Please be aware that we cannot guarantee the correctness of the translation.

To make sure, you have the correct and complete version, please look at the German version of the official announcements of BASG on fee regulations

Regulation issued by the Federal Office for Safety in Health Care regarding the Schedule of Fees pursuant to the GESG

On the basis of § 6a para 6 of the Health and Food Safety Act, Federal Law Gazette I No 63/2002, as modified by Federal Act I No 37/2018, the following regulation is issued:

§1. (1) The fees for activities pursuant to § 6a of the Act on Safety in Health and Food shall be determined as per appendix.

(2) The fees – except such fees pursuant to chapter VII of the appendix – are payable within adequate term after administrative validation of the formal requirements or receipt of documentation. Fees pursuant to chapter VII of the appendix and fees ex officio will be charged by decree issued or after invoicing.

(3) If an application is rejected before administrative validation of the formal requirements or withdrawn, 10 percent of the respective fee as assessed shall be payable. If withdrawal is effected at a later date or if the application will be rejected, the complete fee shall be payable.

(4) Liable for payment in the case of official acts pursuant to chapter X of the Appendix is the person launching the product.

§ 1 a (1) „Academic clinical trial" in context of this regulation is a clinical trial of a medicinal product or of a medical device respectively a performance test validation of an in vitro diagnostic medical device where the investigator respectively a university or an operator of a public hospital also performs the duties of the sponsor.

(2) If the notification of a clinical trial of a medical device is submitted at the same time and in the same context as that of a medicinal product by the same applicant, the full fee pursuant to Section XII.1 or XII.2 of the Appendix and 35% of the applicable fee pursuant to Section XI.1 or XI.2 of the Appendix shall be payable.

(3) In the context of an academic clinical trial pursuant to para 1, fees under Appendix VII.6 shall not be payable.

(4) In the context of an academic clinical trial pursuant to para 1 of a medicinal product or of a medical device respectively a performance test validation of an in vitro diagnostic medical device pursuant to the Medical Devices Act as amended by Federal Law Gazette I No. 46/2021, fees under Appendix XI.3 and XII.1.b are not payable.

(5) In the context of an academic clinical trial pursuant to para 1 of a medicinal product or of a medical device respectively a performance test validation of an in vitro diagnostic medical device pursuant to the Medical Devices Act as amended by Federal Law Gazette I No. 46/2021, fees under Appendix XI.1, XI.2 and XII.1.a shall be paid in the amount of 20% of the applicable fee.

§ 2. (1) A marketing authorisation of a known active ingredient in terms of this Schedule of Fees is the case if the particular proprietary medicinal product contains only such active ingredients of the same type as contained in proprietary medicinal products.

1. which at the time of application are approved in a member state of the European Economic Area, and
2. of which the marketing authorisation refers to a comparable application with regard to the evaluation.

(2) A marketing authorisation of a new active ingredient in terms of the subject Schedule of Fees is the case if not all prerequisites of para 1 are given.

(3) I change of an existing marketing authorisation (" Extension" in terms of Regulation 1234/2008), which leads to a new registration number, will be charged in accordance with chapter I of the appendix.

§ 3. For the marketing authorisation of two or more proprietary medicinal products of one pallet in terms of chapter I.1, I.2 or I.3.paras a,b,c and d or chapter I.4. of the appendix,

1. which are being submitted simultaneously by the same applicant,
2. of which the active ingredients are of the same type, and
3. of which the application is comparable with regard to the evaluation,

the full fee shall be payable for the first of these applications, and 50 percent of the fee for the following applications.

§ 3a If in the mutual recognition procedure or decentralized procedure with Austria as RMS further doublets (identical dossiers, with the exception of the name of the proprietary medicinal product) are filed simultaneously or during an ongoing marketing authorisation procedure, a 50 percent reduction of the fee shall apply to such doublets and their subsequent applications pursuant to chapters I.1.a, I.2.a., and IX.1.a of the appendix. This reduction applies only if the applicant or marketing authorisation holder of the filed doublets is identical.

§ 4. For the presentation of „Periodic Safety Update Report (PSUR)" (definition § 2b para 12 AMG [Medicinal Product Act]) of two or more medicinal products

1. if they are presented simultaneously by the same marketing authorisation holder,
2. of which the active ingredients are the same, and
3. if their application is comparable with regard to the evaluation,

the full fee shall be payable for the highest priced of such applications, and 50 percent of the respective fee for the further applications.

