Statutory Cost Regulation for Official Duties of the Paul-Ehrlich-Institut pursuant to the German Medicinal Products Act

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"Statutory cost regulation for official duties of the Paul-Ehrlich-Institut pursuant to the German Medicinal Products Act in the version of the announcement of 26 March 2010 (Federal Law Gazette I, p 331) amended by Article 1 in the Statutory Regulation of 9 October 2017 (Federal Law Gazette I, p. 3918)."

Regulation repealed by Article 4(2) Act of 18 July 2016 I 1666 with effect from 1 October 2021

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Footnote
(+++ Text reference as from: 24 December 1996 +++

Section 1

(1) This Statutory Regulation stipulates the costs (fees and expenses) the Paul-Ehrlich-Institut charges for its decisions on the granting of a marketing authorisation of a medicinal product, the authorisation of a tissue preparation or an advanced therapy medicinal product, the release of batches, and other individually assignable public services pursuant to the German Medicinal Products Act.

(2) For the rejection of an application for performing an individually assignable public service and in case of a withdrawal of an application for performing an individually assignable public service, fees will be levied pursuant to Section 15 of the Verwaltungskostengesetz (Law on Administration Costs) in its version applicable up to 14 August 2013.

Section 2

(1) The following fees shall apply to the granting of authorisations

1.	Sera	16,110 EUR
2.	bacterial, toxoid, parasite and fungal vaccines	
	a) against one infectious disease	12,530 EUR
	b) against multiple infectious diseases, per type of disease	10,740 EUR
3.	Viral vaccines	
	a) against one infectious disease	21,470 EUR

	b) against multiple infectious diseases, per type of disease	13,800 EUR
	c) if tests on monkeys are required, a surcharge of	40,900 EUR
3a.	combination vaccines against bacterial and viral diseases - the total of the relevant rates indicated in 2. and 3. respectively	
4.	a) therapy allergens and test allergens except epidermal tests	11,250 EUR
	b) Epidermal tests	6,750 EUR
5.	xenogeneic cell therapeutics	10,000 to 27,000 EUR
6.	blood preparations	
	a) coagulation factors	27,100 EUR
	b) albumin	14,830 EUR
	c) virus-inactivated plasmas	16,360 EUR
	d) non-virus-inactivated red blood cell concentrates, platelet concentrates, and fresh plasma	12,780 EUR
	e) stem cells and other blood products	10,230 to 25,560 EUR
6a.	Tissue preparations	10,230 to 25,560 EUR
7.	granting of a marketing authorisation pursuant to Section 25b (2) of the German Medicinal Products Act	3,830 EUR
8.	granting of a marketing authorisation of medicinal products sold as parallel imports	1,530 EUR

(2) If an application is made for a marketing authorisation for additional concentrations, strengths, or pharmaceutical forms of a medicinal product, half of the fee pursuant to paragraph 1 shall apply accordingly for the granting of a marketing authorisation. For therapy allergens and test allergens, a tenth of the fee shall apply pursuant to paragraph 1 and, if paragraph 3 applies, a tenth of the reduced fee pursuant to paragraph 3. If a medicinal product is authorised for more than one route of administration or presentation, an additional 500 EUR is charged for each additional presentation.

(3) If a pharmaceutical manufacturer simultaneously applies for marketing authorisations for the following products:
1. therapy allergens and test allergens of biologically uniform groups,
2. epidermal tests,
the full fee shall apply to the first marketing authorisation, and a tenth of the fee shall apply pursuant to paragraph 1 to each further marketing authorisation.

(4) If, in specific cases, the granting of the marketing authorisation has required an exceptionally heavy workload, the fee pursuant to 1, notwithstanding Section 4c, can be increased to up to double the amount. The party obliged to pay the fee must be heard if a surcharge is expected.

(5) If the granting of a marketing authorisation has required an exceptionally light workload, the fee can be reduced down to a quarter of the fee pursuant to paragraph 1, and in the event of paragraph 3 to a tenth of the reduced fee pursuant to paragraph 3.

(6) A fee of between 510 EUR and the amount laid down in paragraph 1 shall apply to preparing or updating an assessment report.

