

Brussels, 6 September 2023 (OR. en)

12664/23

Interinstitutional File: 2022/0417(COD)

PHARM 114 SAN 500 MI 712 COMPET 834 CODEC 1532 VETER 81

WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Delegations
Subject:	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

Delegations will find enclosed the four column table on the above mentioned proposal.

This document contains in Annex A the explanations on the layout of the table used in this document and in Annex B the text of the Commission proposal, the amendments voted by the European Parliament on 12 July 2023 and changes to the Proposal approved by the Council on 13 June 2023.

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Explanation of the table layout

Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
	July 2023	13 June 2023	text, compromise
			proposals and
			comments
	Plain text in this column is text from the Commission proposal that the European Parliament proposes to maintain. Text in bold italics in this column is text that the EP proposes to add to the Commission proposal. When an empty cell in this column is on the same row as a Commission proposal, it means that that text was not changed by the EP.	Plain text in this column is text from the Commission proposal that Council wishes to maintain. Text in bold underlined in this column is text that Council has agreed to add. Text in strikethrough in this column is text that Council has agreed to delete.	This column will contains comments, compromise proposals and tentatively agreed text.

ANNEX B

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
1	REGULATION OF THE EUROPEAN		REGULATION OF THE	
	PARLIAMENT AND OF THE COUNCIL		EUROPEAN PARLIAMENT	
	on fees and charges payable to the European		AND OF THE COUNCIL on	
	Medicines Agency, amending Regulation		fees and charges payable to the	
	(EU) 2017/745 of the European Parliament		European Medicines Agency,	
	and of the Council and repealing Council		amending Regulations (EU)	
	Regulation (EC) No 297/95 and Regulation		2017/745 and (EU) 2022/123 of	
	(EU) 658/2014 of the European Parliament		the European Parliament and of	
	and of the Council		the Council and repealing	
			Council Regulation (EC)	
			No 297/95 and Regulation	
			(EU) 658/2014 of the European	

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			Parliament and of the Council	
2	THE EUROPEAN PARLIAMENT AND		THE EUROPEAN	
	THE COUNCIL OF THE EUROPEAN		PARLIAMENT AND THE	
	UNION,		COUNCIL OF THE	
			EUROPEAN UNION,	
3	Having regard to the Treaty on the		Having regard to the Treaty on	
	Functioning of the European Union, and in		the Functioning of the European	
	particular Article 114 and Article 168(4),		Union, and in particular	
	points (b) and (c), thereof,		Article 114 and Article 168(4),	
			points (b) and (c), thereof,	
4	Having regard to the proposal from the		Having regard to the proposal	
	European Commission,		from the European Commission,	
5	After transmission of the draft legislative act		After transmission of the draft	
	to the national parliaments,		legislative act to the national	
			parliaments,	
6	Having regard to the opinion of the		Having regard to the opinion of	
	European Economic and Social Committee ¹ ,		the European Economic and	

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

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

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

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		provided through a single	
		Union remuneration amount	
		per relevant type of fee,	
		regardless of the Member	
		State of origin of the	
		competetent authority. Cost-	
		based fees should take into	
		account an evaluation of costs of	
		the Agency's activities and of	
		the contributions of competent	
		authorities of the Member States	
		to its work. In addition, this	
		Regulation aims to establish a	
		single framework for a	
		streamlined fee system of the	
		Agency and to introduce	
		regulatory flexibility for	
	1	1	

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			adjustment to that fee system in	
			the future.	
11a			(2a) This Regulation should	
			only regulate fees and charges	
			which are to be levied by the	
			Agency, whereas the	
			competence to decide on	
			possible fees levied by the	
			national competent authorities	
			remains with the Member	
			States. Applicants and	
			marketing authorisation	
			holders are not to be charged	
			twice for the same activity.	
12	(3) The fees payable to the Agency should	(3) The fees payable to the	(3) The fees payable to the	
	be proportionate to the work carried out in	Agency should be proportionate	Agency should be proportionate	
	relation to obtaining and maintaining a	to the work carried out in relation	to the work carried out in	

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Union authorisation, and should be based on	to obtaining and maintaining a	relation to obtaining and	
an evaluation of the Agency's estimations	Union authorisation, and should	maintaining a Union	
and forecasts as regards the workload and	be based on <i>a transparent</i>	authorisation, and should be	
related costs for that work, as well as on an	evaluation of the Agency's	based on an evaluation of the	
evaluation of the costs of the services	estimations and forecasts as	Agency's estimations and	
provided to the Agency by the competent	regards the workload and related	forecasts as regards the	
authorities of Member States that are	costs for that work, as well as on	workload and related costs for	
responsible for regulating medicinal	an evaluation of the costs of the	that work, as well as on an	
products, which act as rapporteurs and,	services provided to the Agency	evaluation of the costs of the	
where applicable, co-rapporteurs appointed	by the competent authorities of	services provided to the Agency	
by the scientific committees of the Agency.	Member States that are	by the competent authorities of	
	responsible for regulating	Member States that are	
	medicinal products, which act as	responsible for regulating	
	rapporteurs and, where applicable,	medicinal products, which act as	
	co-rapporteurs appointed by the	rapporteurs and, where	
	scientific committees of the	applicable, co-rapporteurs	
	Agency. The fees and fee	appointed by the scientific	

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		structure should take into	committees of the Agency.	
		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.		
13	(4) Pursuant to Article 67(3) of		(4) Pursuant to Article 67(3)	
	Regulation (EC) No 726/2004 of the		of Regulation (EC) No 726/2004	
	European Parliament and of the Council ⁵ ,		of the European Parliament and	
	the revenue of the Agency consists of a		of the Council ⁷ , the revenue of	
	contribution from the Union, a contribution		the Agency consists of a	
	from third countries participating in the		contribution from the Union, a	
	work of the Agency with which the Union		contribution from third countries	
	has concluded international agreements for		participating in the work of the	

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this purpose, fees paid by undertakings for		Agency with which the Union	
obtaining and maintaining Union marketing		has concluded international	
authorisations and for services provided by		agreements for this purpose,	
the coordination group as regards the		fees paid by undertakings for	
fulfilment of its tasks in accordance with		obtaining and maintaining	
Articles 107c, 107e, 107g, 107k and 107q of		Union marketing authorisations	
Directive 2001/83/EC of the European		and for services provided by the	
Parliament and of the Council ⁶ , charges for		coordination group as regards	
other services provided by the Agency, and		the fulfilment of its tasks in	
Union funding in the form of grants for		accordance with Articles 107c,	
participation in research and assistance		107e, 107g, 107k and 107q of	
projects, in accordance with the Agency's		Directive 2001/83/EC of the	
financial rules and with the provisions of the		European Parliament and of the	
relevant instruments supporting the policies		Council ⁸ , charges for other	
of the Union.		services provided by the	
		Agency, and Union funding in	
⁵ Regulation (EC) No 726/2004 of the European		the form of grants for	
Parliament and of the Council of 31 March 2004			

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laying down Union procedure	s for the authorisation		participation in research and	
and supervision of medicinal p	products for human and		assistance projects, in	
veterinary use and establishing	g a European Medicines		accordance with the Agency's	
Agency, (OJ L 136 30.4.2004,			financial rules and with the	
⁶ Directive 2001/83/EC of the	-			
and of the Council of 6 Novem			provisions of the relevant	
Community code relating to m	_		instruments supporting the	
human use (OJ L 311, 28.11.2	2001, p. 67).		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	
			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	

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			Council of 6 November 2001 on the	
			Community code relating to medicinal	
			products for human use (OJ L 311,	
			28.11.2001, p. 67).	
13a		(4a) Following the COVID-19		
		pandemic and increased		
		initiatives in the field of health at		
		the Union level, the agency is		
		faced with a constantly		
		increasing workload, which		
		entails additional budgetary		
		needs in terms of staff and		
		financial resources. The		
		additional work, which includes		
		following the adoption of		
		Regulation (EU) 2022/123 of the		
		European Parliament and of the		
		Council ^{1a} and the creation of the		

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

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

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

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should be taken into account when	legislation governing the	All relevant Union legislation	
establishing the fees and charges, including	Agency's activities and fees	governing the Agency's	
Regulation (EC) No 726/2004, Regulation	should be taken into account when	activities and fees should be	
(EU) 2019/6 of the European Parliament and	establishing the fees and charges,	taken into account when	
of the Council ⁹ , Directive 2001/83/EC,	including Regulation (EC) No	establishing the fees and	
Regulation (EC) No 1901/2006 of the	726/2004, Regulation (EU)	charges, including Regulation	
European Parliament and of the Council ¹⁰ ,	2019/6 of the European	(EC) No 726/2004, Regulation	
Regulation (EC) No 141/2000 of the	Parliament and of the Council ²¹ ,	(EU) 2019/6 of the European	
European Parliament and of the Council ¹¹ ,	Directive 2001/83/EC, Regulation	Parliament and of the Council ²⁰ ,	
Regulation (EC) No 1394/2007 of the	(EC) No 1901/2006 of the	Directive 2001/83/EC,	
European Parliament and of the Council ¹² ,	European Parliament and of the	Regulation (EC) No 1901/2006	
Commission Regulation (EC) No	Council ²² , Regulation (EC) No	of the European Parliament and	
2049/2005 ¹³ , Commission Regulation (EC)	141/2000 of the European	of the Council ²¹ , Regulation	
No 1234/2008 ¹⁴ , Regulation (EU) 2017/745	Parliament and of the Council ²³ ,	(EC) No 141/2000 of the	
of the European Parliament and of the	Regulation (EC) No 1394/2007 of	European Parliament and of the	
Council ¹⁵ , Regulation (EC) No 470/2009 of	the European Parliament and of	Council ²² , Regulation (EC) No	
the European Parliament and of the	the Council ²⁴ , Commission	1394/2007 of the European	

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Council ¹⁶ , Commission Regulation (EU)	Regulation (EC) No 2049/2005 ²⁵ ,	Parliament and of the Council ²³ ,	
2018/782 ¹⁷ , Commission Implementing	Commission Regulation (EC) No	Commission Regulation (EC)	
Regulation (EU) 2021/1281 ¹⁸ and	1234/2008 ²⁶ , Regulation (EU)	No 2049/2005 ²⁴ , Commission	
Commission Regulation (EC) No 2141/96 ¹⁹ .	2017/745 of the European	Regulation (EC) No	
	Parliament and of the Council ²⁷ ,	1234/2008 ²⁵ , Regulation (EU)	
⁹ Regulation (EU) 2019/6 of the European Parliament	Regulation (EC) No 470/2009 of	2017/745 of the European	
and of the Council of 11 December 2018 on	the European Parliament and of	Parliament and of the Council ²⁶ ,	
veterinary medicinal products and repealing Directive	the Council ²⁸ , Regulation (EU)	Regulation (EU) 2017/746 of	
2001/82/EC (OJ L 4, 7.1.2019, p. 43).	2022/123, Commission	the European Parliament and	
Regulation (EC) No 1901/2006 of the European	Regulation (EU) 2018/782 ²⁹ ,	of the Council ²⁷ , Regulation	
Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and	Commission Implementing	(EC) No 470/2009 of the	
amending Regulation (EEC) No 1768/92, Directive	Regulation (EU) 2021/1281 ³⁰ and	European Parliament and of the	
2001/20/EC, Directive 2001/83/EC and Regulation	Commission Regulation (EC) No	Council ²⁸ , Commission	
(EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).	2141/96 ³¹ .	Regulation (EU) 2018/782 ²⁹ ,	
¹¹ Regulation (EC) No 141/2000 of the European		Commission Implementing	
Parliament and of the Council of 16 December 1999	²¹ Regulation (EU) 2019/6 of the	Regulation (EU) 2021/1281 ³⁰	
on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).	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,	and Commission Regulation	

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¹² Regulation (EC) No 1394/2007 of the European	p. 43).	(EC) No 2141/96 ³¹ .	
Parliament and of the Council of 13 November 2007	²² Regulation (EC) No 1901/2006 of the European Parliament and of the Council		
on advanced therapy medicinal products and	of 12 December 2006 on medicinal	²⁰ Regulation (EU) 2019/6 of the	
amending Directive 2001/83/EC and Regulation (EC)	products for paediatric use and amending Regulation (EEC) No 1768/92, Directive	European Parliament and of the	
No 726/2004 (OJ L 324, 10.12.2007, p. 121).	2001/20/EC, Directive 2001/83/EC and	Council of 11 December 2018 on	
¹³ Commission Regulation (EC) No 2049/2005 of 15	Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).	veterinary medicinal products and	
December 2005 laying down, pursuant to Regulation	²³ Regulation (EC) No 141/2000 of the	repealing Directive 2001/82/EC (OJ L	
(EC) No 726/2004 of the European Parliament and of	European Parliament and of the Council of 16 December 1999 on orphan	4, 7.1.2019, p. 43).	
the Council, rules regarding the payment of fees to,	medicinal products (OJ L 18, 22.1.2000,	, , ,	
and the receipt of administrative assistance from, the	p. 1). ²⁴ Regulation (EC) No 1394/2007 of the	²¹ Regulation (EC) No 1901/2006 of	
European Medicines Agency by micro, small and	European Parliament and of the Council	the European Parliament and of the	
medium-sized enterprises (OJ L 329, 16.12.2005, p.	of 13 November 2007 on advanced therapy medicinal products and	Council of 12 December 2006 on	
4).	amending Directive 2001/83/EC and	medicinal products for paediatric use	
14 Commission Regulation (EC) No 1234/2008 of 24	Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).	and amending Regulation (EEC) No	
	²⁵ Commission Regulation (EC) No	1768/92, Directive 2001/20/EC,	
November 2008 concerning the examination of	2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No	Directive 2001/83/EC and Regulation	
variations to the terms of marketing authorisations for	726/2004 of the European Parliament	(EC) No 726/2004 (OJ L 378,	
medicinal products for human use and veterinary	and of the Council, rules regarding the payment of fees to, and the receipt of	27.12.2006, p. 1).	
medicinal products (OJ L 334, 12.12.2008, p. 7).	administrative assistance from, the	²² Regulation (EC) No 141/2000 of the	
¹⁵ Regulation (EU) 2017/745 of the European	European Medicines Agency by micro,	European Parliament and of the	
Parliament and of the Council of 5 April 2017 on	small and medium-sized enterprises (OJ L 329, 16.12.2005, p. 4).	Council of 16 December 1999 on	
	²⁶ Commission Regulation (EC) No		

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medical devices, amending Directive 2001/83/EC,	1234/2008 of 24 November 2008	orphan medicinal products (OJ L 18,	
Regulation (EC) No 178/2002 and Regulation (EC)	concerning the examination of variations to the terms of marketing authorisations	22.1.2000, p. 1).	
No 1223/2009 and repealing Council Directives	for medicinal products for human use	²³ Regulation (EC) No 1394/2007 of	
90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p.	and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7).	the European Parliament and of the	
1).	²⁷ Regulation (EU) 2017/745 of the	Council of 13 November 2007 on	
¹⁶ Regulation (EC) No 470/2009 of the European	European Parliament and of the Council of 5 April 2017 on medical devices,	advanced therapy medicinal products	
Parliament and of the Council of 6 May 2009 laying	amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and	and amending Directive 2001/83/EC	
down Community procedures for the establishment of	Regulation (EC) No 1223/2009 and	and Regulation (EC) No 726/2004 (OJ	
residue limits of pharmacologically active substances	repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117,	L 324, 10.12.2007, p. 121).	
in foodstuffs of animal origin, repealing Council	5.5.2017, p. 1).	²⁴ Commission Regulation (EC) No	
Regulation (EEC) No 2377/90 and amending	²⁸ Regulation (EC) No 470/2009 of the European Parliament and of the Council	2049/2005 of 15 December 2005	
Directive 2001/82/EC of the European Parliament	of 6 May 2009 laying down Community	laying down, pursuant to Regulation	
and of the Council and Regulation (EC) No 726/2004	procedures for the establishment of residue limits of pharmacologically	(EC) No 726/2004 of the European	
of the European Parliament and of the Council (OJ L	active substances in foodstuffs of animal	Parliament and of the Council, rules	
152, 16.6.2009, p. 11).	origin, repealing Council Regulation (EEC) No 2377/90 and amending	regarding the payment of fees to, and	
¹⁷ Commission Regulation (EU) 2018/782 of 29 May	Directive 2001/82/EC of the European	the receipt of administrative assistance	
2018 establishing the methodological principles for	Parliament and of the Council and Regulation (EC) No 726/2004 of the	from, the European Medicines Agency	
the risk assessment and risk management	European Parliament and of the Council	by micro, small and medium-sized	
recommendations referred to in Regulation (EC) No	(OJ L 152, 16.6.2009, p. 11). ²⁹ Commission Regulation (EU)	enterprises (OJ L 329, 16.12.2005, p.	
470/2009 (OJ L 132, 30.5.2018, p. 5).	2018/782 of 29 May 2018 establishing	4).	
	the methodological principles for the risk assessment and risk management		

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2021/1281 of 2 Aug the application of Ro European Parliamen good pharmacovigil content and summar system master file fo	plementing Regulation (EU) gust 2021 laying down rules for egulation (EU) 2019/6 of the at and of the Council as regards lance practice and on the format, ry of the pharmacovigilance for veterinary medicinal products	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 for	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).	
November 1996 con application for the translation for a n	gulation (EC) No 2141/96 of 7 neerning the examination of an ransfer of a marketing medicinal product falling within ll Regulation (EC) No 2309/93	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).	
			27 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and	

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		repealing Directive 98/79/EC and	
		Commission Decision 2010/227/EU	
		(Text with EEA relevance. OJ L 117,	
		5.5.2017, p. 176–332)	
		²⁸ Regulation (EC) No 470/2009 of the	
		European Parliament and of the	
		Council of 6 May 2009 laying down	
		Community procedures for the	
		establishment of residue limits of	
		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	

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		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	
		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	

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			Council Regulation (EEC) No 2309/93	
			(OJ L 286, 8.11.1996, p. 6).	
15	(6) Pursuant to Article 6(1) of Regulation		(6) Pursuant to Article 6(1) of	
	(EC) No 726/2004, each application for the		Regulation (EC) No 726/2004,	
	authorisation of a medicinal product for		each application for the	
	human use is to be accompanied by the fee		authorisation of a medicinal	
	payable to the Agency for the examination		product for human use is to be	
	of that application. Pursuant to Article 43(1)		accompanied by the fee payable	
	of Regulation (EU) 2019/6, an application		to the Agency for the	
	for a centralised marketing authorisation for		examination of that application.	
	a veterinary medicinal product is to be		Pursuant to Article 43(1) of	
	accompanied by the fee payable to the		Regulation (EU) 2019/6, an	
	Agency for the examination of the		application for a centralised	
	application.		marketing authorisation for a	
			veterinary medicinal product is	
			to be accompanied by the fee	
			payable to the Agency for the	
			examination of the application.	

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16	(7) In line with the Joint Statement of the	(7) In line with the Joint	(7) In line with the Joint	
	European Parliament, the Council of the EU	Statement of the European	Statement of the European	
	and the Commission of 19 July 2012 on	Parliament, the Council of the EU	Parliament, the Council of the	
	decentralised agencies, for bodies for which	and the Commission of 19 July	EU and the Commission of	
	the revenue is constituted by fees and	2012 on decentralised agencies,	19 July 2012 on decentralised	
	charges in addition to the Union	for bodies for which the revenue	agencies, for bodies for which	
	contribution, fees should be set at a level	is constituted by fees and charges	the revenue is constituted by	
	that avoids a deficit or a significant	in addition to the Union	fees and charges in addition to	
	accumulation of surplus, and should be	contribution, fees should be set at	the Union contribution, fees	
	revised when this is not the case. Therefore,	a level that avoids a deficit or a	should be set at a level that	
	a cost monitoring system should be put in	significant accumulation of	avoids a deficit or a significant	
	place. The purpose of such monitoring	surplus, and should be revised	accumulation of surplus, and	
	system should be to detect significant	when this is not the case.	should be revised when this is	
	changes of costs of the Agency that, taking	Therefore, a <i>transparent</i> cost	not the case. Therefore, a cost	
	into account the Union contribution and	monitoring system should be put	monitoring system should be put	
	other non-fee revenue, could require a	in place. The purpose of such	in place. The purpose of such	
	change in fees, charges or remuneration	monitoring system should be to	monitoring system should be to	

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establis	hed under this regulation. That	detect significant changes of costs	detect significant changes of	
monitor	ring system should equally be able to	of the Agency that, taking into	costs of the Agency that, taking	
detect, 1	based on objective and verifiable	account the Union contribution	into account the Union	
informa	ation, significant changes of costs of	and other non-fee revenue, could	contribution and other non-fee	
remune	ration of services provided to the	require a change in fees, charges	revenue, could require a change	
Agency	by the competent authorities of	or remuneration established under	in fees, charges or remuneration	
Membe	r States, which act as rapporteurs	this regulation. That monitoring	established under this regulation.	
and, wh	nere applicable, co-rapporteurs and by	system should equally be able to	That monitoring system should	
experts	contracted by the Agency for the	detect, based on objective and	equally be able to detect, based	
procedu	ares of the expert panels on medical	verifiable information, significant	on objective and verifiable	
devices	. Cost information relating to	changes of costs of remuneration	information, significant changes	
services	s remunerated by the Agency should	of services provided to the	of costs of remuneration of	
be audit	table in accordance with Article 257	Agency by the competent	services provided to the Agency	
of Regu	ulation (EU, Euratom) 2018/1046 of	authorities of Member States,	by the competent authorities of	
the Euro	opean Parliament and of the	which act as rapporteurs and,	Member States, which act as	
Council	1 ³² .	where applicable, co-rapporteurs	rapporteurs and, where	
		and by experts contracted by the	applicable, co-rapporteurs and	

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

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			Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).	
17	(8) Fees should be levied on marketing		(8) Fees should be levied on	
	authorisation applicants and holders on a fair		marketing authorisation	
	basis whereby the fee charged is		applicants and holders on a fair	
	proportionate to the assessment work.		basis whereby the fee charged is	
	Therefore, for the purpose of charging some		proportionate to the assessment	
	post-authorisation fees where products		work. Therefore, for the purpose	
	authorised by the Member States are		of charging some post-	
	included in the assessment performed by the		authorisation fees where	
	Agency, a chargeable unit should be		products authorised by the	
	established, irrespective not only of the		Member States are included in	
	procedure under which the product has been		the assessment performed by the	
	authorised, namely under Regulation (EC)		Agency, a chargeable unit	
	No 726/2004 or Regulation (EU) 2019/6 or		should be established,	
	Directive 2001/83/EC, but also of the way in		irrespective not only of the	
	which authorisation numbers are assigned by		procedure under which the	

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

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medicinal products, the same objective of		substances and the	
fairness and proportionality should be met		pharmaceutical form of the	
by establishing the chargeable unit based on		products that are subject to the	
information contained in the Union product		obligation to be registered in the	
database referred to in Article 55(1) of		database referred to in Article	
Regulation (EU) 2019/6, such as the active		57(1), second subparagraph,	
substances, the pharmaceutical form and the		point (l), of Regulation (EC)	
strength of veterinary medicinal products,		No 726/2004, based on	
which are taken into account in the Product		information from the list of all	
Identifier referred to under Data Field ID 3.2		medicinal products for human	
in Annex III to Commission Implementing		use authorised in the Union	
Regulation (EU) 2021/16 ³⁴ , as well as the		referred to in Article 57(2),	
Permanent Identifier referred to under Data		second subparagraph, of that	
Field ID 3.1 in Annex III to that		Regulation. The active	
Implementing Regulation.		substances should not be taken	
		into account when establishing	
³⁴ Commission Implementing Regulation (EU)		the chargeable unit in respect of	
2021/16 of 8 January 2021 laying down the necessary			

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measures and practical arrangements for the Union		homeopathic medicinal products	
database on veterinary medicinal products (Union		or herbal medicinal products.	
product database) (OJ L 7, 11.1.2021, p. 1).		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	

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

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	corresponding to those authorisations should		authorisation holders, the	
	take into account the number of Member		number of chargeable units	
	States in which the marketing authorisation		corresponding to those	
	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		(10) In order to take account of	
	of the statutory tasks of the Agency and of		the variety of the statutory tasks	
	the rapporteurs and, where applicable, co-		of the Agency and of the	
	rapporteurs, fees should be levied per		rapporteurs and, where	
	procedure, for costs relating to the		applicable, co-rapporteurs, fees	
	assessment of medicinal products for human		should be levied per procedure,	
	use and for veterinary medicinal products,		for costs relating to the	
	and on an annual basis for costs incurred by		assessment of medicinal	
	the Agency for other ongoing activities that		products for human use and for	
	it carries out under its mandate that benefit		veterinary medicinal products,	

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	marketing authorisation holders overall. For		and on an annual basis for costs	
	the purpose of simplification, the costs		incurred by the Agency for other	
	related to minor variations of Type I should		ongoing activities that it carries	
	equally be included in the annual fee on the		out under its mandate that	
	basis of an average estimation.		benefit marketing authorisation	
			holders overall. For the purpose	
			of simplification, the costs	
			related to minor variations of	
			Type I and renewals should are	
			equally be included in the annual	
			fee on the basis of an average	
			estimation.	
20	(11) An annual fee for medicinal products		(11) An annual fee for	
	authorised in accordance with the centralised		medicinal products authorised in	
	procedure set out in Regulation (EC)		accordance with the centralised	
	No 726/2004 or the centralised procedure set		procedure set out in Regulation	
	out in Regulation (EU) 2019/6 should be		(EC) No 726/2004 or the	

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levied to ensure coverage of the costs		centralised procedure set out in	
connected with the overall post-		Regulation (EU) 2019/6 should	
authorisation supervision and maintenance		be levied to ensure coverage of	
activities for those products. Those activities		the costs connected with the	
include the recording of the actual marketing		overall post-authorisation	
of medicinal products authorised in		supervision and maintenance	
accordance with Union procedures, the		activities for those products.	
maintenance of marketing authorisation		Those activities include the	
dossiers and of the various databases		recording of the actual	
managed by the Agency, and activities		marketing of medicinal products	
contributing to a continuous follow-up of the		authorised in accordance with	
risk-benefit balance of authorised medicinal		Union procedures, the	
products. They also comprise access to and		maintenance of marketing	
analysis of Union-wide health data to		authorisation dossiers and of the	
support better decision-making throughout		various databases managed by	
the product lifecycle on medicines with		the Agency, minor variations	
valid and reliable real-world evidence. The		of Type I and renewals and	

