

Kostenverordnung für die Zulassung von Arzneimitteln durch das Bundesinstitut für Arzneimittel und Medizinprodukte und das Bundesamt für Verbraucherschutz und Lebensmittelsicherheit – AMGKostV (AMG-Kostenverordnung)

TRANSLATION

Ordinance

**Regulating the Fees Payable for Marketing Authorisations granted by the Federal Institute for Drugs and Medical Devices and/or the Federal Office of Consumer Protection and Food Safety
(AMG Fees Ordinance – AMGKostV)**

of December 10, 2003

(Federal Gazette Vol. 2003 Part I No. 59, p. 2510 of 16 December 2003)

amended by the First Ordinance of 21 December 2004

(Federal Gazette Vol. 2004 Part I No. 73, p. 3719 of 28 December 2004)

last amended by the Second Ordinance of 23 April 2008

(Federal Gazette Vol. 2008 Part I No. 16, p. 749 of 30 April 2008)

Section 1

Principle

- (1) For decisions relating to the granting of marketing authorisations for medicinal products, for the processing of applications, for activities of collation and assessment of drug associated risks, for appeal procedures against administrative acts or against the assessment of costs under the AMG Fees Ordinance, as well as for other official acts, the Federal Institute for Drugs and Medical Devices and the Federal Office of Consumer Protection and Food Safety will levy fees as set out in the enclosed Schedule of Fees and in compliance with the following rules and regulations.
- (2) No fee will be charged for announcing the expiration and/or suspension of a marketing authorisation in the Federal Gazette.

Section 2

Fees payable in case of refusal and/or withdrawal of an application

If an application for taking an official act subject to a fee should be decided in the negative or such application should be withdrawn after its official processing has started, a fee amounting to 75% of the fee normally payable for such official act will be charged. It may be reduced up to one quarter of the fee specified or it may be waived completely, as is just and proper under the circumstances.

Section 3

Increases and reductions

- (1) In an individual case where the official act may have required extraordinary expenses, the said fee can be increased up to the double of the fee specified originally. If such an increase in the fee payable pursuant to sentence 1 is to be expected, the debtor of this fee shall be heard.
- (2) The fee payable may be reduced up to half of the fee specified originally if such reduction is justified on the one hand by the staff costs and operating expenditures incurred in connection with the official act and, on the other hand, by the importance, the economic benefit or any other benefit arising from the official act for the debtor of this fee.
- (3) Unless sub-section 2 should apply, the fees payable in compliance with Numbers 1 to 18 of the Schedule of Fees can be reduced up to one quarter of the fee specified originally upon application of the debtor of such fee if the applicant cannot expect a benefit adequate to the costs incurred for the development and the marketing authorisation procedure, and
 1. if there is a public interest in placing the medicinal product on the market due to its therapeutical indication, or
 2. if the cases are rare or the target group is small for which the medicinal product is intended to be used.

Section 4

Credit for fees payable for experts

In a case where it is provided by law that one of the official acts mentioned in the Schedule of Fees under the Numbers 1 to 12 and 14 to 18, respectively, be performed based on the evaluation of documents by independent experts, the fees payable for this shall be credited against the applicable fee.

Section 5

Transitional provisions

- (1) The AMG Fees Ordinance in the version of 10 December 2003 (Federal Gazette I p. 2510), amended by the Ordinance of 21 December 2004 (Federal Gazette I p. 3719)

shall continue to be applicable if the relevant official act was applied for, in so far as an application is required, prior to May 1, 2008. Sentence 1 applies accordingly if no application is required and the official act was completed prior to May 1, 2008.

- (2) For official acts performed after December 31, 2003 and prior to May 1, 2008, fees may be levied subject to this Ordinance in so far as a decision on the costs has been explicitly reserved with reference to the impending issue of this Ordinance.

Section 6

Entry into force, Inoperativeness

This Ordinance shall enter into force on January 1, 2004. At the same time, the Ordinance Regulating the Fees Payable for Marketing Authorisations granted by the Federal Institute for Drugs and Medicinal Devices and/or the Federal Office of Consumer Protection and Food Safety in the version as published on November 7, 2002 (Federal Gazette I p 4340) shall become inoperative.