(7) Notwithstanding the fee laid down in paragraph 6, a fee of between 2,050 EUR and 12,780 EUR shall apply to performing a mutual recognition procedure, if the Federal Republic of Germany acts as reference member state. In the event of an arbitration procedure pursuant to Articles 30, 32, 33, or Article 34 of Directive 2001/83/EC, the fee is doubled. Paragraphs 4 and 5 shall apply mutatis mutandis. For performing a decentralised procedure as defined in Section 25b (3) of the German Medicinal Products Act a fee in the amount of 2,050 EUR to 12,780 EUR shall apply in addition to the fee pursuant to Section 2 paragraph 1 No 1 to 6a. Paragraphs 2 to 5 and 7, sentence 2 shall apply mutatis mutandis.

(8) The fee for processing a plasma master file is 2,760 EUR, and the fee for processing a donation master file is 1,180 EUR. Paragraphs 4 and 5 shall apply mutatis mutandis.

(9) For the refusal to grant of the marketing authorisation as defined in Section 25 (6) of the German Medicinal Products Act due to a pending marketing authorisation in another member state, a fee in the amount of 200 EUR shall apply.

(10) For the extension of the protective period pursuant to Section 24b (1), sentence 3 of the German Medicinal Products Act, a fee in the amount of 800 EUR shall apply.

Section 2a

(1) The following fees shall apply to the granting of authorisations of tissue preparations and blood stem cell preparations pursuant to Section 21a (1) of the German Medicinal Products Act

1.	stem cell preparations from blood and bone marrow	6,250 EUR
2.	musculosceletal tissue preparations including skin, amnion, soft tissues (tendon, fascias), placental tissue, tumour tissue, embryonic/foetal tissue, and preparations from thyroid gland tissue	8,000 EUR
3.	cardio-vascular tissue preparations	7,350 EUR
4.	ocular tissue preparations	6,250 EUR
5.	other tissue preparations	2,000 to 10,000 EUR

(2) If tissue preparations pursuant to paragraph 1 subpara 2 to 4 are essentially prepared in accordance with the same manufacturing procedure, or if an applicant has made more than one application for authorisations, and if therefore the work load for processing the application decreases essentially, the fee shall be 2,500 EUR each.

(3) For a decision on granting a certification as defined in Section 21a (9) sentence 1 of the German Medicinal Products Act, a fee in the amount of 250 EUR shall apply.

(4) If the granting of the authorisation has required an exceptionally light workload, the fee can be reduced down to a quarter of the fee pursuant to paragraph 1, and in the event of paragraph 23 to a tenth of the reduced fee pursuant to paragraph 2.

Section 2b

(1) A fee of 4,250 to 17,000 EUR shall apply for advanced therapies pursuant to Section 4b (3) of the German Medicinal Products Act.

(2) If the granting of the authorisation has required an exceptionally heavy workload, Section 2 (4) shall apply mutatis mutandis.

Section 3

If a condition pursuant to Section 36 Verwaltungsverfahrensgesetz (Administrative Procedures Act), or Section 21a (5), Section 28, or Section 30 (2a) of the German Medicinal Products Act is imposed after the granting of the marketing authorisation pursuant to Section 21 of the German Medicinal Products Act, or within the framework of an authorisation pursuant to Section 4b (3) or Section 21a (1) of the German Medicinal Products Act, each in connection with Section 21a (5) German Medicinal Products Act, the fee shall be between 260 and 1,020 EUR. Section 2 paragraphs 2 and 3 shall apply mutatis mutandis. If the same condition is imposed for other medicinal products of a pharmaceutical manufacturer and this does not entail a significant additional workload for processing the application, the fee for each additional medicinal product shall be a tenth of the fee levied for the first medicinal product. If the same condition applies to more than one pharmaceutical manufacturer, the fee shall be calculated on the basis of the actual workload as a pro rata share depending on the number of the pharmaceutical manufacturers concerned. Subparagraph 1 notwithstanding, in these cases, the fee shall be at least 100 EUR each.

Section 4

(1) The following fees shall apply to decisions concerning the granting of a marketing authorisation pursuant to Section 21 German Medicinal Products Act or the granting of an authorisation pursuant to Section 21a or Section 4b German Medicinal Products Act

