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

On the basis of § 6a para 6 of the Act on Safety in Health and Food, Federal Law Gazette I No 63/2002, as modified by Federal Act BGBl I No 63/2009, 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 IX of the appendix – are payable within adequate term after administrative validation of the formal requirements or receipt of documentation. Fees pursuant to chapter IX 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(3) If an application is rejected before administrative validation of the formal requirements or withdrawn, 10 percent of the respective fee as assessed shall be payable.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 XII of the annex is the person who launched the product.

§ 1 a. (1) If the investigator undertakes the tasks of the sponsor pursuant to § 2a para 17 of the Austrian Medicinal Products Act, Federal Law Gazette No. 185/1983, as published in the Federal Law Gazette No. I 115/2008, or to § 3 para 5 of the Austrian Medical Devices Act, Federal Law Gazette No. 657/1996, as published in the Federal Law Gazette No. I 77/2008, no fees according to chapter IX.6 and XIV will be charged.

(2) Where the submission for a clinical trial for a medical device coincides in timing and context with that of a medicinal product held by the same applicant, fees as laid out in section XIV.1 are to be paid.

§ 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) An 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. For the marketing authorisation of two or more proprietary medicinal products in terms of chapter

I 1, I 2 or I.3.paras a,b,c and d of the annex,

1. the marketing authorisation of which is being applied for simultaneously by another 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 one of such applications, and 50% of such fee for (a) further application(s).

§ 3a. (1) For variations pursuant to article 7 para 2 lit a, in conjunction with article 8 para 1, first subparagraph of Commission Regulation (EC) No. 1234/2008, full fees as laid out in annex II.1 are payable for the submission of the Annual Report of the first marketing authorisation concerned, for each further submission 65% of the applicable fees are to be paid.

(2) For variations pursuant to article 7 para 2 point (a), in conjunction with article 8 para 1, second subparagraph of Commission Regulation (EC) No. 1234/2008, full fees are payable for each variation according to annex II.1 of the first marketing authorisation concerned; 65% of the fees apply to further variations of other marketing authorisations.

(3) For variations pursuant to article 7 para 2 lit b of Commission Regulation (EC) No. 1234/2008, full fees are payable for each variation according to annex II.1 of the first marketing authorisation concerned; 65% of the fees apply to further variations of other marketing authorisations.

(4) For variations pursuant to article 20 of Commission Regulation (EC) No. 1234/2008 with Austria as reference authority, full fees as laid out in annex II.1 lit a are payable for each variation of the first marketing authorisation concerned, for each further variation of a marketing authorisation 65% of the fees apply.

(5) For variations pursuant to article 20 of Commission Regulation (EC) No. 1234/2008 with Austria as concerned authority, full fees as laid out in annex II.1 lit b are payable for each variation of the first marketing authorisation concerned, for each further variation of a marketing authorisation 65% of the fees apply.

(6) For variations pursuant to article 20 para 2 lit a of Commission Regulation (EC) No. 1234/2008 with the agency (EMA) as reference authority, 50% of the fees laid out in annex II.1 lit b are payable for each variation of the first marketing authorisation concerned, for each further variation of a marketing authorisation 65% of the intended fees apply.

(7) For transfers pursuant to § 25 of the Austrian Medicinal Product Act full fees as laid out in Section II.3 are payable for the first marketing authorisation concerned, for each further marketing authorisation 65% of the intended fees apply.

§ 3b. No fees apply when a variation in accordance with section II.2 involves only the change of the name or the address of the marketing authorisation holder or registration holder.

§ 4. For the presentation of „Periodic Safety Update Report (PSUR)” (definition § 2b para 8 AMG [Medicinal Product Act]) of two or more medicinal products of which the active ingredient is (the active ingredients are) identical, and

1. if they are presented simultaneously by the same marketing authorisation holder
2. of which the active ingredients are of the same type, 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% of the respective fee for (a) further application(s).

