articles 8, 23 or Article 25 of Regulation (EU) 2019/6 where the applicant claims a		4.1. A fee of EUR 295 500 311 500 shall apply to an application for a marketing authorisation for a veterinary medicinal product pursuant to	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	new active substance. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application, irrespective of the number of target species. The remuneration shall be EUR 107 000 for the rapporteur and EUR 38 100 for the co-rapporteur.		Articles 8, 23 or Article 25 of Regulation (EU) 2019/6 where the applicant claims a new active substance. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application, irrespective of the number of target species. The remuneration shall be EUR 107 000 112 800 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 application for a marketing authorisation for a veterinary medicinal product pursuant to Articles 8, 20, 22, 23 or Article 25 of Regulation (EU) 2019/6 where the applicant claims a known active substance. That fee		4.2. A fee of EUR 267 700 282 200 shall apply to an application for a marketing authorisation for a veterinary medicinal product pursuant to Articles 8, 20, 22, 23 or Article	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application, irrespective of the number of target species. The remuneration shall be EUR 82 100 for the rapporteur and EUR 35 300 for the co-rapporteur.		25 of Regulation (EU) 2019/6 where the applicant claims a known active substance. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application, irrespective of the number of target species. The remuneration shall be EUR 82 100 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 any of the following applications:		4.3. A fee of EUR 136 800 144 200 shall apply for any of the following applications:	
280	(a) an application for a marketing authorisation for a generic veterinary medicinal product pursuant to Article 18 of Regulation (EU) 2019/6;		(a) an application for a marketing authorisation for a generic veterinary medicinal	(a) an application for a marketing authorisation for a generic veterinary medicinal product

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			product pursuant to Article 18 of Regulation (EU) 2019/6;	pursuant to Article 18 of Regulation (EU) 2019/6;
281	(b) an application for a marketing authorisation for a hybrid veterinary medicinal product pursuant to Article 19 of Regulation (EU) 2019/6;		(b) an application for a marketing authorisation for a hybrid veterinary medicinal product pursuant to Article 19 of Regulation (EU) 2019/6;	(b) an application for a marketing authorisation for a hybrid veterinary medicinal product pursuant to Article 19 of Regulation (EU) 2019/6;
282	(c) an application based on informed consent for a marketing authorisation for a veterinary medicinal product pursuant to Article 21 of Regulation (EU) 2019/6.		(c) an application based on informed consent for a marketing authorisation for a veterinary medicinal product pursuant to Article 21 of Regulation (EU) 2019/6.	(c) an application based on informed consent for a marketing authorisation for a veterinary medicinal product pursuant to Article 21 of Regulation (EU) 2019/6.
283	That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application,		That fee shall cover all strengths, all pharmaceutical forms and all presentations	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	irrespective of the number of target species. The remuneration shall be EUR 30 800 for the rapporteur and EUR 17 900 for the co-rapporteur.		submitted in the same application, irrespective of the number of target species. The 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 authorisation for limited markets		5. Re-examination of a marketing authorisation for limited markets	5. Re-examination of a marketing authorisation for limited markets
285	A fee of EUR 19 000 shall apply to an application for a re-examination of a marketing authorisation for a limited market pursuant to Article 24(3) of Regulation (EU) 2019/6. The remuneration shall be EUR 3 100 for the rapporteur and EUR 2 400 for the co-rapporteur.		A fee of EUR 19 000 20 000 shall apply to an application for a re-examination of a marketing authorisation for a limited market pursuant to Article 24(3) of Regulation (EU) 2019/6. The remuneration shall be EUR 3 100 3 300 for the rapporteur and	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			EUR 2 400 <u>2 500</u> for the co-rapporteur.	
286	6. Variations to the terms of a marketing authorisation, requiring assessment in accordance with Articles 64, 65 and 66 of Regulation (EU) 2019/6		6. Variations to the terms of a marketing authorisation, requiring assessment in accordance with Articles 64, 65 and 66 of Regulation (EU) 2019/6	6. Variations to the terms of a marketing authorisation, requiring assessment in accordance with Articles 64, 65 and 66 of Regulation (EU) 2019/6
287	6.1. A fee of EUR 87 800 shall apply to a variation requiring assessment introducing changes of active substance(s), strength, pharmaceutical form, route of administration or food-producing target species, which are to be assessed within 90 days in accordance with Article 66(3) of Regulation (EU) 2019/6. That fee shall be charged for each single pharmaceutical form or each single associated strength/potency.		6.1. A fee of EUR 87 800 <u>92 600</u> shall apply to a variation requiring assessment introducing changes of active substance(s), strength, pharmaceutical form, route of administration or food-producing target species, which are to be assessed within 90 days in accordance with Article	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	The remuneration shall be EUR 28 600 for the rapporteur and EUR 8 600 for the co-rapporteur.		66(3) of Regulation (EU) 2019/6. That fee shall be charged for each single pharmaceutical form or each single associated strength/potency. The remuneration shall be EUR 28 600 <u>30 100</u> for the rapporteur and EUR 8 600 <u>9 100</u> for the co-rapporteur.	
288	6.2. A fee of EUR 47 500 shall apply to variations requiring assessment that introduce changes to safety, efficacy or pharmacovigilance, which are to be assessed within 60 or 90 days, as the case may be, in accordance with Article 66(3) of Regulation (EU) 2019/6. The remuneration shall be EUR 9 800 for the rapporteur and EUR 7 600 for the co-rapporteur.		6.2. A fee of EUR 47 500 <u>50 100</u> shall apply to variations requiring assessment that introduce changes to safety, efficacy or pharmacovigilance, which are to be assessed within 60 or 90 days, as the case may be, in accordance with Article 66(3) of Regulation (EU)	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			2019/6. The remuneration shall be EUR 9 800 <u>10 300</u> for the rapporteur and EUR 7 600 <u>8 000</u> for the co-rapporteur.	
289	6.3. A fee of EUR 23 900 shall apply to variations requiring assessment introducing quality changes only, which are to be assessed within 60 days in accordance with Article 66(3) of Regulation (EU) 2019/6. The remuneration shall be EUR 3 600 for the rapporteur and EUR 3 600 for the co-rapporteur.		6.3. A fee of EUR 23 900 <u>25 200</u> shall apply to variations requiring assessment introducing quality changes only, which are to be assessed within 60 days in accordance with Article 66(3) of Regulation (EU) 2019/6. The remuneration shall be EUR 3 600 <u>3 800</u> for the rapporteur and EUR 3 600 <u>3 800</u> for the co-rapporteur.	
290	6.4. Where several variations requiring assessment are grouped in a single application under Article 64 of Regulation (EU) 2019/6, the corresponding fee as set		6.4. Where several variations requiring assessment are grouped in a single application under Article 64 of Regulation	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	out in points 6.1, 6.2 and 6.3 of this Annex shall apply to each of the first two variations. Remuneration shall be paid in accordance with those points. For the third and subsequent variations, the fee shall be EUR 12 000 per variation and the remuneration shall be EUR 1 800 per variation for the rapporteur and EUR 1 800 for the co-rapporteur.		(EU) 2019/6, the corresponding fee as set out in points 6.1, 6.2 and 6.3 of this Annex shall apply to each of the first two variations. Remuneration shall be paid in accordance with those points. For the third and subsequent variations, the fee shall be EUR 12 000 12 600 per variation and the remuneration shall be EUR 1 800 1 900 per variation for the rapporteur and EUR 1 800 1 900 for the co-rapporteur.	
291	6.5. Where a work-sharing application pursuant to Article 65 of Regulation (EU) 2019/6 includes more than one centrally authorised product, the fees and remuneration specified in points 6.1, 6.2		6.5. Where a work-sharing application pursuant to Article 65 of Regulation (EU) 2019/6 includes more than one centrally authorised product, the fees and	6.5. Where a work-sharing application pursuant to Article 65 of Regulation (EU) 2019/6 includes more than one