§ 5. For approvals and other activities concerning proprietary medicinal products exclusively intended for animals a fee of 60 percent pursuant to the Schedule is payable with regard to §7 para 4 and chapter I, IV, V.6, VI, VII, VIII (except for VIII.6 and 7) and IX of the appendix and a fee of 55 percent of the fee pursuant to chapter II of the appendix.

§ 6. (1) A "half inspection day" is each period of time or part thereof amounting to a maximum of 4 working hours an inspector needs to spend on site or in direct connection with an inspection.

(2)Travelling expenses for carrying out inspections outside Austria pursuant to chapter VII of the appendix are not part of the fees as specified and must be paid additionally; for national inspections the overall fee is 218 Euros.

§ 7 (1) Cash expenses pursuant to § 76 of the General Administrative Proceeding Act 1991, Federal Law Gazette No. 51 arising in the course of the proceeding or a related activity shall be deemed to be part of the fee in terms of the Schedule of Fees, unless such cash expenses exceed the fee payable. In this case the party shall pay a fee of 20 percent of the fee resulting from the Schedule of Fees and the full amount of the cash expenses. In the course of the proceeding being part of the annual fee pursuant to chapter II extra arising cash expenses are to be paid in full amount by the party.

(2) Other services not specified in the appendix or additional services shall be checked with the applicant and charged at a rate of 167 Euros per hour.

(3) The flat annual fee as laid out in chapter II of the appendix has to be paid by the authorisation or registration holder or owner of a permit pursuant § 7a Medicinal Product Act. At the end of each quarter on the last working day pro rata payment will be required for all authorised/registered/approved/licensed proprietary medicinal products/medicinal products. The flat annual fee pursuant to chapter II of the appendix has to be paid for the first time for the year 2014.

(3a) The flat annual fee pursuant to chapter III. 2 of the appendix shall be paid by the holder of approval for parallel import. The fee will be laid down proportionately at the end of each quarter and has to be paid for each registration for parallel import on the last working day of the applicable quarter.

(3b) The flat annual fee pursuant to section VII.11 of the appendix will be required from the owner of a registered domestic public pharmacy pursuant to § 59a para 2. AMG (Medicinal Product Act), an invoice will be sent by 31. May of each subsequent year, which must be paid within the period specified in the invoice.

(4) For applications corresponding to chapter I to III, IV,and IX of the appendix which are not exclusively submitted electronically the scheduled fee is increased by 5 percent.

§ 8. This regulation shall in enter into force on January 1st, 2022.

Appendix

I. Marketing authorisation for proprietary medicinal products

I.1	Marketing authorisation in a mutual recognition procedure (MRP) pursuant to § 18a Austrian Medicinal Product Act (AMG)	
I.1.a	MRP- RMS - Update	
I.1.a.1	for a new active ingredient	43.992 EURO
I.1.a.2	for a known active ingredient	33.582 EURO
I.1.a.3	Repeat use procedure (repeated marketing authorisation procedure)	6.716 EURO
I.1.a.4	Day 0 Repeat Use - procedures (repeated administrative authorisation procedure)	829 EURO
I.1.b	MRP- CMS	7.611 EURO
I.2	Marketing authorisation in a decentralised procedure (DCP) pursuant to § 18a AMG	
I.2.a	DCP-RMS	
I.2.a.1	for a new active ingredient	55.969 EURO
I.2.a.2	for a known active ingredient	41.416 EURO
I.2.b	DCP-CMS	
I.2.b.1	for a new active ingredient	9.583 EURO
I.2.b.2	for a known active ingredient	7.611 EURO
I.3	Marketing authorisation in a national procedure	
I.3.a	Marketing authorisation pursuant to § 9a AMG	
I.3.a.1	for a new active ingredient	11.978 EURO
I.3.a.2	for a known active ingredient	7.835 EURO
I.3.b	Marketing authorisation pursuant to § 10a AMG (bibliographic application)	7.575 EURO
I.3.c	Marketing authorisation pursuant to § 10 AMG (generic application)	7.575 EURO
I.3.d	Marketing authorisation pursuant to § 10b AMG (new combinations)	7.835 EURO
I.3.e	Special marketing authorisation circumstances with simplified prerequisites	
I.3.e.1	Admission of active ingredients or manufacturing methods pursuant to § 7a AMG	2.240 EURO
I.3.e.2	Marketing authorisation pursuant to § 9b AMG	
I.3.e.2.a	of a homoeopathic single pharmaceutical product	1.120 EURO
I.3.e.2.b	of a homoeopathic complex product	3.918 EURO
I.3.e.3	Pharmacopoeia monograph pursuant to §§ 9c or 9d AMG	1.343 EURO

