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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(3) If an application is rejected before administrative validation of the formal requirements or withdrawn, 10 percent of the respective fee as assessed shall be payable.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 210 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 161 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. January 2021.

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	42.463 EURO
	I.1.a.2	for a known active ingredient	32.415 EURO
	I.1.a.3	Repeat use procedure (repeated marketing authorisation procedure)	6.483 EURO
I.1.b		MRP- CMS	7.347 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	54.024 EURO
	I.2.a.2	for a known active ingredient	39.977 EURO
I.2.b		DCP-CMS	
	I.2.b.1	for a new active ingredient	9.250 EURO
	I.2.b.2	for a known active ingredient	7.347 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	11.562 EURO
	I.3.a.2	for a known active ingredient	7.563 EURO
I.3.b		Marketing authorisation pursuant to § 10a AMG (bibliographic application)	7.312 EURO
I.3.c		Marketing authorisation pursuant to § 10 AMG (generic application)	7.312 EURO
I.3.d		Marketing authorisation pursuant to § 10b AMG (new combinations)	7.563 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	2.162 EURO
	I.3.e.2	Marketing authorisation pursuant to § 9b AMG	
	I.3.e.2.a	of a homoeopathic single pharmaceutical product	1.081 EURO
	I.3.e.2.b	of a homoeopathic complex product	3.782 EURO
	I.3.e.3	Pharmacopoeia monograph pursuant to §§ 9c or 9d AMG	1.296 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	1.460 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	3.673 EURO

II. Flat-rate annual fee per authorised medicinal product

II.1	for authorised medicinal products with Austria as RMS	3.134 EURO
II.2	for authorised medicinal products with Austria as CMS	1.622 EURO
II.3	for national authorised medicinal products	1.350 EURO
II.4	for authorised products pursuant to § 9b AMG	325 EURO
II.5	for authorised products pursuant to § 9c AMG	325 EURO
II.6	for authorised products pursuant to § 9b AMG with Austria as RMS	648 EURO
II.7	for authorised products pursuant to § 9b AMG with Austria as CMS	325 EURO

	Registered products	
II.8	for medicinal products pursuant to § 7a AMG	325 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	325 EURO
II.12	for registered homeopathic medicinal products pursuant to § 11 AMG, with Austria as RMS	648 EURO
II.13	for registered homeopathic medicinal products pursuant to § 11 AMG, with Austria as CMS	325 EURO
II.14	for registered traditional herbal medicinal products pursuant to § 12 AMG, with Austria as RMS	648 EURO
II.15	for registered traditional herbal medicinal products pursuant to § 12 AMG, with Austria as CMS	325 EURO

III. Approval of parallel import

III.1	Application for approval of a parallel import	1.081 EURO
III.2	Flat annual fee for each medicinal product with an approval for distribution as parallel import	541 EURO

IV. Registrations/Notifications pursuant to AMG

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

	IV.1.a	homeopathic single remedies	432 EURO
	IV.1.b	homeopathic complex remedies	1.512 EURO
IV.2		Registration of traditional herbal medicinal products	
	IV.2.a	pursuant to § 12 AMG	3.026 EURO
	IV.2.b	pursuant to § 12 AMG according to a pharmacopoeial monograph	1.296 EURO
IV.3		reduced quantity notification for radioactive medicinal products pursuant to § 7 (8) AMG	432 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	4.321 EURO
	IV.4.b	with Austria acting as CMS	864 EURO
IV.5		Registration of pharmacy proprietary medicinal products pursuant to § 11a AMG	1.075 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	6.021 EURO
	IV.6.a.2	not according to a pharmacopoeial monograph pursuant to article 16 h para 3 regulation 2001/83/EG	18.061 EURO
IV.6.b		with Austria acting as CMS	3.026 EURO

V. Miscellaneous

V.1		Transcripts of the marketing authorisation notification	130 EURO
V.2		Declaratory applications pursuant to § 1 Abs. 3b AMG	1.081 EURO
V.3		National Scientific Advice	
	V.3.a	concerning new active substances as well as biosimilars	9.508 EURO
	V.3.b	concerning existing active substances	5.943 EURO
V.4		Laboratory Analysis for Competent authorities for each sample	
	V.4.a	qualitative and quantitative analysis	538 EURO
	V.4.b	qualitative Analysis	323 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	323 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	215 EURO