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	and 6.3 of this Annex shall apply for each variation to the first centrally authorised product, whereas a charge of EUR 800 shall apply for each variation to the second and subsequent centrally authorised product included in the same application.		remuneration specified in points 6.1, 6.2 and 6.3 of this Annex shall apply for each variation to the first centrally authorised product, whereas a charge of EUR 800 shall apply for each variation to the second and subsequent centrally authorised product included in the same application.	centrally authorised product, the fees and remuneration specified in points 6.1, 6.2 and 6.3 of this Annex shall apply for each variation to the first centrally authorised product, whereas a charge of EUR 800 shall apply for each variation to the second and subsequent centrally authorised product included in the same application.
292	7. Referrals and arbitration procedures		7. Referrals and arbitration procedures	7. Referrals and arbitration procedures
293	7.1. A fee of EUR 152 700 shall apply to an assessment carried out in the context of a	7.1. A fee of EUR 152 700 shall apply to an assessment	7.1. A fee of EUR 152 700 161 000 shall apply to an	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	procedure initiated under Article 54(8) of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR 21 100 for the rapporteur and EUR 9 600 for the co-rapporteur.	carried out in the context of a procedure initiated under Article 54(8) of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR 10 550 for the rapporteur and EUR 4 800 for the co-rapporteur.	assessment carried out in the context of a procedure initiated under Article 54(8) of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR 21 400 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 the assessment carried out in the context of a procedure initiated under Article 70(11) of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR 29 200 for the rapporteur and EUR 12 900 for the co-rapporteur.	7.2. A fee of EUR 209 300 shall apply to the assessment carried out in the context of a procedure initiated under Article 70(11) of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR 14 600 for the rapporteur and EUR 6 450 for the co-rapporteur.	7.2. A fee of EUR 209 300 220 600 shall apply to the assessment carried out in the context of a procedure initiated under Article 70(11) of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR 29 200 30 800 for the rapporteur	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			and EUR 12 900 13 600 for the co-rapporteur.	
295	7.3. A fee of EUR 147 200 shall apply to the assessment carried out pursuant to Article 141(1), points (c) and (e), of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR 17 500 for the rapporteur and EUR 7 700 for the co-rapporteur.	7.3. A fee of EUR 147 200 shall apply to the assessment carried out pursuant to Article 141(1), points (c) and (e), of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR 8 750 for the rapporteur and EUR 3 850 for the co-rapporteur.	7.3. A fee of EUR 147 200 155 200 shall apply to the assessment carried out pursuant to Article 141(1), points (c) and (e), of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR 17 500 18 400 for the rapporteur and EUR 7 700 8 100 for the co-rapporteur.	
296	7.4. A fee of EUR 209 300 shall apply to the assessment carried out in the context of a procedure initiated under Article 82 of Regulation (EU) 2019/6. The remuneration shall be EUR 29 200 for the rapporteur and EUR 12 900 for the co-rapporteur.		7.4. A fee of EUR 209 300 220 600 shall apply to the assessment carried out in the context of a procedure initiated under Article 82 of Regulation (EU) 2019/6. The remuneration shall be EUR 29 200 30 800 for	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise 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 the assessment carried out in the context of a procedure initiated under Article 129(3) or Article 130(4) of Regulation (EU) 2019/6. The remuneration shall be EUR 17 500 for the rapporteur and EUR 7 700 for the co-rapporteur.		7.5. A fee of EUR 147 200 155 200 shall apply for the assessment carried out in the context of a procedure initiated under Article 129(3) or Article 130(4) of Regulation (EU) 2019/6. The remuneration shall be EUR 17 500 18 400 for the rapporteur and EUR 7 700 8 100 for the co-rapporteur.	
298	7.6. Where two or more marketing authorisation holders are involved in the procedures referred to in points 7.4 or 7.5, the amount payable by each marketing authorisation holder shall be calculated by the Agency in two steps, as follows:		7.6. Where two or more marketing authorisation holders are involved in the procedures referred to in points 7.4 or 7.5, the amount payable by each marketing authorisation holder	7.6. Where two or more marketing authorisation holders are involved in the procedures referred to in points 7.4 or 7.5, the amount payable by each

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			shall be calculated by the Agency in two steps, as follows:	marketing authorisation holder shall be calculated by the Agency in two steps, as follows:
299	(a) by dividing the total amount of the fee among the marketing authorisation holders proportionally to the number of chargeable units – veterinary corresponding to products included in the procedure which are held by each of those marketing authorisation holders;		(a) by dividing the total amount of the fee among the marketing authorisation holders proportionally to the number of chargeable units – veterinary corresponding to products included in the procedure which are held by each of those marketing authorisation holders;	(a) by dividing the total amount of the fee among the marketing authorisation holders proportionally to the number of chargeable units – veterinary corresponding to products included in the procedure which are held by each of those marketing authorisation holders;

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
300	(b) by subsequently applying the fee reduction laid down in point 1 of Annex V, where relevant.		(b) by subsequently applying the fee reduction laid down in point 1 of Annex V, where relevant.	(b) by subsequently applying the fee reduction laid down in point 1 of Annex V, where relevant.
301	8. Certification of compliance with Union legislation for vaccine antigen master files (VAMF)		8. Certification of compliance with Union legislation for vaccine antigen master files (VAMF)	8. Certification of compliance with Union legislation for vaccine antigen master files (VAMF)
302	8.1. A fee of EUR 23 900 shall apply to an application for review of a VAMF and its certification pursuant to point V.2 of Annex II to Regulation (EU) 2019/6 when it is submitted simultaneously with an initial application for marketing authorisation for a veterinary medicinal product under the centralised procedure containing the named antigen. The remuneration shall be EUR 3		8.1. A fee of EUR 23 900 25 200 shall apply to an application for review of a VAMF and its certification pursuant to point V.2 of Annex II to Regulation (EU) 2019/6 when it is submitted simultaneously with an initial application for marketing	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	600 for the rapporteur and EUR 3 600 for the co-rapporteur.		authorisation for a veterinary 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 submitted simultaneously in the context of the same initial marketing authorisation application, a fee of EUR 23 900 shall apply per VAMF. The maximum total amount charged by the Agency shall not exceed EUR 71 700. The remuneration shall be EUR 3 600 for the rapporteur and EUR 3 600 for the co-rapporteur. For multiple VAMF applications submitted simultaneously in the context of the same		8.2. For multiple VAMF applications submitted simultaneously in the context of the same initial marketing authorisation application, a fee of EUR 23 900 25 200 shall apply per VAMF. The maximum total amount charged by the Agency shall not exceed EUR 71 700 74 800 . The remuneration shall be EUR 3 600 3 800 for the	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	initial marketing authorisation application, the remuneration shall not exceed EUR 10 800 for the rapporteur and EUR 10 800 for the co-rapporteur.		rapporteur and EUR 3 600 3 800 for the co-rapporteur. For multiple VAMF applications submitted simultaneously in the context of the same initial marketing authorisation application, the remuneration shall not exceed EUR 10 800 11 400 for the rapporteur and EUR 10 800 11 400 for the co-rapporteur.	
304	8.3. A fee of EUR 33 100 shall apply to an application for the review of a VAMF and its certification when submitted as a separate application for an antigen in vaccine(s) already authorised under the centralised, decentralised or mutual recognition procedure. The remuneration		8.3. A fee of EUR 33 100 34 900 shall apply to an application for the review of a VAMF and its certification when submitted as a separate application for an antigen in vaccine(s) already authorised under the centralised, decentralised or mutual	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	shall be EUR 5 000 for the rapporteur and EUR 5 000 for the co-rapporteur.		recognition procedure. The remuneration shall be EUR 5 000 <u>5 300</u> for the rapporteur and EUR 5 000 <u>5 300</u> for the co-rapporteur.	
305	8.4. Section 6 [of this Annex] shall apply by analogy to variations to a certified VAMF.		8.4. Section 6 [of this Annex] shall apply by analogy to variations to a certified VAMF.	8.4. Section 6 [of this Annex] shall apply by analogy to variations to a certified VAMF.
306	9. Certification of compliance with Union legislation for vaccine platform technology master files (vPTMF)		9. Certification of compliance with Union legislation for vaccine platform technology master files (vPTMF)	9. Certification of compliance with Union legislation for vaccine platform technology master files (vPTMF)
307	9.1. A fee of EUR 23 900 shall apply to an application for review of a vPTMF and its certification pursuant to point V.4 of Annex II to Regulation (EU) 2019/6 when submitted simultaneously with an initial		9.1. A fee of EUR 23 900 <u>25 200</u> shall apply to an application for review of a vPTMF and its certification pursuant to point V.4 of Annex II to Regulation	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	application for marketing authorisation for a veterinary medicinal product under the centralised procedure containing the named platform. The remuneration shall be EUR 3 600 for the rapporteur and EUR 3 600 for the co-rapporteur.		(EU) 2019/6 when submitted simultaneously with an initial application for marketing authorisation for a veterinary medicinal product under the centralised procedure containing the named platform. The remuneration shall be EUR 3 600 <u>3 800</u> for the rapporteur and EUR 3 600 <u>3 800</u> for the co-rapporteur.	
308	9.2. A fee of EUR 33 100 shall apply to an application for review of a vPTMF and its certification when submitted as a separate application for a platform in vaccines already authorised under the centralised, decentralised or mutual recognition procedure. The remuneration shall be EUR		9.2. A fee of EUR 33 100 <u>34 900</u> shall apply to an application for review of a vPTMF and its certification when submitted as a separate application for a platform in vaccines already authorised under the centralised, decentralised or mutual	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	5 000 for the rapporteur and EUR 5 000 for the co-rapporteur.		recognition procedure. The remuneration shall be EUR 5 000- <u>5 300</u> for the rapporteur and EUR 5-000- <u>5 300</u> for the co-rapporteur.	
309	9.3. Section 6 of this Annex shall apply by analogy to variations to a certified vPTMF.		9.3. Section 6 of this Annex shall apply by analogy to variations to a certified vPTMF.	9.3. Section 6 of this Annex shall apply by analogy to variations to a certified vPTMF.
310	10. Assessment of post-marketing surveillance studies		10. Assessment of post-marketing surveillance studies	10. Assessment of post-marketing surveillance studies
311	10.1. A fee of EUR 37 800 shall apply to the assessment of post-marketing surveillance studies pursuant to Article 76(3) of Regulation (EU) 2019/6 that are conducted in more than one Member States.		10.1. A fee of EUR 37 800 <u>39 800</u> shall apply to the assessment of post-marketing surveillance studies pursuant to Article 76(3) of Regulation (EU) 2019/6 that are conducted in more than one Member States.	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
312	10.2. The fee shall be charged as follows:		10.2. The fee shall be charged as follows:	10.2. The fee shall be charged as follows:
313	(a) EUR 18 900 shall be due at the date of the start of the procedure for the approval of the draft study protocol as referred to in Article 15(3) of Commission Implementing Regulation (EU) 2021/1281⁶⁵. The remuneration shall be EUR 7 700 for the rapporteur; _____ ⁶⁵ Commission Implementing Regulation (EU) 2021/1281 of 2 August 2021 laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products (OJ L 279, 3.8.2021, p. 15).		(a) EUR 18 900 19 900 shall be due at the date of the start of the procedure for the approval of the draft study protocol as referred to in Article 15(3) of Commission Implementing Regulation (EU) 2021/1281⁶⁶. The remuneration shall be EUR 7 700 8 100 for the rapporteur; _____ ⁶⁶ Commission Implementing Regulation (EU) 2021/1281 of 2 August 2021 laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise 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 the start of the procedure for the assessment of the final study report as referred to in Article 15(5) of Implementing Regulation (EU) 2021/1281. The remuneration shall be EUR 7 700 for the rapporteur.		(b) EUR 18 900 19 900 shall be due at the date of the start of the procedure for the assessment of the final study report as referred to in Article 15(5) of Implementing Regulation (EU) 2021/1281. The remuneration shall be EUR 7 700 8 100 for the rapporteur.	
315	10.3. Where the obligation to conduct a post-authorisation surveillance study is imposed on more than one marketing authorisation holder and the marketing authorisation holders concerned conduct a joint post-authorisation safety study, the		10.3. Where the obligation to conduct a post-authorisation marketing surveillance study is imposed on more than one marketing authorisation holder and the marketing authorisation holders concerned conduct a	10.3. Where the obligation to conduct a post-authorisation marketing surveillance study is imposed on more than one marketing authorisation