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revenue from that annual fee should be used		activities contributing to a	
to fund an annual remuneration of the		continuous follow-up of the	
services of rapporteurs and co-rapporteurs		risk-benefit balance of	
from competent authorities of the Member		authorised medicinal products.	
States for their respective contributions to		They also comprise access to	
the supervision and maintenance activities of		and analysis of Union-wide	
the Agency.		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	

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			respective contributions to the	
			supervision and maintenance	
			activities of the Agency.	
21	(12) A specific annual fee should be		(12) A specific annual fee	
	charged for medicinal products authorised in		should be charged for medicinal	
	accordance with Directive 2001/83/EC and		products authorised in	
	for veterinary medicinal products authorised		accordance with Directive	
	by the Member States in accordance with		2001/83/EC and for veterinary	
	Regulation (EU) 2019/6 specifically for the		medicinal products authorised	
	pharmacovigilance activities carried out by		by the Member States in	
	the Agency that benefit marketing		accordance with Regulation	
	authorisation holders overall. Those		(EU) 2019/6 specifically for the	
	activities relate to information technology,		pharmacovigilance activities	
	in particular maintenance of the		carried out by the Agency that	
	EudraVigilance database referred to in		benefit marketing authorisation	
	Article 24(1) of Regulation (EC)		holders overall. Those activities	
	No 726/2004, the Union product database		relate to information technology,	

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referred to in Article 55(1) of Regulation in particular maintenance of the	
(EU) 2019/6 and the Union EudraVigilance database	
pharmacovigilance database referred to in referred to in Article 24(1) of	
Article 74(1) of that Regulation, the Regulation (EC) No 726/2004,	
monitoring of selected medical literature and the Union product database	
the timely access to and analysis of Union-	
wide health data to support decision-making Regulation (EU) 2019/6 and the	
throughout the product lifecycle on Union pharmacovigilance	
medicines with valid and reliable real-world database referred to in	
evidence. Article 74(1) of that Regulation,	
the monitoring of selected	
medical literature and the timely	
access to and analysis of Union-	
wide health data to support	
decision-making throughout the	
product lifecycle on medicines	
with valid and reliable real-	

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			world evidence.	
22	(13) Charges should be levied for activities		(13) Charges should can be	
	and services of an administrative nature,		levied for activities and services	
	such as issuing certificates, that are not		of an administrative nature, such	
	covered by a fee provided for in this		as issuing certificates, that are	
	Regulation, whereas fees levied by the		not covered by a fee provided	
	Agency should correspond to services of a		for in this Regulation, whereas	
	scientific nature provided by the Agency		fees levied by the Agency	
	under its mandate, which contribute to the		should-correspond to services of	
	assessment relating to medicinal products		a scientific nature provided by	
	and the maintenance of authorised products,		the Agency under its mandate,	
	including a continuous monitoring of the		which contribute to the	
	risk-benefit balance.		assessment relating to medicinal	
			products and the maintenance of	
			authorised products, including a	
			continuous monitoring of the	
			risk-benefit balance. Fees for	

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

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

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			fees for veterinary medicinal	
			products and to closely monitor	
			associated costs for competent	
			authorities of the Member	
			States and the Agency, in	
			order to support the objectives	
			of Regulation (EU) 2019/6.	
			Therefore, the adjustment to	
			inflation applied to the	
			amounts in Annex II takes into	
			account only fifty percent of	
			the annual inflation rates for	
			the calendar years 2021 and	
			<u>2022.</u>	
26	(17) The Management Board of the Agency	(17) The Management Board of	(17) The Management Board of	
	should be empowered to provide further fee	the Agency should be empowered	the Agency should be	
	reductions for justified reasons of protection	to provide further fee reductions	empowered to provide further	

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

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		imperative reasons of public or	Executive Director of the	
		animal health, it should also be	Agency to reduce certain types	
		possible for the Executive	of fees on the basis of a critical	
		Director of the Agency to reduce	examination of the situation	
		certain types of fees on the basis	specific to each case.	
		of a critical examination of the		
		situation specific to each case.		
		The Agency should ensure that		
		such decisions of the Executive		
		Director are made publicly		
		available on its website and set		
		out the reasons for those		
		decisions.		
27	(18) In order to provide flexibility, in	(18) In order to provide	(18) In order to provide	
	particular to adapt to developments in	flexibility, in particular to adapt to	flexibility, in particular to adapt	
	science, the Management Board of the	developments in science and to	to developments in science, the	
	Agency should be enabled to specify	address unforeseen	Management Board of the	

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working arrangements to facilitate the	circumstances and medical	Agency should be enabled to	
application of this Regulation, on a duly	<i>needs</i> , the Management Board of	specify working arrangements to	
justified proposal from the Executive	the Agency should be enabled to	facilitate the application of this	
Director. In particular, the Management	specify working arrangements to	Regulation, on a duly justified	
Board should be able to establish due dates	facilitate the application of this	proposal from the Executive	
and deadlines for payment, payment	Regulation, on a duly justified	Director. In particular, the	
methods, timetables, detailed classifications,	proposal from the Executive	Management Board should be	
lists of additional fee reductions, and	Director. In particular, the	able to establish due dates and	
detailed amounts within the limits of an	Management Board should be	deadlines for payment, payment	
established range. A favourable opinion	able to establish due dates and	methods, timetables, detailed	
from the Commission should be mandatory	deadlines for payment, payment	classifications, lists of additional	
before the proposal is put to the	methods, timetables, detailed	fee reductions, and detailed	
Management Board for adoption, in order to	classifications, lists of additional	amounts within the limits of an	
ensure alignment with Union law and with	fee reductions, and detailed	established range and a	
overall policies of the Union.	amounts within the limits of an	common format sufficiently	
	established range. A favourable	flexible for financial	
	opinion from the Commission	information to be provided by	

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		should be mandatory before the	the National Competent	
		proposal is put to the Management	Authorities to the Agency and	
		Board for adoption, in order to	what constitutes a distinct	
		ensure alignment with Union law	inspection, for each type of	
		and with overall policies of the	inspection. A favourable	
		Union.	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.	
28	(19) For their assessments, rapporteurs and	(19) For their assessments,	(19) For their assessments,	
	co-rapporteurs and the other roles	rapporteurs and co-rapporteurs	rapporteurs and co-rapporteurs	
	considered as equivalent for the purposes of	and the other roles considered as	and the other roles considered as	
	this regulation in scientific advice and	equivalent for the purposes of this	equivalent for the purposes of	

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inspections rely on the scientific evaluations	regulation in scientific advice and	this regulation in scientific	
and resources of the competent authorities of	inspections rely on the scientific	advice and inspections rely on	
Member States, while it is the responsibility	evaluations and resources of the	the scientific evaluations and	
of the Agency to coordinate the existing	competent authorities of Member	resources of the competent	
scientific resources put at its disposal by the	States, while it is the	authorities of Member States,	
Member States, in accordance with Article	responsibility of the Agency to	while it is the responsibility of	
55 of Regulation (EC) No 726/2004. In light	coordinate the existing scientific	the Agency to coordinate the	
of that, and to ensure appropriate resources	resources put at its disposal by the	existing scientific resources put	
for the scientific assessments relating to the	Member States, in accordance	at its disposal by the Member	
procedures carried out at Union level, the	with Article 55 of Regulation	States, in accordance with	
Agency should remunerate the scientific	(EC) No 726/2004. In light of	Article 55 of Regulation (EC)	
assessment services provided by the	that, and to ensure appropriate	No 726/2004. In light of that,	
rapporteurs and co-rapporteurs appointed by	resources for the scientific	and to ensure appropriate	
the Member States as members of the	assessments relating to the	resources for the scientific	
scientific committees of the Agency, or,	procedures carried out at Union	assessments relating to the	
where relevant, provided by rapporteurs and	level, the Agency should	procedures carried out at Union	
co-rapporteurs in the coordination group	remunerate the scientific	level, the Agency should	

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referred to in Article 27 of Directive	assessment services provided by	remunerate the scientific	
2001/83/EC. The amount of remuneration	the rapporteurs and co-rapporteurs	assessment services provided by	
for the services provided by those	appointed by the Member States	the rapporteurs and co-	
rapporteurs and co-rapporteurs should be	as members of the scientific	rapporteurs appointed by the	
based on estimations of the workload	committees of the Agency, or,	Member States as members of	
involved and should be taken into account in	where relevant, provided by	the scientific committees of the	
setting the level of the fees charged by the	rapporteurs and co-rapporteurs in	Agency, or, where relevant,	
Agency.	the coordination group referred to	provided by rapporteurs and co-	
	in Article 27 of Directive	rapporteurs in the coordination	
	2001/83/EC. The amount of	group referred to in Article 27 of	
	remuneration for the services	Directive 2001/83/EC. The	
	provided by those rapporteurs and	amount of remuneration for the	
	co-rapporteurs should be based on	services provided by those	
	estimations of the workload	rapporteurs and co-rapporteurs	
	involved and should be taken into	should be based on estimations	
	account in setting the level of the	of the workload involved and	
	fees charged by the Agency.	should be taken into account in	

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		Based on a specific public	setting the level of the fees	
		interest benefitting both the	charged by the Agency.	
		Union and the Member States,		
		where the Agency grants a total		
		waiver of fees, the remuneration		
		of rapporteurs and co-		
		rapporteurs should be reduced by		
		50% or 100%, as specified in		
		Annex V.		
29	(20) In line with the policy of the Union to		(20) In line with the policy of	
	support SMEs within the meaning of		the Union to support SMEs <u>as</u>	
	Commission Recommendation		defined in within the meaning	
	2003/361/EC ³⁶ , fee reductions should apply		of -Commission	
	to them. Such reductions should be		Recommendation	
	established on a basis that takes due account		2003/361/EC ³⁸ , fee reductions	
	of the ability of SMEs to pay. In order to		should apply to them. Such	
	ensure that the current framework for		reductions should be are to be	

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support to SMEs remains unchanged u	until a	established on a basis that takes	
possible revision of Commission Regu	ulation	due account of the ability of	
(EC) No 2049/2005 ³⁷ , current post-		SMEs to pay. In order to ensure	
authorisation fee reduction rates shoul	d be	consistency of that the current	
granted to SMEs. Furthermore,		framework for support to SMEs	
microenterprises should be exempted	from	withremains unchanged until a	
all post-authorisation fees.		possible revision of Commission	
		Regulation (EC)	
³⁶ Commission Recommendation of 6 May 20	003	No 2049/2005 ³⁹ , current post-	
concerning the definition of micro, small and		authorisation fee reduction rates	
medium-sized enterprises (2003/361/EC) (OJ	L 124,	should be granted to SMEs.	
20.5.2003, p. 36).		Furthermore, microenterprises	
³⁷ Commission Regulation (EC) No 2049/200		should be exempted from all	
December 2005 laying down, pursuant to Reg		post-authorisation fees.	
(EC) No 726/2004 of the European Parliamen		post dutionsation rees.	
the Council, rules regarding the payment of fe	ees to,		
and the receipt of administrative assistance from	om, the	³⁸ Commission Recommendation of 6	
European Medicines Agency by micro, small	and	May 2003 concerning the definition of	
medium-sized enterprises (OJ L 329, 16.12.20	005, p.	micro, small and medium-sized	

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

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medicinal products for human use and		under the provisions relating to	
homeopathic veterinary medicinal products	,	well-established medicinal use,	
as well as herbal medicinal products for		homeopathic medicinal products	
human use should be subject to a reduced		for human use and homeopathic	
annual pharmacovigilance fee, as those		veterinary medicinal products,	
medicinal products generally have a well-		as well as herbal medicinal	
established safety profile. However, in case	es	products for human use should	
where such medicinal products are subject		be subject to a reduced annual	
of any of the pharmacovigilance procedure	S	pharmacovigilance fee, as those	
carried out at Union level, the full fee shou	ld	medicinal products generally	
be charged in view of the work involved.		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		(22) In order to avoid a	
	administrative workload for the Agency, fee		disproportionate administrative	
	reductions and fee exemptions should be		workload for the Agency, fee	
	applied on the basis of a declaration of the		reductions and fee exemptions	
	marketing authorisation holder or applicant		should be applied on the basis of	
	claiming to be entitled to such a measure.		a declaration of the marketing	
	The submission of incorrect information in		authorisation holder or applicant	
	that respect should be discouraged by means		claiming to be entitled to such a	
	of the application of a specific charge if the		measure. The submission of	
	Agency establishes that such incorrect		incorrect information in that	
	information has been submitted.		respect should be discouraged	
			by means of the application of a	
			specific charge if the Agency	
			establishes that such incorrect	
			information has been submitted.	

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

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

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			and the house price index, and	
			repealing Council Regulation (EC) No	
			2494/95 (OJ L 135, 24.5.2016, p. 11).	
34	(25) In order to ensure swift adjustment of		(25) In order to ensure swift	
	the structure and amounts of fees, charges		adjustment of the structure and	
	and remuneration to competent authorities of		amounts of fees, charges and	
	the Member States to significant changes of		remuneration to competent	
	costs or processes, the power to adopt acts in		authorities of the Member States	
	accordance with Article 290 of the Treaty on		to significant changes of costs or	
	the Functioning of the European Union		processes, the power to adopt	
	should be delegated to the Commission in		acts in accordance with	
	respect of the relevant amounts and the		Article 290 of the Treaty on the	
	activities subject to fees and charges and		Functioning of the European	
	remuneration, on the basis of objective		Union should be delegated to	
	information related to costs or changes to the		the Commission in respect of	
	regulatory framework. It is of particular		the relevant amounts and the	
	importance that the Commission carry out		activities subject to fees and	
	appropriate consultations during its		charges and remuneration, on	

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

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		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 Agreement of	
		13 April 2016 on Better Law-	
		Making ⁴³ . In particular, to	
		ensure equal participation in the	
		preparation of delegated acts,	
		the European Parliament and the	
		Council receive all documents at	
		the same time as Member States'	
		experts, and their experts	

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		systematically have access to	
		meetings of Commission expert	
		groups dealing with the	
		preparation of delegated acts. If	
		a change of the fees were to	
		result in an increased share on	
		the side of the Agency, special	
		consideration should be given	
		that the aim of a balanced,	
		objective and fair distribution	
		of fees between the Agency	
		and the competent authorities	
		of the Member States is	
		maintained.	
		⁴³ Interinstitutional Agreement	
		between the European Parliament, the	
		Council of the European Union and the	

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			European Commission on Better Law-	
			Making (OJ L 123, 12.5.2016, p. 1).	
35	(26) In order to ensure cost recovery, the		(26) In order to ensure cost	
	Agency should provide services by virtue of		recovery, the Agency should	
	the tasks entrusted to it only after the		provide services by virtue of the	
	corresponding fee or charge has been paid in		tasks entrusted to it only after	
	its entirety. However, in accordance with		the corresponding fee or charge	
	Article 71, fourth subparagraph, of		has been paid in its entirety.	
	Commission Delegated Regulation (EU)		However, in accordance with	
	2019/715 ⁴⁴ , in exceptional circumstances, a		Article 71, fourth subparagraph,	
	service may be provided without prior		of Commission Delegated	
	payment of the corresponding fee or charge.		Regulation (EU) 2019/715 ⁴⁵ , in	
			exceptional circumstances, a	
	44 Commission Delegated Regulation (EU) 2019/715		service may be provided without	
	of 18 December 2018 on the framework financial		prior payment of the	
	regulation for the bodies set up under the TFEU and		corresponding fee or charge.	
	Euratom Treaty and referred to in Article 70 of			
	Regulation (EU, Euratom) 2018/1046 of the		45 Commission Del. (1.12)	
	European Parliament and of the Council. (OJ L 122,		⁴⁵ Commission Delegated Regulation	

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	10.5.2019, p. 1).		(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		(26a) Member States should		
		ensure that adequate financial		
		resources are available to 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		

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		Article 11 should also be taken		
		into account.		
35b		(26b) The calculation of the		
		amounts of the fees, charges and		
		remuneration take into account		
		the inflation rate measured by		
		means of the Harmonised Index		
		of Consumer Prices published by		
		Eurostat pursuant to Regulation		
		(EU) No 2016/792 until the date		
		of adoption of the proposal for		
		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		

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		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		
		months before the date of		
		application of this Regulation.		
36	(27) In accordance with Article 30 of		(27) In accordance with Article	
	Regulation (EU) 2022/123 ⁴⁶ , the Agency		30 of Regulation (EU)	

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provides, on behalf of the Commission, the		2022/123 ⁴⁷ , the Agency	
secretariat for the expert panels designated		provides, on behalf of the	
in accordance with Regulation (EU)		Commission, the secretariat for	
2017/745. The provision in Article 106 of		the expert panels designated in	
Regulation (EU) 2017/745 concerning the		accordance with Regulation	
payment of fees for advice provided by		(EU) 2017/745. The provision in	
expert panels should therefore be amended		Article 106 of Regulation (EU)	
in order to allow the Agency to receive those		2017/745 concerning the	
fees, once such fees are established by the		payment of fees for advice	
Commission in accordance with that		provided by expert panels	
Regulation.		should therefore be amended in	
		order to allow the Agency to	
⁴⁶ Regulation (EU) 2022/123 of the European		receive charge those fees, once	
Parliament and of the Council of 25 January 2022 on		such fees are established by the	
a reinforced role for the European Medicines Agency		Commission in accordance with	
in crisis preparedness and management for medicinal		that Regulation.	
products and medical devices (OJ L 20, 31.1.2022, p. 1).			
1/-			

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			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,		(28) Since the objective of this	
	namely to ensure appropriate funding of		Regulation, namely to ensure	
	Agency activities carried out at Union level,		appropriate funding of Agency	
	cannot sufficiently be achieved by the		activities carried out at Union	
	Member States but can rather, by reason of		level, cannot sufficiently be	
	the scale of the measure, be better achieved		achieved by the Member States	
	at Union level, the Union may adopt		but can rather, by reason of the	
	measures, in accordance with the principle		scale of the measure, be better	
	of subsidiarity as set out in Article 5 of the		achieved at Union level, the	
	Treaty on European Union. In accordance		Union may adopt measures, in	
	with the principle of proportionality, as set		accordance with the principle of	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
	out in that Article, this Regulation does not		subsidiarity as set out in	
	go beyond what is necessary in order to		Article 5 of the Treaty on	
	achieve that objective,		European Union. In accordance	
			with the principle of	
			proportionality, as set out in that	
			Article, this Regulation does not	
			go beyond what is necessary in	
			order to achieve that objective.	
37a			28a) In order to allow for the	
			prompt application of the	
			measures provided for in this	
			Regulation, it should enter	
			into force on the day following	
			that of its publication in the	
			Official Journal of the	
			European Union.	
38	HAVE ADOPTED THIS REGULATION:		HAVE ADOPTED THIS	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			REGULATION:	
39	Article 1		Article 1	
	Subject matter		Subject matter and scope	
40	This Regulation lays down the following:		<u>1.</u> This Regulation lays down	
			the following:	
41	(a) the amounts of the fees and charges		(a) the amounts of the fees	
	established on cost-based evaluation and		and charges established on cost-	
	levied by the European Medicines Agency		based evaluation and levied by	
	(the 'Agency') for assessment activities		the European Medicines Agency	
	relating to obtaining and maintaining a		(the 'Agency') for assessment	
	Union authorisation to market medicinal		activities relating to obtaining	
	products for human use and veterinary		and maintaining a Union	
	medicinal products and for other services		authorisation to market	
	provided or tasks carried out by the Agency,		medicinal products for human	
	as provided for in Regulations (EC)		use and veterinary medicinal	
	726/2004 and (EU) 2019/6;		products and for other services	
			provided or tasks carried out by	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			the Agency, as provided for in	
			Regulations (EC) 726/2004 and	
			(EU) 2019/6;	
42	(b) the corresponding amounts of		(b) the corresponding amounts	
	remuneration established on cost-based		of remuneration established on	
	evaluation and payable by the Agency to the		cost-based evaluation and	
	competent authorities of the Member States		payable by the Agency to the	
	for the services provided by rapporteurs and,		competent authorities of the	
	where applicable, co-rapporteurs from		Member States for the services	
	competent authorities of the Member States,		provided by rapporteurs and,	
	or by other roles considered as equivalent		where applicable, co-rapporteurs	
	for the purposes of this regulation, as		from competent authorities of	
	referred to in the Annexes to this		the Member States, or by other	
	Regulation; and		roles considered as equivalent	
			for the purposes of this	
			regulation, as referred to in the	
			Annexes to this Regulation; and	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
43	(c) the monitoring of costs of activities		(c) the monitoring of costs of	
	and services provided by the Agency and of		activities and services provided	
	costs for remuneration referred to in point		by the Agency and of costs for	
	(b).		remuneration referred to in point	
			(b).	
43a			2. Medicinal products for	
			human use which are	
			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.	
44	Article 2		Article 2	
	Definitions		Definitions	

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

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

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	points 5 and 30, respectively, of Directive		or herbal medicinal products, as	
	2001/83/EC;		defined in Article 1, points 5 and	
			30, respectively, of Directive	
			2001/83/EC;	
51	(e) pharmaceutical form;		(e) pharmaceutical form;	
52	(2) 'chargeable unit in relation to		(2) 'chargeable unit in relation	
	veterinary medicinal products' ('chargeable		to veterinary medicinal	
	unit - veterinary') means a unit defined by		products' ('chargeable unit -	
	the unique combination of the following		veterinary') means a unit defined	
	data fields contained in the Union product		by the unique combination of the	
	database established pursuant to		following data fields contained	
	Article 55(1) of Regulation (EU) 2019/6:		in the Union product database	
			established pursuant to	
			Article 55(1) of Regulation (EU)	
			2019/6:	
53	(a) the Permanent Identifier referred to		(a) the Permanent Identifier	
	under Data Field ID 3.1 in Annex III to		referred to under Data Field ID	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
		July 2023	13 June 2023	text, compromise
				proposals and
				comments
	Implementing Regulation (EU) 2021/16;		3.1 in Annex III to	
			Implementing Regulation (EU)	
			2021/16;	
54	(b) the Product Identifier referred to under		(b) the Product Identifier	
	Data Field ID 3.2 in Annex III to		referred to under Data Field ID	
	Implementing Regulation (EU) 2021/16;		3.2 in Annex III to	
			Implementing Regulation (EU)	
			2021/16;	
55	(3) 'medium-sized enterprise' means a		(3) 'medium-sized enterprise'	
	medium-sized enterprise within the meaning		means a medium-sized	
	of Recommendation 2003/361/EC;		enterprise within the meaning of	
			Recommendation 2003/361/EC;	
56	(4) 'small enterprise' means a small		(4) 'small enterprise' means a	
	enterprise within the meaning of		small enterprise within the	
	Recommendation 2003/361/EC;		meaning of Recommendation	
			2003/361/EC;	
57	(5) 'microenterprise' means a		(5) 'microenterprise' means a	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	microenterprise within the meaning of		microenterprise within the	
	Recommendation 2003/361/EC;		meaning of Recommendation	
			2003/361/EC;	
57a		(5a) 'Academia' or 'academic		
		sector' means public or private		
		higher education establishments		
		awarding academic degrees,		
		public or private non-profit		
		research organisations whose		
		primary mission is to pursue		
		research, and international		
		European interest organisations;		
57b		(5b) 'Non-profit organisation'		
		or 'non-profit legal entity' means		
		a legal entity which by its legal		
		form is non-profit-making or		
		which has a legal or statutory		

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
		July 2023	13 June 2023	text, compromise
				proposals and
				comments
		obligation not to distribute profits		
		to its shareholders or individual		
		members;		
57c		(5c) 'International European		
		interest organisation' means an		
		international organisation, the		
		majority of whose members are		
		Member States or associated		
		countries, and whose principal		
		objective is to promote scientific		
		and technological cooperation in		
		the Union;		
58	(6) 'public health emergency' means a	(6) 'public health emergency'	(6) 'public health emergency'	
	situation of public health emergency	means a situation of public health	means a situation of public	
	recognised by the Commission in	emergency recognised by the	health emergency recognised by	
	accordance with Article 12(1) of Decision	Commission in accordance with	the Commission in accordance	
	No 1082/2013/EU of the European	Article 23 of Regulation (EU)	with Article 23(1) of	

Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
	July 2023	13 June 2023	text, compromise
			proposals and
			comments
Parliament and of the Council ⁴⁸ .	2022/2371 of the European	Regulation (EU) 2022/2371 of	
	Parliament and of the Council ⁴⁰ .	the European Parliament and	
48 Decision No 1082/2013/EU of the European		of the Council 12(1) of	
Parliament and of the Council of 22 October 2013 on	⁴⁰ Regulation (EU) 2022/2371 of the	Decision No 1082/2013/EU of	
serious cross-border threats to health and repealing	European Parliament and of the Council of 23 November 2022 on serious cross-	the European Parliament and of	
Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).	border threats to health and repealing Decision <i>No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26)</i> .	the Council ⁴⁸ .	
		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). 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	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			OJ L 314, 6.12.2022, p. 26–63	
59	Article 3		Article 3	
	Types of fees and charges		Types of fees and charges	
60	The Agency may levy the following types of		The Agency may levy the	
	fees or charges:		following types of fees or	
			charges:	
61	(a) fees and charges for assessment		(a) fees and charges for	
	procedures and services relating to		assessment procedures and	
	medicinal products for human use, set out in		services relating to medicinal	
	Annex I;		products for human use, set out	
			in Annex I;	
62	(b) fees for and charges for assessment		(b) fees for and charges for	
	procedures and services relating to		assessment procedures and	
	veterinary medicinal products, set out in		services relating to veterinary	
	Annex II;		medicinal products, set out in	
			Annex II;	
63	(c) annual fees for authorised medicinal		(c) annual fees for authorised	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	products for human use and for authorised		medicinal products for human	
	veterinary medicinal products, set out in		use and for authorised veterinary	
	Annex III;		medicinal products, set out in	
			Annex III;	
64	(d) other fees and charges for medicinal		(d) other fees and charges for	
	products for human use, veterinary		medicinal products for human	
	medicinal products and consultations on		use, veterinary medicinal	
	medical devices, set out in Annex IV.		products and consultations on	
			medical devices, set out in	
			Annex IV.	
65	Article 4		Article 4	
	Additional fees and charges		Additional fees and charges	
66	1. The Agency may levy a scientific		1. The Agency may levy a	
	service fee for scientific services it provides		scientific service fee for	
	if these services are not covered by another		scientific services it provides if	
	fee or charge provided for in this		these services are not covered by	
	Regulation. The amount of the scientific		another fee or charge provided	