1.	ordering a temporary suspension of a marketing authorisation pursuant to Section 30 (2), sentence 2 of the German Medicinal Products Act or the granting of an authorisation pursuant to Section 21a (8) or Section 4b (3) German Medicinal Products Act	1,020 EUR
2.	the extension of a marketing authorisation pursuant to Section 31 (3) German Medicinal Products Act	3,120 EUR
2a.	the extension of a marketing authorisation of products sold as parallel imports	800 EUR
2b.	the extension of a marketing authorisation of epidermal tests	1,560 EUR
3.	the processing of a variation to an authorisation pursuant to Section 21a (1) or pursuant to Section 4b (3) German Medicinal Products Act and of a variation pursuant to Section 21a (9) sentence 4 German Medicinal Products Act	
	a) for an extension of an indication	930 EUR
	b) for variations to the route and duration of administration	1,120 EUR
	c) for variations to the processing and testing procedures	between 1,120 EUR and the fee laid down for each authorisation pursuant to Section 2a
	d) for variations to the specifications on the extraction, donor testing, preservation, storage, shelf-life, and type of keeping	800 EUR
	e) for variations to the product name	220 EUR
	f) for variations to the name, company or address of the processor or the requirements pursuant to Section 21a (9), sentence 4 of the German Medicinal Products Act or a variation as defined in No 4 letter e	100 EUR
4.	processing a variation to an existing marketing authorisation	
	a) for variations requiring consent except for changes in the package size and the testing and manufacturing procedure	1,120 EUR
	b) for variations to the testing and manufacturing procedure	between 1,120 EUR and the amount of fee laid down for the marketing authorisation
	c) for the inclusion of a certificate from the European Medicines Agency on a plasma master file in the marketing authorisation documents	260 EUR
	d) for a variation to a plasma master file or donor master file	between 260 EUR and the amount of fee laid down for each authorisation in Section 2 (8) Sentence 1
	e) for all other variations, unless f) or g) are applicable	260 EUR
	f) in the event of a change in the company or manufacturer's or applicant's address, transfer to another manufacturer or	

	pharmaceutical company, or in the event of joint distribution	100 EUR
	g) If the variation serves to adapt the manufacturing and testing procedure to an amendment of a monograph in the Ph. Eur., the fee shall be	100 EUR
5.	the processing of a variation to an authorisation of a medicinal product in the event of	
	a) a minor variation of type IA as defined in Article 2 Number 2 of Commission Regulation (EC) No. 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for human use and veterinary medicinal products (OJ L 334 of 12 December 2008, p. 7), last amended by Regulation (EU) No. 712/2012 (OJ L 209 of 4 August 2012, p. 4).	between 20 EUR and 500 EUR
	b) a minor variation of type IB as defined in Article 2 Number 5 of Commission Regulation (EC) No. 1234/2008	between 20 EUR and 5,050 EUR
	c) a major variation of type II as defined in Article 2 Number 3 of Commission Regulation (EC) No. 1234/2008	between 20 EUR and 5,350 EUR

(2) If a variation leads to a change in the labelling, package leaflet or SPC, no surcharge shall apply to this follow-up variation. For a notification of the fulfilment of a condition, no fee shall apply.

(3) If the same variation is submitted for several medicinal products of the same pharmaceutical manufacturer, the full fee shall apply to one product and a tenth of the statutory fee for each additional product, if the processing of the variation does not entail a significant additional workload. If this submission also includes variations pursuant to Commission Regulation (EC) No 1084/2003, the full fee shall apply pursuant to paragraph 1 No 5, and if variations pursuant to paragraph 1 No 4 are submitted simultaneously, a tenth of the fee indicated therein.

(4) If paragraph 1, No 2, 2a, 2b, 4 and 5 applies, then Section 2 paragraphs 3 and 5 shall apply mutatis mutandis with the fee amounting to at least 100 EUR.

(5) If paragraph 1 applies in the event of additional concentrations, strengths or pharmaceutical forms, Section 2 paragraph 2 shall apply mutatis mutandis for additional concentrations, strengths and pharmaceutical forms.

(6) If paragraph 1, No 4a applies, the rates laid down in paragraph 1 No 4c shall apply to medicinal products bought as parallel imports.

(7) If paragraph 1 No 1 and No 5c applies, then Section 2 paragraphs 4 and 5 shall apply mutatis mutandis.

(8) If a variation pursuant to paragraph 1 No 3c or No 4b or paragraph 1, No 5c, which relates to a change in the testing procedure, is also in the public interest, the fee can be reduced to a quarter; if the variation leads to a replacement or avoidance of animal tests, the fee can be waived.

(9) If paragraph 1 No 3a to d applies, the fee laid down can be reduced to a quarter, if the variation notification requires a particularly light workload and the fee laid down or the minimum fee is therefore not appropriate.