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	Agency shall calculate the fee to be charged in two steps, as follows:		joint post-authorisation safety <u>marketing surveillance</u> study, the Agency shall calculate the fee to be charged in two steps, as follows:	holder and the marketing authorisation holders concerned conduct a joint post-authorisation safety <u>marketing surveillance</u> study, the Agency shall calculate the fee to be charged in two steps, as follows: <i>12/09 to match the section title</i>
316	(a) by evenly dividing the total amount of the fee among those marketing authorisation holders;		(a) by evenly dividing the total amount of the fee among those marketing authorisation holders;	(a) by evenly dividing the total amount of the fee among those marketing authorisation holders;

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	to this Regulation shall apply for an application for a scientific opinion for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union pursuant to Article 138 of Regulation (EU) 2019/6.		5 of Annex IV and points 6.1, 6.2 and 6.4 of that Annex to this Regulation shall apply for an application for a scientific opinion for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union pursuant to Article 138 of Regulation (EU) 2019/6.	and in points 1, 3, 4 and 5 of Annex IV and points 6.1, 6.2 and 6.4 of that Annex to this Regulation shall apply for an application for a scientific opinion for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union pursuant to Article 138 of Regulation (EU) 2019/6.
320	ANNEX III Annual fees and remuneration		ANNEX III Annual fees and remuneration	ANNEX III Annual fees and remuneration

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

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

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	pursuant to Article 18, 19 or 21 of Regulation (EU) 2019/6. The remuneration shall be EUR 5 000 for the rapporteur and EUR 4 600 for the co-rapporteur.		a veterinary medicinal product authorised pursuant to Article 18, 19 or 21 of Regulation (EU) 2019/6. The remuneration shall be EUR 5 000 <u>6 000</u> 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 apply to each marketing authorisation not covered by point 2.1. The remuneration shall be EUR 20 400 for the rapporteur and EUR 18 800 for the co-rapporteur.		2.2 An annual fee of EUR 87 500 <u>101 800</u> shall apply to each marketing authorisation not covered by point 2.1. The remuneration shall be EUR 20 400 <u>24 500</u> for the rapporteur and EUR 18 800 <u>22 600</u> for the co-rapporteur.	
327a			<u>2.2a. The annual fees as specified in points 2.1 and 2.2 shall relate to the preceding year.</u>	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
328	3. Annual pharmacovigilance fee for medicinal products for human use authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by competent authorities of the Member States in accordance with Regulation (EU) 2019/6		3. Annual pharmacovigilance fee for medicinal products for human use authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by competent authorities of the Member States in accordance with Regulation (EU) 2019/6	3. Annual pharmacovigilance fee for medicinal products for human use authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by competent authorities of the Member States in accordance with Regulation (EU) 2019/6
329	3.1. For medicinal products for human use authorised in accordance with Directive 2001/83/EC, a fee of EUR 190 per chargeable unit-human, shall apply once per year for the Agency's pharmacovigilance activities including analysis of Union-wide		3.1. For medicinal products for human use authorised in accordance with Directive 2001/83/EC, a fee of EUR 190 220 per chargeable unit-human, shall apply once per year for the	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	health data to support better decision-making with real world evidence. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.		Agency's pharmacovigilance activities including analysis of Union-wide health data to 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 authorised by competent authorities of the Member States in accordance with Chapter III, Sections 2 to 5 of Regulation (EU) 2019/6, a fee of EUR 80 per chargeable unit-veterinary shall apply once per year for the Agency's pharmacovigilance activities. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.		3.2 For veterinary medicinal products authorised by competent authorities of the Member States in accordance with Chapter III, Sections 2 to 5 of Regulation (EU) 2019/6, a fee of EUR 80 <u>90</u> per chargeable unit-veterinary shall apply once per year for the Agency's pharmacovigilance activities. The Agency shall retain the fee	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			revenue from the annual pharmacovigilance fee.	
331	3.3 The total payable amount of the annual fees referred to in points 3.1 and 3.2 for each marketing authorisation holder shall be calculated by the Agency on the basis of the number of chargeable units-human and chargeable units-veterinary, respectively, which correspond to the information recorded on 1 July of each year.		3.3 The total payable amount of the annual fees referred to in points 3.1 and 3.2 for each marketing authorisation holder shall be calculated by the Agency on the basis of the number of chargeable units-human and chargeable units-veterinary, respectively, which correspond to the information recorded on 1 July of each year.	3.3 The total payable amount of the annual fees referred to in points 3.1 and 3.2 for each marketing authorisation holder shall be calculated by the Agency on the basis of the number of chargeable units-human 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 3.1 and 3.2 shall be due on 1 July of every		3.4. The annual fees referred to in points 3.1 and 3.2 shall be	3.4. The annual fees referred to in points 3.1

