Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

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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 BGBl 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(3) If an application is rejected before administrative validation of the formal requirements or withdrawn, 10 percent of the respective fee as assessed shall be payable.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 annex is the person launching the product.

§ 1 a . (1) If the notification for a clinical trial for a medical device is submitted at the same time and in the same context with that of a medicinal product and by the same applicant, the full fees as laid out in section XII.1 of the appendix and 35 percent of the applicable fees as laid out in section XII.2 or XII.3 are to be paid.

(2) If the investigator undertakes the tasks of the sponsor pursuant to § 2a para 16 of the Austrian Medicinal Products Act, Federal Law Gazette No. 185/1983, as amended, or to § 3 para 5 of the Austrian Medical Devices Act, Federal Law Gazette No.657/1996, as amended, no fees according to chapter VII.6 and XII.4 will be charged. Fees according to chapter XII.1, XII.2. and XII.3 will be charged with 20 percent 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 authorization (" 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 authorization 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 authorization 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 208 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 159 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. (1) The subject Regulation shall be effective as per 01. July 2020.

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	42001 EURO
	I.1.a.2	for a known active ingredient	32062 EURO
	I.1.a.3	Repeat use procedure (repeated marketing authorisation procedure)	6412 EURO
I.1.b		MRP- CMS	7267 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	53436 EURO
	I.2.a.2	for a known active ingredient	39542 EURO
I.2.b		DCP-CMS	
	I.2.b.1	for a new active ingredient	9149 EURO
	I.2.b.2	for a known active ingredient	7267 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	11436 EURO
	I.3.a.2	for a known active ingredient	7481 EURO
I.3.b		Marketing authorisation pursuant to § 10a AMG (bibliographic application)	7232 EURO
I.3.c		Marketing authorisation pursuant to § 10 AMG (generic application)	7232 EURO
I.3.d		Marketing authorisation pursuant to § 10b AMG (new combinations)	7481 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	2138 EURO
	I.3.e.2	Marketing authorisation pursuant to § 9b AMG	
	I.3.e.2.a	of a homoeopathic single pharmaceutical product	1069 EURO
	I.3.e.2.b	of a homoeopathic complex product	3741 EURO
	I.3.e.3	Pharmacopoeia monograph pursuant to §§ 9c or 9d AMG	1282 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	1444 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	3633 EURO

II. Flat-rate annual fee per authorised medicinal product

	II.1	for authorised medicinal products with Austria as RMS	3100 EURO
	II.2	for authorised medicinal products with Austria as CMS	1604 EURO
	II.3	for national authorised medicinal products	1335 EURO
	II.4	for authorised products pursuant to § 9b AMG	321 EURO
	II.5	for authorised products pursuant to § 9c AMG	321 EURO
	II.6	for authorised products pursuant to § 9b AMG with Austria as RMS	641 EURO
	II.7	for authorised products pursuant to § 9b AMG with Austria as CMS	321 EURO

	Registered products	
II.8	for medicinal products pursuant to § 7a AMG	321 EURO
II.9	for registered homeopathic medicinal products pursuant to § 11 AMG	27 EURO
II.10	for registered medicinal products pursuant to § 11a AMG	27 EURO
II.11	for registered traditional herbal medicinal products pursuant to § 12 AMG	321 EURO
II.12	for registered homeopathic medicinal products pursuant to § 11 AMG, with Austria as RMS	641 EURO
II.13	for registered homeopathic medicinal products pursuant to § 11 AMG, with Austria as CMS	321 EURO
II.14	for registered traditional herbal medicinal products pursuant to § 12 AMG, with Austria as RMS	641 EURO
II.15	for registered traditional herbal medicinal products pursuant to § 12 AMG, with Austria as CMS	321 EURO

III. Approval of parallel import

	III.1	Application for approval of a parallel import	1069 EURO
	III.2	Flat annual fee for each medicinal product with an approval for distribution as parallel import	535 EURO

IV. Registrations/Notifications pursuant to AMG

IV.1	Registration of homeopathic medicinal products pursuant to § 11 AMG	

	IV.1.a	homeopathic single remedies	427	EURO
	IV.1.b	homeopathic complex remedies	1496	EURO
IV.2		Registration of traditional herbal medicinal products		
	IV.2.a	pursuant to § 12 AMG	2993	EURO
	IV.2.b	pursuant to § 12 AMG according to a pharmacopoeial monograph	1282	EURO
IV.3		reduced quantity notification for radioactive medicinal products pursuant to § 7 (8) AMG	427	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	4274	EURO
	IV.4.b	with Austria acting as CMS	855	EURO
IV.5		Registration of pharmacy proprietary medicinal products pursuant to § 11a AMG	1063	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	5955	EURO
	IV.6.a.2	not according to a pharmacopoeial monograph pursuant to article 16 h para 3 regulation 2001/83/EG	17864	EURO
IV.6.b		with Austria acting as CMS	2993	EURO

V. Miscellaneous

V.1		Transcripts of the marketing authorisation notification	129	EURO
V.2		Declaratory applications pursuant to § 1 Abs. 3b AMG	1069	EURO
V.3		National Scientific Advice		
	V.3.a	concerning new active substances as well as biosimilars	9405	EURO
	V.3.b	concerning existing active substances	5878	EURO
V.4		Laboratory Analysis for Competent authorities for each sample		
	V.4.a	qualitative and quantitative analysis	532	EURO
	V.4.b	qualitative Analysis	319	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	319	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	213	EURO