Annex
(to Section 1)

Terms and definitions

The terms used in the Schedule of Fees below shall have the following meaning:

Known substance:

A medicinal product that meets the requirements set out in Section 22 sub-section 3 numbers 1, 2 or 3 of the German Medicines Act (AMG).

New substance:

A medicinal product that does not meet any of the requirements set out in Section 22 sub-section 3 numbers 1, 2 or 3 AMG.

Complete reference:

Reference of a second applicant to all documents submitted by a previous applicant except for the documentation on the quality.

Partial reference:

Reference of a second applicant to parts of the documents submitted by a previous applicant (except for the documentation on the quality) as well as submission of own documents.

Duplicate:

Complete reference of an applicant to an identical medicinal product of the same applicant with a marketing authorisation issued no longer than 5 years from the date of application.

Reference pursuant to Section 24a AMG:

Reference of the same applicant or a second applicant to all documents including the documentation on the quality of an authorised medicinal product pursuant to Section 24a AMG providing the permission of the previous applicant.

Series:

Several applications filed simultaneously by the same applicant (in case of renewals: by the same marketing authorisation holder) for medicinal products which have the same active substance, which are different, however, in respect to their pharmaceutical form, strength, and indication where applicable.

Identical series:

Several applications filed simultaneously by the same applicant (in case of renewals: by the same marketing authorisation holder) for an identical medicinal product.

Fees payable for official acts are specified in accordance with the following Schedule of Fees:

Number	Official act subject to a fee	Fee in €
1.	National marketing authorisation for a medicinal product	
1.1	Marketing authorisation for a medicinal product / new substance	
1.1.1	Marketing authorisation for a medicinal product / new substance no reference	
1.1.1.1	including assessment of potential ecological risks by the Federal Environment Agency	57 500
1.1.1.2	without assessment of potential ecological risks by the Federal Environment Agency	51 400
1.1.2	Marketing authorisation for a medicinal product /new substance in case of partial reference if this leads to a significant reduction in staff costs and operating expenditures	
1.1.2.1	including assessment of potential ecological risks by the Federal Environment Agency	40 000
1.1.2.2	without assessment of potential ecological risks by the Federal Environment Agency	33 900
1.1.3	Marketing authorisation for a medicinal product /new substance complete reference	
1.1.3.1	including assessment of potential ecological risks by the Federal Environment Agency	30 100
1.1.3.2	without assessment of potential ecological risks by the Federal Environment Agency	24 000
1.2	Marketing authorisation for a medicinal product/known substance	
1.2.1	Marketing authorisation for a medicinal product / known substance no reference	
1.2.1.1	including assessment of potential ecological risks by the Federal Environment Agency	27 700
1.2.1.2	without assessment of potential ecological risks by the Federal Environment Agency	21 600

Number	Official act subject to a fee	Fee in €
1.2.2	Marketing authorisation for a medicinal product /known substance in case of partial reference if this leads to a significant reduction in staff costs and operating expenditures	
1.2.2.1	including assessment of potential ecological risks by the Federal Environment Agency	25 300
1.2.2.2	without assessment of potential ecological risks by the Federal Environment Agency	19 200
1.2.3	Marketing authorisation for a medicinal product /known substance complete reference	
1.2.3.1	including assessment of potential ecological risks by the Federal Environment Agency	21 800
1.2.3.2	without assessment of potential ecological risks by the Federal Environment Agency	15 700
1.2.4	Marketing authorisation for a duplicate as well as marketing authorisation in case of reference in accordance with Section 24a AMG	
1.2.4.1	including assessment of potential ecological risks by the Federal Environment Agency	8 900
1.2.4.2	without assessment of potential ecological risks by the Federal Environment Agency	2 800
1.3	Marketing authorisation for a series or an identical series, in addition to the fee payable for the first marketing authorisation, per authorisation	
1.3.1	Marketing authorisation for a series	6 000
1.3.2	Marketing authorisation for an identical series	2 800
1.4	Marketing authorisation for a parallel imported medicinal product not considered authorised pursuant to Section 105 sub-section 1 AMG	2 800