§ 5. For approvals and other activities concerning proprietary medicinal products exclusively intended for animals

1. a fee of 50 percent of the fee pursuant to the schedule is payable with regard to appendix I and X (except for X.6 and 7) and
2. a fee of 30 percent of the fee pursuant to the schedule is payable with regard to appendix II, IV, V, VI, VIII, IX and XI.

§ 6. 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.

§ 7. (1) In case in the course of the proceeding or a related activity cash expenses pursuant to § 76 of the General Administrative Proceeding Act 1991, Federal Law Gazette No. 51, arise, these expenses 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.

(2) Travelling expenses for carrying out inspections outside Austria pursuant to chapter IX of the appendix are not part of the fees as specified and must be paid additionally; for national inspections the overall fee is 140,00 Euros.

(3) Other services not specified in the appendix or additional services shall be checked with the

applicant and charged at a rate of 150 EUR/hour.

§ 8. (1) The subject Regulation shall be effective as of 15 January 2006¹.

¹**Explanation:** The Regulation of the Federal Office for Safety in Health Care on the Schedule of Fees pursuant to the Health and Food Safety Act (GESG) became effective on January 15, 2006 (as published in the "Amtsblatt der Wiener Zeitung" dated 18 Jan 2006).

The amendment of the Schedule of Fees by the Regulation of the Federal Office for Safety in Health Care – BASG VO No 02/2006 shall be effective as of 15 January 2007.

The amendment of the Schedule of Fees by the Regulation of the Federal Office for Safety in Health Care – BASG VO No 01/2008 shall be effective as of 03 November 2008.

The amendment of the Schedule of Fees by the Regulation of the Federal Office for Safety in Health Care – BASG VO No 01/2009 shall be effective as of 26 March 2009.

The amendment of the Schedule of Fees by the Regulation of the Federal Office for Safety in Health Care – BASG VO No 02/2009 shall be effective as of 02 January 2010.

The BASG VO No 02/2006, BASG VO No 01/2008, BASG VO No 01/2009 and VO No 02/2009 shall not apply to proceedings already pending – as filed before their coming into force.

I. Marketing authorisation for proprietary medicinal products

I.1 Marketing authorisation in a mutual recognition procedure pursuant to § 18a Austrian Medicinal Product Act (AMG)

a. as Reference Member State - RMS - Update	
a. for a new active ingredient	39.300,00 EURO
b. for a known active ingredient	30.000,00 EURO
c. Repeat use procedure (repeated marketing authorisation procedure)	6.000,00 EURO
b. as Concerned Member State - CMS	6.800,00 EURO

I.2 Marketing authorisation in a decentralised procedure pursuant to § 18a AMG

a. as Reference Member State - RMS	
a. for a new active ingredient	50.000,00 EURO
b. for a known active ingredient	37.000,00 EURO
b. as Concerned Member State - „CMS“	
a. for a new active ingredient	8.560,00 EURO
b. for a known active ingredient	6.800,00 EURO

I.3 Marketing authorisation in a national procedure

a. Marketing authorisation pursuant to § 9a AMG	
a. for a new active ingredient	10.700,00 EURO
b. for a known active ingredient	7.000,00 EURO
b. Marketing authorisation pursuant to §§ 10 para. 8 („bio-similar“) and 10a AMG (bibliographic application)	5.600,00 EURO
c. Marketing authorisation pursuant to § 10 AMG (generic application, except § 10 para. 8 AMG)	4.200,00 EURO
d. Marketing authorisation pursuant to § 10b AMG (new combinations)	7.000,00 EURO
e. Special marketing authorisation circumstances with simplified prerequisites	
1. Admission of active ingredients or manufacturing methods pursuant to § 7a AMG	2.000,00 EURO
2. Marketing authorisation pursuant to § 9b AMG	1.000,00 EURO
a. of a homoeopathic single pharmaceutical	
b. of a homoeopathic complex product	3.500,00 EURO
3. Pharmacopoeia monograph pursuant to §§ 9c or 9d AMG	1200,00 EURO