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	year and shall cover the period from 1 January to 31 December of that calendar year.		due on 1 July of every year and shall cover the period from 1 January to 31 December of that calendar year.	and 3.2 shall be due on 1 July of every year and shall cover the period from 1 January to 31 December of that calendar year.
333	ANNEX IV Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices		ANNEX IV Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices	ANNEX IV Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices
334	1. Inspections pursuant to Article 8(2), 19 and Article 57(1), point (i) of Regulation (EC) No 726/2004		1. Inspections pursuant to Article 8(2), 19 and Article 57(1), point (i) of Regulation (EC) No 726/2004 <u>and Article 126(2) of Regulation No 2019/6</u>	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
335	1.1. Inspections in relation to medicinal products for human use and veterinary medicinal products		1.1. Inspections in relation to medicinal products for human use and veterinary medicinal products	1.1. Inspections in relation to medicinal products for human use and veterinary medicinal products
336	1.1.1. For any distinct Good Manufacturing Practice inspection within the Union a fee of EUR 24 800 shall apply. The remuneration shall be EUR 8 600 for the leading supervisory authority and EUR 5 200 for the supporting supervisory authority.		1.1.1. For any distinct Good Manufacturing Practice inspection within the Union a fee of EUR 24 800 29 000 shall apply. The remuneration shall be EUR 8 600 10 300 for the leading supervisory authority and EUR 5 200 6 200 for the supporting supervisory authority.	
337	1.1.2. For any distinct Good Manufacturing Practice inspection outside the Union a fee of EUR 37 800 shall apply. The remuneration shall be EUR 15 600 for the		1.1.2. For any distinct Good Manufacturing Practice inspection outside the Union a fee of EUR 37 800 56 000 shall	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	leading supervisory authority and EUR 9 400 for the supporting supervisory authority.		apply. The remuneration shall be EUR 15 600 24 800 for the leading supervisory authority and EUR 9 400 16 700 for the supporting supervisory authority.	
338	1.1.3. For any distinct Good Clinical Practice inspection within the Union a fee of EUR 37 100 shall apply. The remuneration shall be EUR 14 700 for the leading supervisory authority and EUR 9 100 for the supporting supervisory authority.		1.1.3. For any distinct Good Clinical Practice inspection within the Union a fee of EUR 37 100 43 700 shall apply. The remuneration shall be EUR 14 700 17 600 for the leading supervisory authority and EUR 9 100 10 900 for the supporting supervisory authority.	
339	1.1.4. For any distinct Good Clinical Practice inspection outside the Union a fee of EUR 44 200 shall apply. The remuneration shall be EUR 19 600 for the		1.1.4. For any distinct Good Clinical Practice inspection outside the Union a fee of EUR 44 200 56 600 shall apply. The	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	leading supervisory authority and EUR 10 400 for the supporting supervisory authority.		remuneration shall be EUR 49 600 <u>25 800</u> for the leading supervisory authority and EUR 10 400 <u>14 700</u> for the supporting supervisory authority.	
340	1.1.5. For any distinct Plasma Master File inspection within or outside the Union a fee of EUR 36 100 shall apply. The remuneration shall be EUR 13 400 for the leading supervisory authority and EUR 8 200 for the supporting supervisory authority.		1.1.5. For any distinct Plasma Master File inspection within or outside the Union a fee of EUR 36 100 <u>47 300</u> shall apply. The remuneration shall be EUR 13 400 <u>16 700</u> for the leading supervisory authority and EUR 8 200 <u>14 100</u> for the supporting supervisory authority.	
341	1.1.6. For any consecutive Plasma Master File inspection within or outside the Union a fee of EUR 36 100 shall apply. The remuneration shall be EUR 13 400 for the		1.1.6. For any consecutive Plasma Master File inspection within or outside the Union a fee of EUR 36 100 <u>42 400</u> shall	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	leading supervisory authority and EUR 8 200 for the supporting supervisory authority.		apply. The remuneration shall be EUR 13 400 16 100 for the leading supervisory authority and EUR 8 200 9 800 for the supporting supervisory authority.	
342	1.1.7. For any distinct Good Laboratory Practice inspection within or outside the Union a fee of EUR 34 900 shall apply. The remuneration shall be EUR 13 200 for the leading supervisory authority and EUR 8 700 for the supporting supervisory authority.		1.1.7. For any distinct Good Laboratory Practice inspection within or outside the Union a fee of EUR 34 900 41 000 shall apply. The remuneration shall be EUR 13 200 15 800 for the leading supervisory authority and EUR 8 700 10 400 for the supporting supervisory authority.	
343	1.1.8. For any distinct pharmacovigilance inspection within or outside the Union a fee of EUR 52 700 shall apply. The		1.1.8. For any distinct pharmacovigilance inspection within or outside the Union a fee	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	remuneration shall be EUR 16 200 for the leading supervisory authority and EUR 10 100 for the supporting supervisory authority.		of EUR 52 700 61 500 shall apply. The remuneration shall be EUR 16 200 19 400 for the leading supervisory authority and EUR 10 100 12 100 for the supporting supervisory authority.	
344	1.2. If a scheduled inspection is cancelled 30 calendar days or less before the first day of the inspection for reasons attributable to the applicant, the applicable fee referred to in point 1.1 shall apply.		1.2. If a scheduled inspection is cancelled 30 calendar days or less before the first day of the inspection for reasons attributable to the applicant, the applicable fee referred to in point 1.1 shall apply.	1.2. If a scheduled inspection is cancelled 30 calendar days or less before the first day of the inspection for reasons attributable to the applicant, the applicable fee referred to in point 1.1 shall apply.
345	1.3. If a scheduled inspection is cancelled more than 30 calendar days before the first		1.3. If a scheduled inspection is cancelled more than 30	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	day of the inspection, a charge of EUR 840 shall apply.		calendar days before the first day of the inspection <u>for reasons attributable to the applicant</u> , a charge of EUR 840 <u>1 000</u> shall apply.	
346	1.4. The supervisory authorities shall charge the applicant the travel expenses separately from the fee specified in this Annex, based on actual cost. In case of a cancelled inspection as per points 1.2 or 1.3, the applicant shall be charged for any travel expenses already incurred by the inspecting authority on the date of cancellation for which that authority is not able to obtain reimbursement.		1.4. The supervisory authorities shall charge the applicant the travel expenses separately from the fee specified in this Annex, based on actual cost. In case of a cancelled inspection as per points 1.2 or 1.3, the applicant shall be charged for any travel expenses already incurred by the inspecting authority on the date of cancellation for which that authority is not able to obtain reimbursement.	1.4. The supervisory authorities shall charge the applicant the travel expenses separately from the fee specified in this Annex, based on actual cost. In case of a cancelled inspection as per points 1.2 or 1.3, the applicant shall be charged for any travel expenses already incurred by the inspecting authority on

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
				the date of cancellation for which that authority is not able to obtain reimbursement.
347	2. Transfer of a marketing authorisation		2. Transfer of a marketing authorisation	2. Transfer of a marketing authorisation
348	A charge of EUR 3 700 shall apply to an application for the transfer of a marketing authorisation pursuant to Article 3 of Commission Regulation (EC) No 2141/96⁶⁷. This covers all authorised presentations of a given medicinal product. ⁶⁷ Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorization for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93 (OJ L 286, 8.11.1996, p. 6).		A charge of EUR 3 700 4 200 shall apply to an application for the transfer of a marketing authorisation pursuant to Article 3 of Commission Regulation (EC) No 2141/96⁶⁸. This covers all authorised presentations of a given medicinal product. ⁶⁸ Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			marketing authorization for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93 (OJ L 286, 8.11.1996, p. 6).	
349	The charge shall be levied to the marketing authorisation holder that requested the transfer, according to the application submitted to the Agency.		The charge shall be levied to the marketing authorisation holder that requested the transfer, according to the application submitted to the Agency.	The charge shall be levied to the marketing authorisation holder that requested the transfer, according to the application submitted to the Agency.
350	3. Pre-submission requests by a prospective applicant prior to a potential submission of an application for a marketing authorisation falling within the scope of the centralised procedure		3. Pre-submission requests by a prospective applicant prior to a potential submission of an application for a marketing authorisation falling within the scope of the centralised procedure	3. Pre-submission requests by a prospective applicant prior to a potential submission of an application for a marketing authorisation falling within the scope

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
				of the centralised procedure
351	3.1. A fee of EUR 7 100 shall apply to each eligibility request submitted with a notification of intention to submit an application for a marketing authorisation falling within the scope of Regulation (EC) No 726/2004 or the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6. The fee shall cover any costs related to pre-submission activities up until the potential submission of the marketing authorisation application. The fee shall apply irrespective of whether or not a marketing authorisation application for the concerned product is subsequently submitted. If an eligibility request has not been submitted, the fee shall		3.1. A fee of EUR 7 100<u>8 200</u> shall apply to each eligibility request submitted with a notification of intention to submit an application for a marketing authorisation falling within the scope of Regulation (EC) No 726/2004 or the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6. The fee shall cover any costs related to pre-submission activities up until the potential submission of the marketing authorisation application. The fee shall apply irrespective of	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	apply in addition to the applicable authorisation fee.		whether or not a marketing authorisation application for the concerned product is subsequently submitted. If an eligibility request has not been submitted, the fee shall apply in addition to the applicable authorisation fee.	
352	The remuneration of the national competent authority, where applicable, shall be EUR 1 300 for the rapporteur and EUR 1 300 for the co-rapporteur.		The remuneration of the national competent authority, where applicable, shall be EUR 1 300 1 600 for the rapporteur and EUR 1 300 1 600 for the co-rapporteur.	
353	3.2. Where the applicant changes the intended submission date by more than 60 days, an additional fee of EUR 3 500 shall apply. The additional remuneration of the national competent authority, where		3.2. Where the applicant changes the intended submission date by more than 60 days, an additional fee of EUR 3 500 4 000 shall apply. The additional	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	applicable, shall be EUR 600 for the rapporteur and EUR 600 for the co-rapporteur.		remuneration of the national competent authority, where 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 Committees referred to in Article 56(1) of Regulation (EC) No 726/2004 and in Article 139(1) of Regulation (EU) 2019/6		4. Re-examination of an opinion of the Committees referred to in Article 56(1) of Regulation (EC) No 726/2004 and in Article 139(1) of Regulation (EU) 2019/6	4. Re-examination of an opinion of the Committees referred to in Article 56(1) of Regulation (EC) No 726/2004 and in Article 139(1) of Regulation (EU) 2019/6
355	The fee for the re-examination of an opinion of any of the committees referred to in Article 56(1) of Regulation (EC) No 726/2004 and in Article 139(1) of Regulation (EU) 2019/6 shall be 30% of the fee applicable to the initial opinion in		The fee for the re-examination of an opinion of any of the committees referred to in Article 56(1) of Regulation (EC) No 726/2004 and in Article 139(1) of Regulation	The fee for the re-examination of an opinion of any of the committees referred to in Article 56(1) of Regulation (EC)