I.4	Fees for Liechtenstein according to the Agreement between the Austrian Federal Government and the Government of the Principality of Liechtenstein (Federal Law Gazette III No. 126/2010)	
I.4.a	Austria acts as CMS for Liechtenstein, if a request according to I.1 or I.2 (DCP, MRP) is applied simultaneously in Austria	1.513 EURO
I.4.b	Austria acts as CMS for Liechtenstein, if a request according to I.1 or I.2 (DCP, MRP) is applied later in Austria	3.805 EURO

II. Flat-rate annual fee per authorised medicinal product

II.1	for authorised medicinal products with Austria as RMS	3.247 EURO
II.2	for authorised medicinal products with Austria as CMS	1.680 EURO
II.3	for national authorised medicinal products	1.399 EURO
II.4	for authorised products pursuant to § 9b AMG	337 EURO
II.5	for authorised products pursuant to § 9c AMG	337 EURO
II.6	for authorised products pursuant to § 9b AMG with Austria as RMS	671 EURO
II.7	for authorised products pursuant to § 9b AMG with Austria as CMS	337 EURO
	Registered products	
II.8	for medicinal products pursuant to § 7a AMG	337 EURO
II.9	for registered homeopathic medicinal products pursuant to § 11 AMG	28 EURO
II.10	for registered medicinal products pursuant to § 11a AMG	28 EURO
II.11	for registered traditional herbal medicinal products pursuant to § 12 AMG	337 EURO
II.12	for registered homeopathic medicinal products pursuant to § 11 AMG, with Austria as RMS	671 EURO
II.13	for registered homeopathic medicinal products pursuant to § 11 AMG, with Austria as CMS	337 EURO
II.14	for registered traditional herbal medicinal products pursuant to § 12 AMG, with Austria as RMS	671 EURO
II.15	for registered traditional herbal medicinal products pursuant to § 12 AMG, with Austria as CMS	337 EURO

III. Approval of parallel import

III.1	Application for approval of a parallel import	1.120 EURO
III.2	Flat annual fee for each medicinal product with an approval for distribution as parallel import	560 EURO

IV. Registrations/Notifications pursuant to AMG

IV.1	Registration of homeopathic medicinal products pursuant to § 11 AMG	
IV.1.a	homeopathic single remedies	448 EURO
IV.1.b	homeopathic complex remedies	1.566 EURO
IV.2	Registration of traditional herbal medicinal products	
IV.2.a	pursuant to § 12 AMG	3.135 EURO
IV.2.b	pursuant to § 12 AMG according to a pharmacopoeial monograph	1.343 EURO
IV.3	reduced quantity notification for radioactive medicinal products pursuant to § 7 (8) AMG	448 EURO
IV.4	Registration of homeopathic medicinal products in a DCP or MRP pursuant to §18a AMG	
IV.4.a	with Austria acting as RMS	4.477 EURO
IV.4.b	with Austria acting as CMS	895 EURO
IV.5	Registration of pharmacy proprietary medicinal products pursuant to § 11a AMG	1.114 EURO
IV.6	Registration of traditional herbal medicinal products in a DCP or MRP pursuant to §18a AMG	
IV.6.a	with Austria acting as RMS	
IV.6.a.1	according to a pharmacopoeial monograph pursuant to article 16 h para 3 regulation 2001/83/EG	6.238 EURO
IV.6.a.2	not according to a pharmacopoeial monograph pursuant to article 16 h para 3 regulation 2001/83/EG	18.711 EURO
IV.6.b	with Austria acting as CMS	3.135 EURO