Number	Official act subject to a fee	Fee in €
1.5	Marketing authorisation for a medicinal product, also a duplicate, that is subject to the authorisation procedure only because it has been treated with ionising rays, or marketing authorisation for a medicinal product, also a duplicate, that has already been authorised or is considered to be authorised, if the authorisation is granted in respect of its treatment with ionising rays	4 500
2	Marketing authorisation for a medicinal product in a Mutual Recognition Procedure (MRP)*)	
2.1	Germany acting as Reference Member State (RMS)*; in addition to the fees payable pursuant to Numbers 1.1 to 1.3	
2.1.1	Marketing authorisation for a medicinal product/new substance	
2.1.1.1	Marketing authorisation for a medicinal product/new substance no reference	
2.1.1.1.1	including assessment of potential ecological risks by the Federal Environment Agency	59 400
2.1.1.1.2	without assessment of potential ecological risks by the Federal Environment Agency	51 300
2.1.1.2	Marketing authorisation for a medicinal product/new substance/ partial reference	
2.1.1.2.1	including assessment of potential ecological risks by the Federal Environment Agency	49 000
2.1.1.2.2	without assessment of potential ecological risks by the Federal Environment Agency	40 900
2.1.1.3	Marketing authorisation for a medicinal product/new substance/ complete reference	
2.1.1.3.1	including assessment of potential ecological risks by the Federal Environment Agency	35 700
2.1.1.3.2	without assessment of potential ecological risks by the Federal Environment Agency	27 600

Number	Official act subject to a fee	Fee in €
2.1.2	Marketing authorisation for a medicinal product/ known substance	
2.1.2.1	Marketing authorisation for a medicinal product/known substance/ no reference	
2.1.2.1.1	including assessment of potential ecological risks by the Federal Environment Agency	35 400
2.1.2.1.2	without assessment of potential ecological risks by the Federal Environment Agency	27 300
2.1.2.2	Marketing authorisation for a medicinal product/ known substance/ partial reference	
2.1.2.2.1	including assessment of potential ecological risks by the Federal Environment Agency	32 500
2.1.2.2.2	without assessment of potential ecological risks by the Federal Environment Agency	24 400
2.1.2.3	Marketing authorisation for a medicinal product/known substance/ complete reference	
2.1.2.3.1	including assessment of potential ecological risks by the Federal Environment Agency	29 100
2.1.2.3.2	without assessment of potential ecological risks by the Federal Environment Agency	21 000
2.1.3	Marketing authorisation for a medicinal product in the Repeat Use Procedure (further MRP for further EU Member States upon completion of an MRP in accordance with numbers 2.1)	
2.1.3.1	with a new substance	
2.1.3.1.1	including assessment of potential ecological risks by the Federal Environment Agency	28 600
2.1.3.1.2	without assessment of potential ecological risks by the Federal Environment Agency	20 500
2.1.3.2	with a known substance	

Number	Official act subject to a fee	Fee in €
2.1.3.2.1	including assessment of potential ecological risks by the Federal Environment Agency	23 700
2.1.3.2.2	without assessment of potential ecological risks by the Federal Environment Agency	15 600
2.1.4	Marketing authorisation for a series or identical series, in addition to the fee payable for the first marketing authorisation, per marketing authorisation	
2.1.4.1	Marketing authorisation for a series	10 500
2.1.4.2	Marketing authorisation for an identical series	5 200
2.2	Germany acting as Concerned Member State (CMS)	
2.2.1	Marketing authorisation for a medicinal product/new substance	
2.2.1.1	Marketing authorisation for a medicinal product/new substance/ no or partial reference	
2.2.1.1.1	including assessment of potential ecological risks by the Federal Environment Agency	23 500
2.2.1.1.2	without assessment of potential ecological risks by the Federal Environment Agency	18 500
2.2.1.2	Marketing authorisation for a medicinal product/new substance/ complete reference	
2.2.1.2.1	including assessment of potential ecological risks by the Federal Environment Agency	20 900
2.2.1.2.2	without assessment of potential ecological risks by the Federal Environment Agency	15 900
2.2.2	Marketing authorisation for a medicinal product/known substance	
2.2.2.1	Marketing authorisation for a medicinal product/known substance/ no or partial reference	
2.2.2.1.1	including assessment of potential ecological risks by the Federal Environment Agency	19 900