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	accordance with points 3, 4, 5 and 6 of Annex I and points 3, 4, 6 and 7 of Annex II to this Regulation. The remuneration to the rapporteur and the co-rapporteur shall be calculated based on the same proportion of the respective remuneration.		(EU) 2019/6 shall be 30% of the fee applicable to the initial opinion in accordance with points 3, 4, 5 and 6 of Annex I and points 3, 4, 6 and 7 of Annex II to this Regulation. The remuneration to the rapporteur and the co-rapporteur shall be calculated based on the same proportion of the respective remuneration.	No 726/2004 and in Article 139(1) of Regulation (EU) 2019/6 shall be 30% of the fee applicable to the initial opinion in accordance with points 3, 4, 5 and 6 of Annex I and points 3, 4, 6 and 7 of Annex II to this Regulation. The remuneration to the rapporteur and the co-rapporteur shall be calculated based on the same proportion of the respective remuneration.
356	5. Scientific services referred to in Article 4(1)		5. Scientific services referred to in Article 4(1)	5. Scientific services referred to in Article 4(1)

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357	The range for fees for scientific services referred to in Article 4(1) shall be EUR 4 100 to EUR 684 500. The range for the remuneration shall be EUR 1 000 to EUR 217 300 for the rapporteur and the co-rapporteur. The applicable amounts of the fee and the remuneration within the above ranges shall be determined in accordance with Article 8.		The range for fees for scientific services referred to in Article 4(1) shall be EUR 4 100 4 800 to EUR 684 500 805 100 . The range for the remuneration shall be EUR 1 000 1 200 to EUR 217 300 261 000 for the rapporteur and the co-rapporteur. The applicable amounts of the fee and the remuneration within the above ranges shall be determined in accordance with Article 8.	
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 applications subject to a fee set out in		A charge of EUR 3 700 4 200 shall apply for applications	

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

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

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
369	6.3.1. A charge of EUR 1 200 shall apply to each initial notification for each presentation of a medicinal product, for one Member State of destination having one or more official languages or for several Member States of destination having the same official language. That charge shall cover any subsequent safety update notification relating to the initial notification.		6.3.1. A charge of EUR 1 200 <u>1 400</u> shall apply to each initial notification for each presentation of a medicinal product, for one Member State of destination having one or more official languages or for several Member States of destination having the same official language. That charge shall cover any subsequent safety update notification relating to the initial notification.	
370	6.3.2. A charge of EUR 350 shall apply to each notification of a bulk change. That charge shall cover all initial notifications approved by the date of submission of the notification of bulk changes.		6.3.2. A charge of EUR 350 <u>400</u> shall apply to each notification of a bulk change. That charge shall cover all initial notifications approved by the	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			date of submission of the notification of bulk changes.	
371	6.3.3. A charge of EUR 350 shall apply to each annual update notification. That charge shall cover all the presentations belonging to the same pharmaceutical form of the same medicinal product for one Member State of destination having one or more official languages, or for several Member States of destination having the same official language. No charge shall apply if there have been no regulatory updates in the past twelve months or if the product was dormant.		6.3.3. A charge of EUR 350 400 shall apply to each annual update notification. That charge shall cover all the presentations belonging to the same pharmaceutical form of the same medicinal product for one Member State of destination having one or more official languages, or for several Member States of destination having the same official language. No charge shall apply if there have been no regulatory updates in the past twelve months or if the product was dormant.	

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	of Annex IX to Regulation (EU) 2017/745, where the medicinal substance(s) from the specified manufacturer has not been evaluated by the Agency or a competent authority designated by the Member States in accordance with Directive 2001/83/EC (hereafter ‘medicinal products authority’) in connection with a previous marketing authorisation or through a previous consultation by a notified body. One application may include a range of strength or concentrations of the ancillary substance(s) or a range of similar devices from the same medical device manufacturer incorporating the same substance(s) or both. The remuneration shall be EUR 23 500 for the rapporteur and EUR 23 500 for the co-rapporteur.		medicinal substances pursuant to section 5.2 of Annex IX to Regulation (EU) 2017/745, where the medicinal substance(s) from the specified manufacturer has not been evaluated by the Agency or a competent authority designated by the Member States in accordance with Directive 2001/83/EC (hereafter ‘medicinal products authority’) in connection with a previous marketing authorisation or through a previous consultation by a notified body. One application may include a range of strength or concentrations of the ancillary substance(s) or a	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			range of similar devices from the same medical device manufacturer incorporating the same substance(s) or both. The remuneration shall be EUR 23 500 28 200 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 consultation on one or more ancillary medicinal substance(s) pursuant to section 5.2 of Annex IX to Regulation (EU) 2017/745, where the medicinal substance(s) from the specified manufacturer has been evaluated by a medicinal products authority in connection with a previous marketing authorisation or through a previous consultation by a notified body. One application may include a range of strengths		7.1.2. A fee of EUR 46 900 54 700 shall apply to a consultation on one or more ancillary medicinal substance(s) pursuant to section 5.2 of Annex IX to Regulation (EU) 2017/745, where the medicinal substance(s) from the specified manufacturer has been evaluated by a medicinal products authority in connection with a	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	or concentrations of the ancillary substance(s) or a range of similar devices from the same medical device manufacturer incorporating the same substance(s) or both. The remuneration shall be EUR 11 500 for the rapporteur and EUR 11 500 for the co-rapporteur.		previous marketing authorisation or through a previous consultation by a notified body. One application may include a range of strengths or concentrations of the ancillary substance(s) or a range of similar devices from the same medical device manufacturer incorporating the same substance(s) or both. The remuneration shall be EUR 11 500 13 800 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 fee of EUR 4 100 shall apply to a consultation, pursuant to section 5.2, point (f), of Annex IX to Regulation (EU)		7.1.3. For the purpose of 7.1.1. and 7.1.2., a fee of EUR 4 100 700 shall apply to a consultation, pursuant to section	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	2017/745, regarding a change with respect to an ancillary medicinal substance incorporated in a device. The remuneration shall be EUR 1 400 for the rapporteur.		5.2, point (f), of Annex IX to Regulation (EU) 2017/745, regarding a change with respect to an ancillary medicinal substance incorporated in a device. The remuneration shall be EUR 1 400 1 700 for the rapporteur.	
379	7.2. Medical devices composed of a substance or a combination of substances that are systemically absorbed to achieve their intended purpose.		7.2. Medical devices composed of a substance or a combination of substances that are systemically absorbed to achieve their intended purpose.	7.2. Medical devices composed of a substance or a combination of substances that are systemically absorbed to achieve their intended purpose.
380	A fee of EUR 70 600 shall apply to a consultation on a medical device or a range of similar devices composed of a substance or a combination of substances that are		A fee of EUR 70 600 82 400 shall apply to a consultation on a medical device or a range of similar devices composed of a	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	absorbed by or locally dispersed in the human body, pursuant to section 5.4 of Annex IX, to Regulation (EU) 2017/745. The remuneration shall be EUR 17 500 for the rapporteur and EUR 17 500 for the co-rapporteur.		substance or a combination of substances that are absorbed by or locally dispersed in the human body, pursuant to section 5.4 of Annex IX, to Regulation (EU) 2017/745. The remuneration shall be EUR 17 500 21 000 for the rapporteur and EUR 17 500 21 000 for the co-rapporteur.	
381	7.3. <i>Companion diagnostic</i>		7.3. <i>Companion diagnostic</i>	7.3. <i>Companion diagnostic</i>
382	7.3.1. A fee of EUR 46 900 shall apply to a consultation on the suitability of a companion diagnostic in relation to a concerned medicinal product, pursuant to Article 48(3) or (4), of Regulation (EU) 2017/746, and section 5.2 of Annex IX, or section 3, point (k), of Annex X to that		7.3.1. A fee of EUR 46 900 54 000 shall apply to a consultation on the suitability of a companion diagnostic in relation to a concerned medicinal product, pursuant to Article 48(3) or (4), of Regulation (EU) 2017/746,	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	Regulation. The remuneration shall be EUR 11 800 for the rapporteur.		and section 5.2 of Annex IX, or section 3, point (k), of Annex X to that Regulation. The remuneration shall be EUR 11 800 14 200 for the rapporteur.	
383	A fee of EUR 4 100 shall apply to a consultation on a change affecting the suitability of the companion diagnostic in relation to the medicinal product concerned, pursuant to section 5.2, point (f), of Annex IX to Regulation (EU) 2017/746. The remuneration shall be EUR 1 400 for the rapporteur.		A fee of EUR 4 100 4 700 shall apply to a consultation on a change affecting the suitability of the companion diagnostic in relation to the medicinal product concerned, pursuant to section 5.2, point (f), of Annex IX to Regulation (EU) 2017/746. The remuneration shall be EUR 1 400 1 700 for the rapporteur.	
384	7.4. The fees set out in points 7.1, 7.2 and 7.3 shall be charged to the medical device manufacturer that, according to the application form submitted to the Agency,		7.4. The fees set out in points 7.1, 7.2 and 7.3 shall be charged to the medical device manufacturer that, according to	7.4. The fees set out in points 7.1, 7.2 and 7.3 shall be charged to the medical device