	V.4.e	Sampling for laboratory analysis on behalf of other authorities for each sample	210 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	1.622 EURO
	V.5.b	class I defects	1.622 EURO
	V.5.c	class II defects	1.081 EURO
	V.5.d	class III defects	864 EURO
V.6		RMS-change (Austria takes over the role as RMS)	4.863 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)	159 EURO
	V.7.b	1 to 5 active ingredients	538 EURO
	V.7.c	6 to 20 active ingredients	1.075 EURO
	V.7.d	more than 20 active ingredients	2.150 EURO

VI. Batch testing pursuant to § 26 AMG

VI.1		Notifications of batch releases	108 EURO
VI.2		Evaluation of plasma pools	216 EURO
VI.3		Batch testing of plasma products:	
	VI.3.a	human albumin	1.438 EURO
	VI.3.b	immunoglobulines	1.438 EURO
	VI.3.c	coagulation factors, tissue adhesives, plasmas	2.162 EURO
VI.4		Batch testing of vaccines without animal trials	1.438 EURO
VI.5		Batch testing of vaccines with animal trials	5.403 EURO
VI.6		Batch testing of medicinal products with a blood product as excipiens	648 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	3.241 EURO
VII.2	Change of the manufacturing authorization § 65 AMG and § 14 para. 3 BSG or § 22 para 2 GSG	2.162 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	1.075 EURO
	VII.3.b	each half inspection day started, abroad	1.182 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.)	54 EURO
VII.5		Inspection of a pharmacovigilance recording system pursuant to § 75f AMG for each half inspection day started	1.026 EURO
VII.6		Inspection of a clinical trial pursuant to § 47 AMG and § 41 MPG each half inspection day	1.350 EURO
VII.7		Inspection of a design qualification for each working hour started	162 EURO
VII.8		Authorisation of a procurement organisation pursuant to § 19 GSG	1.622 EURO
VII.9		Variation of the authorisation of a procurement organisation (§ 19 para. 2 GSG)	811 EURO
VII.10		Declaration of intended starting of activity pursuant §59a AMG	1.783 EURO
VII.11		Flat-rate annual fee for activity pursuant §59a AMG	378 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	1.075 EURO

VIII. Import of medicinal products

VIII.1	Issue of an import permit for bulk ware, for each medicinal product	269 EURO
VIII.2	Issue of an import permit for medicinal products	269 EURO
VIII.3	Issue of an import permit for medicinal products imported for the purpose of reexport, for each medicinal product	269 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)	53 EURO
VIII.5	Issue of a marketability certificate pursuant to § 12 AWEG 2010 (except for beneficiaries pursuant to. § 2 Fees Act 1957)	269 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)	269 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)	136 EURO

VIII.8	Issue of an import permit for natural sources of healing pursuant to § 18 AWEG 2010	269 EURO
VIII.9	Issue of an import permit for medicinal products with the purpose of destruction	269 EURO
VIII.10	Notification of blood products pursuant to § 14 para 1 AWEG 2010	268 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	3.889 EURO
IX.1.b	following a marketing authorisation with Austria as CMS or following other marketing authorisation in an exclusively national procedure	541 EURO
IX.1.c	following a marketing authorisation pursuant to § 9b or a registration pursuant to §11a AMG	108 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	2.702 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	2.702 EURO
XI.3	Declaratory proceeding pursuant to § 5a MPG (classification of a medical device) plus expenses for external experts	2.702 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	3.225 EURO
XII.2	Notification of a clinical trial of a medical product (clinical trials phase I- III)	3.225 EURO
XII.3	Notification of a clinical trial of a medical product (clinical trials	1.622 EURO
XII.4	Notification of a substantial amendment within a clinical trial according to § 37a AMG or § 40a MPG	538 EURO
XII.5	Notification of a NIS according to § 2a Abs. 3 AMG	648 EURO

XII.6		Notification of a compassionate use program according to § 8a AMG	
	XII.6.a	with an opinion of the CHMP	541 EURO
	XII.6.b	without an opinion of the CHMP	1.622 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	521 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	676 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	832 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	989 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	521 EURO
	XIII.2.b	Application for issue of a confirmation for one country, if application includes 11 to 50 items	676 EURO
	XIII.2.c	Application for issue of a confirmation for one country, if application includes 51 to 250 items	832 EURO

XIII.2.d	Application for issue of a confirmation for one country, if application includes 251 items and beyond	989 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	104 EURO

XIV. Official confirmations

XIV.1	Each	269 EURO
XIV.2	Each further copy when more than one identical official confirmation are issued simultaneously	54 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	671 EURO