Number	Official act subject to a fee	Fee in €
2.2.2.1.2	including assessment of potential ecological risks by the Federal Environment Agency	14 900
2.2.2.2	Marketing authorisation for a medicinal product/known substance/ complete reference	
2.2.2.2.1	including assessment of potential ecological risks by the Federal Environment Agency	17 600
2.2.2.2.2	without assessment of potential ecological risks by the Federal Environment Agency	12 600
2.2.3	Marketing authorisation for a series or an identical series, in addition to the fees payable for the first marketing authorisation, per marketing authorisation	
2.2.3.1	Marketing authorisation for a series	6 200
2.2.3.2	Marketing authorisation an identical series	3 700
3	Marketing authorisation for a medicinal product in a Decentralised Procedure pursuant to Section 25b sub-section 3 AMG	
3.1	Germany acting as Reference Member State (RMS)	
3.1.1	Marketing authorisation for a medicinal product/new substance	
3.1.1.1	Marketing authorisation for a medicinal product/new substance/ no reference	
3.1.1.1.1	including assessment of potential ecological risks by the Federal Environment Agency	110 800
3.1.1.1.2	without assessment of potential ecological risks by the Federal Environment Agency	102 700
3.1.1.2	Marketing authorisation for a medicinal product/new substance/ partial reference	
3.1.1.2.1	including assessment of potential ecological risks by the Federal Environment Agency	82 900
3.1.1.2.2	without assessment of potential ecological risks by the Federal Environment Agency	74 800

Number	Official act subject to a fee	Fee in €
3.1.1.3	Marketing authorisation for a medicinal product/new substance/ complete reference	
3.1.1.3.1	including assessment of potential ecological risks by the Federal Environment Agency	59 700
3.1.1.3.2	without assessment of potential ecological risks by the Federal Environment Agency	51 600
3.1.2	Marketing authorisation for a medicinal product/known substance	
3.1.2.1	Marketing authorisation for a medicinal product/known substance/ no reference	
3.1.2.1.1	including assessment of potential ecological risks by the Federal Environment Agency	57 000
3.1.2.1.2	without assessment of potential ecological risks by the Federal Environment Agency	48 900
3.1.2.2	Marketing authorisation for a medicinal product/known substance/ partial reference	
3.1.2.2.1	including assessment of potential ecological risks by the Federal Environment Agency	51 700
3.1.2.2.2	without assessment of potential ecological risks by the Federal Environment Agency	43 600
3.1.2.3	Marketing authorisation for a medicinal product/known substance/ complete reference	
3.1.2.3.1	including assessment of potential ecological risks by the Federal Environment Agency	44 700
3.1.2.3.2	without assessment of potential ecological risks by the Federal Environment Agency	36 600
3.1.3	Marketing authorisation for a series or an identical series, in addition to the fees payable for the first marketing authorisation, per marketing authorisation	
3.1.3.1	Marketing authorisation for a series	16 500
3.1.3.2	Marketing authorisation for an identical series	8 000

Number	Official act subject to a fee	Fee in €
3.2	Germany acting as Concerned Member State (CMS)	
3.2.1	Marketing authorisation for a medicinal product/new substance	
3.2.1.1	Marketing authorisation for a medicinal product/new substance/ no or partial reference	
3.2.1.1.1	including assessment of potential ecological risks by the Federal Environment Agency	30 400
3.2.1.1.2	without assessment of potential ecological risks by the Federal Environment Agency	25 400
3.2.1.2	Marketing authorisation for a medicinal product/new substance/ complete reference	
3.2.1.2.1	including assessment of potential ecological risks by the Federal Environment Agency	26 000
3.2.1.2.2	without assessment of potential ecological risks by the Federal Environment Agency	21 000
3.2.2	Marketing authorisation for a medicinal product/known substance	
3.2.2.1	Marketing authorisation for a medicinal product/known substance/ no or partial reference	
3.2.2.1.1	including assessment of potential ecological risks by the Federal Environment Agency	25 700
3.2.2.1.2	without assessment of potential ecological risks by the Federal Environment Agency	20 700
3.2.2.2	Marketing authorisation for a medicinal product/known substance/ complete reference	
3.2.2.2.1	including assessment of potential ecological risks by the Federal Environment Agency	23 100
3.2.2.2.2	without assessment of potential ecological risks by the Federal Environment Agency	18 100
3.2.3	Marketing authorisation for a series or an identical series, in addition to the fees payable for the first marketing authorisation, per marketing authorisation	