V. Miscellaneous

V.1	Transcripts of the marketing authorisation notification	135 EURO
V.2	Declaratory applications pursuant to § 1 Abs. 3b AMG	1.120 EURO
V.3	National Scientific Advice	
V.3.a	concerning new active substances as well as biosimilars	9.850 EURO
V.3.b	concerning existing active substances	6.157 EURO
V.4	Laboratory Analysis for Competent authorities for each sample	
V.4.a	qualitative and quantitative analysis	557 EURO
V.4.b	qualitative Analysis	335 EURO
V.4.c	for qualitative and quantitative analysis of qualitative identical samples applied simultaneously (by the same applicant) full fees will be charged for the first sample pursuant to V.4.a and for each additional sample	335 EURO
V.4.d	for qualitative analysis of qualitative identical samples applied simultaneously (by the same applicant) full fees will be charged for the first sample pursuant to V.4.b and for each additional sample	223 EURO

V.4.e	Sampling for laboratory analysis on behalf of other authorities	218 EURO
V.5	Fees to be paid by the holder of a marketing authorisation, or registration or approval for parallel import distribution of a medicinal product for the processing of quality defects pursuant to § 75q AMG or recalls (Classification according to the guidelineof the European Medicines Agency „*Crisis Management regarding Defects of Centrally Authorised Products*" Classification of Batch Recalls for Quality Defects") for	
V.5.a	quality defects pursuant to § 75q AMG	1.680 EURO
V.5.b	class I defects	1.680 EURO
V.5.c	class II defects	1.120 EURO
V.5.d	class III defects	895 EURO
V.6	RMS-change (Austria takes over the role as RMS)	5.038 EURO
V.7	Notification of narcotics commerce in terms of § 6 para 1 lit 1 SMG per company according the number of announced active ingredients	
V.7.a	0 ingredients (basic fee)	165 EURO
V.7.b	1 to 5 active ingredients	557 EURO
V.7.c	6 to 20 active ingredients	1.114 EURO
V.7.d	more than 20 active ingredients	2.227 EURO

VI. Batch testing pursuant to § 26 AMG

VI.1	Notifications of batch releases	112 EURO
VI.2	Evaluation of plasma pools	224 EURO
VI.3	Batch testing of plasma products:	
VI.3.a	human albumin	1.490 EURO
VI.3.b	immunoglobulines	1.490 EURO
VI.3.c	coagulation factors, tissue adhesives, plasmas	2.240 EURO
VI.4	Batch testing of vaccines without animal trials	1.490 EURO
VI.5	Batch testing of vaccines with animal trials	5.598 EURO
VI.6	Batch testing of medicinal products with a blood product as excipiens	671 EURO

VII. Inspection of manufacturing premises, manufacturing authorisation and notification of a procurement organisation

VII.1	Approval of premises pursuant to §§ 63, 63a AMG, § 14 para. 1 BSG or § 22 GSG	3.358 EURO
VII.2	Change of the manufacturing authorisation § 65 AMG and § 14 para. 3 BSG or § 22 para 2 GSG	2.240 EURO
VII.3	Inspection of premises pursuant to §§ 59a, 67 AMG, § 68 MPG as amended by Federal Law Gazette I No. 46/2021 respectively § 38 MPG 2021, Article 93 Regulation 2017/745, Article 88 Regulation 2017/746, § 26 GSG, § 18 BSG, § 6a para 1 lines 7 and 8 and para 1b GESG, as well as inspection of labors for GLP certificate	
VII.3.a	each half inspection day started, domestic	1.114 EURO
VII.3.b	each half inspection day started, abroad	1.225 EURO
VII.4	Notification of a specialist subject to registry pursuant to AMG, GSG or BSG or of one of its regulations (qualified person, person in charge of information, etc.)	56 EURO
VII.5	Inspection of a pharmacovigilance recording system pursuant to § 75f AMG for each half inspection day started	1.063 EURO
VII.6	Inspection of a clinical trial pursuant to § 47 AMG or § 41 MPG as amended by Federal Law Gazette I No. 46/2021 respectively § 31 MPG 2021, each half inspection day	1.399 EURO
VII.7	Inspection of a design qualification for each working hour started	168 EURO
VII.8	Authorisation of a procurement organisation pursuant to § 19 GSG	1.680 EURO
VII.9	Variation of the authorisation of a procurement organisation (§ 19 para. 2 GSG)	840 EURO
VII.10	Declaration of intended starting of activity pursuant § 59a AMG (Internet pharmacy)	1.847 EURO
VII.11	Flat-rate annual fee for activity pursuant § 59a AMG (Internet pharmacy)	392 EURO
VII.12	This amount pursuant to VII.1, VII.2, VII.8 and VII.9 increases for each half day of inspection with needed checks in this context	1.114 EURO