Section 4a

(1) The following fees shall apply to the performing of official duties in connection with clinical trials:

Authorisation of a clinical trial pursuant to Section 42 (2) German Medicinal Products Act,

1.	a Phase I study, if No 2 does not apply to the medicinal products	3,000 EUR
2.	a Phase I study with medicinal products	
	a) to which applies Part A of the Annex of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ EU No L 214 p. 1)	3,500 EUR
	b) which are somatic cell therapeutics, xenogeneic cell therapeutics, or gene transfer medicinal products	4,000 EUR
	c) the active ingredient of which is a biological product of human or animal origin or contains biological components of human or animal origin, or the manufacture of which requires such components	3,500 EUR
	d) which are or contain genetically modified organisms	7,500 EUR
3.	a Phase II or III study, unless No 4 applies to the medicinal products	4,000 EUR
4.	a Phase II and a Phase III study on medicinal products	
	a) to which Part A of the Annex of Regulation (EEC) No 2309/93 applies	5,000 EUR
	b) which are somatic cell therapeutics, xenogeneic cell therapeutics, or gene transfer medicinal products	6,000 EUR
	c) the active ingredient of which is a biological product of human or animal origin, contains biological components of human or animal origin, or the manufacture of which requires such components	5,000 EUR
	d) which are or contain genetically modified organisms	9,500 EUR
5.	a) a Phase IV study	3,000 EUR
6.	a) in the event of essential changes pursuant to Section 42 (3) of the German Medicinal Products Act in connection with Section 10 (1) GCP Regulation	780 EUR
	b) for all other variations for which an application has been made	85 EUR

(2) Notwithstanding Section 4c, and if the authorisation for the clinical trial required an unusually heavy workload, the fee laid down in paragraph 1 can be doubled. The party obliged to pay the fee must be heard, if a surcharge is expected. If the authorisation has required an unusually light workload and an application has been made for a follow-up study enabling the assessors to use data from previous authorisation procedures for clinical trials with the same investigational product, the fee laid down in paragraph 1 can be reduced to a quarter. The same applies if an application is made for an authorisation of a study involving a product that has a marketing authorisation or an authorisation pursuant to Section 21 or Section 4b German Medicinal Products Act, and for which tests are planned that are not in accordance with the conditions of use laid down in the SPC.

(3) The following fees shall apply to the performance of other individually assignable public services as below:

1.	If a suspension of a marketing authorisation is imposed pursuant to Section 42a (1), sentence 2 of the German Medicinal Products Act	1,000 EUR

2.	if measures are imposed as defined in Section 42a (5) of the German Medicinal Products Act	250 to 1,000 EUR
3.	a) for transmission of the data to the EudraCT database established by the European Medicines Agency (EMA) for clinical trials pursuant to Section 42 (3) of the German Medicinal Products Act in connection with Section 14 (3) of the GCP Regulation	340 EUR
	b) if the data have been submitted by presenting a complete XML file, the fee shall be	85 EUR

Section 4b

(1) The following fees shall apply to the assessment of the periodic safety update report of the medicinal product pursuant to Section 63b (5) of the German Medicinal Products Act if

1.	the medicinal product has been authorised only in the scope of the German Medicinal Products Act	
	a) without an assessment report	1,800 EUR
	b) with comprehensive assessment report	2,250 EUR
2.	the medicinal product has been authorised within the mutual recognition procedure or within the decentralised procedure with the Federal Republic of Germany as Reference Member State	3,600 EUR
3.	the medicinal product has been authorised within the mutual recognition procedure or within the decentralised procedure with the Federal Republic of Germany as Concerned Member State	2,400 EUR

(2) A fee of 1,000 EUR shall apply to the assessment of the annual reports for the safety of the trial subjects pursuant to Section 42 (3) German Medicinal Products Act in connection with Section 13 (6) Statutory GCP Regulation.

(3) The following fees shall apply to the assessment of the periodic safety update report of a Medicinal Product on the basis of the obligations laid down in Section 63c (4) German Medicinal Products Act

1.	without an assessment report	1,800 EUR
2.	with comprehensive assessment report	2,200 EUR

(4) A fee in the amount of 400 EUR shall apply for a prolongation of the intervals between the reports pursuant to Section 63b (5) sentence 5 of the German Medicinal Products Act

Section 4c

If an inspection is performed for the assessment of marketing authorisation related information pursuant to Section 25 (5) of the German Medicinal Products Act, or for the assessment of the collection and evaluation of pharmaceutical product risks and the co-ordination of measures pursuant to Section 63b (5a) of the German Medicinal Products Act, or for the assessment of marketing authorisation related information pursuant to Section 42 (3) German Medicinal Products Act in connection with Section 9 (5) of the Statutory GCP Regulation, or for the assessment of the collection and evaluation of risks pursuant to Section 63b (5a) or Section 63c (5) of the German Medicinal Products Act, the fee shall depend on the staff hours required. It shall amount to a maximum of 25,000 EUR. The party obliged to pay the fee must be heard if such an inspection is planned, if the fee is likely to exceed 5,000 EUR.