LIFE.5

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

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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	involved. Its minimum and maximum		amount of the charge for	
	amount are set out in point 6.4 of Annex IV.		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		3. Fees and charges levied	
	paragraphs 1 and 2 shall be set by the		pursuant to paragraphs 1 and 2	
	Management Board of the Agency following		shall be set by the Management	
	a favourable opinion by the Commission, in		Board of the Agency following a	
	accordance with the procedure established		favourable opinion by the	
	under Article 8. The applicable amounts		Commission, in accordance with	
	shall be published on the website of the		the procedure established under	
	Agency.		Article 8. The applicable	
			amounts shall be published on	
			the website of the Agency.	
69	4. The Commission shall take into		4. The Commission shall	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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	account any fees and charges levied in		take into account any fees and	
	accordance with this Article in any revision		charges levied in accordance	
	of this Regulation.		with this Article in any revision	
			of this Regulation.	
70	Article 5		Article 5	
	Payment of remuneration to competent		Payment of remuneration to	
	authorities of the Member States for the		competent authorities of the	
	provision of services to the Agency		Member States for the	
			provision of services to the	
			Agency	
71	1. The Agency shall pay the		1. The Agency shall pay the	
	remuneration referred to in Article 1(b) in		remuneration referred to in	
	accordance with the amounts of		Article 1(b) in accordance with	
	remuneration provided for in this		the amounts of remuneration	
	Regulation.		provided for in this Regulation.	
72	2. Unless otherwise provided for in this	2. Unless otherwise provided	2. Unless otherwise provided	
	Regulation, where fee reductions apply, the	for in this Regulation, where <i>less</i>	for in this Regulation, where fee	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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	remuneration to competent authorities of the	than total fee reductions apply,	reductions or waivers apply, the	
	Member States payable in accordance with	the remuneration to competent	remuneration to competent	
	this Regulation shall not be reduced.	authorities of the Member States	authorities of the Member States	
		payable in accordance with this	payable in accordance with this	
		Regulation shall not be reduced.	Regulation shall not be reduced.	
		However, unless otherwise		
		provided for in this Regulation,		
		where fee waivers are granted,		
		the remuneration shall be		
		reduced as laid down in Annex		
		V.		
73	3. The remuneration to competent		3. The remuneration to	
	authorities of the Member States shall be		competent authorities of the	
	paid in accordance with the written contract		Member States shall be paid in	
	referred to in Article 62(3), first		accordance with the written	
	subparagraph, of Regulation (EC)		contract referred to in	
	No 726/2004. The remuneration shall be		Article 62(3), first subparagraph,	

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				comments
	paid in euro. Any bank charges related to the		of Regulation (EC)	
	payment of such remuneration shall be		No 726/2004. The remuneration	
	borne by the Agency. Detailed rules		shall be paid in euro. Any bank	
	concerning the payment of remuneration		charges related to the payment	
	shall be established by the Management		of such remuneration shall be	
	Board of the Agency, in accordance with		borne by the Agency. Detailed	
	Article 8 of this Regulation.		rules concerning the payment of	
			remuneration shall be	
			established by the Management	
			Board of the Agency, in	
			accordance with Article 8 of this	
			Regulation.	
74	Article 6		Article 6	
	Reductions of fees and charges		Reductions of fees and charges	
75	1. The Agency shall apply the reductions		1. The Agency shall apply	
	set out in Annex V.		the reductions set out in Annex	
			V.	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
76	2. Where an assessment, an opinion or a		2. Where an assessment, an	
	service of the Agency is requested either by		opinion or a service of the	
	a Member State or by a Union institution,		Agency is requested either by a	
	the Agency shall waive the respective fee or		Member State or by a Union	
	charge, as applicable, in full.		institution, the Agency shall	
			may waive the respective fee	
			or charge, as applicable. The	
			Agency shall not levy the	
			respective fee or charge to any	
			Member State or Union	
			institution. waive the respective	
			fee or charge, as applicable, in	
			full.	
77	3. Where the applicant or marketing		3. Without prejudice to	
	authorisation holder may also benefit from		Article 5(2), $\underline{\mathbf{W}}_{\underline{w}}$ here the	
	another reduction provided for in Union		applicant or marketing	
	legislation, only the reduction that is the		authorisation holder may also	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
	most favourable to the applicant or		benefit from another reduction	
	marketing authorisation holder shall apply.		provided for in Union	
			legislation, only the reduction	
			that is the most favourable to the	
			applicant or marketing	
			authrisation holder shall apply.	
78	4. On a duly justified proposal from the	4. On a duly justified proposal	4. On a duly justified	
	Executive Director of the Agency, in	from the Executive Director of the	proposal from the Executive	
	particular for the protection of public or	Agency, in particular for the	Director of the Agency, in	
	animal health or for the support of specific	protection of public or animal	particular for the protection of	
	types of products or applicants, selected for	health or for the support of	public or animal health or for	
	duly justified reasons, the Management	specific types of products or <i>types</i>	the support of specific types of	
	Board of the Agency may grant, following a	of applicants, selected for duly	products or applicants, selected	
	favourable opinion from the Commission, a	justified reasons, the Management	for duly justified reasons, the	
	total or partial reduction of the applicable	Board of the Agency may grant,	Management Board of the	
	amount, in accordance with Article 8.	following a favourable opinion	Agency may grant, following a	
		from the Commission, a total or	favourable opinion from the	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
		partial reduction of the applicable	Commission, a total or partial	
		amount, in accordance with	reduction of the applicable <u>fee</u>	
		Article 8. <i>The Agency shall make</i>	or charge amount, in	
		information on such reductions	accordance with Article 8.	
		publicly available on the		
		Agency's website, setting out the		
		reasons for the reduction.		
79	5. In exceptional circumstances and for	5. In exceptional	5. In exceptional	
	imperative reasons of public or animal	circumstances and for duly	circumstances and for such as	
	health, the Executive Director of the Agency	<i>justified</i> imperative reasons of	imperative reasons of public or	
	may grant, on a case-by-case basis, total or	public or animal health, the	animal health, the Executive	
	partial reductions for the fees set out in	Executive Director of the Agency	Director of the Agency may	
	Annexes I, II, III and IV, with the exception	may grant, on a case-by-case	grant, on a case-by-case basis,	
	of the fees set out in points 6, 15 and 16 of	basis, total or partial reductions	total or partial reductions for the	
	Annex I, points 7 and 10 of Annex II and	for the fees set out in Annexes I,	fees set out in Annexes I, II, III	
	point 3 of Annex III. Any decision taken	II, III and IV, with the exception	and IV, with the exception of	
	pursuant to this Article shall state the	of the fees set out in points 6, 15	the fees set out in points 6, 1 <u>45</u>	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	reasons on which it is based.	and 16 of Annex I, points 7 and	and 1 <u>5</u> 6 of Annex I, points 7 and	
		10 of Annex II and point 3 of	10 of Annex II and point 3 of	
		Annex III. Any decision taken	Annex III. Any decision taken	
		pursuant to this Article shall state	pursuant to this Article shall	
		the reasons on which it is based.	state the reasons on which it is	
		The Agency shall make	based.	
		information on such decisions by		
		the Executive Director, including		
		the reasons for the reduction,		
		publicly available on the		
		Agency's website.		
80	Article 7		Article 7	
	Payment of fees and charges		Payment of fees and charges	
81	1. Fees and charges due under this		1. Fees and charges due	
	Regulation shall be paid in euro.		under this Regulation shall be	
			paid in euro.	
82	2. Payment of the fees and charges shall		2. Payment of the fees and	

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	be made after the payer has received a		charges shall be made after the	
	request for payment issued by the Agency		payer has received a request for	
	specifying the deadline for payment.		payment issued by the Agency	
			specifying the deadline for	
			payment.	
83	3. Payment of the fees and charges shall		3. Payment of the fees and	
	be made by means of a transfer to the bank		charges shall be made by means	
	account of the Agency specified in the		of a transfer to the bank account	
	request for payment. Any bank charges		of the Agency specified in the	
	related to that payment shall be borne by the		request for payment. Any bank	
	payer.		charges related to that payment	
			shall be borne by the payer.	
84	4. The deadline for payment shall be		4. The deadline for payment	
	considered to have been complied with only		shall be considered to have been	
	if the full amount has been paid in due time.		complied with only if the full	
	The date on which the full amount of the		amount has been paid in due	
	payment is received in the bank account held		time. The date on which the full	

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	by the Agency shall constitute the date on		amount of the payment is	
	which the payment has been made.		received in the bank account	
			held by the Agency shall	
			constitute the date on which the	
			payment has been made.	
85	Article 8		Article 8	
	Working arrangements		Working arrangements	
86	The Management Board of the Agency shall,		The Management Board of the	
	on a justified proposal from the Executive		Agency shall, on a justified	
	Director and following a favourable opinion		proposal from the Executive	
	from the Commission, establish working		Director and following a	
	arrangements to facilitate the application of		favourable opinion from the	
	this Regulation, including payment methods		Commission, establish working	
	of the fees and charges levied by the Agency		arrangements to facilitate the	
	and the mechanism for payment of		application of this Regulation,	
	remuneration to competent authorities of the		including payment methods of	
	Member States under this Regulation.		the fees and charges levied by	

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			the Agency, and the mechanism	
			for payment of remuneration to	
			competent authorities of the	
			Member States under this	
			Regulation, 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 Agency the	
			financial information in	
			accordance with Article 10(3).	
86a			The Management Board of the	
			Agency shall also define in the	
			working arrangements the	

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				comments
			scope of a distinct 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.	
87	Those arrangements shall be made publicly		Those arrangements shall be	
	available on the Agency's website.		made publicly available on the	
			Agency's website.	
88	Article 9		Article 9	
	Due date and measures in case of non-		Due date and measures in case	
	payment		of non-payment	
89	1. The due dates of the fees or charges		1. By [OP: please insert date	
	levied in accordance with this Regulation		of application of this Regulation]	
	shall be specified in the working		$\pm \underline{t}$ the due dates of the fees or	

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	arrangements set out in accordance with		charges levied in accordance	
	Article 8 of this Regulation. Due account		with this Regulation shall be	
	shall be taken of the deadlines of the		specified in the working	
	assessment procedures provided for in		arrangements set out in	
	Regulations (EC) No 726/2004 and (EU)		accordance with Article 8 of this	
	2019/6 and in Directive 2001/83/EC.		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		2. Where the payment of any	
	charge levied in accordance with this		fee or charge levied in	
	Regulation is overdue and without prejudice		accordance with this Regulation	
	to the Agency's capacity to institute legal		is overdue and without prejudice	
	proceedings to ensure payment pursuant to		to the Agency's capacity to	
	Article 71 of Regulation (EC) No 726/2004,		institute legal proceedings to	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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	the Executive Director of the Agency may		ensure payment pursuant to	
	decide that the Agency will not provide the		Article 71 of Regulation (EC)	
	services or will not carry out the procedures		No 726/2004, the Executive	
	to which the respective fee or charge relates,		Director of the Agency may	
	or that the Agency will suspend any ongoing		decide that the Agency will not	
	or future services and procedures until the		provide the services or will not	
	respective fee or charge has been paid,		carry out the procedures to	
	including relevant interest as provided for in		which the respective fee or	
	Article 99 of Regulation (EU, Euratom)		charge relates, or that the	
	2018/1046.		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.	
1				

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
91	Article 10		Article 10	
	Transparency and monitoring		Transparency and monitoring	
92	1. The amounts set out in the annexes	1. The amounts set out in the	1. The amounts set out in the	
	shall be published on the website of the	annexes shall be published on the	annexes shall be published on	
	Agency.	website of the Agency and shall	the website of the Agency.	
		be updated to reflect any		
		changes.		
93	2. The Agency shall monitor its costs and	2. The Agency shall monitor	2. The Agency shall monitor	
	the Executive Director of the Agency shall	its costs and the Executive	its costs and the Executive	
	provide, as part of the annual activity report	Director of the Agency shall	Director of the Agency shall	
	delivered to the European Parliament, the	provide, without delay as part of	provide, as part of the annual	
	Council, the Commission and the Court of	the annual activity report	activity report delivered to the	
	Auditors, detailed and substantiated	delivered to the European	European Parliament, the	
	information on the costs to be covered by	Parliament, the Council, the	Council, the Commission and	
	fees and charges that are within the scope of	Commission and the Court of	the Court of Auditors, detailed	
	this Regulation. That information shall	Auditors, detailed and	and substantiated information on	
	include the performance information set out	substantiated information on the	the costs to be covered by fees	

Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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			comments
in Annex VI and a cost breakdown related to	costs to be covered by fees and	and charges that are within the	
the previous calendar year and to a forecast	charges that are within the scope	scope of this Regulation. That	
for the following calendar year. The Agency	of this Regulation. That	information shall include the	
shall also publish an overview of that	information shall include the	performance information set out	
information in its annual report.	performance information set out	in Annex VI and a cost	
	in Annex VI and other relevant	breakdown related to the	
	information, in particular on the	previous calendar year and to a	
	practical aspects of carrying out	forecast for the following	
	the activities for which the	calendar year. The Agency shall	
	Agency collects fees or charges,	also publish an overview of that	
	and a cost breakdown related to	information in its annual report.	
	the previous calendar year and to		
	a forecast for the following		
	calendar year. The Agency shall		
	also publish without delay, an		
	overview of that information in its		
	annual report.		

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
93a		2a. All fees received, including		
		those where reductions and		
		waivers have been granted, and		
		fees which are due but not yet		
		received by the Agency shall be		
		published on the Agency's		
		website and listed in its annual		
		report.		
		The Agency's annual report shall		
		furthermore list a detailed		
		breakdown of all remunerated		
		amounts paid to national		
		authorities for their work.		
94	3. Evidence of significant changes in the		3. Evidence of significant	
	costs of services provided to the Agency,		changes in the costs of services	
	excluding any effect of inflationary		provided to the Agency,	
	adjustments and any costs for activities that		excluding any effect of	

Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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			proposals and
			comments
do not constitute a service to the Agency,		inflationary adjustments and any	
may be provided by competent authorities of		costs for activities that do not	
the Member States responsible for medicinal		constitute a service to the	
products or by experts contracted for the		Agency, may be provided by	
procedures of the expert panels on medical		competent authorities of the	
devices to the Agency. Such information		Member States responsible for	
may be provided once per calendar year or		medicinal products or by experts	
less frequently, as a complement to the		contracted for the procedures of	
information provided in accordance with		the expert panels on medical	
Annex VI. Such evidence shall be based on		devices to the Agency. Such	
duly justified and specific official financial		information may be provided	
information on the nature and the extent of		once per calendar year or less	
the financial impact on costs for services to		frequently, as a complement to	
the Agency. To that end, the Agency may		the information provided in	
provide a common format facilitating		accordance with Annex VI. Such	
comparison and consolidation. The		evidence shall be based on duly	
competent authorities of the Member States		justified and specific official	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	and the experts contracted for the procedures		financial information on the	
	of the expert panels on medical devices to		nature and the extent of the	
	the Agency shall provide such information		financial impact on costs for	
	in the format provided by the Agency,		services to the Agency. To that	
	together with any supporting information		end, the Agency may provide	
	allowing to verify the correctness of the		the a common format facilitating	
	amounts submitted. The Agency shall		comparison and consolidation.	
	review and aggregate that information and		established in accordance with	
	shall use it, in accordance with paragraph 6,		Article 8 shall be used. The	
	as a source for the special report provided		competent authorities of the	
	for in that paragraph.		Member States and the experts	
			contracted to the Agency for the	
			procedures of the expert panels	
			on medical devices to the	
			Agency shall provide such	
			information in the format	
			provided by the Agency,	
1				

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			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	
			provided for in that paragraph.	
95	4. Article 257 of Regulation (EU,		4. Article 257 of Regulation	
	Euratom) 2018/1046 shall apply to the		(EU, Euratom) 2018/1046 shall	
	information provided to the Agency in		apply to the information	
	accordance with paragraph 3 of this Article		provided to the Agency in	
	and Annex VI to this Regulation.		accordance with paragraph 3 of	
			this Article and Annex VI to this	
			Regulation.	
96	5. The Commission shall monitor the	5. The Commission shall	5. The Commission shall	

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			proposals and
			comments
inflation rate, measured by means of the	monitor the inflation rate,	monitor the inflation rate,	
Harmonised Index of Consumer Prices	measured by means of the	measured by means of the	
published by Eurostat pursuant to	Harmonised Index of Consumer	Harmonised Index of Consumer	
Regulation (EU) No 2016/792, in relation to	Prices published by Eurostat	Prices published by Eurostat	
the amounts of fees, charges and	pursuant to Regulation (EU) No	pursuant to Regulation (EU)	
remuneration set out in the Annexes to this	2016/792, in relation to the	No 2016/792, in relation to the	
Regulation. The monitoring exercise shall	amounts of fees, charges and	amounts of fees, charges and	
take place no earlier than [OP: please insert	remuneration set out in the	remuneration set out in the	
date one year after the date of application of	Annexes to this Regulation. The	Annexes to this Regulation. The	
this Regulation], and thereafter on an annual	monitoring exercise shall take	monitoring exercise shall take	
basis. Any adjustment, in line with inflation,	place no earlier than [OP: please	place no earlier than start at the	
to fees, charges and remuneration	insert date one year after the date	date [OP: please insert date one	
established in accordance with this	of application of this Regulation],	year after the date of application	
regulation shall become applicable, at the	and thereafter on an annual basis.	of this Regulation <u></u>], shall cover	
earliest, on 1 January of the calendar year	On the basis of this exercise, the	the period since the last	
following the calendar year in which the	Commission shall draw up a	inflation adjustment and shall	
monitoring exercise took place.	report and submit it to the	thereafter take place and	

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				comments
		European Parliament and to the	thereafter on an annual basis.	
		Council. Any adjustment, in line	Any adjustment, in line with	
		with inflation and following the	inflation, to fees, charges and	
		annual activity report referred to	remuneration established in	
		in Article 10(2), to fees, charges	accordance with this regulation	
		and remuneration established in	shall become applicable, at the	
		accordance with this regulation	earliest, on 1 January of the	
		shall become applicable, at the	calendar year following the	
		earliest, on 1 January of the	calendar year in which the	
		calendar year following the	monitoring exercise took place.	
		calendar year in which the		
		monitoring exercise took place.		
97	6. At the earliest on [OP: please insert	6. At the earliest on [OP:	6. At the earliest on [<i>OP</i> :	
	date 3 years after the date of application]	please insert date 3 years after the	please insert date 3 years9	
	and at three-year intervals thereafter, the	date of application] and at three-	months after the date of	
	Executive Director of the Agency may,	year intervals thereafter, the	application] and at three-year	
	where considered relevant in view of Article	Executive Director of the Agency	intervals thereafter, the	

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

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				proposals and
				comments
	report;		respective costs as identified,	
			documented and justified in the	
			report;	
98a		(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;		
99	(b) to amend any other element of the		(b) to amend any other	
	Annexes pertaining to the levying of fees		element of the Annexes	
	and charges, including additional fees and		pertaining to the levying of fees	
	charges referred to in Article 4.		and charges, including additional	
			fees and charges referred to in	
			Article 4;	
99a			(c) adapt the specification of	

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				proposals and
				comments
			activities for which the Agency	
			collects fees or charges to	
			changing conditions and	
			requirements.	
99b			(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;	
99c		The special report shall be		
		submitted to the European		
		Parliament and to the Council		
		for information.		
99d		6a. With a view to supporting		
		the Agency reach its conclusions		
		in an efficient and effective		

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				proposals and
				comments
		manner, during the preparation		
		of a report, the Agency shall		
		organise consultations with		
		stakeholders in order to receive		
		input on the structure and level		
		of fees, charges and		
		remuneration, including the		
		reasons for any change thereto.		
99e		6b. The special report shall be		
		made publicly available without		
		delay on the Agency's website.		
		The special report shall include		
		information on the stakeholders		
		consulted in the preparation of		
		that report.		
100	7. The special report referred to in		7. The special report referred	
	paragraph 6 and the recommendations it		to in paragraph 6 and the	

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				proposals and
				comments
	contains shall be based on the following:		recommendations it contains	
			shall be based on the following:	
101	(a) continuous monitoring of the		(a) continuous monitoring of	
	information referred to in paragraphs 2 and 3		the information referred to in	
	and of the cost of the activities necessary for		paragraphs 2 and 3 and of the	
	the fulfilment of the statutory tasks of the		cost of the activities necessary	
	Agency, aimed at identifying significant		for the fulfilment of the statutory	
	changes to the cost base of services and		tasks of the Agency, aimed at	
	activities of the Agency;		identifying significant changes	
			to the cost base of services and	
			activities of the Agency;	
102	(b) objective and verifiable information		(b) objective and verifiable	
	and quantification that directly supports the		information, and including	
	relevance of the recommended adjustments.		quantification, that directly	
			supports the relevance of the	
			recommended adjustments.	
103	8. The Commission may request any	8. The Commission, <i>the</i>	8. The Commission may	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
	clarification or further substantiation of the	European Parliament or the	request any clarification or	
	report and its recommendations, if	Council may request any	further substantiation of the	
	considered necessary. Following such a	clarification or further	report and its recommendations,	
	request, the Agency shall without undue	substantiation of the report and its	if considered necessary.	
	delay provide the Commission with an	recommendations, if considered	Following such a request, the	
	updated version of the report which	necessary. Following such a	Executive Director of the	
	addresses any comments made and questions	request, the Agency shall without	Agency shall without undue	
	raised by the Commission.	undue delay provide the	delay provide the Commission	
		Commission, the European	with an updated version of the	
		Parliament and the Council with	report adopted in accordance	
		an updated version of the report	with paragraph 6 which	
		which addresses any comments	addresses any comments made	
		made and questions raised by the	and questions raised by the	
		respective institution.	Commission.	
104	9. The reporting time interval referred to	9. The time interval for the	9. The <u>time interval to the</u>	
	in paragraph 6 may be shortened in any of	first special report as well as the	first special report as well as	
	the following situations:	reporting time interval referred to	the reporting time interval	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
		in paragraph 6 may be shortened	referred to in paragraph 6 may	
		in any of the following situations:	be shortened in any of the	
			following situations:	
105	(a) in the case of a public health		(a) in the case of a public	
	emergency;		health emergency;	
106	(b) in the case of a change of the legal		(b) in the case of a change of	
	mandate of the Agency;		the legal mandatein the	
			statutory tasks of the Agency;	
107	(c) in the case there is clear and		(c) in the case there is clear	
	compelling evidence of significant changes		and compelling evidence of	
	in the costs or the cost-revenue balance of		significant changes in the costs	
	the Agency, including costs for cost-based		or the cost-revenue balance of	
	remuneration to competent authorities of the		the Agency:	
	Member States.			
107a			(d) in case there is evidence	
			of significant changes in the	
			costs including costs for cost-	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			based remuneration to	
			competent authorities of the	
			Member States;	
107b			(de) upon request of the	
			Management Board of the	
			Agency.	
108	Article 11		Article 11	
	Revision		Revision	
108a		-1. By [four months before		
		the date of application of this		
		Regulation], the Commission		
		shall adopt, notwithstanding		
		Article 10(5), a delegated act in		
		accordance with Article 13, to		
		amend Annexes I, II, III and IV,		
		in order to adjust the amounts set		
		out therein to the inflation rate		

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				proposals and
				comments
		published four months before		
		[the date of application of this		
		Regulation].		
109	1. The Commission is empowered to		1. The Commission is	
	adopt delegated acts in accordance with		empowered to adopt delegated	
	Article 13 to amend the Annexes where		acts in accordance with Article	
	justified in view of any of the following:		13 to amend the Annexes where	
			justified in view of any of the	
			following:	
110	(a) a special report received by the		(a) a special report received	
	Commission in accordance with Article		by the Commission in	
	10(6);		accordance with Article 10(6);	
111	(b) the findings from the monitoring of the		(b) the findings from the	
	inflation rate referred to in Article 10(5);		monitoring of the inflation rate	
			referred to in Article 10(5);	
112	(c) a change in the statutory tasks of the	deleted	(c) a change in the statutory	
	Agency leading to a significant change in its		tasks of the Agency leading to a	

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

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				proposals and
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			the services provided to the	
			Agency in the scope of this	
			Regulation by the competent	
			authorities of the Member	
			States, taking into account also	
			the sustainability of the Union	
			regulatory network including	
			a fair and objective allocation	
			of fees, charges and	
			remuneration.	
115a		By way of derogation from the		
		first subparagraph, the		
		Commission may take into		
		account other factors that could		
		have a substantive impact on the		
		Agency's budget, including but		
		not limited to its workload and		

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		potential risks related to		
		fluctuations in its fee revenues.		
		The level of fees shall be set at a		
		level which ensures that the		
		revenue derived from them, when		
		combined with other sources of		
		revenue of the Agency, is		
		sufficient to cover the costs of the		
		services delivered in accordance		
		with the key performance		
		indicators and transparency		
		principles set out in Annex VI.		
115b			3. In any revision of the	
			Annexes, the amounts of	
			remuneration paid to	
			competent authorities of the	
			Member States provided for in	

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			this Regulation shall be	
			maintained as a single	
			amounts of remuneration	
			irrespective of the Member	
			State of the competent	
			authority concerned.	
116	Article 12		Article 12	
	Estimate of the Agency's budget		Estimate of the Agency's	
			budget	
117	The Agency shall, when producing an		The Agency shall, when	
	estimate of revenue and expenditure for the		producing an estimate of	
	following financial year in accordance with		revenue and expenditure for the	
	Article 67(6) of Regulation (EC)		following financial year in	
	No 726/2004, include detailed information		accordance with Article 67(6) of	
	on income from each type of fees and		Regulation (EC) No 726/2004,	
	charges and respective remuneration. In		include detailed information on	
	accordance with the typology of fees and		income from each type of fees	

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	charges set out in Article 3 of this		and charges and respective	
	Regulation, that information shall		remuneration. In accordance	
	distinguish, respectively, between the		with the typology of fees and	
	following:		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		(a) medicinal products for	
	consultations on medical devices;		human use and consultations on	
			medical devices;	
119	(b) veterinary medicinal products;		(b) veterinary medicinal	
			products;	
120	(c) annual fees, by type;		(c) annual fees, by type;	
121	(d) other fees and charges, by type.		(d) other fees and charges, by	
			type.	
122	A breakdown by type of procedure may be		A breakdown by type of	
	provided by the Agency in an annex to the		procedure may be provided by	

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	single programming document produced in		the Agency in an annex to the	
	accordance with Article 32(1) of Delegated		single programming document	
	Regulation (EU) 2019/715.		produced in accordance with	
			Article 32(1) of Delegated	
			Regulation (EU) 2019/715.	
123	Article 13		Article 13	
	Exercise of the delegation		Exercise of the delegation	
124	1. The power to adopt delegated acts is		1. The power to adopt	
	conferred on the Commission subject to the		delegated acts is conferred on	
	conditions laid down in this Article.		the Commission subject to the	
			conditions laid down in this	
			Article.	
125	2. The power to adopt delegated acts		2. The power to adopt	
	referred to in Article 11(1) shall be		delegated acts referred to in	
	conferred on the Commission for a period of		Article 11(1) shall be conferred	
	5 years from [tbc] 20[xx]. The Commission		on the Commission for a period	
	shall draw up a report in respect of the		of 5 years from [tbc] 20[xx].	