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	requested the assessment of conformity of the medical device for which the notified body is consulting the Agency.		the application form submitted to the Agency, requested the assessment of conformity of the medical device for which the notified body is consulting the Agency.	manufacturer that, according to the application form submitted to the Agency, requested the assessment of conformity of the medical device for which the notified body is consulting the Agency.
385	ANNEX V Fee reductions		ANNEX V Fee reductions	ANNEX V Fee reductions
386	1. Fee reductions granted to micro, small- and medium-sized enterprises		1. Fee reductions granted to micro, small- and medium-sized enterprises	Fee reductions granted to micro, small- and medium-sized enterprises
387	1.1. The following total or partial reductions to the fees laid down in this Regulation shall		1.1. The following total or partial reductions to the fees laid	1.1. The following total or partial reductions to

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	5 of Annex I, excluding point 5.4 of that section;		use pursuant to section 5 of Annex I, excluding point 5.4 of that section;	products for human use pursuant to section 5 of Annex I, excluding point 5.4 of that section;
391	(c) referral procedures for medicinal products for human use pursuant to points 6.4 to 6.7 of Annex I;		(c) referral procedures for medicinal products for human use pursuant to points 6.4 to 6.7 of Annex I;	(c) referral procedures for medicinal products for human use pursuant to points 6.4 to 6.7 of Annex I;
392	(d) request for scientific support and advice by the Committee on Herbal Medicinal Products related to traditional herbal medicinal products pursuant to section 7 of Annex I;		(d) request for scientific support and advice by the Committee on Herbal Medicinal Products related to traditional herbal medicinal products pursuant to section 7 of Annex I;	
393	(e) certification of compliance with Union legislation for plasma master files pursuant to section 9 of Annex I;		(e) certification of compliance with Union legislation for plasma master files pursuant to section 9 <u>8</u> of Annex I;	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
394	(f) certification of compliance with Union legislation regarding vaccine antigen master files (VAMF) pursuant to section 10 of Annex I;		(f) certification of compliance with Union legislation regarding vaccine antigen master files (VAMF) pursuant to section 10 <u>9</u> of Annex I;	
395	(g) assessment of periodic safety update reports for medicinal products for human use pursuant to section 15 of Annex I;		(g) assessment of periodic safety update reports for medicinal products for human use pursuant to section 15 <u>14</u> of Annex I;	
396	(h) assessment of post-authorisation safety studies for medicinal products for human use pursuant to section 16 of Annex I;		(h) assessment of post-authorisation safety studies for medicinal products for human use pursuant to section 16 <u>15</u> of Annex I;	
397	(i) variations requiring assessment pursuant to section 6 of Annex II, excluding point 6.5 of that section;		(i) variations requiring assessment pursuant to section 6 of Annex II, excluding point 6.5 of that section;	(i) variations requiring assessment pursuant to section 6 of Annex II, excluding point 6.5 of that section;

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398	(j) referral procedures for veterinary medicinal products pursuant to points 7.4 to 7.7 of Annex II;		(j) referral procedures for veterinary medicinal products pursuant to points 7.4 to 7.57 of Annex II;	
399	(k) certification of compliance with Union legislation regarding VAMF pursuant to section 8 of Annex II;		(k) certification of compliance with Union legislation regarding VAMF pursuant to section 8 of Annex II;	(k) certification of compliance with Union legislation regarding VAMF pursuant to section 8 of Annex II;
400	(l) certification of compliance with Union legislation regarding vaccine platform technology master files (vPTMF) pursuant to section 9 of Annex II;		(l) certification of compliance with Union legislation regarding vaccine platform technology master files (vPTMF) pursuant to section 9 of Annex II;	(l) certification of compliance with Union legislation regarding vaccine platform technology master files (vPTMF) pursuant to section 9 of Annex II;
401	(m) assessment of post-marketing surveillance studies for veterinary medicinal products pursuant to section 10 of Annex II;		(m) assessment of post-marketing surveillance studies for veterinary medicinal	(m) assessment of post-marketing surveillance studies for veterinary

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			products pursuant to section 10 of Annex II;	medicinal products pursuant to section 10 of Annex II;
402	(n) annual fee, for medicinal products for human use or for veterinary medicinal products, or both, pursuant to section 1 or 2, respectively, of Annex III;		(n) annual fee, for medicinal products for human use or for veterinary medicinal products, or both, pursuant to section 1 or 2, respectively, of Annex III;	(n) annual fee, for medicinal products for human use or for veterinary medicinal products, or both, pursuant to section 1 or 2, respectively, of Annex III;
403	(o) pharmacovigilance annual fee, for medicinal products for human use or veterinary medicinal products pursuant to Annex III;		(o) pharmacovigilance annual fee, for medicinal products for human use or veterinary medicinal products pursuant to Annex III;	(o) pharmacovigilance annual fee, for medicinal products for human use or veterinary medicinal products pursuant to Annex III;
404	(p) transfer of a marketing authorisation to another micro-, small- or medium-sized		(p) transfer of a marketing authorisation to another micro-,	(p) transfer of a marketing authorisation

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			the small and medium-sized enterprise status by the Agency;	medical device 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 100 % shall apply to the fees set out in points 1.1.1. and 1.1.2.		1.1.2. for a micro enterprise, a reduction of 100 % shall apply to the fees set out in points 1.1.1. and 1.1.2.	1.1.2. for a micro enterprise, a reduction of 100 % shall apply to the 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 shall apply in addition to fee reductions and incentives provided for in Regulation (EC) No 2049/2005 or in the Union pharmaceutical legislation.		1.2. The fee reductions set out in point 1.1.1 shall apply in addition to fee reductions and incentives provided for in Regulation (EC) No 2049/2005 or in the Union pharmaceutical legislation.	1.2. The fee reductions set out in point 1.1.1 shall apply in addition to fee reductions and incentives provided for in Regulation (EC) No 2049/2005 or in the Union pharmaceutical legislation.

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

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		<i>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.</i> <i>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:</i>		

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
		<i>(a) the Legal Entity Form (LEF) and the “founding document” (or any other suitable document provided during the application process);</i> <i>(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;</i> <i>(c) proof that the applicant is not under direct or indirect control of any PPO.</i> <i>For the purposes of paragraph 2, point (c), control may, in particular, take either of the following forms:</i>		

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
		<i>(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</i> <i>(ii) the direct or indirect holding, in fact or in law, of decision-making powers in the applicant.</i> <i>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.</i> <i>The Agency shall reserve its right to conduct an ex-post check</i>		

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
		<i>and to request evidence confirming that the criteria for the fee exemption are fulfilled at any time before the adoption of the final advice letter.</i> <i>3. Where reductions apply pursuant to point 1a, no remuneration shall be paid to the national competent authorities in Member States.</i>		
409	2. Applications relating to core dossier medicinal products to be used in a human pandemic situation		2. Applications relating to core dossier medicinal products to be used in a human pandemic situation	2. Applications relating to core dossier medicinal products to be used in a human pandemic situation
410	2.1. The payment of the fee for an application for a marketing authorisation of a medicinal product to be used in a human		2.1. The payment of the fee for an application for a marketing authorisation of a	2.1. The payment of the fee for an application for a marketing

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	pandemic situation shall be deferred until the pandemic situation is duly recognised, either by the World Health Organisation or by the Union in accordance with Decision No 1082/2013/EU.		medicinal product to be used in a human pandemic situation shall be deferred until the pandemic situation is duly recognised, either by the World Health Organisation or by the Union <u>Commission</u> in accordance with <u>Article 23(1) of Regulation (EU) 2022/2371 on serious cross-border threats to health and repealing</u> Decision No 1082/2013/EU.	authorisation of a medicinal product to be used in a human pandemic situation shall be deferred until the pandemic situation is duly recognised, either by the World Health Organisation or by the Union <u>Commission</u> in accordance with <u>Article 23(1) of Regulation (EU) 2022/2371 on serious cross-border threats to health and repealing</u> Decision No 1082/2013/EU.
411	Such deferral shall not exceed 5 years.		Such deferral shall not exceed 5 years.	Such deferral shall not exceed 5 years.