VIII. Import of medicinal products

VIII.1	Issue of an import permit for bulk ware, for each medicinal product	279 EURO
VIII.2	Issue of an import permit for medicinal products	279 EURO
VIII.3	Issue of an import permit for medicinal products imported for the purpose of reexport, for each medicinal product	279 EURO
VIII.4	Issue of an import permit for medicinal products pursuant to § 5 para 1 subpara 2 AWEG 2010 (scientific purpose, not for use)	55 EURO
VIII.5	Issue of a marketability certificate pursuant to § 12 AWEG 2010 (except for beneficiaries pursuant to. § 2 Fees Act 1957)	279 EURO
VIII.6	Issue of an import permit of immunological veterinary medicinal products of sub-item 3002 30 (from a state not belonging to the EEA)	279 EURO
VIII.7	Notification pursuant to § 8 AWEG 2010 (immunological veterinary medicinal products of sub-item 3002 30) if they require approval pursant to § 12 Tierseuchengesetz (Epizootic Act)	141 EURO
VIII.8	Issue of an import permit for natural sources of healing pursuant to § 18 AWEG 2010	279 EURO
VIII.9	Issue of an import permit for medicinal products with the purpose of destruction	279 EURO
VIII.10	Notification of blood products pursuant to § 14 para 1 AWEG 2010	278 EURO

IX. Periodic Safety Update Reports (PSURs)

IX.1	Presentation of PSURs for medicinal products	
IX.1.a	following a marketing authorisation with Austria as RMS	4.029 EURO
IX.1.b	following a marketing authorisation with Austria as CMS or following other marketing authorisation in an exclusively national procedure	560 EURO
IX.1.c	following a marketing authorisation pursuant to § 9b or a registration pursuant to §11a AMG	112 EURO

X. Annex X. Conformity assessment procedures– medical devices within the scope of market surveillance

X.1	Fees according to § 22 para 3 MPG as amended by Federal Law Gazette I No. 46/2021 on basis of time expended according to § 7 para 2 plus expenses for external experts	
X.2	Classification of devices persuant to § 26 MPG as amended by Federal Law Gazette I No. 46/2021, Article 51 para 2 Regulation 2017/745 respectively Article 47 para 2 Regulation 2017/746 plus expenses for external experts	2.799 EURO
X.3	Declaratory proceeding pursuant to § 5a MPG as amended by Federal Law Gazette I No. 46/2021 respectively § 10 MPG 2021 (declaration, whether an item is to be deemed to fall into the scope of these) plus expenses for external experts	2.799 EURO
X.4	Declaratory proceeding pursuant to § 5a MPG as amended by Federal Law Gazette I No. 46/2021 respectively § 10 MPG 2021 (declaration with respect to correct classification of a product) plus expenses for external experts	2.799 EURO

XI. Clinical trials with medicinal products

XI.1	Notification of a clinical trial of a medicinal product (clinical trials phase I- III)	3.341 EURO
XI.2	Notification of a clinical trial of a medicinal product (clinical trials phase IV)	1.680 EURO
XI.3	Notification of a substantial amendment within a clinical trial persuant to § 37a AMG	557 EURO
XI.4	Notification of a NIS according to § 2a Abs. 3 AMG	671 EURO
XI.5	Notification of a compassionate use program according to § 8a AMG	
XI.5.a	with an opinion of the CHMP	560 EURO
XI.5.b	without an opinion of the CHMP	1.680 EURO