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	delegation of power not later than 6 months		The Commission shall draw up	
	before the end of the 5-year period. The		a report in respect of the	
	delegation of power shall be tacitly extended		delegation of power not later	
	for periods of an identical duration, unless		than 6 9 months before the end	
	the European Parliament or the Council		of the 5-year period. The	
	opposes such extension not later than 3		delegation of power shall be	
	months before the end of each period.		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.	
126	3. The delegation of power referred to in		3. The delegation of power	
	Article 11(1) may be revoked at any time by		referred to in Article 11(1) may	
	the European Parliament or by the Council.		be revoked at any time by the	
	A decision to revoke shall put an end to the		European Parliament or by the	
	delegation of the power specified in that		Council. A decision to revoke	

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

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

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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	not object. That period shall be extended by		Council or if, before the expiry	
	2 months at the initiative of the European		of that period, the European	
	Parliament or of the Council.		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	Article 14		Article 14	
	Amendment to Regulation (EU)		Amendment to Regulation	
	No 2017/745		(EU) No 2017/745	
131	Article 106 of Regulation (EU)		Article 106 of Regulation (EU)	
	No 2017/745, paragraph 14 is replaced by		No 2017/745, paragraph 14 is	
	the following:		replaced by the following:	
132	'14. The fees payable to EMA in		'14. The fees <u>established</u>	
	accordance with the procedure under		payable to EMA in accordance	

Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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			comments
paragraph 13 of this Article related to the		with the procedure under	
advice provided by expert panels for which		paragraph 13 of this Article	
EMA provides the secretariat in accordance		related to the advice provided by	
with Article 30 of Regulation (EU)		expert panels for which EMA	
2022/123 of the European Parliament and of		provides the secretariat in	
the Council ⁵⁰ shall be set in a transparent		accordance with Article 30 of	
manner and on the basis of the costs for the		Regulation (EU) 2022/123 of the	
services provided. The fees payable shall be		European Parliament and of the	
reduced in the case of a clinical evaluation		Council ⁵¹ -shall be set in a	
consultation procedure initiated in		transparent manner and on the	
accordance with section 5.1, point (c), of		basis of the costs for the services	
Annex IX to this Regulation involving a		provided. The fees payable shall	
manufacturer who is a micro, small or		be reduced in the case of a	
medium-sized enterprise within the meaning		clinical evaluation consultation	
of Recommendation 2003/361/EC.'.		procedure initiated in	
		accordance with section 5.1,	
⁵⁰ Regulation (EU) 2022/123 of the European		point (c), of Section 5.1 of	
Parliament and of the Council of 25 January 2022 on			

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				proposals and
				comments
	a reinforced role for the European Medicines Agency		Annex IX to this Regulation	
	in crisis preparedness and management for medicinal		involving a manufacturer who is	
	products and medical devices (OJ L 20, 31.1.2022, p. 1).		a micro, small or medium-sized	
	1).		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	
122			devices (OJ L 20, 31.1.2022, p. 1).	
132a			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	

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				proposals and
				comments
			the European Parliament and	
			of the Council. ⁵²	
			52 <u>Regulation (EU) 2022/123 of</u>	
			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).	
132b			The fees related to the advice	
			provided by expert	
			laboratories are payable to the	
			Commission.'.	
132c			Article 14a	
			Amendment to Regulation	

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				comments
			(EU) 2022/123	
132d			Article 30, point (f) of	
			Regulation (EU) 2022/123, is	
			replaced by the following:	
			'(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	
			adopted by the	
			Commission pursuant to	
			Article 106(1) of	
			Regulation (EU)	

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				comments
			<u>2017/745.'.</u>	
133	Article 15		Article 15	
	Repeal		Repeal	
134	Regulations (EC) No 297/95 and (EU)		Regulations (EC) No 297/95 and	
	No 658/2014 are repealed.		(EU) No 658/2014 are repealed	
			as of [OP: please insert date of	
			application of this Regulation].	
135	References to Regulation (EC) No 297/95		References to Regulation (EC)	
	shall be construed as references to this		No 297/95 shall be construed as	
	Regulation and read in accordance with the		references to this Regulation and	
	correlation table in Annex VII to this		read in accordance with the	
	Regulation.		correlation table in Annex VII to	
			this Regulation.	
136	Article 16		Article 16	
	Transitional provisions		Transitional provisions	
137	1. This Regulation shall not apply to		1. This Regulation shall not	
	procedures and services for which the		apply to annual fees,	

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	payable amount became due before [OP:		procedures and services for	
	please insert date of application].		which the payable amount	
			became due <u>pursuant to</u>	
			Regulation (EC) No 297/95 or	
			Regulation (EU) No 658/2014	
			before [OP: please insert date	
			of application].	
138	2. With regard to annual fees set out in		2. With regard to annual fees	
	Annex III, this Regulation shall not apply to		set out in Annex III, this	
	products for which an annual fee has		Regulation shall not apply to	
	become due pursuant to Regulation (EC) No		products for which an annual fee	
	297/95 or Regulation (EU) No 658/2014 in		has become due pursuant to	
	the year [OP: please insert calendar year of		Regulation (EC) No 297/95 or	
	application].		Regulation (EU) No 658/2014 in	
			the year [OP: please insert	
			calendar year of application].	
139	Article 17		Article 17	

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				comments
	Entry into force and date of application		Entry into force and date of	
			application	
140	This Regulation shall enter into force on the		This Regulation shall enter into	
	twentieth day following that of its		force on the twentieth-day	
	publication in the Official Journal of the		following that of its publication	
	European Union.		in the Official Journal of the	
			European Union.	
141	It shall apply from [OP: please insert date of		It shall apply from [OP: please	
	first day of the month following expiration of		insert date of 1 January of the	
	6 months after entry into force].		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	
			<u>vear</u> first day of the month	

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				comments
			following expiration of 6-9	
			months after entry into force].	
141a		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].		
142	This Regulation shall be binding in its		This Regulation shall be binding	
	entirety and directly applicable in all		in its entirety and directly	
	Member States.		applicable in all Member States.	
143	Done at Brussels,		Done at Brussels,	
144	For the European Parliament		For the European Parliament	
145	The President		The President	
146	For the Council		For the Council	
147	The President		The President	

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				comments
148	ANNEX I		ANNEX I	
	Fees, charges and remuneration for		Fees, charges and remuneration	
	assessment procedures and services relating		for assessment procedures and	
	to medicinal products for human use		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		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	1.1 A fee of EUR 94 000 shall	1.1 A fee of EUR 55 200 <u>79</u>	
	of the following requests:	apply to any of the following	400 shall apply to any of the	
		requests:	following requests:	
151	(a) a request on quality, non-clinical and		(a) a request on quality, non-	
	clinical development;		clinical and clinical	
			development;	
152	(b) a request on quality and clinical		(b) a request on quality and	
	development;		clinical development;	

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

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				comments
	defined in Article 10(2), point (b) of		bioequivalence studies for	
	Directive 2001/83/EC.		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	The remuneration shall be EUR	The remuneration shall be EUR	
	each of the two scientific advice co-	<i>17 650</i> for each of the two	6-500 <u>13 400</u> for each of the two	
	ordinators.	scientific advice co-ordinators.	scientific advice co-ordinators.	
161	1.3. A fee of EUR 37 200 shall apply to any	1.3 A fee of EUR 46 900 shall	1.3. A fee of EUR 37 200 <u>49</u>	
	of the following requests:	apply to any of the following	600 shall apply to any of the	
		requests:	following requests:	
162	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;	
164	c) a request on bioequivalence studies for		c) a request on bioequivalence	
	generic medicinal products as defined in		studies for generic medicinal	
	Article 10(2), point (b), of Directive		products as defined in Article	

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				comments
	2001/83/EC.		10(2), point (b), of Directive	
			2001/83/EC.	
165	The remuneration shall be EUR 5 300 for	The remuneration shall be EUR	The remuneration shall be EUR	
	each of the two scientific advice co-	<i>11 730</i> for each of the two	5 300 9 700 for each of the two	
	ordinators.	scientific advice co-ordinators.	scientific advice co-ordinators.	
166	2. Scientific opinions and assessments		2. Scientific opinions and	
	prior to potential submission of an		assessments prior to potential	
	application for a marketing authorisation		submission of an application for	
			a marketing authorisation	
167	2.1. A fee of EUR 549 800 shall apply to		2.1. A fee of EUR 549 800 828	
	any of the following:		100 shall apply to any of the	
			following:	
168	(a) an opinion on a medicinal product for		(a) an opinion on a medicinal	
	compassionate use pursuant to Article 83 of		product for compassionate use	
	Regulation (EC) No 726/2004;		pursuant to Article 83 of	
			Regulation (EC) No 726/2004;	
169	(b) an assessment on an on-going basis of		(b) an assessment on an on-	

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				proposals and
				comments
	data packages of particulars and documents		going basis of data packages of	
	submitted to the Agency by a prospective		particulars and documents	
	applicant prior to a formal submission of an		submitted to the Agency by a	
	application for a marketing authorisation		prospective applicant prior to a	
	falling within the scope of Regulation (EC)		formal submission of an	
	No 726/2004.		application for a marketing	
			authorisation falling within the	
			scope of Regulation (EC) No	
			726/2004.	
170	That fee shall cover all strengths, all		That fee shall cover all	
	pharmaceutical forms and all presentations		strengths, all pharmaceutical	
	submitted in the same application. The		forms and all presentations	
	remuneration shall be EUR 153 000 for the		submitted in the same	
	rapporteur and EUR 143 300 for the co-		application. The remuneration	
	rapporteur.		shall be EUR 153 000 260 800	
			for the rapporteur and, EUR 143	
			300 <u>227 200</u> for the co-	

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				comments
			rapporteur and 24 400 for the	
			PRAC-rapporteur.	
170a			2.1a(new) An additional fee of	
			EUR 124 200 shall apply to the	
			assessment set out in point	
			2.1(b). The remuneration shall	
			be EUR 39 100 for the	
			rapporteur, EUR 34 100 for	
			the co-rapporteur and EUR	
			3 700 for the PRAC-	
			rapporteur.	
171	2.2. In the event of multiple submissions of		2.2. In the event of multiple	
	data packages submitted by the same		submissions of data packages	
	prospective applicant for the same product,		submitted by the same	
	the fee set out in point 2.1 (b) shall only be		prospective applicant for the	
	charged once.		same product, the fee set out in	
			point 2.1 (b) and 2.1a(new)	

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				proposals and
				comments
			shall only be charged once.	
172	2.3. The amounts set out in point 2.1 shall be		2.3. The amounts set out in point	
	deducted from the respective fee and from		2.1 shall be deducted from the	
	the remuneration to competent authorities of		respective fee and from the	
	the Member States payable for a marketing		remuneration to competent	
	authorisation application for the same		authorities of the Member States	
	product, where such application is submitted		payable for a marketing	
	by the same applicant.		authorisation application for the	
			same product, where such	
			application is submitted by the	
			same applicant.	
173	3. Authorisation to market a medicinal		3. Authorisation to market a	
	product falling within the scope of		medicinal product falling within	
	Regulation (EC) No 726/2004		the scope of Regulation (EC) No	
			726/2004	
174	3.1. A fee of EUR 684 900 shall apply to an		3.1. A fee of EUR 684 900	
	application for a marketing authorisation for		828 100 shall apply to an	

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

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	application for a marketing authorisation for		<u>000</u> shall apply to an application	
	a medicinal product pursuant to Article 8(3)		for a marketing authorisation for	
	of Directive 2001/83/EC when the applicant		a medicinal product pursuant to	
	claims a known active substance. That fee		Article 8(3) of Directive	
	shall cover all strengths, all pharmaceutical		2001/83/EC when the applicant	
	forms and all presentations submitted in the		claims a known active	
	same application. The remuneration shall be		substance. That fee shall cover	
	EUR 153 000 for the rapporteur and EUR		all strengths, all pharmaceutical	
	143 300 for the co-rapporteur.		forms and all presentations	
			submitted in the same	
			application. The remuneration	
			shall be EUR 153 000 <u>183 600</u>	
			for the rapporteur and, EUR 143	
			300 <u>172 000</u> for the co-	
			rapporteur and EUR 17 800 for	
			the PRAC-rapporteur.	
176	3.3 A fee of EUR 456 800 shall apply to an		3.3 A fee of EUR 4 56	

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	application for a fixed combination		800 <u>546 500</u> shall apply to an	
	medicinal product pursuant to Article 10b of		application for a fixed	
	Directive 2001/83/EC. That fee shall cover		combination medicinal product	
	all strengths, all pharmaceutical forms and		pursuant to Article 10b of	
	all presentations submitted in the same		Directive 2001/83/EC. That fee	
	application. The remuneration shall be EUR		shall cover all strengths, all	
	141 500 for the rapporteur and EUR 83 000		pharmaceutical forms and all	
	for the co-rapporteur.		presentations submitted in the	
			same application. The	
			remuneration shall be EUR 141	
			500 169 800 for the rapporteur,	
			and EUR 83 000 99 600 for the	
			co-rapporteur and EUR 13 500	
			for the PRAC-rapporteur.	
177	3.4 A fee of EUR 575 000 shall apply to an		3.4. A fee of EUR 575 000	
	application for a biological medicinal		701 100 shall apply to an	
	product which is similar to a reference		application for a biological	

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	biological product pursuant to Article 10(4)		medicinal product which is	
	of Directive 2001/83/EC. That fee shall		similar to a reference biological	
	cover all strengths, all pharmaceutical forms		product pursuant to Article	
	and all presentations submitted in the same		10(4) of Directive 2001/83/EC.	
	application. The remuneration shall be EUR		That fee shall cover all	
	236 500 for the rapporteur and EUR 151 700		strengths, all pharmaceutical	
	for the co-rapporteur.		forms and all presentations	
			submitted in the same	
			application. The remuneration	
			shall be EUR 236 500 283 800	
			for the rapporteur and, EUR 151	
			700 <u>182 000</u> for the co-	
			rapporteur and EUR 23 500 for	
			the PRAC-rapporteur.	
178	3.5. A fee of EUR 624 300 shall apply to an		3.5. A fee of EUR 624 300	
	application for a marketing authorisation for		747 300 shall apply to an	
	a medicinal product pursuant to Article 10a		application for a marketing	

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	of Directive 2001/83/EC. That fee shall		authorisation for a medicinal	
	cover all strengths, all pharmaceutical forms		product pursuant to Article 10a	
	and all presentations submitted in the same		of Directive 2001/83/EC. That	
	application. The remuneration shall be EUR		fee shall cover all strengths, all	
	160 600 for the rapporteur and EUR 149 400		pharmaceutical forms and all	
	for the co-rapporteur.		presentations submitted in the	
			same application. The	
			remuneration shall be	
			EUR 160 600 192 700 for the	
			rapporteur and, EUR 149	
			400 <u>179 300</u> for the co-	
			rapporteur and EUR 18 600 for	
			the PRAC-rapporteur.	
179	3.6. A fee of EUR 141 200 shall apply to		3.6. A fee of EUR 141 200 239	
	any of the following:		500 shall apply to any of the	
			following:	
180	(a) an application for a marketing		(a) an application for a	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
	authorisation for a generic medicinal product		marketing authorisation for a	
	pursuant to Article 10(1) of Directive		generic medicinal product	
	2001/83/EC,		pursuant to Article 10(1) of	
			Directive 2001/83/EC,	
181	(b) an application based on informed		(b) an application based on	
	consent for a marketing authorisation for a		informed consent for a	
	medicinal product pursuant to Article 10c of		marketing authorisation for a	
	Directive 2001/83/EC.		medicinal product pursuant to	
			Article 10c of Directive	
			2001/83/EC.	
182	That fee shall cover all strengths, all		That fee shall cover all	
	pharmaceutical forms and all presentations		strengths, all pharmaceutical	
	submitted in the same application. The		forms and all presentations	
	remuneration shall be EUR 40 200 for the		submitted in the same	
	rapporteur.		application. The remuneration	
			shall be EUR 40 200 118 900	
			for the rapporteur and EUR 5	
			The same state of the same sta	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
			900 for the PRAC-rapporteur.	
183			3.6a A fee of EUR 141 200 165	
			300 shall apply to any of the	
			following:	
184			(c) an application for a	
			marketing authorisation for a	
			generic medicinal product	
			pursuant to Article 10(1) of	
			Directive 2001/83/EC,	
185			(d) an application based on	
			informed consent for a	
			marketing authorisation for a	
			medicinal product pursuant to	
			Article 10c of Directive	
			2001/83/EC.	
186			That fee shall cover all strengths,	
			all pharmaceutical forms and all	

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				proposals and
				comments
			presentations submitted in the	
			same application. The	
			remuneration shall be EUR 40	
			48 200 for the rapporteur and	
			EUR 2 400 for the PRAC-	
			<u>rapporteur</u> .	
187	3.7. A fee of EUR 339 700 shall apply to an		3.7. A fee of EUR 339	
	application for a marketing authorisation for		700 407 800 shall apply to an	
	a medicinal product pursuant to Article		application for a marketing	
	10(3) of Directive 2001/83/EC. That fee		authorisation for a medicinal	
	shall cover all strengths, all pharmaceutical		product pursuant to Article	
	forms and all presentations submitted in the		10(3) of Directive 2001/83/EC.	
	same application. The remuneration shall be		That fee shall cover all	
	EUR 89 100 for the rapporteur and EUR 89		strengths, all pharmaceutical	
	100 for the co-rapporteur.		forms and all presentations	
			submitted in the same	
			application. The remuneration	
			1	

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

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			presentations submitted in the	
			same application. The	
			remuneration shall be EUR 6	
			800 8 200 for the rapporteur and	
			EUR 1 000 1 200 for the co-	
			rapporteur.	
189	4. Extension of a marketing authorisation within the meaning of Annex I to Commission Regulation (EC) No 1234/2008 ⁵³		4. Extension of a marketing authorisation within the meaning of Annex I to Commission Regulation (EC) No 1234/2008 ⁵⁴	
	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).		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).	
190	4.1 A fee of EUR 138 000 shall apply to an		4.1. A fee of EUR 138 000 <u>161</u>	

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

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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	fee shall cover a single pharmaceutical form		authorisation not covered by	
	and a single associated strength. The		point 4.1. That fee shall cover a	
	remuneration shall be EUR 55 300 for the		single pharmaceutical form and	
	rapporteur and EUR 31 200 for the co-		a single associated strength. The	
	rapporteur.		remuneration shall be EUR 55	
			300 <u>66 400</u> for the rapporteur	
			and EUR 31 200 37 400 for the	
			co-rapporteur.	
192	4.3 Without prejudice to points 4.1 and 4.2,		4.3. Without prejudice to	
	a fee of EUR 27 600 shall apply to each		points 4.1 and 4.2, a fee of EUR	
	application for extension of a marketing		27-600 31 800 shall apply to	
	authorisation on the basis of an application		each application for extension of	
	submitted under Article 10(1), (3) or (4) of		a marketing authorisation on the	
	Directive 2001/83/EC on usage patent		basis of an application submitted	
	grounds as referred to in point 3.8 of this		under Article 10(1), (3) or (4) of	
	Annex. The remuneration shall be EUR 6		Directive 2001/83/EC on usage	
	800 for the rapporteur and EUR 1 000 for		patent grounds as referred to in	

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				comments
	the co-rapporteur.		point 3.8 of this Annex. The	
			remuneration shall be EUR 6	
			800 8 200 for the rapporteur and	
			EUR 1 000 <u>1 200</u> for the co-	
			rapporteur.	
193	5. Major variation of type II to the terms		5. Major variation of type II	
	of a marketing authorisation in accordance		to the terms of a marketing	
	with Commission Regulation (EC) No		authorisation in accordance with	
	1234/2008		Commission Regulation (EC)	
			No 1234/2008	
194	5.1. A fee of EUR 99 800 shall apply to an		5.1. A fee of EUR 99 800	
	application for a major variation of type II as		175 300 shall apply to an	
	defined in Article 2(3) of Regulation (EC)		application for a major variation	
	No 1234/2008 ('major variation of type II')		of type II as defined in Article	
	for an addition of a new therapeutic		2(3) of Regulation (EC) No	
	indication or modification of an approved		1234/2008 ('major variation of	
	indication. The remuneration shall be EUR		type II') for an addition of a new	

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	29 400 for the rapporteur and EUR 29 400		therapeutic indication or	
	for the co-rapporteur.		modification of an approved	
			indication. The remuneration	
			shall be EUR 29 400 64 400 for	
			the rapporteur and EUR 29	
			400 <u>64 400</u> for the co-rapporteur.	
195	5.2. A fee of EUR 13 000 shall apply to an		5.2. A fee of EUR 13 000	
	application for a major variation of type II		28 500 shall apply to an	
	not covered by point 5.1. The remuneration		application for a major variation	
	shall be EUR 6 800 for the rapporteur.		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		5.3. For each application for a	
	variation of type II that is grouped in a		major variation of type II that is	
	single application pursuant to Article 7 of		grouped in a single application	
	Regulation (EC) No 1234/2008, the		pursuant to Article 7 of	

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

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			apply to each variation of the	
			second and subsequent centrally	
			authorised product included in	
			the application.	
198	6. Referrals and scientific opinions		6. Referrals and scientific	
	pursuant to Article 5(3) of Regulation (EC)		opinions pursuant to Article 5(3)	
	No 726/2004		of Regulation (EC) No 726/2004	
199	6.1. A fee of EUR 136 700 shall apply to the	6.1. A fee of EUR 136 700 shall	6.1. A fee of EUR 136 700 <u>156</u>	
	assessment carried out in the context of a	apply to the assessment carried	700 shall apply to the	
	procedure initiated under Article 5(3) of	out in the context of a procedure	assessment carried out in the	
	Regulation (EC) No 726/2004. Such fee	initiated under Article 5(3) of	context of a procedure initiated	
	shall be waived in full. The remuneration	Regulation (EC) No 726/2004.	under Article 5(3) of Regulation	
	shall be EUR 12 400 for the rapporteur and	Such fee shall be waived in full.	(EC) No 726/2004. Such fee	
	EUR 12 400 for the co-rapporteur.	The remuneration shall be EUR 6	shall be waived in full. The	
		200 for the rapporteur and EUR 6	remuneration shall be EUR 12	
		200 for the co-rapporteur.	400 <u>14 900</u> for the rapporteur and	
			EUR 12 400 14 900 for the co-	

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				comments
			rapporteur.	
200	6.2. A fee of EUR 262 400 shall apply to the	6.2. A fee of EUR 262 400 shall	6.2. A fee of EUR 262 400 299	
	assessment carried out in the context of a	apply to the assessment carried	800 shall apply to the	
	procedure initiated under Article 13 of	out in the context of a procedure	assessment carried out in the	
	Regulation (EC) No 1234/2008. Such fee	initiated under Article 13 of	context of a procedure initiated	
	shall be waived in full. The remuneration	Regulation (EC) No 1234/2008.	under Article 13 of Regulation	
	shall be EUR 15 300 for the rapporteur and	Such fee shall be waived in full.	(EC) No 1234/2008. Such fee	
	EUR 15 300 for the co-rapporteur.	The remuneration shall be EUR 7	shall be waived in full. The	
		650 for the rapporteur and EUR 7	remuneration shall be EUR 15	
		650 for the co-rapporteur.	300 <u>18 400</u> for the rapporteur and	
			EUR <u>15 300</u> 18 400 for the co-	
			rapporteur.	
201	6.3. A fee of EUR 83 000 shall apply to the	6.3. A fee of EUR 83 000 shall	6.3. A fee of EUR 83 000 <u>94</u>	
	assessment carried out in the context of a	apply to the assessment carried	600 shall apply to the	
	procedure initiated under Article 29(4) of	out in the context of a procedure	assessment carried out in the	
	Directive 2001/83/EC. Such fee shall be	initiated under Article 29(4) of	context of a procedure initiated	
	waived in full. The remuneration shall be	Directive 2001/83/EC. Such fee	under Article 29(4) of Directive	