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
412	2.2. In addition to the deferral provided for in point 2.1, for regulatory activities within the framework of the submission of a core dossier for a pandemic influenza vaccine and the follow-up submission of a pandemic variation, a fee reduction of 100 % shall apply in the following cases:		2.2. In addition to the deferral provided for in point 2.1, for regulatory activities within the framework of the submission of a core dossier for a pandemic influenza -vaccine and the follow-up submission of a pandemic variation, a fee reduction of 100 % shall apply in the following cases:	2.2. In addition to the deferral provided for in point 2.1, for regulatory activities within the framework of the submission of a core dossier for a pandemic influenza -vaccine and the follow-up submission of a pandemic variation, a fee reduction of 100 % shall apply in the following cases:
413	(a) pre-submission activities pursuant to section 9 of Annex IV;		(a) pre-submission activities pursuant to section 39 of Annex IV;	

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
414	(b) scientific advice pursuant to section 1 of Annex I;		(b) scientific advice pursuant to section 1 of Annex I;	(b) scientific advice pursuant to section 1 of Annex I;
415	(c) extension of marketing authorisation pursuant to section 4 of Annex I;		(c) extension of marketing authorisation pursuant to section 4 of Annex I;	(c) extension of marketing authorisation pursuant to section 4 of Annex I;
416	(d) major type-II variation pursuant to section 5 of Annex I;		(d) major type-II variation pursuant to section 5 of Annex I;	(d) major type-II variation pursuant to section 5 of Annex I;
417	(e) annual fee pursuant to section 1 of Annex III. Those reductions shall apply until the human pandemic situation is duly recognised.		(e) annual fee pursuant to section 1 of Annex III. Those reductions shall apply until the human pandemic situation is duly recognised.	(e) annual fee pursuant to section 1 of Annex III. Those reductions shall apply until the human pandemic situation is duly recognised.
418	2.3. Where reductions apply pursuant to point 2.2, no remuneration shall be paid to		2.3. Where reductions apply pursuant to point 2.2, no remuneration shall be paid to the	2.3. Where reductions apply pursuant to point 2.2, no

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	the national competent authorities for the annual fees referred to in point 2.2(e).		national competent authorities for the annual fees referred to in point 2.2(e).	remuneration shall be paid to the national competent authorities for the annual fees referred to in point 2.2(e).
419	3. Applications submitted under Article 30 of Regulation (EC) No 1901/2006		3. Applications submitted under Article 30 of Regulation (EC) No 1901/2006	3. Applications submitted under Article 30 of Regulation (EC) No 1901/2006
420	A 50 % fee reduction shall apply to paediatric use marketing authorisation applications submitted under Article 30 of Regulation (EC) No 1901/2006 for the following services:		A 50 % fee reduction shall apply to paediatric use marketing authorisation applications submitted under Article 30 of Regulation (EC) No 1901/2006 for the following services:	A 50 % fee reduction shall apply to paediatric use marketing authorisation applications submitted under Article 30 of Regulation (EC) No 1901/2006 for the following services:

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
421	(a) initial marketing authorisation application pursuant to section 3 of Annex I, to this Regulation;		(a) initial marketing authorisation application pursuant to section 3 of Annex I, to this Regulation;	(a) initial marketing authorisation application pursuant to section 3 of Annex I, to this Regulation;
422	(b) pre-authorisation inspection pursuant to section 1 of Annex IV, to this Regulation;		(b) pre-authorisation inspection pursuant to section 1 of Annex IV, to this Regulation;	(b) pre-authorisation inspection pursuant to section 1 of Annex IV, to this Regulation;
423	(c) extension of a marketing authorisation pursuant to section 4 of Annex I, to this Regulation, in the first year from granting of the marketing authorisation;		(c) extension of a marketing authorisation pursuant to section 4 of Annex I, to this Regulation, in the first year from granting of the marketing authorisation;	(c) extension of a marketing authorisation pursuant to section 4 of Annex I, to this Regulation, in the first year from granting of the marketing authorisation;
424	(d) major type-II variation pursuant to section 5 of Annex I, to this Regulation, in		(d) major type-II variation pursuant to section 5 of Annex I,	(d) major type-II variation pursuant to

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	the first year from granting of a marketing authorisation;		to this Regulation, in the first year from granting of a marketing authorisation;	section 5 of Annex I, to this Regulation, in the first year from granting of a marketing authorisation;
425	(e) annual fee pursuant to section 1 of Annex III, to this Regulation, in the first year from granting of a marketing authorisation;		(e) annual fee pursuant to section 1 of Annex III, to this Regulation, in the first year from granting of a marketing authorisation;	(e) annual fee pursuant to section 1 of Annex III, to this Regulation, in the first year from granting of a marketing authorisation;
426	(f) post-authorisation inspection pursuant to section 1 of Annex IV, to this Regulation, in the first year from granting of a marketing authorisation.		(f) post-authorisation inspection pursuant to section 1 of Annex IV, to this Regulation, in the first year from granting of a marketing authorisation.	(f) post-authorisation inspection pursuant to section 1 of Annex IV, to this Regulation, in the first year from granting of a marketing authorisation.

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
427	4. Immunological veterinary medicinal products		4. Immunological veterinary medicinal products	4. Immunological veterinary medicinal products
428	A fee reduction of 50 % shall apply to immunological veterinary medicinal products for the following activities:		A fee reduction of 50 % shall apply to immunological veterinary medicinal products for the following activities:	A fee reduction of 50 % shall apply to immunological veterinary medicinal products for the following activities:
429	(a) scientific advice pursuant to section 1 of Annex II;		(a) scientific advice pursuant to section 1 of Annex II;	(a) scientific advice pursuant to section 1 of Annex II;
430	(b) request for classification of a veterinary medicinal product as intended for a limited market as defined in Article 4, point 29 of Regulation (EU) 2019/6 and for consideration for eligibility for authorisation according to Article 23 of that Regulation,		(b) request for classification of a veterinary medicinal product as intended for a limited market as defined in Article 4, point 29 of Regulation (EU) 2019/6 and for consideration for eligibility for authorisation according to	(b) request for classification of a veterinary medicinal product as intended for a limited market as defined in Article 4, point 29 of Regulation

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	pursuant to section 2 of Annex II, to this Regulation;		Article 23 of that Regulation, pursuant to section 2 of Annex II, to this Regulation;	(EU) 2019/6 and for consideration for eligibility for authorisation according to Article 23 of that Regulation, pursuant to section 2 of Annex II, to this Regulation;
431	(c) authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6, pursuant to section 4 of Annex II, to this Regulation;		(c) authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6, pursuant to section 4 of Annex II, to this Regulation;	(c) authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6, pursuant to section 4 of Annex II, to this Regulation;

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			VAMF pursuant to section 8 of Annex II;	pursuant to section 8 of Annex II;
434	(f) certification of compliance with Union legislation for vPTMF pursuant to section 9 of Annex II;		(f) certification of compliance with Union legislation for vPTMF pursuant to section 9 of Annex II;	(f) certification of compliance with Union legislation for vPTMF pursuant to section 9 of Annex II;
435	(g) assessment of post-marketing surveillance studies pursuant to section 10 of Annex II;		(g) assessment of post-marketing surveillance studies pursuant to section 10 of Annex II;	(g) assessment of post-marketing surveillance studies pursuant to section 10 of Annex II;
436	(h) annual fee pursuant to section 2 of Annex III;		(h) annual fee pursuant to section 2 of Annex III;	(h) annual fee pursuant to section 2 of Annex III;
437	(i) pre-submission services pursuant to section 3 of Annex IV.		(i) pre-submission services pursuant to section 3 of Annex IV.	(i) pre-submission services pursuant to section 3 of Annex IV.