Section 5

(1) The fee for batch releases of the products below shall be

1.	Sera	

	a) monoclonal antibodies	2,150 EUR
	b) other sera	1,430 EUR
2.	Bacterial and toxoid vaccines	
	a) against one infectious disease	1,480 EUR
	b) against multiple infectious diseases, per type of disease	970 UR
	c) if animal tests are required, a surcharge of	1,500 EUR
3.	Parasite and fungal vaccines	970 EUR
4.	Viral vaccines	
	a) against one infectious disease	2,660 EUR
	b) against multiple infectious diseases, per type of disease	1,530 EUR
4a.	For combined vaccines against bacterial and viral infections, the total of the relevant rates in No 2b, 2c, and 4 b, as applicable	
5.	Therapy allergens	610 EUR
6.	Test allergens	
	a) from biological materials	310 EUR
	b) from biological materials if the medicinal products have been prepared from allergen extract solutions already tested	150 EUR
	c) from other material	150 EUR
7.	Tuberculin	1,020 EUR
8.	(repealed)	
9.	Blood preparations	
	a) PPSB	3,630 EUR
	b) Factor VIII (human and veterinary), Factor IX	3,320 EUR
	c) other coagulation factors, fibrin sealants	3,020 EUR
	d) Albumin	1,790 EUR
	e) Plasma	2,660 EUR

(2) If an application is made for the release of more than one batch of a blood preparation and the batches differ only in their concentration, the full fee shall apply to the release of the first batch and half the fee to the release of each additional batch pursuant to paragraph 1 No 9.

(3) If an application is made simultaneously for the release of more than one batch of a therapy allergen, and the batches only differ in their concentration, the full fee shall apply to the release of the first batch and half the fee for the release of each additional batch pursuant to paragraph 1 No 5.

(4) If the release of a batch required an exceptionally heavy workload, the fee can be increased to the rates laid down in Section 2 (1). The party obliged to pay the fee must be heard, if a surcharge is expected.

(5) If controls of a batch that has already been released or simultaneously been submitted for testing can be taken into account in a decision on a batch release, thus reducing the workload considerably, the fee can be reduced down to a quarter.

(6) The fee for the exemption from official batch control tests pursuant to Section 32 (4) of the German Medicinal Products Act shall be three times the fee laid down in paragraph 1 for the appropriate medicinal product and 300 EUR for medicinal products sold as parallel imports. Section 2 (3) shall apply mutatis mutandis.

(7) The fee shall be 100 EUR if the release of a batch has been granted on the basis of a test by the competent authority of a Member State of the European Union or another signatory state of the agreement creating the European Economic Area, or if the batch was certified by the Paul-Ehrlich-Institut as defined in Section 8 No 5.

Section 6

Certain circumstances may justify halving the fee which is payable pursuant to Sections 2 to 5. Such circumstances include specific financial circumstances of the company and/or cases where the services provided by the Paul-Ehrlich-Institut are of particular importance, economic value or of other particular benefit to the company.

Section 7

The fees laid down in Sections 2 to 5 can be reduced down to a quarter at the request of the party obliged to pay the fee, if the marketing of the medicinal product serves the public interest owing to the product's indication and if the rareness of the product's indications implies that the applicant cannot expect an economic benefit in keeping with the costs of the development. The applicant can be exempted from the fees entirely, if the expected economic benefit is particularly low in relation to the costs of development.

Section 8

The following fees shall apply to individually assignable public services performed upon application:

1.	scientific comments on the manufacturing procedure, quality, efficacy, or safety of a medicinal product	260 to 22,000 EUR
2.	independent advice including preparatory and follow-up work	68 EUR per assessor per hour
3.	complex written information	100 EUR
4.	certifications, second copies, notarisations	50 EUR
5.	certifications of a batch control test – for batches not released pursuant to Section 32 (1) sentence 1 of the German Medicinal Products Act	the fee laid down in Section 5 (1)
6.	certificates for batches released pursuant to Section 32 (1), sentence 1 of the German Medicinal Products Act	50 EUR
7.	testing of a plasma pool	
	a) per NAT marker	80 EUR
	b) virus serology including a NAT marker	100 EUR
8.	Reinstatement in the previous status pursuant to Section 32 Verwaltungsverfahrensgesetz (Administrative Procedures Act)	200 EUR