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	EUR 2 800 for the rapporteur and EUR 2	shall be waived in full. The	2001/83/EC. Such fee shall be	
	800 for the co-rapporteur.	remuneration shall be EUR 1 400	waived in full. The	
		for the rapporteur and EUR 1 400	remuneration shall be EUR 2	
		for the co-rapporteur.	8003 400 for the rapporteur and	
			EUR 2-8003 400 for the co-	
			rapporteur.	
202	6.4. A fee of EUR 128 200 shall apply to the		6.4. A fee of EUR 128 200 146	
	assessment carried out in the context of a		400 shall apply to the	
	procedure initiated under Article 30 of		assessment carried out in the	
	Directive 2001/83/EC. The remuneration		context of a procedure initiated	
	shall be EUR 6 800 for the rapporteur and		under Article 30 of Directive	
	EUR 6 800 for the co-rapporteur.		2001/83/EC. The remuneration	
			shall be EUR 6-800 <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		6.5. A fee of EUR 180 700206	
	assessment carried out in the context of a		700 shall apply to the	

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	procedure initiated under Article 31 of		assessment carried out in the	
	Directive 2001/83/EC where the procedure		context of a procedure initiated	
	is initiated as a result of the evaluation of		under Article 31 of Directive	
	data other than data relating to		2001/83/EC where the	
	pharmacovigilance. The remuneration shall		procedure is initiated as a result	
	be EUR 12 400 for the rapporteur and EUR		of the evaluation of data other	
	12 400 for the co-rapporteur.		than data relating to	
			pharmacovigilance. The	
			remuneration shall be EUR 12	
			400 <u>14 900</u> for the rapporteur	
			and EUR 12 400 14 900 for the	
			co-rapporteur.	
204	6.6. A fee of EUR 172 100 shall apply to the		6.6. A fee of EUR 172 100 197	
	assessment carried out in accordance with a		600 shall apply to the	
	procedure initiated under Article 20 of		assessment carried out in	
	Regulation (EC) No 726/2004 where that		accordance with a procedure	
	procedure is initiated as a result of the		initiated under Article 20 of	

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				comments
	evaluation of data other than data relating to		Regulation (EC) No 726/2004	
	pharmacovigilance. The remuneration shall		where that procedure is initiated	
	be EUR 17 500 for the rapporteur and EUR		as a result of the evaluation of	
	17 500 for the co-rapporteur.		data other than data relating to	
			pharmacovigilance. The	
			remuneration shall be EUR 17	
			500-21 000 for the rapporteur	
			and EUR 17 500 21 000 for the	
			co-rapporteur.	
205	6.7. For an assessment carried out in the		6.7. For an	
	context of a procedure initiated as a result of		assessment carried out in the	
	the evaluation of pharmacovigilance data		context of a procedure initiated	
	under Article 31(1), second subparagraph,		as a result of the evaluation of	
	Article 31(2) and Articles 107i, 107j		pharmacovigilance data under	
	and 107k of Directive 2001/83/EC or under		Article 31(1), second	
	Article 20(8) of Regulation (EC) No		subparagraph, Article 31(2) and	
	726/2004, the following fees shall apply:		Articles 107i, 107j and 107k of	

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				comments
			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		6.7.1.a fee of EUR 172 100 210	
	active substance or combination of active		200 where one active substance	
	substances and one marketing authorisation		or combination of active	
	holder are included in the assessment. The		substances and one marketing	
	remuneration shall be EUR 17 500 for the		authorisation holder are	
	rapporteur and EUR 17 500 for the co-		included in the assessment. The	
	rapporteur;		remuneration shall be EUR 17	
			500 <u>27 300</u> 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		6.7.2.a fee of EUR 258 200296	
	more active substances or combinations of		400 where two or more active	
	active substances and one marketing		substances or combinations of	

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				comments
	authorisation holder are included in the		active substances and one	
	assessment. The remuneration shall be EUR		marketing authorisation holder	
	26 300 for the rapporteur and EUR 26 300		are included in the assessment.	
	for the co-rapporteur;		The remuneration shall be EUR	
			26 300 31 600 for the rapporteur	
			and EUR 26 30031 600 for the	
			co-rapporteur;	
208	6.7.3. a fee of EUR 314 100 where one or		6.7.3.a fee of EUR 314 100360	
	two active substances or combinations of		600 where one or two active	
	active substances and two or more		substances or combinations of	
	marketing authorisation holders are included		active substances and two or	
	in the assessment. The remuneration shall be		more marketing authorisation	
	EUR 32 000 for the rapporteur and EUR 32		holders are included in the	
	000 for the co-rapporteur;		assessment. The remuneration	
			shall be EUR 32 00038 400 for	
			the rapporteur and EUR 32	
			00038 400 for the co-rapporteur;	

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

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
			Agency in two steps, as follows:	
211	(a) by dividing the total amount of the fee		(a) by dividing the total	
	among the marketing authorisation holders		amount of the fee among the	
	proportionally to the number of chargeable		marketing authorisation holders	
	units-human corresponding to products		proportionally to the number of	
	included in the procedure which are held by		chargeable units-human	
	each of those marketing authorisation		corresponding to products	
	holders;		included in the procedure which	
			are held by each of those	
			marketing authorisation holders;	
212	(b) by subsequently applying, where		(b) by subsequently applying,	
	relevant, the fee reduction laid down in		where relevant, the fee reduction	
	Annex V.		laid down in Annex V.	
213	7. Evaluation of traditional herbal		7. Evaluation of traditional	
	medicinal products in accordance with		herbal medicinal products in	
	Article 57(1)(n) of Regulation (EC) No		accordance with Article 57(1)(n)	
	726/2004		of Regulation (EC) No 726/2004	

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				comments
214	A fee of EUR 29 700 shall apply to a request		A fee of EUR 29 700 <u>34 000</u>	
	for scientific advice from the Committee on		shall apply to a request for	
	Herbal Medicinal Products related to		scientific advice from the	
	traditional herbal medicinal products. The		Committee on Herbal Medicinal	
	remuneration shall be EUR 4 100 for the		Products related to traditional	
	rapporteur.		herbal medicinal products. The	
			remuneration shall be EUR 4	
			<u>9</u> 100 for the rapporteur.	
215	8. Certification of compliance with		8. Certification of	
	Union legislation for a plasma master file		compliance with Union	
	(PMF) in accordance with Part III of Annex		legislation for a plasma master	
	I of Directive 2001/83/EC		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		8.1. A fee of EUR 57 20066 000	
	application for review of a PMF and its		shall apply to an application for	
	initial certification pursuant to Part III,		review of a PMF and its initial	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
	point 1.1 of Annex I to Directive		certification pursuant to Part III,	
	2001/83/EC. The remuneration shall be		point 1.1 of Annex I to Directive	
	EUR 8 600 for the rapporteur and EUR 8		2001/83/EC. The remuneration	
	600 for the co-rapporteur.		shall be EUR 8 600 <u>10 300</u> for	
			the rapporteur and EUR 8 60010	
			<u>300</u> for the co-rapporteur.	
217	8.2. A charge of EUR 5 800 shall apply to		8.2. A charge of EUR <u>5 8006</u>	
	the issuing of an initial PMF certification		<u>600</u> shall apply to the issuing of	
	where it is submitted simultaneously with an		an initial PMF certification	
	application for a marketing authorisation for		where it is submitted	
	a medicinal product under the centralised		simultaneously with an	
	procedure. The PMF documentation shall be		application for a marketing	
	evaluated within the centralised marketing		authorisation for a medicinal	
	authorisation application.		product under the centralised	
			procedure. The PMF	
			documentation shall be	
			evaluated within the centralised	

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				comments
			marketing authorisation	
			application.	
218	8.3. A fee of EUR 10 600 shall apply to an		8.3. A fee of EUR 10 600 <u>12</u>	
	application for review and certification of a		200 shall apply to an application	
	major variation of type II to the PMF		for review and certification of a	
	pursuant to Regulation (EC) No 1234/2008.		major variation of type II to the	
	The remuneration shall be EUR 1 600 for		PMF pursuant to Regulation	
	the rapporteur and EUR 1 600 for the co-		(EC) No 1234/2008. The	
	rapporteur.		remuneration shall be EUR 4	
			600 <u>1 900</u> for the rapporteur and	
			EUR 1 <u>9</u> 600 for the co-	
			rapporteur.	
219	For two or more major variations of type II		For two or more major	
	grouped in a single application pursuant to		variations of type II grouped in a	
	Regulation (EC) No 1234/2008, the fee and		single application pursuant to	
	remuneration laid down in point 9.4 of this		Regulation (EC) No 1234/2008,	
	Annex shall apply.		the fee and remuneration laid	

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				proposals and
				comments
			down in point 98.4 of this Annex	
			shall apply.	
220	8.4. A fee of EUR 17 000 shall apply for an		8.4. A fee of EUR 17 000 19	
	application for review and annual re-		500 shall apply for an	
	certification of a PMF which may include		application for review and	
	any variation pursuant to Regulation (EC)		annual re-certification of a PMF	
	No 1234/2008 submitted simultaneously		which may include any variation	
	with the application for a PMF annual re-		pursuant to Regulation (EC) No	
	certification. The remuneration shall be		1234/2008 submitted	
	EUR 1 900 for the rapporteur and EUR 1		simultaneously with the	
	900 for the co-rapporteur.		application for a PMF annual re-	
			certification. The remuneration	
			shall be EUR <u>1-900</u> 2 300 for the	
			rapporteur and EUR 1 9002 300	
			for the co-rapporteur.	
221	9. Certification of compliance with		9. Certification of	
	Union legislation for a vaccine antigen		compliance with Union	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
	master file (VAMF) in accordance with Part		legislation for a vaccine antigen	
	III of Annex I of Directive 2001/83/EC		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		9.1. A fee of EUR 57 200 <u>66</u>	
	application for review of a VAMF and its		<u>000</u> shall apply for an	
	initial certification not submitted		application for review of a	
	simultaneously with a new application for		VAMF and its initial	
	marketing authorisation under the		certification not submitted	
	centralised procedure pursuant to Part III,		simultaneously with a new	
	point 1.2 of Annex I to Directive		application for marketing	
	2001/83/EC. The remuneration shall be		authorisation under the	
	EUR 8 600 for the rapporteur and EUR 8		centralised procedure pursuant	
	600 for the co-rapporteur.		to Part III, point 1.2 of Annex I	
			to Directive 2001/83/EC. The	
			remuneration shall be EUR 8	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			60010 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		9.2. In the case of a group of	
	at preventing a single infectious disease, a		antigens aimed at preventing a	
	fee shall be charged for the VAMF		single infectious disease, a fee	
	application for one antigen and remuneration		shall be charged for the VAMF	
	shall be paid pursuant to point 10.1. The		application for one antigen and	
	second and subsequent VAMF applications		remuneration shall be paid	
	submitted simultaneously for antigens as		pursuant to point 109.1. The	
	part of the same group shall be charged a fee		second and subsequent VAMF	
	of EUR 7 800 per VAMF. The maximum		applications submitted	
	total amount charged by the Agency for		simultaneously for antigens as	
	VAMF applications submitted		part of the same group shall be	
	simultaneously for antigens as part of the		charged a fee of EUR 7 8009	
	same group shall not exceed EUR 68 600. In		100 per VAMF. The maximum	
	that case, the remuneration per each second		total amount charged by the	

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

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

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

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
	The remuneration shall be EUR 47 400 for	the European Parliament and of	of the European Parliament and	
	the rapporteur.	the Council ⁴³ . Such fee shall be	of the Council ⁵⁶ . Such fee shall	
		waived in full. The remuneration	be waived in full. The	
	⁵⁵ Regulation (EC) No 1394/2007 of the European	shall be EUR 23 700 for the	remuneration shall be EUR 47	
	Parliament and of the Council of 13 November 2007	rapporteur.	400 <u>56 900</u> for the rapporteur.	
	on advanced therapy medicinal products and			
	amending Directive 2001/83/EC and Regulation (EC)		⁵⁶ Regulation (EC) No 1394/2007 of	
	No 726/2004 (OJ L 324, 10.12.2007, p. 121).		the European Parliament and of the	
			Council of 13 November 2007 on	
			advanced therapy medicinal products	
			and amending Directive 2001/83/EC	
			and Regulation (EC) No 726/2004 (OJ	
			L 324, 10.12.2007, p. 121).	
228	10.2. A fee of EUR 95 200 shall apply to an	10.2. A fee of EUR 95 200 shall	10.2. A fee of EUR 95 200110	
	application for evaluating and certifying	apply to an application for	100 shall apply to an application	
	only the quality data pursuant to Article 18	evaluating and certifying only the	for evaluating and certifying	
	of Regulation (EC) No 1394/2007. Such fee	quality data pursuant to Article 18	only the quality data pursuant to	
	shall be waived in full. The remuneration	of Regulation (EC) No	Article 18 of Regulation (EC)	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
	shall be EUR 31 500 for the rapporteur.	1394/2007. Such fee shall be	No 1394/2007. Such fee shall be	
		waived in full. The remuneration	waived in full. The	
		shall be EUR 15 750 for the	remuneration shall be EUR 31	
		rapporteur.	500 <u>37 800</u> for the rapporteur.	
229	11. Paediatric applications in accordance		11. Paediatric applications in	
	with Regulation (EC) No 1901/2006 of the		accordance with Regulation	
	European Parliament and of the Council ⁵⁷		(EC) No 1901/2006 of the	
			European Parliament and of the	
	⁵⁷ Regulation (EC) No 1901/2006 of the European		Council ⁵⁸	
	Parliament and of the Council of 12 December 2006			
	on medicinal products for paediatric use and			
	amending Regulation (EEC) No 1768/92, Directive		⁵⁸ Regulation (EC) No 1901/2006 of the European Parliament and of the	
	2001/20/EC, Directive 2001/83/EC and Regulation		Council of 12 December 2006 on	
	(EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).		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).	
230	11.1. A fee of EUR 31 700 shall apply to an	11.1. A fee of EUR 31 700 shall	11.1. A fee of EUR 31 700 <u>36</u>	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	application for agreement of a paediatric	apply to an application for	400 shall apply to an application	
	investigation plan requested pursuant to	agreement of a paediatric	for agreement of a paediatric	
	Article 15 of Regulation (EC) No	investigation plan requested	investigation plan requested	
	1901/2006. Such fee shall be waived in full.	pursuant to Article 15 of	pursuant to Article 15 of	
	The remuneration shall be EUR 6 700 for	Regulation (EC) No 1901/2006.	Regulation (EC) No 1901/2006.	
	the rapporteur.	Such fee shall be waived in full.	Such fee shall be waived in full.	
		The remuneration shall be EUR 3	The remuneration shall be EUR	
		<i>350</i> for the rapporteur.	6 700 8 000 for the rapporteur.	
231	11.2. A fee of EUR 17 600 shall apply to an	11.2. A fee of EUR 17 600 shall	11.2. A fee of EUR 17 60020	
	application for a modification of an agreed	apply to an application for a	400 shall apply to an application	
	paediatric investigation plan pursuant to	modification of an agreed	for a modification of an agreed	
	Article 22 of Regulation (EC) No	paediatric investigation plan	paediatric investigation plan	
	1901/2006. Such fee shall be waived in full.	pursuant to Article 22 of	pursuant to Article 22 of	
	The remuneration shall be EUR 6 400 for	Regulation (EC) No 1901/2006.	Regulation (EC) No 1901/2006.	
	the rapporteur.	Such fee shall be waived in full.	Such fee shall be waived in full.	
		The remuneration shall be EUR 3	The remuneration shall be EUR	
		200 for the rapporteur.	6 400 <u>7 700</u> for the rapporteur.	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
232	11.3. A fee of EUR 12 000 shall apply to an	11.3. A fee of EUR 12 000 shall	11.3. A fee of EUR 12 000 <u>13</u>	
	application for a product-specific waiver	apply to an application for a	700 shall apply to an application	
	pursuant to Article 13 of Regulation (EC)	product-specific waiver pursuant	for a product-specific waiver	
	No 1901/2006. Such fee shall be waived in	to Article 13 of Regulation (EC)	pursuant to Article 13 of	
	full. The remuneration shall be EUR 1 800	No 1901/2006. Such fee shall be	Regulation (EC) No 1901/2006.	
	for the rapporteur.	waived in full. The remuneration	Such fee shall be waived in full.	
		shall be EUR 900 for the	The remuneration shall be EUR	
		rapporteur.	1 800 2 200 for the rapporteur.	
233	11.4. A fee of EUR 8 000 shall apply to a	11.4. A fee of EUR 8 000 shall	11.4. A fee of EUR 8 0009	
	request for compliance check with the	apply to a request for compliance	100 shall apply to a request for	
	paediatric investigation plan pursuant to	check with the paediatric	compliance check with the	
	Article 23 of Regulation (EC) No	investigation plan pursuant to	paediatric investigation plan	
	1901/2006. Such fee shall be waived in full.	Article 23 of Regulation (EC) No	pursuant to Article 23 of	
	The remuneration shall be EUR 1 000 for	1901/2006. Such fee shall be	Regulation (EC) No 1901/2006.	
	the rapporteur.	waived in full. The remuneration	Such fee shall be waived in full.	
		shall be EUR 500 for the	The remuneration shall be EUR	
		rapporteur.	1 000 1 200 for the rapporteur.	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
		July 2023	13 June 2023	text, compromise
				proposals and comments
234	12. Orphan designation in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council ⁵⁹ 59 Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).		12. Orphan designation in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council 60 60 Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).	
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 waived in full. The remuneration shall be EUR 1	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 80019 200 shall apply to an application for or reassessment of the designation of an orphan medicinal product pursuant to	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
	500 for the rapporteur.	Such fee shall be waived in full.	Regulation (EC) No 141/2000.	
		The remuneration shall be EUR	Such fee shall be waived in full.	
		750 for the rapporteur.	The remuneration shall be EUR	
			1 500 <u>1 800</u> for the rapporteur.	
236	13. Scientific opinion on the evaluation of		13. Scientific opinion on the	
	medicinal product intended exclusively for		evaluation of medicinal product	
	markets outside the Union		intended exclusively for markets	
			outside the Union	
237	A fee and corresponding remuneration as		A fee and corresponding	
	specified in points 1 to 5 of this Annex and		remuneration as specified in	
	sections 1, 3, 4 and 5 of Annex IV and		points 1 to 5 of this Annex and	
	points 6.1, 6.2 and 6.4 thereof shall apply for		sections 1, 3, 4 and 5 of Annex	
	an application for a scientific opinion		IV and points 6.1, 6.2 and 6.4	
	following the evaluation of a medicinal		thereof shall apply for an	
	product intended exclusively for markets		application for a scientific	
	outside the Union pursuant to Article 58 of		opinion following the evaluation	
	Regulation (EC) No 726/2004.		of a medicinal product intended	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			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	
239	14.1 A fee of EUR 27 000 shall apply per		14.1 A fee of EUR 27 00032	
	procedure for the assessment of periodic		600 shall apply per procedure	
	safety update reports referred to in Articles		for the assessment of periodic	
	107e and 107g of Directive 2001/83/EC and		safety update reports referred to	
	in Article 28 of Regulation (EC) No		in Articles 107e and 107g of	
	726/2004. The remuneration shall be EUR		Directive 2001/83/EC and in	
	12 900 for the rapporteur.		Article 28 of Regulation (EC)	
			No 726/2004. The remuneration	
			shall be EUR 12 900 16 600 for	
			the rapporteur.	
240	14.2. Where two or more marketing		14.2. Where two or more	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	authorisation holders are subject to the		marketing authorisation holders	
	obligation to submit periodic safety update		are subject to the obligation to	
	reports in the context of the procedures		submit periodic safety update	
	referred to in point 14.1, the amount payable		reports in the context of the	
	by each marketing authorisation holder shall		procedures referred to in point	
	be calculated by the Agency in two steps, as		14.1, the amount payable by	
	follows:		each marketing authorisation	
			holder shall be calculated by the	
			Agency in two steps, as follows:	
241	(a) by dividing the total amount of the fee		(a) by dividing the total amount	
	among the marketing authorisation holders		of the fee among the marketing	
	proportionally to the number of chargeable		authorisation holders	
	units-human corresponding to products		proportionally to the number of	
	included in the procedure which are held by		chargeable units-human	
	each of those marketing authorisation		corresponding to products	
	holders;		included in the procedure which	
			are held by each of those	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			marketing authorisation holders;	
242	(b) by subsequently applying, where		(b) by subsequently applying,	
	relevant, the fee reduction laid down in point		where relevant, the fee reduction	
	1 of Annex V.		laid down in point 1 of Annex	
			V.	
243	15. Post-authorisation safety studies		15. Post-authorisation safety studies	
244	15.1 A fee of EUR 88 200 shall apply to an		15.1. A fee of EUR 88	
	assessment carried out under Articles 107n		200 102 400 shall apply to an	
	to 107q of Directive 2001/83/EC and Article		assessment carried out under	
	28b of Regulation (EC) No 726/2004 of		Articles 107n to 107q of	
	post-authorisation safety studies as referred		Directive 2001/83/EC and	
	to in Article 21a, point (b), or Article 22a(1),		Article 28b of Regulation (EC)	
	point (a), of Directive 2001/83/EC, or in		No 726/2004 of post-	
	Article 9(4), point (cb), or Article 10a(1),		authorisation safety studies as	
	point (a), of Regulation (EC) No 726/2004,		referred to in Article 21a, point	
	that are conducted in more than one Member		(b), or Article 22a(1), point (a),	

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	State.		of Directive 2001/83/EC, or in	
			Article 9(4), point (cb), or	
			Article 10a(1), point (a), of	
			Regulation (EC) No 726/2004,	
			that are conducted in more than	
			one Member State.	
245	15.2 The fee shall be charged in two		15.2 The fee shall be charged in	
	instalments, as follows:		two instalments, as follows:	
246	15.2.1. EUR 44 100 shall be due on the date		15.2.1. EUR 44-100 <u>51 200</u>	
	of the start of the procedure for the		shall be due on the date of the	
	assessment of the draft protocol referred to		start of the procedure for the	
	in Article 107n of Directive 2001/83/EC; the		assessment of the draft protocol	
	remuneration shall be EUR 17 800 for the		referred to in Article 107n of	
	rapporteur.		Directive 2001/83/EC; the	
			remuneration shall be EUR 17	
			800 <u>21 400</u> for the rapporteur.	
247	15.2.2. EUR 44 100 shall be due at the date		15.2.2 EUR 44 100 <u>51 200</u>	

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	of the start of the procedure for the		shall be due at the date of the	
	assessment of the final study report, as		start of the procedure for the	
	referred to in Article 107p of Directive		assessment of the final study	
	2001/83/EC, by the Pharmacovigilance Risk		report, as referred to in Article	
	Assessment Committee; the remuneration		107p of Directive 2001/83/EC,	
	shall be EUR 17 800 for the rapporteur.		by the Pharmacovigilance Risk	
			Assessment Committee; the	
			remuneration shall be EUR 17	
			800 <u>21 400</u> for the rapporteur.	
248	15.3. Where the obligation to conduct a		15.3. Where the obligation to	
	post-authorisation safety study is imposed		conduct a post-authorisation	
	by the Commission on more than one		safety study is imposed by the	
	marketing authorisation holder, the same		Commission on more than one	
	concerns apply to more than one medicinal		marketing authorisation holder,	
	product and the marketing authorisation		the same concerns apply to more	
	holders concerned conduct a joint post-		than one medicinal product and	
	authorisation safety study, the Agency shall		the marketing authorisation	

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				comments
	calculate the amount payable by each		holders concerned conduct a	
	marketing authorisation holder in two steps,		joint post-authorisation safety	
	as follows:		study, the Agency shall calculate	
			the amount payable by each	
			marketing authorisation holder	
			in two steps, as follows:	
249	(a) by evenly dividing the total amount of		(a) by evenly dividing the total	
	the fee among those marketing authorisation		amount of the fee among those	
	holders;		marketing authorisation holders;	
250	(b) by subsequently applying the fee		(b) by subsequently applying the	
	reduction as set out in point 1 of Annex V,		fee reduction as set out in point	
	where relevant.		1 of Annex V, where relevant.	
250a			15.4 Marketing authorisation	
			holders who are charged the	
			fee under this point shall be	
			exempted from the payment of	
			any other fee charged by the	

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				proposals and
				comments
			Agency or competent	
			authorities of the Member	
			State for the submission of the	
			studies referred to in	
			paragraph 15.1.	
251	ANNEX II		ANNEX II	
	Fees, charges and remuneration for		Fees, charges and remuneration	
	assessment procedures and services relating		for assessment procedures and	
	to veterinary medicinal products		services relating to veterinary	
			medicinal products	
252	Scientific advice in accordance with		Scientific advice in	
	Article 57(1)(n) of Regulation (EC) No		accordance with Article 57(1)(n)	
	726/2004		of Regulation (EC) No 726/2004	
253	1.1. A fee of EUR 33 100 shall apply to		1.1. A fee of EUR 33 100-34	
	any of the following requests:		900 shall apply to any of the	
			following requests:	
254	(a) a request on quality, safety and clinical		(a) a request on quality, safety	