II. Variations to marketing authorisations

II.1 Variations pursuant to the Regulation (EC) Nr. 1234/2008 (OJ. L 334 dd. 12.12.2008)

a. As Reference Member State - RMS	
a. for type IA _{in} - variations	1.200,00 EURO
b. for type IB - variations	2.000,00 EURO
c. for type II - variations	6.000,00 EURO
d. for notifications/reports pursuant to Art 61(3) of Directive 2001/83 EC as amended (OJ. Nr. L 311 dd. 28.11.2001)	600,00 EURO
e. for the Annual Report	1.4000 EURO
b. As Concerned Member State - „CMS“	
a. for type IA _{in} - variations	450,00 EURO
b. for type IB - variations	600,00 EURO
c. for type II - variations	1.600,00 EURO
d. for notifications/reports pursuant to Art 61(3) of Directive 2001/83 EC as amended (OJ. Nr. L 311 dd. 28.11.2001)	400,00 EURO
e. for the Annual Report	600,00 EURO

II.2 Variations pursuant to AMG (for exclusively national marketing authorisations)

II.2.1 Variations requiring approval pursuant to § 24 para. 2 AMG

a. Variations of the name	400,00 EURO
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b. Variations of the composition	800,00 EURO
c. Other Variations requiring approval	1.600,00 EURO
II.2.2 Variations requiring marketing authorisation pursuant to § 24 Abs. 4 AMG	400,00 EURO
II.2.3 Variations requiring modification pursuant to § 24 Abs. 6 AMG	400,00 EURO
II.2.4 Variations of medicinal products admitted pursuant to § 7a AMG	400,00 EURO
II.2.5 Variations of medicinal products in accordance with § 24 para 2 AMG, which were admitted pursuant to §11a AMG	300,00 EURO
II.2.6 Other Variations of medicinal products admitted pursuant to § 11a AMG	100,00 EURO
II.2.7 Variations of medicinal products admitted pursuant to § 11 AMG for which a scientific opinion is needed	100,00 EURO
II.3 Notification requiring marketing authorisation pursuant to § 25 AMG (transfer)	400,00 EURO
II.4 Changes concerning prescription requirement status due to amendments to the prescription regulation.	400,00 EURO
III. Approval of parallel import	
III. 1 Application for approval of a parallel import	1.000,00 EURO
IV. Renewal of a marketing authorisation/ registration	
IV. 1 as a Reference Member State (RMS)	17.000,00 EURO
IV.2 as a Concerned Member State (CMS)	1.600,00 EURO
IV.3 national marketing authorisations pursuant to § 9b, 9c or 9d	300,00 EURO
IV.4 national marketing authorisations pursuant to § 9b, 9c or 9d which have been renewed according to § 19a (in the version before Federal Law Gazette I No 153/2005)	180,00 EURO
IV.5 nationally approved products - other	1.600,00 EURO
IV.6 nationally approved products – other, which have been renewed according to § 19a (in the version before Federal Law Gazette I No 153/2005)	900,00 EURO
IV.7 nationally approved products according to § 11	100,00 EURO
IV.8 nationally approved products according to § 11a	100,00 EURO
IV.9 nationally approved products according to § 12	1000,00 EURO
V. Evaluation of conditions imposed	
V. 1 in the mutual recognition procedure / decentralised procedure as Reference Member State - RMS	6.000,00 EURO
V.2. in an exclusively national procedure	1.200,00 EURO
VI. Registrations/Notifications pursuant to AMG	
VI. 1 registration of homeopathic medicinal products pursuant to § 11 AMG	400,00 EURO
VI.2 registration of traditional herbal medicinal products pursuant to § 12 AMG	2.800,00 EURO
VI.3 reduced quantity notification for radioactive medicinal products pursuant to § 7 Abs. 8 AMG	400,00 EURO
VI.4 Registration of homeopathic medicinal products in a decentralised procedure or mutual recognition procedure with Austria acting as:	
a. Reference Member State - "RMS" (primarily authorising country)	4000,00 EURO
b. Concerned Member State - "CMS" (other country involved in the application)	800,00 EURO
VI.5 registration of pharmacy proprietary medicinal products pursuant to § 11a AMG	600,00 EURO
VI.6 registration of traditional herbal medicinal products in a decentralised procedure or mutual recognition procedure with Austria acting as:	
a. Reference Member State - "RMS" (primarily authorising country)	5.600,00 EURO
b. Concerned Member State - "CMS" (other country involved in the application)	2.800,00 EURO