Section 9

(1) The following fees shall apply to the processing of documents for clinical trials pursuant to Section 40 (1), German Medicinal Products Act in its version applicable up to 5 August 2004, i.e. clinical trials of medicinal products for which the required documents have been submitted to the ethics committee responsible for the principal investigator pursuant to Section 40 (1) sentence 2 German Medicinal Products Act, before 5 August 2004:

1.	if a favourable opinion by the ethics committee has been submitted	770 EUR
2.	if no favourable opinion by the ethics committee has been submitted	4,090 EUR

(2) Fees pursuant to the Statutory Cost Regulation in its version applicable as from 24 July 2005 also apply to services as defined in Sections 4a and 4b, Statutory Cost Regulation, which were provided before 24 July 2005, if the manufacturer had been informed that appropriate fees would be charged as soon as the new PEI statutory cost regulation came into force. The PEI has to inform the manufacturer of the probable amount of the applicable fees before providing the services in question.

(3) The Statutory Cost Regulation in its version applicable as from 24 July 2005 shall also apply to variations to the marketing authorisation as defined in Section 4 of Regulation (EC) No 1084/2003 which have been reported between 1st October 2003 and the coming into force of the Second Regulation on the Amendment of

the Statutory Cost Regulation for Official Duties of the Paul-Ehrlich-Institut pursuant to the German Medicinal Products Act.

Section 10

(1) If a protest against a
1. decision on a factual issue

a) is rejected as unjustified, the fee shall be 200 EUR, and if processing the objection requires a complex expertise, 200 EUR minimum up to the amount of the fee laid down in this regulation for the decision pending,

b) is rejected as non-permissible, the fee shall be 200 EUR,

2. cost decision

a) is rejected as unjustified, the fee shall be 10 per cent of the amount which is subject of the dispute, 500 EUR maximum, and if processing of the objection requires a complex expertise, 1,750 EUR maximum,

b) is rejected as non-permissible, the fee shall be 10 per cent of the amount which is subject of the dispute, but 200 EUR maximum. No fees shall be levied below 40 EUR.

(2) If the protest is partly accepted, the fee pursuant to paragraph 1 shall be reduced as a pro rata share of the acceptance.

(3) If a protest is withdrawn after the factual processing has been started and before it has been completed, a fee of 75 per cent maximum of the fee laid down in paragraph 1 applies.

Section 11

Expenses shall be charged pursuant to Section 10 of the Verwaltungskostengesetz (Law on Administration Costs).

Section 12

(1) Fees pursuant to the Statutory cost Regulation in its version applicable as from 4 July 2009 also apply to services as defined in Sections 2a, Statutory Cost Regulation, which were provided before 4 July 2009, if the manufacturer had been informed that appropriate fees would be charged as soon as the amendment to the PEI Statutory Cost Regulation came into force. The PEI has to inform the manufacturer of the probable amount of the applicable fees before providing the services in question.

(2) Fees pursuant to the statutory Cost Regulation in its version applicable as from 12 April 2011 also apply to services as defined in Sections 4b subsection 3, Statutory Cost Regulation, which were provided before 2 April 2011, if the manufacturer had been informed that appropriate fees would be charged as soon as the amendment to the PEI Statutory Cost Regulation came into force. The PEI has to inform the manufacturer of the probable amount of the applicable fees before providing the services in question.

(3) For the collection of fees for individually assignable public services pursuant to Chapter II of Regulation (EC) No. 1234/2008 for which an application was made before 13 October 2017 or the processing of which started before that date but which have not yet been completed, the Statutory Cost Regulation for Official Duties of the Paul-Ehrlich-Institut pursuant to the German Medicinal Products Act in the version applicable on 12 October 2017 shall apply.

(4) This Regulation in the version applicable as from 13 October 2017 shall also apply to cases in which individually assignable public services pursuant to Chapter IIa of Regulation (EC) No. 1234/2008 were

provided before 13 October 2017, and the determination of fees was announced with the note that this regulation will be amended and the applicant was informed on the amount of fees to be charge before the fee-paying service was completed. Sentence 1 shall apply mutatis mutandis if an application for an individually assignable public service mentioned therein was already made before 13 October 2017 or the processing of which was started before that date, but has not yet been completed.