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				comments
	development;		and clinical development;	
255	(b) a request on quality and clinical		(b) a request on quality and	
	development;		clinical development;	
256	(c) a request on safety and clinical		(c) a request on safety and	
	development;		clinical development;	
257	The remuneration shall be EUR 15 800 for		The remuneration shall be	
	the scientific advice co-ordinator.		EUR 15 800 16 700 for the	
			scientific advice co-ordinator.	
258	1.2. A fee of EUR 24 300 shall apply to any		1.2. A fee of EUR 24 300	
	of the following requests:		25 600 shall apply to any of the	
			following requests:	
259	(a) a request on clinical development;		(a) a request on clinical	
			development;	
260	(b) a request on quality and safety		(b) a request on quality and	
	development;		safety development;	
261	(c) a request on quality and bioequivalence		(c) a request on quality	
	studies for generic veterinary medicinal		development and	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
	products as defined in Article 4(9) of (EU)		bioequivalence studies for	
	2019/6.		generic veterinary medicinal	
			products as defined in Article	
			4(9) of Regulation (EU) 2019/6.	
262	The remuneration shall be EUR 10 100 for		The remuneration shall be EUR	
	the scientific advice co-ordinator.		10 100 10 600 for the scientific	
			advice co-ordinator.	
263	1.3. A fee of EUR 21 300 shall apply to a		1.3. A fee of EUR 21 300-22	
	request related to any of the following:		500 shall apply to a request	
			related to any of the following:	
264	(a) a request on quality development;		(a) a request on quality	
			development;	
265	(b) a request on safety development;		(b) a request on safety	
			development;	
266	(c) a request on bioequivalence studies for		(c) a request on bioequivalence	
	generic veterinary medicinal products as		studies for generic veterinary	
	defined in Article 4(9) of (EU) 2019/6;		medicinal products as defined in	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			Article 4(9) of Regulation (EU)	
			2019/6;	
267	(d) a request for preliminary risk profile;		(d) a request for preliminary risk	
			profile;	
268	(e) a request related to setting a new		(e) a request related to setting a	
	maximum residue limit.		new maximum residue limit.	
269	The remuneration shall be EUR 6 100 for		The remuneration shall be EUR	
	the scientific advice co-ordinator.		6-100-6-400 for the scientific	
			advice co-ordinator.	
270	2. Request for classification of a		2. Request for classification	
	veterinary medicinal product as intended for		of a veterinary medicinal	
	a limited market as defined in Article 4,		product as intended for a limited	
	point (29), of Regulation (EU) 2019/6 and		market as defined in Article 4,	
	for consideration for eligibility for		point (29), of Regulation (EU)	
	authorisation in accordance with Article 23		2019/6 and for consideration for	
	of that Regulation		eligibility for authorisation in	
			accordance with Article 23 of	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			that Regulation	
271	A charge of EUR 5 200 shall apply to a		A charge of EUR 5 200 5 500	
	request for classification of a veterinary		shall apply to a request for	
	medicinal product as intended for a limited		classification of a veterinary	
	market within the meaning of Article 4(29)		medicinal product as intended	
	of Regulation (EU) 2019/6 and for		for a limited market within the	
	consideration for eligibility for authorisation		meaning of Article 4(29) of	
	pursuant to Article 23 of Regulation (EU)		Regulation (EU) 2019/6 and for	
	2019/6.		consideration for eligibility for	
			authorisation pursuant to Article	
			23 of Regulation (EU) 2019/6.	
272	3. Establishment, modification or		3. Establishment,	
	extension of a maximum residue limit		modification or extension of a	
	(MRL) in accordance with the procedure		maximum residue limit (MRL)	
	laid down in Regulation (EC) No 470/2009		in accordance with the procedure	
	of the European Parliament and of the		laid down in Regulation (EC)	
	Council ⁶¹		No 470/2009 of the European	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			Parliament and of the Council ⁶²	
	61 Regulation (EC) No 470/2009 of the European			
	Parliament and of the Council of 6 May 2009 laying		⁶² Regulation (EC) No 470/2009 of the	
	down Community procedures for the establishment of		European Parliament and of the	
	residue limits of pharmacologically active substances		Council of 6 May 2009 laying down	
	in foodstuffs of animal origin, repealing Council		Community procedures for the	
	Regulation (EEC) No 2377/90 and amending		establishment of residue limits of	
	Directive 2001/82/EC of the European Parliament		pharmacologically active substances in	
	and of the Council and Regulation (EC) No 726/2004		foodstuffs of animal origin, repealing	
	of the European Parliament and of the Council (OJ L		Council Regulation (EEC) No 2377/90	
	152, 16.6.2009, p. 11).		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		3.1. A fee of EUR 84 700 89	
	application to set an initial MRL for a given		300 shall apply to an application	
	substance. The remuneration shall be EUR		to set an initial MRL for a given	
	21 400 for the rapporteur and EUR 10 300		substance. The remuneration	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	for the co-rapporteur.		shall be EUR 21 400 22 600 for	
			the rapporteur and EUR 10 300	
			10 900 for the co-rapporteur.	
274	3.2. A fee of EUR 53 000 shall apply to each		3.2. A fee of EUR 53 000	
	application to modify or to extend an		55 900 shall apply to each	
	existing MRL. The remuneration shall be		application to modify or to	
	EUR 10 600 for the rapporteur and EUR 9		extend an existing MRL. The	
	700 for the co-rapporteur.		remuneration shall be EUR 10	
			600-11 200 for the rapporteur	
			and EUR 9-700-10 200 for the	
			co-rapporteur.	
275	3.3. A fee of EUR 24 300 shall apply to the		3.3. A fee of EUR 24 300 <u>25</u>	
	assessment to determine whether a		600 shall apply to the	
	chemical-unlike biological substance		assessment to determine whether	
	requires a full MRL evaluation or not		a chemical-unlike biological	
	pursuant to Annex I, Section 1.7, to		substance requires a full MRL	
	Commission Regulation (EU) 2018/782 ⁶³ .		evaluation or not pursuant to	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	The remuneration shall be EUR 10 100 for		Annex I, Section <u>I</u> 1.7, to	
	the rapporteur.		Commission Regulation (EU)	
			2018/782 ⁶⁴ . The remuneration	
	⁶³ Commission Regulation (EU) 2018/782 of 29 May		shall be EUR <u>10 100 10 600</u> for	
	2018 establishing the methodological principles for		the rapporteur.	
	the risk assessment and risk management		⁶⁴ Commission Regulation (EU)	
	recommendations referred to in Regulation (EC) No		2018/782 of 29 May 2018 establishing	
	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		4. Authorisation to market	
	medicinal products falling within the scope		veterinary medicinal products	
	of the centralised marketing authorisation		falling within the scope of the	
	procedure pursuant to Article 42 of		centralised marketing	
	Regulation (EU) 2019/6		authorisation procedure pursuant	
			to Article 42 of Regulation (EU)	

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				comments
			2019/6	
277	4.1. A fee of EUR 295 500 shall apply to an		4.1. A fee of EUR 295 500 <u>311</u>	
	application for a marketing authorisation for		500 shall apply to an application	
	a veterinary medicinal product pursuant to		for a marketing authorisation for	
	Articles 8, 23 or Article 25 of Regulation		a veterinary medicinal product	
	(EU) 2019/6 where the applicant claims a		pursuant to Articles 8, 23 or	
	new active substance. That fee shall cover		Article 25 of Regulation (EU)	
	all strengths, all pharmaceutical forms and		2019/6 where the applicant	
	all presentations submitted in the same		claims a new active substance.	
	application, irrespective of the number of		That fee shall cover all strengths,	
	target species. The remuneration shall be		all pharmaceutical forms and all	
	EUR 107 000 for the rapporteur and EUR 38		presentations submitted in the	
	100 for the co-rapporteur.		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	

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				comments
			200 for the co-rapporteur.	
278	4.2. A fee of EUR 267 700 shall apply to an		4.2. A fee of EUR 267 700 282	
	application for a marketing authorisation for		200 shall apply to an application	
	a veterinary medicinal product pursuant to		for a marketing authorisation for	
	Articles 8, 20, 22, 23 or Article 25 of		a veterinary medicinal product	
	Regulation (EU) 2019/6 where the applicant		pursuant to Articles 8, 20, 22, 23	
	claims a known active substance. That fee		or Article 25 of Regulation (EU)	
	shall cover all strengths, all pharmaceutical		2019/6 where the applicant	
	forms and all presentations submitted in the		claims a known active	
	same application, irrespective of the number		substance. That fee shall cover	
	of target species. The remuneration shall be		all strengths, all pharmaceutical	
	EUR 82 100 for the rapporteur and EUR 35		forms and all presentations	
	300 for the co-rapporteur.		submitted in the same	
			application, irrespective of the	
			number of target species. The	
			remuneration shall be EUR 82	
			100-86 500 for the rapporteur	

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				comments
			and EUR 35 300 37 200 for the	
			co-rapporteur.	
279	4.3. A fee of EUR 136 800 shall apply for		4.3. A fee of EUR 136 800 <u>144</u>	
	any of the following applications:		200 shall apply for any of the	
			following applications:	
280	(a) an application for a marketing		(a) an application for a	
	authorisation for a generic veterinary		marketing authorisation for a	
	medicinal product pursuant to Article 18 of		generic veterinary medicinal	
	Regulation (EU) 2019/6;		product pursuant to Article 18 of	
			Regulation (EU) 2019/6;	
281	(b) an application for a marketing		(b) an application for a	
	authorisation for a hybrid veterinary		marketing authorisation for a	
	medicinal product pursuant to Article 19 of		hybrid veterinary medicinal	
	Regulation (EU) 2019/6;		product pursuant to Article 19 of	
			Regulation (EU) 2019/6;	
282	(c) an application based on informed consent		(c) an application based on	
	for a marketing authorisation for a		informed consent for a	

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				comments
	veterinary medicinal product pursuant to		marketing authorisation for a	
	Article 21 of Regulation (EU) 2019/6.		veterinary medicinal product	
			pursuant to Article 21 of	
			Regulation (EU) 2019/6.	
283	That fee shall cover all strengths, all		That fee shall cover all strengths,	
	pharmaceutical forms and all presentations		all pharmaceutical forms and all	
	submitted in the same application,		presentations submitted in the	
	irrespective of the number of target species.		same application, irrespective of	
	The remuneration shall be EUR 30 800 for		the number of target species.	
	the rapporteur and EUR 17 900 for the co-		The remuneration shall be EUR	
	rapporteur.		30 800 32 500 for the rapporteur	
			and EUR <u>17 900 18 900</u> for the	
			co-rapporteur.	
284	5. Re-examination of a marketing		5. Re-examination of a	
	authorisation for limited markets		marketing authorisation for	
			limited markets	
285	A fee of EUR 19 000 shall apply to an		A fee of EUR 19 000- 20 000	

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				comments
	application for a re-examination of a		shall apply to an application for	
	marketing authorisation for a limited market		a re-examination of a marketing	
	pursuant to Article 24(3) of Regulation (EU)		authorisation for a limited	
	2019/6. The remuneration shall be EUR 3		market pursuant to Article 24(3)	
	100 for the rapporteur and EUR 2 400 for		of Regulation (EU) 2019/6. The	
	the co-rapporteur.		remuneration shall be EUR 3	
			100-3 300 for the rapporteur and	
			EUR 2-400-2 500 for the co-	
			rapporteur.	
286	6. Variations to the terms of a marketing		6. Variations to the terms of	
	authorisation, requiring assessment in		a marketing authorisation,	
	accordance with Articles 64, 65 and 66 of		requiring assessment in	
	Regulation (EU) 2019/6		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		6.1. A fee of EUR 87 800- 92	
	variation requiring assessment introducing		600 shall apply to a variation	

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				comments
	changes of active substance(s), strength,		requiring assessment introducing	
	pharmaceutical form, route of administration		changes of active substance(s),	
	or food-producing target species, which are		strength, pharmaceutical form,	
	to be assessed within 90 days in accordance		route of administration or food-	
	with Article 66(3) of Regulation (EU)		producing target species, which	
	2019/6. That fee shall be charged for each		are to be assessed within 90 days	
	single pharmaceutical form or each single		in accordance with Article 66(3)	
	associated strength/potency. The		of Regulation (EU) 2019/6. That	
	remuneration shall be EUR 28 600 for the		fee shall be charged for each	
	rapporteur and EUR 8 600 for the co-		single pharmaceutical form or	
	rapporteur.		each single associated	
			strength/potency. The	
			remuneration shall be EUR 28	
			600-30 100 for the rapporteur	
			and EUR <u>8 600 9 100</u> for the co-	
			rapporteur.	
288	6.2. A fee of EUR 47 500 shall apply to		6.2. A fee of EUR 4 7 500 50	

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				comments
	variations requiring assessment that		100 shall apply to variations	
	introduce changes to safety, efficacy or		requiring assessment that	
	pharmacovigilance, which are to be assessed		introduce changes to safety,	
	within 60 or 90 days, as the case may be, in		efficacy or pharmacovigilance,	
	accordance with Article 66(3) of Regulation		which are to be assessed within	
	(EU) 2019/6. The remuneration shall be		60 or 90 days, as the case may	
	EUR 9 800 for the rapporteur and EUR 7		be, in accordance with Article	
	600 for the co-rapporteur.		66(3) of Regulation (EU)	
			2019/6. The remuneration shall	
			be EUR 9-800-10 300 for the	
			rapporteur and EUR 7 600 8 000	
			for the co-rapporteur.	
289	6.3. A fee of EUR 23 900 shall apply to		6.3. A fee of EUR 23 900 25	
	variations requiring assessment introducing		200 shall apply to variations	
	quality changes only, which are to be		requiring assessment introducing	
	assessed within 60 days in accordance with		quality changes only, which are	
	Article 66(3) of Regulation (EU) 2019/6.		to be assessed within 60 days in	

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				comments
	The remuneration shall be EUR 3 600 for		accordance with Article 66(3) of	
	the rapporteur and EUR 3 600 for the co-		Regulation (EU) 2019/6. The	
	rapporteur.		remuneration shall be EUR 3	
			600-3 800 for the rapporteur and	
			EUR <u>3 600-3 800</u> for the co-	
			rapporteur.	
290	6.4. Where several variations requiring		6.4. Where several variations	
	assessment are grouped in a single		requiring assessment are	
	application under Article 64 of Regulation		grouped in a single application	
	(EU) 2019/6, the corresponding fee as set		under Article 64 of Regulation	
	out in points 6.1, 6.2 and 6.3 of this Annex		(EU) 2019/6, the corresponding	
	shall apply to each of the first two		fee as set out in points 6.1, 6.2	
	variations. Remuneration shall be paid in		and 6.3 of this Annex shall apply	
	accordance with those points. For the third		to each of the first two	
	and subsequent variations, the fee shall be		variations. Remuneration shall	
	EUR 12 000 per variation and the		be paid in accordance with those	
	remuneration shall be EUR 1 800 per		points. For the third and	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
	variation for the rapporteur and EUR 1 800		subsequent variations, the fee	
	for the co-rapporteur.		shall be EUR 12 000 12 600 per	
			variation and the remuneration	
			shall be EUR <u>1 800 1 900</u> per	
			variation for the rapporteur and	
			EUR <u>1-800-<u>1</u> 900 for the co-</u>	
			rapporteur.	
291	6.5. Where a work-sharing application		6.5. Where a work-sharing	
	pursuant to Article 65 of Regulation (EU)		application pursuant to Article	
	2019/6 includes more than one centrally		65 of Regulation (EU) 2019/6	
	authorised product, the fees and		includes more than one centrally	
	remuneration specified in points 6.1, 6.2 and		authorised product, the fees and	
	6.3 of this Annex shall apply for each		remuneration specified in points	
	variation to the first centrally authorised		6.1, 6.2 and 6.3 of this Annex	
	product, whereas a charge of EUR 800 shall		shall apply for each variation to	
	apply for each variation to the second and		the first centrally authorised	
	subsequent centrally authorised product		product, whereas a charge of	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	included in the same application.		EUR 800 shall apply for each	
			variation to the second and	
			subsequent centrally authorised	
			product included in the same	
			application.	
292	7. Referrals and arbitration procedures		7. Referrals and arbitration procedures	
293	7.1. A fee of EUR 152 700 shall apply to an	7.1. A fee of EUR 152 700 shall	7.1. A fee of EUR 152	
	assessment carried out in the context of a	apply to an assessment carried out	700 161 000 shall apply to an	
	procedure initiated under Article 54(8) of	in the context of a procedure	assessment carried out in the	
	Regulation (EU) 2019/6. Such fee shall be	initiated under Article 54(8) of	context of a procedure initiated	
	waived in full. The remuneration shall be	Regulation (EU) 2019/6. Such fee	under Article 54(8) of	
	EUR 21 100 for the rapporteur and EUR 9	shall be waived in full. The	Regulation (EU) 2019/6. Such	
	600 for the co-rapporteur.	remuneration shall be EUR 10	fee shall be waived in full. The	
		550 for the rapporteur and EUR 4	remuneration shall be EUR 21	
		800 for the co-rapporteur.	100-22 200 for the rapporteur	
			and EUR 9-600-10 100 for the	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			co-rapporteur.	
294	7.2. A fee of EUR 209 300 shall apply to the	7.2. A fee of EUR 209 300 shall	7.2. A fee of EUR 209 300 220	
	assessment carried out in the context of a	apply to the assessment carried	600 shall apply to the	
	procedure initiated under Article 70(11) of	out in the context of a procedure	assessment carried out in the	
	Regulation (EU) 2019/6. Such fee shall be	initiated under Article 70(11) of	context of a procedure initiated	
	waived in full. The remuneration shall be	Regulation (EU) 2019/6. Such fee	under Article 70(11) of	
	EUR 29 200 for the rapporteur and EUR 12	shall be waived in full. The	Regulation (EU) 2019/6. Such	
	900 for the co-rapporteur.	remuneration shall be EUR 14	fee shall be waived in full. The	
		600 for the rapporteur and EUR 6	remuneration shall be EUR 29	
		450 for the co-rapporteur.	200-30 800 for the rapporteur	
			and EUR 12 900 <u>13 600</u> for the	
			co-rapporteur.	
295	7.3. A fee of EUR 147 200 shall apply to the	7.3. A fee of EUR 147 200 shall	7.3. A fee of EUR 147 200 155	
	assessment carried out pursuant to Article	apply to the assessment carried	200 shall apply to the	
	141(1), points (c) and (e), of Regulation	out pursuant to Article 141(1),	assessment carried out pursuant	
	(EU) 2019/6. Such fee shall be waived in	points (c) and (e), of Regulation	to Article 141(1), points (c) and	
	full. The remuneration shall be EUR 17 500	(EU) 2019/6. Such fee shall be	(e), of Regulation (EU) 2019/6.	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	for the rapporteur and EUR 7 700 for the co-	waived in full. The remuneration	Such fee shall be waived in full.	
	rapporteur.	shall be EUR 8 750 for the	The remuneration shall be EUR	
		rapporteur and EUR 3 850 for the	17 500 18 400 for the rapporteur	
		co-rapporteur.	and EUR 7.700 <u>8 100</u> for the co-	
			rapporteur.	
296	7.4. A fee of EUR 209 300 shall apply to the		7.4. A fee of EUR 209 300 220	
	assessment carried out in the context of a		600 shall apply to the	
	procedure initiated under Article 82 of		assessment carried out in the	
	Regulation (EU) 2019/6. The remuneration		context of a procedure initiated	
	shall be EUR 29 200 for the rapporteur and		under Article 82 of Regulation	
	EUR 12 900 for the co-rapporteur.		(EU) 2019/6. The remuneration	
			shall be EUR 29 200 30 800 for	
			the rapporteur and EUR 12 900	
			13 600 for the co-rapporteur.	
297	7.5. A fee of EUR 147 200 shall apply for		7.5. A fee of EUR 147 200-155	
	the assessment carried out in the context of a		200 shall apply for the	
	procedure initiated under Article 129(3) or		assessment carried out in the	

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				proposals and
				comments
	Article 130(4) of Regulation (EU) 2019/6.		context of a procedure initiated	
	The remuneration shall be EUR 17 500 for		under Article 129(3) or Article	
	the rapporteur and EUR 7 700 for the co-		130(4) of Regulation (EU)	
	rapporteur.		2019/6. The remuneration shall	
			be EUR 17 500 18 400 for the	
			rapporteur and EUR 7 700 8 100	
			for the co-rapporteur.	
298	7.6. Where two or more marketing		7.6. Where two or more	
	authorisation holders are involved in the		marketing authorisation holders	
	procedures referred to in points 7.4 or 7.5,		are involved in the procedures	
	the amount payable by each marketing		referred to in points 7.4 or 7.5,	
	authorisation holder shall be calculated by		the amount payable by each	
	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		(a) by dividing the total amount	
	among the marketing authorisation holders		of the fee among the marketing	

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				comments
	proportionally to the number of chargeable		authorisation holders	
	units – veterinary corresponding to products		proportionally to the number of	
	included in the procedure which are held by		chargeable units – veterinary	
	each of those marketing authorisation		corresponding to products	
	holders;		included in the procedure which	
			are held by each of those	
			marketing authorisation holders;	
300	(b) by subsequently applying the fee		(b) by subsequently applying the	
	reduction laid down in point 1 of Annex V,		fee reduction laid down in point	
	where relevant.		1 of Annex V, where relevant.	
301	8. Certification of compliance with		8. Certification of	
	Union legislation for vaccine antigen master		compliance with Union	
	files (VAMF)		legislation for vaccine antigen	
			master files (VAMF)	
302	8.1. A fee of EUR 23 900 shall apply to an		8.1. A fee of EUR 23 900	
	application for review of a VAMF and its		25 200 shall apply to an	
	certification pursuant to point V.2 of Annex		application for review of a	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	II to Regulation (EU) 2019/6 when it is		VAMF and its certification	
	submitted simultaneously with an initial		pursuant to point V.2 of Annex	
	application for marketing authorisation for a		II to Regulation (EU) 2019/6	
	veterinary medicinal product under the		when it is submitted	
	centralised procedure containing the named		simultaneously with an initial	
	antigen. The remuneration shall be EUR 3		application for marketing	
	600 for the rapporteur and EUR 3 600 for		authorisation for a veterinary	
	the co-rapporteur.		medicinal product under the	
			centralised procedure containing	
			the named antigen. The	
			remuneration shall be EUR 3	
			600-3 800 for the rapporteur and	
			EUR 3 600 3 800 for the co-	
			rapporteur.	
303	8.2. For multiple VAMF applications		8.2. For multiple VAMF	
	submitted simultaneously in the context of		applications submitted	
	the same initial marketing authorisation		simultaneously in the context of	

Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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			proposals and
			comments
application, a fee of EUR 23 900 shall apply		the same initial marketing	
per VAMF. The maximum total amount		authorisation application, a fee	
charged by the Agency shall not exceed		of EUR 23 900 25 200 shall	
EUR 71 700. The remuneration shall be		apply per VAMF. The maximum	
EUR 3 600 for the rapporteur and EUR 3		total amount charged by the	
600 for the co-rapporteur. For multiple		Agency shall not exceed EUR	
VAMF applications submitted		71 700 74 800 . The	
simultaneously in the context of the same		remuneration shall be EUR 3	
initial marketing authorisation application,		600-3 800 for the rapporteur and	
the remuneration shall not exceed EUR 10		EUR 3 600 3 800 for the co-	
800 for the rapporteur and EUR 10 800 for		rapporteur. For multiple VAMF	
the co-rapporteur.		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	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			rapporteur and EUR 10 800 11	
			400 for the co-rapporteur.	
304	8.3. A fee of EUR 33 100 shall apply to an		8.3. A fee of EUR 33 100 <u>34</u>	
	application for the review of a VAMF and		900 shall apply to an application	
	its certification when submitted as a separate		for the review of a VAMF and	
	application for an antigen in vaccine(s)		its certification when submitted	
	already authorised under the centralised,		as a separate application for an	
	decentralised or mutual recognition		antigen in vaccine(s) already	
	procedure. The remuneration shall be EUR 5		authorised under the centralised,	
	000 for the rapporteur and EUR 5 000 for		decentralised or mutual	
	the co-rapporteur.		recognition procedure. The	
			remuneration shall be EUR 5	
			000-5 300 for the rapporteur and	
			EUR <u>5 000 <u>5</u> 300 for the co-</u>	
			rapporteur.	
305	8.4. Section 6 [of this Annex] shall apply by		8.4. Section 6 [of this Annex]	
	analogy to variations to a certified VAMF.		shall apply by analogy to	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			variations to a certified VAMF.	
306	9. Certification of compliance with		9. Certification of	
	Union legislation for vaccine platform		compliance with Union	
	technology master files (vPTMF)		legislation for vaccine platform	
			technology master files	
			(vPTMF)	
307	9.1. A fee of EUR 23 900 shall apply to an		9.1. A fee of EUR 23 900 25	
	application for review of a vPTMF and its		200 shall apply to an application	
	certification pursuant to point V.4 of Annex		for review of a vPTMF and its	
	II to Regulation (EU) 2019/6 when		certification pursuant to point	
	submitted simultaneously with an initial		V.4 of Annex II to Regulation	
	application for marketing authorisation for a		(EU) 2019/6 when submitted	
	veterinary medicinal product under the		simultaneously with an initial	
	centralised procedure containing the named		application for marketing	
	platform. The remuneration shall be EUR 3		authorisation for a veterinary	
	600 for the rapporteur and EUR 3 600 for		medicinal product under the	
	the co-rapporteur.		centralised procedure containing	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
		July 2023	13 June 2023	text, compromise
				proposals and
				comments
			the named platform. The	
			remuneration shall be EUR 3	
			600-3 800 for the rapporteur and	
			EUR 3-600-3-800 for the co-	
			rapporteur.	
308	9.2. A fee of EUR 33 100 shall apply to an		9.2. A fee of EUR 33 100 <u>34</u>	
	application for review of a vPTMF and its		900 shall apply to an application	
	certification when submitted as a separate		for review of a vPTMF and its	
	application for a platform in vaccines		certification when submitted as a	
	already authorised under the centralised,		separate application for a	
	decentralised or mutual recognition		platform in vaccines already	
	procedure. The remuneration shall be EUR 5		authorised under the centralised,	
	000 for the rapporteur and EUR 5 000 for		decentralised or mutual	
	the co-rapporteur.		recognition procedure. The	
			remuneration shall be EUR 5	
			000- <u>5</u> 300 for the rapporteur and	
			EUR <u>5 000-5 300</u> for the co-	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			rapporteur.	
309	9.3. Section 6 of this Annex shall apply by		9.3. Section 6 of this Annex	
	analogy to variations to a certified vPTMF.		shall apply by analogy to	
			variations to a certified vPTMF.	
310	10. Assessment of post-marketing		10. Assessment of post-	
	surveillance studies		marketing surveillance studies	
311	10.1. A fee of EUR 37 800 shall apply to the		10.1. A fee of EUR 37 800	
	assessment of post-marketing surveillance		39 800 shall apply to the	
	studies pursuant to Article 76(3) of		assessment of post-marketing	
	Regulation (EU) 2019/6 that are conducted		surveillance studies pursuant to	
	in more than one Member States.		Article 76(3) of Regulation (EU)	
			2019/6 that are conducted in	
			more than one Member States.	
312	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		(a) EUR 18 900 19 900 shall	
	the start of the procedure for the approval of		be due at the date of the start of	

Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
	July 2023	13 June 2023	text, compromise
			proposals and
			comments
the draft study protocol as referred to in		the procedure for the approval of	
Article 15(3) of Commission Implementing		the draft study protocol as	
Regulation (EU) 2021/1281 ⁶⁵ . The		referred to in Article 15(3) of	
remuneration shall be EUR 7 700 for the		Commission Implementing	
rapporteur;		Regulation (EU) 2021/1281 ⁶⁶ .	
		The remuneration shall be EUR	
⁶⁵ Commission Implementing Regulation (EU)		7 700 <u>8 100</u> for the rapporteur;	
2021/1281 of 2 August 2021 laying down rules for			
the application of Regulation (EU) 2019/6 of the		⁶⁶ Commission Implementing	
European Parliament and of the Council as regards		Regulation (EU) 2021/1281 of 2	
good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance		August 2021 laying down rules for the	
system master file for veterinary medicinal products		application of Regulation (EU) 2019/6	
(OJ L 279, 3.8.2021, p. 15).		of the European Parliament and of the	
(1)		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).	