XII. Clinical trials – medicinal products, medical devices; performance test validation – in-vitro diagnostics (IVD)

XII.1	Clinical trial of a medical device pursuant to Directive 90/385/EEC respectively Directive 93/42/EEC or a performance test validation of an IVD pursuant to Directive 98/79/EC	
XII.1.a	Notification of a clinical trial of a medical device or a performance test validation of an IVD	3.305 EURO
XII.1.b	Notification of a substantial amendment within a clinical trial respectively a performance test validation according to § 40a MPG as amended by Federal Law Gazette I No. 46/2021	551 EURO
XII.2	Clinical trial of medical devices pursuant to Regulation 2017/745 respectively § 13 para 3 MPG 2021	
XII.2.a	Application for approval of a clinical trial of a medical device pursuant to Article 70 para 7 b of Regulation 2017/745 respectively § 13 para 3 MPG 2021, which consists of at least one medical device without CE-mark or of a modified device	6.838 EURO
XII.2.b	Application for approval of a clinical trial of a medical device pursuant to Article 70 para 7 b of Regulation 2017/745 respectively § 13 para 3 MPG 2021, consisting exclusively of CE-affixed medical devices or unmodified devices	2.486 EURO
XII.2.c	Notification of a clinical trial pursuant to Article 70 para 7 b of Regulation 2017/745 respectively § 13 para 3 MPG 2021, which consists of at least one medical device without CE-mark or of a modified device	4.351 EURO
XII.2.d	Notification of a clinical trial pursuant to Article 70 para 7 b of Regulation 2017/745 respectively § 13 para 3 MPG 2021, consisting exclusively of CE-affixed medical devices or unmodified devices	1.865 EURO
XII.2.e	Notification of a clinical trial pursuant to Article 74 para 1 Regulation 2017/745 („PMCF investigation“)	777 EURO
XII.2.f	Notification of a substantial modification to clinical trials pursuant to Article 75 Regulation 2017/745 respectively § 13 para 3 MPG 2021, concerning the clinical investigation plan, the investigator's Brochure or the investigational device	1.140 EURO
XII.2.g	Notification of a modification concerning the clinical investigation plan, the investigator's Brochure or the investigational device, which is not deemed to fall within the scope of Article 75 Regulation 2017/745 respectively § 13 para 3 MPG 2021, and which is not already part of a notification pursuant to XII.2.f	777 EURO

XIII. Free Sales Certificate (e.g. for export to countries outside of the EEA/EU area) – medical devices, IVD

XIII.1	Application for issue of a free sales certificate (new issue) for one country for medical devices and IVDs, based on the number of items included in an application	
XIII.1.a	Application for issue of a free sales certificate for one country for single devices, accessories and components of a device, if application includes 1 to 10 items	540 EURO
XIII.1.b	Application for issue of a free sales certificate for one country for single devices, accessories and components of a device, if application includes 11 to 50 items	700 EURO
XIII.1.c	Application for issue of a free sales certificate for one country for single devices, accessories and components of a device, if application includes 51 to 250 items	862 EURO
XIII.1.d	Application for issue of a free sales certificate for one country for single devices, accessories and components of a device, if application includes 251 items and beyond	1.025 EURO
XIII.2	Application for issue of a confirmation for one country, stating that the product as described in the application, intended exclusively for export to a country outside of the EEA, is not marketed in Austria as a medicinal device	
XIII.2.a	Application for issue of a confirmation for one country, if application includes 1 to 10 items	540 EURO
XIII.2.b	Application for issue of a confirmation for one country, if application includes 11 to 50 items	700 EURO
XIII.2.c	Application for issue of a confirmation for one country, if application includes 51 to 250 items	862 EURO
XIII.2.d	Application for issue of a confirmation for one country, if application includes 251 items and beyond	1.025 EURO
XIII.3	For each further identical free sales certificate pursuant to item XIII.1 for one country in case more than one is issued simultaneously as well as for each further identical confirmation pursuant to item XIII.2 for one country in case more than one is issued simultaneously	108 EURO

XIV. Official confirmations

XIV.1	Each	279 EURO
XIV.2	Each further copy when more than one identical official confirmation are issued simultaneously	56 EURO

XV. Notifications pursuant regulation on ensuring the provision of medicinal products

XV.1	Notifications pursuant to § 1 para 1 and procedures pursuant to § 3 para 1 of the regulation on ensuring the provision of medicinal products	695 EURO

XVI. Conformity assessment bodies

XVI.1	Application by conformity assessment bodies for designation pursuant to Article 38 Regulation 2017/745 respectively Article 34 Regulation 2017/746	352.240 Euro
XVI.2	Monitoring and re-assessment of notified bodies pursuant to Article 44 Regulation 2017/745 respectively Article 40 Regulation 2017/746 on basis of time expended according to § 7 para 2 plus expenses for external experts	
XVI.3	Changes to designations and notifications pursuant to Article 46 Regulation 2017/745 respectively Article 42 Regulation 2017/746 on basis of time expended according to § 7 para 2 plus expenses for external experts	