VII. Miscellaneous	
VII. 1 suspension of a marketing authorisation	400,00 EURO
VII.2 cancellation ex officio of a marketing authorisation	400,00 EURO
VII.3 transcripts of the marketing authorisation notification	120,00 EURO
VII.4 declaratory applications pursuant to § 1 Abs. 3b AMG	1.000,00 EURO
VII.5 Notice pursuant to § 22 Austrian Medicinal Product Act (expiration of the marketing authorisation)	400,00 EURO
VIII. Batch testing pursuant to § 26 AMG	
VIII.1 notifications of batch releases	100,00 EURO
VIII.2 evaluation of plasma pools	200,00 EURO
VIII.3 batch testing of plasma products:	
VIII.3.1 human albumin	1.330,00 EURO
VIII.3.2 immunoglobulines	1.330,00 EURO
VIII.3 .3 coagulation factors, tissue adhesives, plasmas	2.000,00 EURO
VIII.4 batch testing of vaccines without animal trials	1.330 ,00 EURO
VIII.5 batch testing of vaccines with animal trials	5.000,00 EURO
VIII.6 batch testing of medicinal products with a blood product as excipients	600,00 EURO
IX. Inspection of manufacturing premises, manufacturing authorization and notification of a procurement organisation	
IX.1 approval of premises pursuant to § 63 AMG, § 14 para. 1 BSG or § 22 GSG (Austrian Tissue Safety Act)	3.000,00 EURO
IX.2 variation of the manufacturing authorization § 65 AMG and § 14 para. 3 BSG or § 22 para. 2 GSG	2.000,00 EURO
IX.3 inspection premises pursuant § 67 AMG und § 68 Medical Devices Act (MPG) or § 26 GSG	
a. each half inspection day, domestic	650,00 EURO
b. each half inspection day, abroad	750,00 EURO
IX.4 notification of a specialist subject to registry pursuant to AMG or GSG or of one of its regulations (qualified person, person in charge of information, ..)	50,00 EURO
IX.5 inspection of a pharmacovigilance – recording system pursuant to § 75c AMG for each half inspection day	950,00 EURO
IX.6 inspection of a clinical trial pursuant to § 47 AMG and § 41 MPG each half inspection day	1.250,00 EURO

IX.7 design qualification for each working hour or part thereof	150,00 EURO
IX.8 laboratory inspection for issue of a GLP certificate, each half inspection day	650,00 EURO
IX.9 Authorisation of a procurement organisation pursuant to § 19 GSG	1500,00 EURO
IX. 10 variation of the authorisation of a procurement organisation (§ 19 para. 2 GSG)	750,00 EURO
IX. 11 hourly rate for each started hour in connection with inspections according to § 6a para 1 Z 7 und 8 of the Act on Safety in Health and Food, Federal Law Gazette I No 63/2002, as modified by Federal Act BGBl I No 143/2008	150,00 EURO
IX. 12 This amount increases for each half day of inspection or part thereof according to IX.1-2 and IX. 9-10, by	650,00 EURO