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

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			marketing surveillance study,	
			the Agency shall calculate the	
			fee to be charged in two steps, as	
			follows:	
316	(a) by evenly dividing the total amount of		(a) by evenly dividing the	
	the fee among those marketing authorisation		total amount of the fee among	
	holders;		those marketing authorisation	
			holders;	
317	(b) by subsequently applying the fee		(b) by subsequently applying	
	reduction as set out in Annex V, point 1,		the fee reduction as set out in	
	where relevant.		Annex V, point 1, where	
			relevant.	
318	11. Scientific opinions in the context of		11. Scientific opinions in the	
	cooperation with international organisations		context of cooperation with	
	for animal health for the evaluation of		international organisations for	
	veterinary medicinal products intended		animal health for the evaluation	
	exclusively for markets outside the Union		of veterinary medicinal products	

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

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

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

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	covered by point 1.1 or 1.2. The		medicinal product for human use	
	remuneration shall be EUR 25 700 for the		not covered by point 1.1 or 1.2.	
	rapporteur and EUR 22 700 for the co-		The remuneration shall be	
	rapporteur.		EUR <u>25 700 30 800</u> for the	
			rapporteur and EUR 22 700	
			27 200 for the co-rapporteur and	
			EUR 5 800 for the PRAC-	
			rapporteur.	
			1.3a. The annual fees as	
			specified in points 1.1, 1.2 and	
			1.3 shall relate to the	
			preceding year.	
325	2. Annual fee for veterinary medicinal		2. Annual fee for veterinary	
	products authorised through the centralised		medicinal products authorised	
	procedure in accordance with Regulation		through the centralised	
	(EU) 2019/6		procedure in accordance with	
			Regulation (EU) 2019/6	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
326	2.1. An annual fee of EUR 21 500 for shall		2.1. An annual fee of EUR 21	
	apply for each marketing authorisation of a		500 <u>25 000</u> for shall apply for	
	veterinary medicinal product authorised		each marketing authorisation of	
	pursuant to Article 18, 19 or 21 of		a veterinary medicinal product	
	Regulation (EU) 2019/6. The remuneration		authorised pursuant to Article	
	shall be EUR 5 000 for the rapporteur and		18, 19 or 21 of Regulation (EU)	
	EUR 4 600 for the co-rapporteur.		2019/6. The remuneration shall	
			be EUR 5 000 for the	
			rapporteur and EUR 4-600 <u>5 500</u>	
			for the co-rapporteur.	
327	2.2. An annual fee of EUR 87 500 shall		2.2 An annual fee of EUR 87	
	apply to each marketing authorisation not		500 <u>101 800</u> shall apply to each	
	covered by point 2.1. The remuneration shall		marketing authorisation not	
	be EUR 20 400 for the rapporteur and EUR		covered by point 2.1. The	
	18 800 for the co-rapporteur.		remuneration shall be EUR 20	
			400 <u>24 500</u> for the rapporteur and	
			EUR <u>18-800</u> for the co-	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			rapporteur.	
327a			2.2a. The annual fees as	
			specified in points 2.1 and 2.2	
			shall relate to the preceding	
			<u>year.</u>	
328	3. Annual pharmacovigilance fee for		3. Annual pharmacovigilance	
	medicinal products for human use authorised		fee for medicinal products for	
	in accordance with Directive 2001/83/EC		human use authorised in	
	and for veterinary medicinal products		accordance with Directive	
	authorised by competent authorities of the		2001/83/EC and for veterinary	
	Member States in accordance with		medicinal products authorised	
	Regulation (EU) 2019/6		by competent authorities of the	
			Member States in accordance	
			with Regulation (EU) 2019/6	
329	3.1. For medicinal products for human use		3.1. For medicinal products for	
	authorised in accordance with Directive		human use authorised in	
	2001/83/EC, a fee of EUR 190 per		accordance with Directive	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	chargeable unit-human, shall apply once per		2001/83/EC, a fee of EUR 190	
	year for the Agency's pharmacovigilance		220 per chargeable unit-human,	
	activities including analysis of Union-wide		shall apply once per year for the	
	health data to support better decision-		Agency's pharmacovigilance	
	making with real world evidence. The		activities including analysis of	
	Agency shall retain the fee revenue from the		Union-wide health data to	
	annual pharmacovigilance fee.		support better decision-making	
			with real world evidence. The	
			Agency shall retain the fee	
			revenue from the annual	
			pharmacovigilance fee.	
330	3.2. For veterinary medicinal products		3.2 For veterinary medicinal	
	authorised by competent authorities of the		products authorised by	
	Member States in accordance with Chapter		competent authorities of the	
	III, Sections 2 to 5 of Regulation (EU)		Member States in accordance	
	2019/6, a fee of EUR 80 per chargeable unit-		with Chapter III, Sections 2 to 5	
	veterinary shall apply once per year for the		of Regulation (EU) 2019/6, a fee	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	Agency's pharmacovigilance activities. The		of EUR 80-90 per chargeable	
	Agency shall retain the fee revenue from the		unit-veterinary shall apply once	
	annual pharmacovigilance fee.		per year for the Agency's	
			pharmacovigilance activities.	
			The Agency shall retain the fee	
			revenue from the annual	
			pharmacovigilance fee.	
331	3.3 The total payable amount of the annual		3.3 The total payable amount	
	fees referred to in points 3.1 and 3.2 for each		of the annual fees referred to in	
	marketing authorisation holder shall be		points 3.1 and 3.2 for each	
	calculated by the Agency on the basis of the		marketing authorisation holder	
	number of chargeable units-human and		shall be calculated by the	
	chargeable units-veterinary, respectively,		Agency on the basis of the	
	which correspond to the information		number of chargeable units-	
	recorded on 1 July of each year.		human and chargeable units-	
			veterinary, respectively, which	
			correspond to the information	

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				comments
			recorded on 1 July of each year.	
332	3.4. The annual fees referred to in points		3.4. The annual fees referred to	
	3.1 and 3.2 shall be due on 1 July of every		in points 3.1 and 3.2 shall be due	
	year and shall cover the period from 1		on 1 July of every year and shall	
	January to 31 December of that calendar		cover the period from 1 January	
	year.		to 31 December of that calendar	
			year.	
333	ANNEX IV		ANNEX IV	
	Other fees and charges for medicinal		Other fees and charges for	
	products for human use, veterinary		medicinal products for human	
	medicinal products and consultations on		use, veterinary medicinal	
	medical devices		products and consultations on	
			medical devices	
334	1. Inspections pursuant to Article 8(2), 19		1. Inspections pursuant to	
	and Article 57(1), point (i) of Regulation		Article 8(2), 19 and Article	
	(EC) No 726/2004		57(1), point (i) of Regulation	
			(EC) No 726/2004 and Article	

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				comments
			126(2) of Regulation No 2019/6	
335	1.1. Inspections in relation to medicinal		1.1. Inspections in relation to	
	products for human use and veterinary		medicinal products for human	
	medicinal products		use and veterinary medicinal	
			products	
336	1.1.1. For any distinct Good Manufacturing		1.1.1. For any distinct Good	
	Practice inspection within the Union a fee of		Manufacturing Practice	
	EUR 24 800 shall apply. The remuneration		inspection within the Union a	
	shall be EUR 8 600 for the leading		fee of EUR 24 800 29 000 shall	
	supervisory authority and EUR 5 200 for the		apply. The remuneration shall be	
	supporting supervisory authority.		EUR <u>8 600</u> 10 300 for the	
			leading supervisory authority	
			and EUR 5 2006 200 for the	
			supporting supervisory	
			authority.	
337	1.1.2. For any distinct Good Manufacturing		1.1.2. For any distinct Good	
	Practice inspection outside the Union a fee		Manufacturing Practice	

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	of EUR 37 800 shall apply. The		inspection outside the Union a	
	remuneration shall be EUR 15 600 for the		fee of EUR 37_800-56 000 shall	
	leading supervisory authority and EUR 9		apply. The remuneration shall be	
	400 for the supporting supervisory authority.		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		1.1.3. For any distinct Good	
	Practice inspection within the Union a fee of		Clinical Practice inspection	
	EUR 37 100 shall apply. The remuneration		within the Union a fee of EUR	
	shall be EUR 14 700 for the leading		37 10043 700 shall apply. The	
	supervisory authority and EUR 9 100 for the		remuneration shall be EUR 14	
	supporting supervisory authority.		700 <u>17 600</u> for the leading	
			supervisory authority and EUR 9	
			100 <u>10 900</u> for the supporting	
			supervisory authority.	

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				comments
339	1.1.4. For any distinct Good Clinical		1.1.4. For any distinct Good	
	Practice inspection outside the Union a fee		Clinical Practice inspection	
	of EUR 44 200 shall apply. The		outside the Union a fee of EUR	
	remuneration shall be EUR 19 600 for the		44 200 <u>56 600</u> shall apply. The	
	leading supervisory authority and EUR 10		remuneration shall be EUR 19	
	400 for the supporting supervisory authority.		600-25 800 for the leading	
			supervisory authority and EUR	
			10_400_14 700 for the	
			supporting supervisory	
			authority.	
340	1.1.5. For any distinct Plasma Master File		1.1.5. For any distinct Plasma	
	inspection within or outside the Union a fee		Master File inspection within or	
	of EUR 36 100 shall apply. The		outside the Union a fee of EUR	
	remuneration shall be EUR 13 400 for the		36 100 47 300 shall apply. The	
	leading supervisory authority and EUR 8		remuneration shall be EUR-13	
	200 for the supporting supervisory authority.		400 <u>16 700</u> for the leading	
			supervisory authority and EUR 8	

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				comments
			200 - <u>14 100</u> for the supporting	
			supervisory authority.	
341	1.1.6. For any consecutive Plasma Master		1.1.6. For any consecutive	
	File inspection within or outside the Union a		Plasma Master File inspection	
	fee of EUR 36 100 shall apply. The		within or outside the Union a fee	
	remuneration shall be EUR 13 400 for the		of EUR 36 100 <u>42 400</u> shall	
	leading supervisory authority and EUR 8		apply. The remuneration shall be	
	200 for the supporting supervisory authority.		EUR 13 <u>400 16 100</u> 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		1.1.7. For any distinct Good	
	Practice inspection within or outside the		Laboratory Practice inspection	
	Union a fee of EUR 34 900 shall apply. The		within or outside the Union a fee	
	remuneration shall be EUR 13 200 for the		of EUR 34 900 <u>41 000</u> shall	
	leading supervisory authority and EUR 8		apply. The remuneration shall be	

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				proposals and
				comments
	700 for the supporting supervisory authority.		EUR 13 200 15 800 for the	
			leading supervisory authority	
			and EUR <u>8 700</u> 10 400 for the	
			supporting supervisory	
			authority.	
343	1.1.8. For any distinct pharmacovigilance		1.1.8. For any distinct	
	inspection within or outside the Union a fee		pharmacovigilance inspection	
	of EUR 52 700 shall apply. The		within or outside the Union a fee	
	remuneration shall be EUR 16 200 for the		of EUR <u>52 700</u> 61 500 shall	
	leading supervisory authority and EUR 10		apply. The remuneration shall be	
	100 for the supporting supervisory authority.		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		1.2. If a scheduled inspection is	
	30 calendar days or less before the first day		cancelled 30 calendar days or	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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	of the inspection for reasons attributable to		less before the first day of the	
	the applicant, the applicable fee referred to		inspection for reasons	
	in point 1.1 shall apply.		attributable to the applicant, the	
			applicable fee referred to in	
			point 1.1 shall apply.	
345	1.3. If a scheduled inspection is cancelled		1.3. If a scheduled inspection is	
	more than 30 calendar days before the first		cancelled more than 30 calendar	
	day of the inspection, a charge of EUR 840		days before the first day of the	
	shall apply.		inspection for reasons	
			attributable to the applicant, a	
			charge of EUR <u>840-</u> 1 000 shall	
			apply.	
346	1.4. The supervisory authorities shall		1.4. The supervisory	
	charge the applicant the travel expenses		authorities shall charge the	
	separately from the fee specified in this		applicant the travel expenses	
	Annex, based on actual cost. In case of a		separately from the fee specified	
	cancelled inspection as per points 1.2 or 1.3,		in this Annex, based on actual	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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	the applicant shall be charged for any travel		cost. In case of a cancelled	
	expenses already incurred by the inspecting		inspection as per points 1.2 or	
	authority on the date of cancellation for		1.3, the applicant shall be	
	which that authority is not able to obtain		charged for any travel expenses	
	reimbursement.		already incurred by the	
			inspecting authority on 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	
348	A charge of EUR 3 700 shall apply to an		A charge of EUR 3 7004 200	
	application for the transfer of a marketing		shall apply to an application for	
	authorisation pursuant to Article 3 of		the transfer of a marketing	
	Commission Regulation (EC) No 2141/96 ⁶⁷ .		authorisation pursuant to Article	
	This covers all authorised presentations of a		3 of Commission Regulation	
	given medicinal product.		(EC) No 2141/96 ⁶⁸ . This covers	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			all authorised presentations of a	
	⁶⁷ Commission Regulation (EC) No 2141/96 of 7		given medicinal product.	
	November 1996 concerning the examination of an			
	application for the transfer of a marketing		⁶⁸ Commission Regulation (EC) No	
	authorization for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93		2141/96 of 7 November 1996	
	(OJ L 286, 8.11.1996, p. 6).		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).	
349	The charge shall be levied to the marketing		The charge shall be levied to the	
	authorisation holder that requested the		marketing authorisation holder	
	transfer, according to the application		that requested the transfer,	
	submitted to the Agency.		according to the application	
			submitted to the Agency.	
350	3. Pre-submission requests by a		3. Pre-submission requests	
	prospective applicant prior to a potential		by a prospective applicant prior	
	submission of an application for a marketing		to a potential submission of an	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
	authorisation falling within the scope of the		application for a marketing	
	centralised procedure		authorisation falling within the	
			scope of the centralised	
			procedure	
351	3.1. A fee of EUR 7 100 shall apply to each		3.1. A fee of EUR 7 1008 200	
	eligibility request submitted with a		shall apply to each eligibility	
	notification of intention to submit an		request submitted with a	
	application for a marketing authorisation		notification of intention to	
	falling within the scope of Regulation (EC)		submit an application for a	
	No 726/2004 or the scope of the centralised		marketing authorisation falling	
	marketing authorisation procedure pursuant		within the scope of Regulation	
	to Article 42 of Regulation (EU) 2019/6.		(EC) No 726/2004 or the scope	
	The fee shall cover any costs related to pre-		of the centralised marketing	
	submission activities up until the potential		authorisation procedure pursuant	
	submission of the marketing authorisation		to Article 42 of Regulation (EU)	
	application. The fee shall apply irrespective		2019/6. The fee shall cover any	
	of whether or not a marketing authorisation		costs related to pre-submission	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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	application for the concerned product is		activities up until the potential	
	subsequently submitted. If an eligibility		submission of the marketing	
	request has not been submitted, the fee shall		authorisation application. The	
	apply in addition to the applicable		fee shall apply irrespective of	
	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		The remuneration of the national	
	authority, where applicable, shall be EUR 1		competent authority, where	
	300 for the rapporteur and EUR 1 300 for		applicable, shall be EUR 1 3001	
	the co-rapporteur.		600 for the rapporteur and EUR	
			1-300 <u>1 600</u> for the co-	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			rapporteur.	
353	3.2. Where the applicant changes the		3.2. Where the applicant	
	intended submission date by more than 60		changes the intended submission	
	days, an additional fee of EUR 3 500 shall		date by more than 60 days, an	
	apply. The additional remuneration of the		additional fee of EUR 3 5004	
	national competent authority, where		<u>000</u> shall apply. The additional	
	applicable, shall be EUR 600 for the		remuneration of the national	
	rapporteur and EUR 600 for the co-		competent authority, where	
	rapporteur.		applicable, shall be EUR 600	
			700 for the rapporteur and EUR	
			600-700 for the co-rapporteur.	
354	4. Re-examination of an opinion of the		4. Re-examination of an	
	Committees referred to in Article 56(1) of		opinion of the Committees	
	Regulation (EC) No 726/2004 and in		referred to in Article 56(1) of	
	Article 139(1) of Regulation (EU) 2019/6		Regulation (EC) No 726/2004	
			and in Article 139(1) of	
			Regulation (EU) 2019/6	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
355	The fee for the re-examination of an opinion		The fee for the re-examination	
	of any of the committees referred to in		of an opinion of any of the	
	Article 56(1) of Regulation (EC)		committees referred to in Article	
	No 726/2004 and in Article 139(1) of		56(1) of Regulation (EC)	
	Regulation (EU) 2019/6 shall be 30% of the		No 726/2004 and in	
	fee applicable to the initial opinion in		Article 139(1) of Regulation	
	accordance with points 3, 4, 5 and 6 of		(EU) 2019/6 shall be 30% of the	
	Annex I and points 3, 4, 6 and 7 of Annex II		fee applicable to the initial	
	to this Regulation. The remuneration to the		opinion in accordance with	
	rapporteur and the co-rapporteur shall be		points 3, 4, 5 and 6 of Annex I	
	calculated based on the same proportion of		and points 3, 4, 6 and 7 of	
	the respective remuneration.		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.	
1	1			

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				comments
356	5. Scientific services referred to in		5. Scientific services referred	
	Article 4(1)		to in Article 4(1)	
357	The range for fees for scientific services		The range for fees for scientific	
	referred to in Article 4(1) shall be EUR 4		services referred to in Article	
	100 to EUR 684 500. The range for the		4(1) shall be EUR 4 1004 800 to	
	remuneration shall be EUR 1 000 to EUR		EUR 684 500805 100. The	
	217 300 for the rapporteur and the co-		range for the remuneration shall	
	rapporteur. The applicable amounts of the		be EUR 1 000 1 200 to EUR 217	
	fee and the remuneration within the above		300 <u>261 000</u> for the rapporteur	
	ranges shall be determined in accordance		and the co-rapporteur. The	
	with Article 8.		applicable amounts of the fee	
			and the remuneration within the	
			above ranges shall be	
			determined in accordance with	
			Article 8.	
358	6. Administrative services		6. Administrative services	
359	6.1. Administrative charge		6.1. Administrative charge	

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				comments
360	A charge of EUR 3 700 shall apply for		A charge of EUR 3 7004 200	
	applications subject to a fee set out in Annex		shall apply for applications	
	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		(a) the application is withdrawn	
	hours of its submission and prior to		after 24 hours of its submission	
	completion of the administrative validation;		and prior to completion of the	
			administrative validation;	
362	(b) the application has been rejected		(b) the application has been	
	following the conclusion of the		rejected following the	
	administrative validation.		conclusion of the administrative	
			validation.	
363	In the cases referred to in the previous		In the cases referred to in the	
	subparagraph, the corresponding fee shall		previous subparagraph, the	
	not be levied.		corresponding fee shall not be	
			levied.	

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

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	each request for a set of certificates issued		shall apply to each request for a	
	by the Agency for a medicinal product,		set of certificates issued by the	
	using the standard procedure for issuing the		Agency for a medicinal product,	
	certificate.		using the standard procedure for	
			issuing the certificate.	
367	6.2.2. A charge of EUR 420 shall apply to		6.2.2. A charge of EUR 420 480	
	each request for a set of certificates issued		shall apply to each request for a	
	by the Agency for a medicinal product,		set of certificates issued by the	
	using the urgent procedure for issuing the		Agency for a medicinal product,	
	certificate.		using the urgent procedure for	
			issuing the certificate.	
368	6.3. Notification of parallel distribution in		6.3. Notification of parallel	
	accordance with Article 57(1), point (o),		distribution in accordance with	
	of Regulation (EC) No 726/2004		Article 57(1), point (o),	
			of Regulation (EC) No 726/2004	
369	6.3.1. A charge of EUR 1 200 shall apply to		6.3.1. A charge of EUR <u>1 2001</u>	
	each initial notification for each presentation		400 shall apply to each initial	

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

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

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

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			comments
medicinal substances pursuant to section 5.2		on one or more ancillary	
of Annex IX to Regulation (EU) 2017/745,		medicinal substances pursuant to	
where the medicinal substance(s) from the		section 5.2 of Annex IX to	
specified manufacturer has not been		Regulation (EU) 2017/745,	
evaluated by the Agency or a competent		where the medicinal	
authority designated by the Member States		substance(s) from the specified	
in accordance with Directive 2001/83/EC		manufacturer has not been	
(hereafter 'medicinal products authority') in		evaluated by the Agency or a	
connection with a previous marketing		competent authority designated	
authorisation or through a previous		by the Member States in	
consultation by a notified body. One		accordance with Directive	
application may include a range of strength		2001/83/EC (hereafter	
or concentrations of the ancillary		'medicinal products authority')	
substance(s) or a range of similar devices		in connection with a previous	
from the same medical device manufacturer		marketing authorisation or	
incorporating the same substance(s) or both.		through a previous consultation	
The remuneration shall be EUR 23 500 for		by a notified body. One	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
	the rapporteur and EUR 23 500 for the co-		application may include a range	
	rapporteur.		of strength or concentrations of	
			the ancillary substance(s) or a	
			range of similar devices from the	
			same medical device	
			manufacturer incorporating the	
			same substance(s) or both. The	
			remuneration shall be EUR 23	
			500 <u>28 200</u> for the rapporteur and	
			EUR 23 500 28 200 for the co-	
			rapporteur.	
377	7.1.2. A fee of EUR 46 900 shall apply to a		7.1.2. A fee of EUR 46 900 <u>54</u>	
	consultation on one or more ancillary		700 shall apply to a consultation	
	medicinal substance(s) pursuant to section		on one or more ancillary	
	5.2 of Annex IX to Regulation (EU)		medicinal substance(s) pursuant	
	2017/745, where the medicinal substance(s)		to section 5.2 of Annex IX to	
	from the specified manufacturer has been		Regulation (EU) 2017/745,	

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evaluated by a medicinal products authority		where the medicinal	
in connection with a previous marketing		substance(s) from the specified	
authorisation or through a previous		manufacturer has been evaluated	
consultation by a notified body. One		by a medicinal products	
application may include a range of strengths		authority in connection with a	
or concentrations of the ancillary		previous marketing authorisation	
substance(s) or a range of similar devices		or through a previous	
from the same medical device manufacturer		consultation by a notified body.	
incorporating the same substance(s) or both.		One application may include a	
The remuneration shall be EUR 11 500 for		range of strengths or	
the rapporteur and EUR 11 500 for the co-		concentrations of the ancillary	
rapporteur.		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	

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			500 <u>13 800</u> for the rapporteur and	
			EUR 11 500 13 800 for the co-	
			rapporteur.	
378	7.1.3. For the purpose of 7.1.1. and 7.1.2., a		7.1.3. For the purpose of 7.1.1.	
	fee of EUR 4 100 shall apply to a		and 7.1.2., a fee of EUR 4-1004	
	consultation, pursuant to section 5.2, point		700 shall apply to a consultation,	
	(f), of Annex IX to Regulation (EU)		pursuant to section 5.2, point (f),	
	2017/745, regarding a change with respect to		of Annex IX to Regulation (EU)	
	an ancillary medicinal substance		2017/745, regarding a change	
	incorporated in a device. The remuneration		with respect to an ancillary	
	shall be EUR 1 400 for the rapporteur.		medicinal substance	
			incorporated in a device. The	
			remuneration shall be EUR 4	
			400 <u>1 700</u> for the rapporteur.	
379	7.2. Medical devices composed of a		7.2. Medical devices composed	
	substance or a combination of substances		of a substance or a combination	
	that are systemically absorbed to achieve		of substances that are	

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	their intended purpose.		systemically absorbed to achieve	
			their intended purpose.	
380	A fee of EUR 70 600 shall apply to a		A fee of EUR 70 600 82 400	
	consultation on a medical device or a range		shall apply to a consultation on a	
	of similar devices composed of a substance		medical device or a range of	
	or a combination of substances that are		similar devices composed of a	
	absorbed by or locally dispersed in the		substance or a combination of	
	human body, pursuant to section 5.4 of		substances that are absorbed by	
	Annex IX, to Regulation (EU) 2017/745.		or locally dispersed in the	
	The remuneration shall be EUR 17 500 for		human body, pursuant to section	
	the rapporteur and EUR 17 500 for the co-		5.4 of Annex IX, to Regulation	
	rapporteur.		(EU) 2017/745. The	
			remuneration shall be EUR 17	
			500 <u>21 000</u> for the rapporteur and	
			EUR 17 500 21 000 for the co-	
			rapporteur.	
381	7.3. Companion diagnostic		7.3. Companion diagnostic	