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
438	5. Veterinary medicinal products for limited markets		5. Veterinary medicinal products for limited markets	5. Veterinary medicinal products for limited markets
439	5.1. A fee reduction of 50 % shall apply to veterinary medicinal products classified as intended for a limited market within the meaning of Article 4(29) of Regulation (EU) 2019/6 and considered eligible for authorisation or authorised pursuant to Article 23 of that Regulation, for the following activities:		5.1. A fee reduction of 50 % shall apply to veterinary medicinal products classified as intended for a limited market within the meaning of Article 4(29) of Regulation (EU) 2019/6 and considered eligible for authorisation or authorised pursuant to Article 23 of that Regulation, for the following activities:	5.1. A fee reduction of 50 % shall apply to veterinary medicinal products classified as intended for a limited market within the meaning of Article 4(29) of Regulation (EU) 2019/6 and considered eligible for authorisation or authorised pursuant to Article 23 of that Regulation, for the following activities:

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
440	(a) scientific advice pursuant to section 1 of Annex II, to this Regulation;		(a) scientific advice pursuant to section 1 of Annex II, to this Regulation;	(a) scientific advice pursuant to section 1 of Annex II, to this Regulation;
441	(b) applications for establishment, modification or extension of a maximum residue limit pursuant to section 3 of Annex II, to this Regulation;		(b) applications for establishment, modification or extension of a maximum residue limit pursuant to section 3 of Annex II, to this Regulation;	(b) applications for establishment, modification or extension of a maximum residue limit pursuant to section 3 of Annex II, to this Regulation;
442	(c) authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6 pursuant to Article 23 of that Regulation, pursuant to point 4.1 or 4.2 of Annex II, to this Regulation;		(c) authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6 pursuant to Article 23 of that Regulation, pursuant to	(c) authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			point 4.1 or 4.2 of Annex II, to this Regulation;	(EU) 2019/6 pursuant to Article 23 of that Regulation, pursuant to point 4.1 or 4.2 of Annex II, to this Regulation;
443	(d) variations to the terms of a marketing authorisation requiring assessment in accordance with Article 66 of Regulation (EU) 2019/6, pursuant to section 6 of Annex II. In the specific case of point 6.5 of Annex II, the reduction shall apply to the variations subject to a fee and shall not apply to the variations subject to a charge;		(d) variations to the terms of a marketing authorisation requiring assessment in accordance with Article 66 of Regulation (EU) 2019/6, pursuant to section 6 of Annex II. In the specific case of point 6.5 of Annex II, the reduction shall apply to the variations subject to a fee and shall not apply to the variations subject to a charge;	(d) variations to the terms of a marketing authorisation requiring assessment in accordance with Article 66 of Regulation (EU) 2019/6, pursuant to section 6 of Annex II. In the specific case of point 6.5 of Annex II, the reduction shall apply to the variations subject to a fee and shall not apply

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
				to the variations subject to a charge;
444	(e) certification of compliance with Union legislation for VAMF pursuant to section 8 of Annex II to this Regulation;		(e) certification of compliance with Union legislation for VAMF pursuant to section 8 of Annex II to this Regulation;	(e) certification of compliance with Union legislation for VAMF pursuant to section 8 of Annex II to this Regulation;
445	(f) certification of compliance with Union legislation for vPTMF pursuant to section 9 of Annex II to this Regulation;		(f) certification of compliance with Union legislation for vPTMF pursuant to section 9 of Annex II to this Regulation;	(f) certification of compliance with Union legislation for vPTMF pursuant to section 9 of Annex II to this Regulation;
446	(g) assessment of post-marketing surveillance studies pursuant to section 10 of Annex II, to this Regulation;		(g) assessment of post-marketing surveillance studies pursuant to section 10 of Annex II, to this Regulation;	(g) assessment of post-marketing surveillance studies pursuant to section 10 of Annex II, to this Regulation;

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
447	(h) annual fee pursuant to section 2 of Annex III, to this Regulation;		(h) annual fee pursuant to section 2 of Annex III, to this Regulation;	(h) annual fee pursuant to section 2 of Annex III, to this Regulation;
448	(i) pre-submission services pursuant section 3 to Annex IV, to this Regulation.		(i) pre-submission services pursuant section 3 to Annex IV, to this Regulation.	(i) pre-submission services pursuant section 3 to Annex IV, to this Regulation.
449	5.2. A reduction of 100 % shall apply to the fee for extension of maximum residues limits set out in section 3 of Annex II, when such extension does not require assessment of data.		5.2. A reduction of 100 % shall apply to the fee for extension of maximum residues limits set out in section 3 of Annex II, when such extension does not require assessment of data.	5.2. A reduction of 100 % shall apply to the fee for extension of maximum residues limits set out in section 3 of Annex II, when such extension does not require assessment of data.
450	6. Veterinary vaccines against certain major epizootic diseases		6. Veterinary vaccines against certain major epizootic diseases	6. Veterinary vaccines against certain major epizootic diseases

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
451	6.1. A fee reduction of 100 % shall apply to the annual fee for vaccines against bluetongue, pandemic avian influenza, foot and mouth disease and classical swine fever, where the vaccine is authorised under normal circumstances and the product has not been marketed within the Union at any time during the totality of the period covered by the fee.		6.1. A fee reduction of 100 % shall apply to the annual fee for vaccines against <u>infection with</u> bluetongue <u>virus (serotypes 1-24)</u> , pandemic <u>highly pathogenic</u> avian influenza, foot and mouth disease and classical swine fever, where the vaccine is authorised under normal circumstances and the product has not been marketed within the Union at any time during the totality of the period covered by the fee.	
452	6.2. Where a reduction applies pursuant to point 6.1, no remuneration shall be paid to the national competent authorities for the annual fees referred to in point 6.1.		6.2. Where a reduction applies pursuant to point 6.1, no remuneration shall be paid to the national competent authorities	6.2. Where a reduction applies pursuant to point 6.1, no remuneration shall be paid to the national

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			for the annual fees referred to in point 6.1.	competent authorities for the annual fees referred to in point 6.1.
453	7. Annual fee for veterinary medicinal products		7. Annual fee for veterinary medicinal products	7. Annual fee for veterinary medicinal products
454	A fee reduction of 25 % shall apply to the annual fee for veterinary medicinal products set out in section 2 of Annex III, with the exclusion of those products already listed in sections 4 and 5 of this Annex.		A fee reduction of 25 % shall apply to the annual fee for veterinary medicinal products set out in section 2 of Annex III, with the exclusion of those products already listed in sections 4 and 5 of this Annex.	A fee reduction of 25 % shall apply to the annual fee for veterinary medicinal products set out in section 2 of Annex III, with the exclusion of those products already listed in sections 4 and 5 of this Annex.
455	8. Annual pharmacovigilance fee for generic, homeopathic and herbal medicinal products		8. Annual pharmacovigilance fee for	8. Annual pharmacovigilance fee for generic,

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
			generic, homeopathic and herbal medicinal products	homeopathic and herbal medicinal products
456	A fee reduction of 20 % shall apply to the annual pharmacovigilance fee set out in section 3 of Annex III for the following medicinal products:	A fee reduction of 30% shall apply to the annual pharmacovigilance fee set out in section 3 of Annex III for the following medicinal products:	A fee reduction of 20 % shall apply to the annual pharmacovigilance fee set out in section 3 of Annex III for the following medicinal products:	
457	(a) medicinal products for human use as referred to in Article 10(1) and Article 10a of Directive 2001/83/EC;		(a) medicinal products for human use as referred to in Article 10(1) and Article 10a of Directive 2001/83/EC;	(a) medicinal products for human use as referred to in Article 10(1) and Article 10a of Directive 2001/83/EC;
458	(b) homeopathic medicinal products for human use;		(b) homeopathic medicinal products for human use;	(b) homeopathic medicinal products for human use;
459	(c) herbal medicinal products for human use;		(c) herbal medicinal products for human use;	(c) herbal medicinal products for human use;

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
460	(d) veterinary medicinal products as referred to in Articles 18 and 22 of Regulation (EU) 2019/6;		(d) veterinary medicinal products as referred to in Articles 18 and 22 of Regulation (EU) 2019/6;	(d) veterinary medicinal products as referred to in Articles 18 and 22 of Regulation (EU) 2019/6;
461	(e) homeopathic veterinary medicinal products;		(e) homeopathic veterinary medicinal products;	(e) homeopathic veterinary medicinal products;
462	(f) homeopathic veterinary medicinal products registered in accordance with Article 87 of Regulation (EU) 2019/6.		(f) homeopathic veterinary medicinal products registered in accordance with Article 87 of Regulation (EU) 2019/6.	(f) homeopathic veterinary medicinal products registered in accordance with Article 87 of Regulation (EU) 2019/6.
463	ANNEX VI Performance information		ANNEX VI Performance information	ANNEX VI Performance information
464	The following information shall relate to each calendar year:	The following information shall relate to each calendar year <i>and</i>	The following information shall relate to each calendar year:	

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

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

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

	Commission proposal	EP amendments voted on 12 July 2023	Text agreed by the Council on 13 June 2023	Tentatively agreed text, compromise proposals and comments
	by the Management Board based on a proposal by the Agency.	devices per procedures on the basis of the information provided to the Agency by the national competent authorities concerned. The procedures to be included shall be decided by the Management Board based on a proposal by the Agency.	devices per <u>type of</u> procedures on the basis of the information provided to the Agency by the national competent authorities concerned. The <u>types of</u> procedures to be included shall be decided by the Management Board based on a proposal by the Agency.	
470a		<i>(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;</i>		
470b		<i>(6b) any additional relevant key performance indicators that impact the evolving workload of the Agency and national</i>		

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

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
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



Council of the European Union
General Secretariat

Brussels, 14 September 2023

Interinstitutional files:
2022/0417 (COD)

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	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

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- 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