	V.4.e	Sampling for laboratory analysis on behalf of other authorities for each sample	208 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 guideline of 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	1604 EURO
	V.5.b	class I defects	1604 EURO
	V.5.c	class II defects	1069 EURO
	V.5.d	class III defects	855 EURO
V.6		RMS-change (Austria takes over the role as RMS)	4810 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)	157 EURO
	V.7.b	1 to 5 active ingredients	532 EURO
	V.7.c	6 to 20 active ingredients	1063 EURO
	V.7.d	more than 20 active ingredients	2127 EURO

VI. Batch testing pursuant to § 26 AMG

VI.1		Notifications of batch releases	107 EURO
VI.2		Evaluation of plasma pools	214 EURO
VI.3		Batch testing of plasma products:	
	VI.3.a	human albumin	1422 EURO
	VI.3.b	immunoglobulines	1422 EURO
	VI.3.c	coagulation factors, tissue adhesives, plasmas	2138 EURO
VI.4		Batch testing of vaccines without animal trials	1422 EURO
VI.5		Batch testing of vaccines with animal trials	5344 EURO
VI.6		Batch testing of medicinal products with a blood product as excipiens	641 EURO

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

VII.1	Approval of premises pursuant to §§ 63, 63a AMG, § 14 para. 1 BSG or § 22 GSG	3206 EURO
VII.2	Change of the manufacturing authorization § 65 AMG and § 14 para. 3 BSG or § 22 para 2 GSG	2138 EURO

VII.3		Inspection of premises pursuant §§ 59a, § 67 AMG und § 68 MPG, § 26 GSG, § 18 BSG, § 6a para 1 lines 7 and 8 and para 1b GESG, as well inspection of labors for GLP certificate	
	VII.3.a	each half inspection day started, domestic	1063 EURO
	VII.3.b	each half inspection day started, abroad	1169 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.)	53 EURO
VII.5		Inspection of a pharmacovigilance recording system pursuant to § 75f AMG for each half inspection day started	1015 EURO
VII.6		Inspection of a clinical trial pursuant to § 47 AMG and § 41 MPG each half inspection day	1335 EURO
VII.7		Inspection of a design qualification for each working hour started	160 EURO
VII.8		Authorisation of a procurement organisation pursuant to § 19 GSG	1604 EURO
VII.9		Variation of the authorisation of a procurement organisation (§ 19 para. 2 GSG)	802 EURO
VII.10		Declaration of intended starting of activity pursuant §59a AMG	1764 EURO
VII.11		Flat-rate annual fee for activity pursuant §59a AMG	374 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	1063 EURO

VIII. Import of medicinal products

VIII.1	Issue of an import permit for bulk ware, for each medicinal product	266 EURO
VIII.2	Issue of an import permit for medicinal products	266 EURO
VIII.3	Issue of an import permit for medicinal products imported for the purpose of reexport, for each medicinal product	266 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)	52 EURO
VIII.5	Issue of a marketability certificate pursuant to § 12 AWEG 2010 (except for beneficiaries pursuant to. § 2 Fees Act 1957)	266 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)	266 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)	135 EURO

VIII.8	Issue of an import permit for natural sources of healing pursuant to § 18 AWEG 2010	266 EURO
VIII.9	Issue of an import permit for medicinal products with the purpose of destruction	266 EURO
VIII.10	Notification of blood products pursuant to § 14 para 1 AWEG 2010	265 EURO

IX. Periodic Safety Update Reports (PSURs)

IX.1	Presentation of PSURs for medicinal products	
IX.1.a	following a marketing authorization with Austria as RMS	3847 EURO
IX.1.b	following a marketing authorisation with Austria as CMS or following other marketing authorisation in an exclusively national procedure	535 EURO
IX.1.c	following a marketing authorisation pursuant to § 9b or a registration pursuant to §11a AMG	107 EURO

X. Conformity assessment procedures– medical devices within the scope of market surveillance (§§ 22 and 23 MPG)

X.1	Fees according to §22 para 3 MPG on basis of time expended according §7 para 2 plus expenses for external experts	

XI. Classification of medical devices

XI.1	Application for classification of a medical device pursuant to § 26 MPG plus expenses for external experts	2673 EURO
XI.2	Declaratory proceeding pursuant to § 5a MPG (declaration, whether an item is to be subsumed under § 2 para 1 to 6 MPG) plus expenses for external experts	2673 EURO
XI.3	Declaratory proceeding pursuant to § 5a MPG (classification of a medical device) plus expenses for external experts	2673 EURO

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

XII.1	Notification of a clinical trial of a medical device or a performance test validation of an IVD pursuant to § 40 MPG	3190 EURO
XII.2	Notification of a clinical trial of a medical product (clinical trials phase I- III)	3190 EURO
XII.3	Notification of a clinical trial of a medical product (clinical trials	1604 EURO
XII.4	Notification of a substantial amendment within a clinical trial according to § 37a AMG or § 40a MPG	532 EURO
XII.5	Notification of a NIS according to § 2a Abs. 3 AMG	641 EURO

XII.6		Notification of a compassionate use program according to § 8a AMG	
	XII.6.a	with an opinion of the CHMP	535 EURO
	XII.6.b	without an opinion of the CHMP	1604 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	515 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	669 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	823 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	978 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	515 EURO
	XIII.2.b	Application for issue of a confirmation for one country, if application includes 11 to 50 items	669 EURO
	XIII.2.c	Application for issue of a confirmation for one country, if application includes 51 to 250 items	823 EURO

XIII.2.d	Application for issue of a confirmation for one country, if application includes 251 items and beyond	978	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	103	EURO

XIV. Official confirmations

XIV.1	Each	266	EURO
XIV.2	Each further copy when more than one identical official confirmation are issued simultaneously	53	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	664	EURO