X. Import of medicinal products

X.1 issue of an import permit for bulk ware, for each medicinal product	250,00 EURO
X.2 issue of an import permit for medicinal products within the scope of a clinical trial	250,00 EURO
X.3 issue of an import permit for medicinal products imported for the purpose of reexport, for each medicinal product	250,00 EURO
X.4 issue of an import permit for medicinal products Pursuant to. § 2 Abs. 3 Z. 2 (scientific purpose, not for use)	10,00 EURO
X.5 issue of a marketability certificate or verification of a global notification pursuant to § 7 AWEG (except for beneficiaries pursuant to. § 2 Fees Act 1957)	250,00 EURO
X.6 issue of an import permit of immunological veterinary medicinal products of sub-item 3002 (from a state not belonging to the EEA)	250,00 EURO
X.7 Notification pursuant to § 2 Medicinal Products Import Act (immunological veterinary medicinal products of sub-item 3002 30) if they require approval pursuant to § 12 Tierseuchengesetz (Epizootic Act)	125,00 EURO

XI. Periodic Safety Update Reports (PSURs)

XI. 1 presentation of a PSURs for a medicinal product	
XI. 1.1 following a marketing authorisation in which Austria is the RMS	3.600,00 EURO
XI. 1.2 following a marketing authorisation in which Austria is a CMS or following other marketing authorisations in an exclusively national procedures	500,00 EURO
XI. 1.3 following a marketing authorisation pursuant to § 9b or a registration pursuant to § 11a	100,00 EURO

XII. Conformity assessment procedures– medical devices within the scope of market surveillance (§ 68 MPG)

XII. 1 application for conformity inspection of a medical device pursuant to MPG	
XII. 1.1 formal inspection of a documentation for conformity of a medical device presented by marketer	560,00 EURO
XII. 1.2 verification of contents with regard to compliance with basic requirements based on conformity documentation presented by marketer	2.200,00 EURO
XII. 1.3 product or system verification in connection with an in-depth conformity assessment procedures conformity inspection, plus expenses for external experts	2.500,00 EURO

XIII. Classification of medical devices

XIII. 1 application for classification of a medical device pursuant to § 26 MPG	
XIII. 1.1 formal inspection for classification of a documentation presented by marketer	990,00 EURO
XIII. 1.2 inspection of contents for classification of a documentation presented by marketer	2.200,00 EURO
XIII. 1.3 notification of classification pursuant to § 26 MPG plus expenses of external experts	2.500,00 EURO
XIII. 2 classification of a medical device pursuant to §§ 2, 4 und 5 MPG	
XIII. 2.1 formal inspection of a documentation for classification submitted by a marketer	990,00 EURO
XIII.2.2 inspection of the contents of a documentation for classification submitted by a marketer	2.200,00 EURO

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

XIV.1 notification of a clinical trial of a medical device or a performance test validation of an IVD pursuant to § 40 MPG	2.500,00 EURO
XIV.2 notification of a clinical trial of a medical product (clinical trials phase I-III)	2.500,00 EURO
XIV.3 notification of a clinical trial of a medical product (clinical trials phase IV)	1.500,00 EURO

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

XV.1 application for issue of a free sales certificate (new issue) for a product list and a country	450,00 EURO
XV.2 application for issue of a confirmation 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 medical device	450,00 EURO
XV.3 for each further identical (except for the country) free sales certificate in case that it is not issued simultaneously	300,00 EURO
XV.4 for each further identical (except for the country) free sales certificate, in case more than one is issued simultaneously	50,00 EURO
XV.5 application for issue of a free sales certificate (new issue) for a product list including all copies without declaration of a state	450,00 EURO

XV.6 for incomplete applications pursuant to items XV.1, XV.2 and XV.5, requiring separate verification of the classification in terms of part XIII of the annex, the respective fees pursuant to part XII and/or XIII of the annex shall be payable

XVI. Official confirmations

XVI. 1 each	250,00 EURO
XVI.2 each further copy when more than one identical official confirmation are issued simultaneously	50,00 EURO