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382	7.3.1. A fee of EUR 46 900 shall apply to a		7.3.1. A fee of EUR 46 900 <u>54</u>	
	consultation on the suitability of a		<u>000</u> shall apply to a consultation	
	companion diagnostic in relation to a		on the suitability of a companion	
	concerned medicinal product, pursuant to		diagnostic in relation to a	
	Article 48(3) or (4), of Regulation (EU)		concerned medicinal product,	
	2017/746, and section 5.2 of Annex IX, or		pursuant to Article 48(3) or (4),	
	section 3, point (k), of Annex X to that		of Regulation (EU) 2017/746,	
	Regulation. The remuneration shall be EUR		and section 5.2 of Annex IX, or	
	11 800 for the rapporteur.		section 3, point (k), of Annex X	
			to that Regulation. The	
			remuneration shall be EUR 11	
			800 <u>14 200</u> for the rapporteur.	
383	A fee of EUR 4 100 shall apply to a		A fee of EUR 4 1004 700 shall	
	consultation on a change affecting the		apply to a consultation on a	
	suitability of the companion diagnostic in		change affecting the suitability	
	relation to the medicinal product concerned,		of the companion diagnostic in	
	pursuant to section 5.2, point (f), of Annex		relation to the medicinal product	

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	IX to Regulation (EU) 2017/746. The		concerned, pursuant to section	
	remuneration shall be EUR 1 400 for the		5.2, point (f), of Annex IX to	
	rapporteur.		Regulation (EU) 2017/746. The	
			remuneration shall be EUR 4	
			400 <u>1 700</u> for the rapporteur.	
384	7.4. The fees set out in points 7.1, 7.2 and		7.4. The fees set out in points	
	7.3 shall be charged to the medical device		7.1, 7.2 and 7.3 shall be charged	
	manufacturer that, according to the		to the medical device	
	application form submitted to the Agency,		manufacturer that, according to	
	requested the assessment of conformity of		the application form submitted	
	the medical device for which the notified		to the Agency, requested the	
	body is consulting the Agency.		assessment of conformity of the	
			medical device for which the	
			notified body is consulting the	
			Agency.	
385	ANNEX V		ANNEX V	
	Fee reductions		Fee reductions	

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386	1. Fee reductions granted to micro, small-		1. Fee reductions granted	
	and medium-sized enterprises		to micro, small- and medium- sized enterprises	
387	1.1. The following total or partial reductions		1.1. The following total or	
	to the fees laid down in this Regulation shall		partial reductions to the fees laid	
	be granted to micro, small and medium-		down in this Regulation shall be	
	sized enterprises:		granted to micro, small and	
			medium-sized enterprises:	
388	1.1.1 for a small or medium-sized		1.1.1 for a small or medium-	
	enterprise, a fee reduction of 40 % of the		sized enterprise, a fee reduction	
	applicable amount shall apply to the		of 40 % of the applicable	
	following fees:		amount shall apply to the	
			following fees:	
389	(a) extension of a marketing authorisation		(a) extension of a marketing	
	for medicinal products for human use		authorisation for medicinal	
	pursuant to section 4 of Annex I;		products for human use pursuant	
			to section 4 of Annex I;	
390	(b) major type-II variations for medicinal		(b) major type-II variations for	

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

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			section 98 of Annex I;	
394	(f) certification of compliance with Union		(f) certification of compliance	
	legislation regarding vaccine antigen master		with Union legislation regarding	
	files (VAMF) pursuant to section 10 of		vaccine antigen master files	
	Annex I;		(VAMF) pursuant to section <u>109</u>	
			of Annex I;	
395	(g) assessment of periodic safety update		(g) assessment of periodic safety	
	reports for medicinal products for human		update reports for medicinal	
	use pursuant to section 15 of Annex I;		products for human use pursuant	
			to section 15-14 of Annex I;	
396	(h) assessment of post-authorisation safety		(h) assessment of post-	
	studies for medicinal products for human		authorisation safety studies for	
	use pursuant to section 16 of Annex I;		medicinal products for human	
			use pursuant to section 16-15 of	
			Annex I;	
397	(i) variations requiring assessment pursuant		(i) variations requiring	
	to section 6 of Annex II, excluding point 6.5		assessment pursuant to section 6	

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	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	of that section;		of Annex II, excluding point 6.5	
			of that section;	
398	(j) referral procedures for veterinary		(j) referral procedures for	
	medicinal products pursuant to points 7.4 to		veterinary medicinal products	
	7.7 of Annex II;		pursuant to points 7.4 to 7. <u>5</u> 7 of	
			Annex II;	
399	(k) certification of compliance with Union		(k) certification of compliance	
	legislation regarding VAMF pursuant to		with Union legislation regarding	
	section 8 of Annex II;		VAMF pursuant to section 8 of	
			Annex II;	
400	(l) certification of compliance with Union		(l) certification of compliance	
	legislation regarding vaccine platform		with Union legislation regarding	
	technology master files (vPTMF) pursuant		vaccine platform technology	
	to section 9 of Annex II;		master files (vPTMF) pursuant	
			to section 9 of Annex II;	
401	(m) assessment of post-marketing		(m) assessment of post-	
	surveillance studies for veterinary medicinal		marketing surveillance studies	

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

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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	products pursuant to section 2, point 2 of		products for human use and	
	Annex IV;		veterinary medicinal products	
			pursuant to section 2 , point 2 of	
			Annex IV;	
405	1.1.1. for a small or medium-sized		1.1.1 for a small or medium-	
	enterprise, a fee reduction of 90 % of the		sized enterprise, a fee reduction	
	applicable amount shall apply to a		of 90 % of the applicable	
	consultation on medical devices pursuant to		amount shall apply to a	
	section 7 of Annex IV, where the medical		consultation on medical devices	
	device manufacturer has been assigned the		pursuant to section 7 of Annex	
	small and medium-sized enterprise status by		IV, where the medical device	
	the Agency;		manufacturer has been assigned	
			the small and medium-sized	
			enterprise status by the Agency;	
406	1.1.2. for a micro enterprise, a reduction of		1.1.2. for a micro enterprise, a	
	100 % shall apply to the fees set out in		reduction of 100 % shall apply	
	points 1.1.1. and 1.1.2.		to the fees set out in points 1.1.1.	

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			and 1.1.2.	
407	1.2. The fee reductions set out in point 1.1.1		1.2. The fee reductions set out in	
	shall apply in addition to fee reductions and		point 1.1.1 shall apply in	
	incentives provided for in Regulation (EC)		addition to fee reductions and	
	No 2049/2005 or in the Union		incentives provided for in	
	pharmaceutical legislation.		Regulation (EC) No 2049/2005	
			or in the Union pharmaceutical	
			legislation.	
408	1.3. The reductions set out in point 1.1		1.3. The reductions set out in	
	shall not be granted to SMEs acting as		point 1.1 shall not be granted to	
	applicant or marketing authorisation holder		SMEs acting as applicant or	
	for the relevant medicinal product by virtue		marketing authorisation holder	
	of a contractual arrangement with a non-		for the relevant medicinal	
	SME legal entity. Such contractual		product by virtue of a	
	arrangements shall be declared to the		contractual arrangement with a	
	Agency ahead of any service listed under		non-SME legal entity. Such	
	point 1.1.1.		contractual arrangements shall	

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			be declared to the Agency ahead	
			of any service listed under point	
			1.1.1.	
408a		1a. Fee reductions granted to		
		academia and the non-profit		
		research sector		
		1. A total reduction to the fee for		
		protocol assistance and scientific		
		advice requests on medicinal		
		products shall be granted to		
		applicants from academia or the		
		academic sector.		
		2. Applicants from academia or		
		the academic sector which are		
		not financed or managed by		
		private profit organisations in the		
		pharmaceutical sector (PPO), or		

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			proposals and
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	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:		
	(a) the Legal Entity Form (LEF)		
	and the "founding document"		
	(or any other suitable document		
	provided during the application		
	process);		
	(b) evidence of the place of		
	establishment, which may be the		
	founding document or any other		
	suitable document proving that		
	the entity's seat is located in the		

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	Union, Iceland, Liechtenstein or		
	Norway;		
	(c) proof that the applicant is not		
	under direct or indirect control of		
	any PPO.		
	For the purposes of paragraph 2,		
	point (c), control may, in		
	particular, take either of the		
	following forms:		
	(i) the direct or indirect holding		
	of more than 50 % of the		
	nominal value of the issued share		
	capital in the applicant, or of a		
	majority of the voting rights of		
	the shareholders or associates of		
	that applicant, or		
	(ii) the direct or indirect holding,		

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	in fact or in law, of decision-		
	making powers in the applicant.		
	Upon receipt of a scientific		
	advice request, the Agency shall		
	check the applicant's declaration		
	of eligibility and the acceptability		
	of the declaration based on		
	defined template as well as the		
	supporting documents.		
	The Agency shall reserve its right		
	to conduct an ex-post check 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.		
	3. Where reductions apply		

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		pursuant to point 1a, no		
		remuneration shall be paid to the		
		national competent authorities in		
		Member States.		
409	2. Applications relating to core dossier		2. Applications relating to core	
	medicinal products to be used in a human		dossier medicinal products to be	
	pandemic situation		used in a human pandemic	
			situation	
410	2.1. The payment of the fee for an		2.1. The payment of the fee for	
	application for a marketing authorisation of		an application for a marketing	
	a medicinal product to be used in a human		authorisation of a medicinal	
	pandemic situation shall be deferred until		product to be used in a human	
	the pandemic situation is duly recognised,		pandemic situation shall be	
	either by the World Health Organisation or		deferred until the pandemic	
	by the Union in accordance with Decision		situation is duly recognised,	
	No 1082/2013/EU.		either by the World Health	

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			Organisation or by the Union	
			Commission in accordance with	
			Article 23(1) of Regulation	
			(EU) 2022/2371 on serious	
			cross-border threats to health	
			and repealing Decision	
			No 1082/2013/EU.	
411	Such deferral shall not exceed 5 years.		Such deferral shall not exceed 5	
			years.	
412	2.2. In addition to the deferral provided for		2.2. In addition to the deferral	
	in point 2.1, for regulatory activities within		provided for in point 2.1, for	
	the framework of the submission of a core		regulatory activities within the	
	dossier for a pandemic influenza vaccine		framework of the submission of	
	and the follow-up submission of a pandemic		a core dossier for a pandemic	
	variation, a fee reduction of 100 % shall		influenza vaccine and the	
	apply in the following cases:		follow-up submission of a	
			pandemic variation, a fee	

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			reduction of 100 % shall apply	
			in the following cases:	
413	(a) pre-submission activities pursuant to		(a) pre-submission activities	
	section 9 of Annex IV;		pursuant to section <u>39</u> of Annex	
			IV;	
414	(b) scientific advice pursuant to section 1 of		(b) scientific advice pursuant to	
	Annex I;		section 1 of Annex I;	
415	(c) extension of marketing authorisation		(c) extension of marketing	
	pursuant to section 4 of Annex I;		authorisation pursuant to section	
			4 of Annex I;	
416	(d) major type-II variation pursuant to		(d) major type-II variation	
	section 5 of Annex I;		pursuant to section 5 of Annex I;	
417	(e) annual fee pursuant to section 1 of Annex III.		(e) annual fee pursuant to section 1 of Annex III.	
	Those reductions shall apply until the human		Those reductions shall apply	
	pandemic situation is duly recognised.		until the human pandemic	
			situation is duly recognised.	

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418	2.3. Where reductions apply pursuant to		2.3. Where reductions apply	
	point 2.2, no remuneration shall be paid to		pursuant to point 2.2, no	
	the national competent authorities for the		remuneration shall be paid to the	
	annual fees referred to in point 2.2(e).		national competent authorities	
			for the annual fees referred to in	
			point 2.2(e).	
419	3. Applications submitted under Article		3. Applications submitted	
	30 of Regulation (EC) No 1901/2006		under Article 30 of Regulation	
			(EC) No 1901/2006	
420	A 50 % fee reduction shall apply to		A 50 % fee reduction shall apply	
	paediatric use marketing authorisation		to paediatric use marketing	
	applications submitted under Article 30 of		authorisation applications	
	Regulation (EC) No 1901/2006 for the		submitted under Article 30 of	
	following services:		Regulation (EC) No 1901/2006	
			for the following services:	
421	(a) initial marketing authorisation		(a) initial marketing	
	application pursuant to section 3 of Annex I,		authorisation application	

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	to this Regulation;		pursuant to section 3 of Annex I,	
			to this Regulation;	
422	(b) pre-authorisation inspection pursuant to		(b) pre-authorisation inspection	
	section 1 of Annex IV, to this Regulation;		pursuant to section 1 of Annex	
			IV, to this Regulation;	
423	(c) extension of a marketing authorisation		(c) extension of a marketing	
	pursuant to section 4 of Annex I, to this		authorisation pursuant to section	
	Regulation, in the first year from granting of		4 of Annex I, to this Regulation,	
	the marketing authorisation;		in the first year from granting of	
			the marketing authorisation;	
424	(d) major type-II variation pursuant to		(d) major type-II variation	
	section 5 of Annex I, to this Regulation, in		pursuant to section 5 of Annex I,	
	the first year from granting of a marketing		to this Regulation, in the first	
	authorisation;		year from granting of a	
			marketing authorisation;	
425	(e) annual fee pursuant to section 1 of		(e) annual fee pursuant to	
	Annex III, to this Regulation, in the first		section 1 of Annex III, to this	

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	year from granting of a marketing		Regulation, in the first year from	
	authorisation;		granting of a marketing	
			authorisation;	
426	(f) post-authorisation inspection pursuant to		(f) post-authorisation inspection	
	section 1 of Annex IV, to this Regulation, in		pursuant to section 1 of Annex	
	the first year from granting of a marketing		IV, to this Regulation, in the	
	authorisation.		first year from granting of a	
			marketing authorisation.	
427	4. Immunological veterinary medicinal		4. Immunological veterinary	
	products		medicinal products	
428	A fee reduction of 50 % shall apply to		A fee reduction of 50 % shall	
	immunological veterinary medicinal		apply to immunological	
	products for the following activities:		veterinary medicinal products	
			for the following activities:	
429	(a) scientific advice pursuant to section 1 of		(a) scientific advice pursuant to	
	Annex II;		section 1 of Annex II;	
430	(b) request for classification of a veterinary		(b) request for classification of a	

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	medicinal product as intended for a limited		veterinary medicinal product as	
	market as defined in Article 4, point 29 of		intended for a limited market as	
	Regulation (EU) 2019/6 and for		defined in Article 4, point 29 of	
	consideration for eligibility for authorisation		Regulation (EU) 2019/6 and for	
	according to Article 23 of that Regulation,		consideration for eligibility for	
	pursuant to section 2 of Annex II, to this		authorisation according to	
	Regulation;		Article 23 of that Regulation,	
			pursuant to section 2 of Annex	
			II, to this Regulation;	
431	(c) authorisation to market veterinary		(c) authorisation to market	
	medicinal products falling within the scope		veterinary medicinal products	
	of the centralised marketing authorisation		falling within the scope of the	
	procedure pursuant to Article 42 of		centralised marketing	
	Regulation (EU) 2019/6, pursuant to section		authorisation procedure pursuant	
	4 of Annex II, to this Regulation;		to Article 42 of Regulation (EU)	
			2019/6, pursuant to section 4 of	
			Annex II, to this Regulation;	

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432	(d) variations to the terms of a marketing		(d) variations to the terms of a	
	authorisation requiring assessment in		marketing authorisation	
	accordance with Article 66 of Regulation		requiring assessment in	
	(EU) 2019/6, pursuant to Annex II, section		accordance with Article 66 of	
	6, to this Regulation. In the specific case of		Regulation (EU) 2019/6,	
	point 6.5 of Annex II, the reduction shall		pursuant to Annex II, section 6,	
	apply to the variations subject to a fee and		to this Regulation. In the specific	
	shall not apply to the variations subject to a		case of point 6.5 of Annex II, the	
	charge;		reduction shall apply to the	
			variations subject to a fee and	
			shall not apply to the variations	
			subject to a charge;	
433	(e) certification of compliance with Union		(e) certification of compliance	
	legislation for VAMF pursuant to section 8		with Union legislation for	
	of Annex II;		VAMF pursuant to section 8 of	
			Annex II;	
434	(f) certification of compliance with Union		(f) certification of compliance	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	legislation for vPTMF pursuant to section 9		with Union legislation for	
	of Annex II;		vPTMF pursuant to section 9 of	
			Annex II;	
435	(g) assessment of post-marketing		(g) assessment of post-marketing	
	surveillance studies pursuant to section 10 of		surveillance studies pursuant to	
	Annex II;		section 10 of Annex II;	
436	(h) annual fee pursuant to section 2 of		(h) annual fee pursuant to	
	Annex III;		section 2 of Annex III;	
437	(i) pre-submission services pursuant to		(i) pre-submission services	
	section 3 of Annex IV.		pursuant to section 3 of Annex	
			IV.	
438	5. Veterinary medicinal products for		5. Veterinary medicinal	
	limited markets		products for limited markets	
439	5.1. A fee reduction of 50 % shall apply to		5.1. A fee reduction of 50 %	
	veterinary medicinal products classified as		shall apply to veterinary	
	intended for a limited market within the		medicinal products classified as	
	meaning of Article 4(29) of Regulation (EU)		intended for a limited market	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	2019/6 and considered eligible for		within the meaning of Article	
	authorisation or authorised pursuant to		4(29) of Regulation (EU) 2019/6	
	Article 23 of that Regulation, for the		and considered eligible for	
	following activities:		authorisation or authorised	
			pursuant to Article 23 of that	
			Regulation, for the following	
			activities:	
440	(a) scientific advice pursuant to section 1 of		(a) scientific advice pursuant to	
	Annex II, to this Regulation;		section 1 of Annex II, to this	
			Regulation;	
441	(b) applications for establishment,		(b) applications for	
	modification or extension of a maximum		establishment, modification or	
	residue limit pursuant to section 3 of Annex		extension of a maximum residue	
	II, to this Regulation;		limit pursuant to section 3 of	
			Annex II, to this Regulation;	
442	(c) authorisation to market veterinary		(c) authorisation to market	
	medicinal products falling within the scope		veterinary medicinal products	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	of the centralised marketing authorisation		falling within the scope of the	
	procedure pursuant to Article 42 of		centralised marketing	
	Regulation (EU) 2019/6 pursuant to Article		authorisation procedure pursuant	
	23 of that Regulation, pursuant to point 4.1		to Article 42 of Regulation (EU)	
	or 4.2 of Annex II, to this Regulation;		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		(d) variations to the terms of a	
	authorisation requiring assessment in		marketing authorisation	
	accordance with Article 66 of Regulation		requiring assessment in	
	(EU) 2019/6, pursuant to section 6 of Annex		accordance with Article 66 of	
	II. In the specific case of point 6.5 of Annex		Regulation (EU) 2019/6,	
	II, the reduction shall apply to the variations		pursuant to section 6 of Annex	
	subject to a fee and shall not apply to the		II. In the specific case of point	
	variations subject to a charge;		6.5 of Annex II, the reduction	
			shall apply to the variations	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
			subject to a fee and shall not	
			apply to the variations subject to	
			a charge;	
444	(e) certification of compliance with Union		(e) certification of compliance	
	legislation for VAMF pursuant to section 8		with Union legislation for	
	of Annex II to this Regulation;		VAMF pursuant to section 8 of	
			Annex II to this Regulation;	
445	(f) certification of compliance with Union		(f) certification of compliance	
	legislation for vPTMF pursuant to section 9		with Union legislation for	
	of Annex II to this Regulation;		vPTMF pursuant to section 9 of	
			Annex II to this Regulation;	
446	(g) assessment of post-marketing		(g) assessment of post-marketing	
	surveillance studies pursuant to section 10 of		surveillance studies pursuant to	
	Annex II, to this Regulation;		section 10 of Annex II, to this	
			Regulation;	
447	(h) annual fee pursuant to section 2 of		(h) annual fee pursuant to	
	Annex III, to this Regulation;		section 2 of Annex III, to this	

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

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
1.51				
451	6.1. A fee reduction of 100 % shall apply to		6.1. A fee reduction of 100 %	
	the annual fee for vaccines against		shall apply to the annual fee for	
	bluetongue, pandemic avian influenza, foot		vaccines against infection with	
	and mouth disease and classical swine fever,		bluetongue virus (serotypes 1-	
	where the vaccine is authorised under		24), pandemic highly	
	normal circumstances and the product has		pathogenic avian influenza, foot	
	not been marketed within the Union at any		and mouth disease and classical	
	time during the totality of the period covered		swine fever, where the vaccine is	
	by the fee.		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		6.2. Where a reduction applies	

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				comments
	point 6.1, no remuneration shall be paid to		pursuant to point 6.1, no	
	the national competent authorities for the		remuneration shall be paid to the	
	annual fees referred to in point 6.1.		national competent authorities	
			for the annual fees referred to in	
			point 6.1.	
453	7. Annual fee for veterinary medicinal		7. Annual fee for veterinary	
	products		medicinal products	
454	A fee reduction of 25 % shall apply to the		A fee reduction of 25 % shall	
	annual fee for veterinary medicinal products		apply to the annual fee for	
	set out in section 2 of Annex III, with the		veterinary medicinal products	
	exclusion of those products already listed in		set out in section 2 of Annex III,	
	sections 4 and 5 of this Annex.		with the exclusion of those	
			products already listed in	
			sections 4 and 5 of this Annex.	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
455	8. Annual pharmacovigilance fee for		8. Annual pharmacovigilance	
	generic, homeopathic and herbal medicinal		fee for generic, homeopathic and	
	products		herbal medicinal products	
456	A fee reduction of 20 % shall apply to the	A fee reduction of 30% shall	A fee reduction of 20 % shall	
	annual pharmacovigilance fee set out in	apply to the annual	apply to the annual	
	section 3 of Annex III for the following	pharmacovigilance fee set out in	pharmacovigilance fee set out in	
	medicinal products:	section 3 of Annex III for the	section 3 of Annex III for the	
		following medicinal products:	following medicinal products:	
457	(a) medicinal products for human use as		(a) medicinal products for	
	referred to in Article 10(1) and Article 10a		human use as referred to in	
	of Directive 2001/83/EC;		Article 10(1) and Article 10a of	
			Directive 2001/83/EC;	
458	(b) homeopathic medicinal products for		(b) homeopathic medicinal	
	human use;		products for human use;	
459	(c) herbal medicinal products for human use;		(c) herbal medicinal products for	
			human use;	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				comments
460	(d) veterinary medicinal products as referred		(d) veterinary medicinal	
	to in Articles 18 and 22 of Regulation (EU)		products as referred to in	
	2019/6;		Articles 18 and 22 of Regulation	
			(EU) 2019/6;	
461	(e) homeopathic veterinary medicinal		(e) homeopathic veterinary	
	products;		medicinal products;	
462	(f) homeopathic veterinary medicinal		(f) homeopathic veterinary	
	products registered in accordance with		medicinal products registered in	
	Article 87 of Regulation (EU) 2019/6.		accordance with Article 87 of	
			Regulation (EU) 2019/6.	
463	ANNEX VI		ANNEX VI	
	Performance information		Performance information	
464	The following information shall relate to	The following information shall	The following information shall	
	each calendar year:	relate to each calendar year and	relate to each calendar year:	
		shall be made publicly available		
		on the Agency's website:		

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
465	(1) the overall cost and breakdown of staff		(1) the overall cost and	
	and non-staff costs relating to the fees and		breakdown of Agency staff and	
	charges referred to in Article 3;		non-staff costs relating to the	
			fees and charges referred to in	
			Article 3;	
466	(2) number of Agency staff involved and		(2) number of Agency staff	
	the overall costs for obtaining and		involved and the overall costs	
	maintaining a Union authorisation to market		for obtaining and maintaining a	
	medicinal products for human use and		Union authorisation to market	
	veterinary medicinal products and for other		medicinal products for human	
	services of the Agency;		use and veterinary medicinal	
			products and for other services	
			of the Agency;	
467	(3) number of procedures for obtaining		(3) number of procedures for	
	and maintaining a Union authorisation to		obtaining and maintaining a	
	market medicinal products for human use		Union authorisation to market	
	and veterinary medicinal products and for		medicinal products for human	

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
	other services of the Agency;		use and veterinary medicinal	
			products and for other services	
			of the Agency;	
468	(4) number of fee reductions granted per		(4) number <u>and amount</u> of	
	type of fee reduction as set out in Annex V;		fee reductions or waivers	
			granted per type of fee reduction	
			or waiver under Union	
			Legislation as set out in Annex	
			V] and number of applicants	
			or holders concerned;	
468a		(4a) number of fee reductions		
		granted as per executive		
		decisions set out in Article 6;		
469	(5) attribution of rapporteurs, co-		(5) attribution of rapporteurs,	
	rapporteurs, or roles considered as		co-rapporteurs, or roles	
	equivalent for the purposes of this regulation		considered as equivalent for the	
	as referred to in the Annexes to this		purposes of this regulation as	

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

	Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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				proposals and
				comments
		competent authorities concerned.	national competent authorities	
		The procedures to be included	concerned. The <u>types of</u>	
		shall be decided by the	procedures to be included shall	
		Management Board based on a	be decided by the Management	
		proposal by the Agency.	Board based on a proposal by	
			the Agency.	
470a		(6a) any performance indicators		
		relevant to scientific service fees		
		or charges for administrative		
		services levied in accordance		
		with Article 4(1) and (2) of this		
		Regulation;		
470b		(6b) any additional relevant key		
		performance indicators that		

Commission proposal	EP amendments voted on 12	Text agreed by the Council on	Tentatively agreed
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			proposals and
			comments
	impact the evolving workload of		
	the Agency and national		
	competent authorities in the		
	Member States in the Union		
	pharmaceutical regulatory		
	framework, including procedures		
	for the authorisation and		
	supervision of medicinal		
	products.		
1			

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