Number	Official act subject to a fee	Fee in €
3.2.3.1	Marketing authorisation for a series	7 100
3.2.3.2	Marketing authorisation for an identical series	4 000
4	Preparation or updating of an assessment report pursuant to Section 25 sub-section 5a AMG, if not already covered by Numbers 2 or 3	
4.1	Preparation of an assessment report	
4.1.1	on a medicinal product with a new substance	22 400
4.1.2	on a medicinal product with a known substance	14 000
4.2	Updating of an assessment report	
4.2.1	on a medicinal product with a new substance	8 700
4.2.2	on a medicinal product with a known substance	5 800
4.3	Preparation or updating of an assessment report for a series or an identical series, in addition to the fees payable pursuant to Numbers 4.1 and 4.2	4 500
5	Renewal of marketing authorisation pursuant to Section 105 sub-section 3 AMG	
5.1	Chemically defined medicinal product	
5.1.1	Basic fee	13 600
5.1.2	Series or identical series, in addition to the fees payable for the first marketing authorisation, per marketing authorisation	3 800
5.2	Phytotherapeutic medicinal product	
5.2.1	Basic fee	10 400
5.2.2	Series or identical series, in addition to the fees payable for the first marketing authorisation, per marketing authorisation	2 900
5.3	Homeopathic or anthroposophic medicinal product including commission involvement pursuant to Section 25 sub-section 7 AMG	

Number	Official act subject to a fee	Fee in €
5.3.1	Basic fee	8 300
5.3.2	Series or identical series, in addition to the fees payable for the first marketing authorisation, per marketing authorisation	6 500
5.4	Homeopathic or anthroposophic medicinal product without commission involvement pursuant to Section 25 sub-section 7 AMG	
5.4.1	Basic fee	7 500
5.4.2	Series or identical series, in addition to the fees payable for the first Marketing authorisation, per marketing authorisation	5 700
5.5	Medicinal product pursuant to Section 109a AMG	
5.5.1	Basic fee	6 200
5.5.2	Series or identical series, in addition to the fees payable for the first marketing authorisation, per marketing authorisation	1 700
6	Renewal of marketing authorisation pursuant to Section 31 sub-section 3 AMG	
6.1	Medicinal product with a new or a known substance	
6.1.1	Basic fee	
6.1.1.1	including assessment of potential ecological risks by the Federal Environment Agency (only for medicines destined for use in animals)	12 800
6.1.1.2	without assessment of potential ecological risks by the Federal Environment Agency	6 700
6.1.2	Series or identical series, in addition to the fees payable for the first renewal, per renewal	
6.1.2.1	including assessment of potential ecological risks by the Federal Environment Agency (only for medicines destined for use in animals)	9 400
6.1.2.2	without assessment of potential ecological risks by the Federal Environment Agency	3 300

Number	Official act subject to a fee	Fee in €
6.2	Renewal completely based on a template published by the competent superior federal authority	
6.2.1	Basic fee	
6.2.1.1	including assessment of potential ecological risks by the Federal Environment Agency (only for medicines destined for use in animals)	8 600
6.2.1.2	without assessment of potential ecological risks by the Federal Environment Agency	2 500
6.2.2	Series or identical series, in addition to the fees payable for the first renewal, per renewal	
6.2.2.1	including assessment of potential ecological risks by the Federal Environment Agency (only for medicines destined for use in animals)	7 700
6.2.2.2	without assessment of potential ecological risks by the Federal Environment Agency	1 600
6.3	Renewal of a parallel imported medicinal product	2 200
7	Renewal of a marketing authorisation in a Mutual Recognition Procedure (MRP)*	
7.1	Germany acting as Reference Member State (RMS)	
7.1.1	Medicinal product with a new or a known substance, basic fee	
7.1.1.1	including assessment of potential ecological risks by the Federal Environment Agency (only for medicines destined for use in animals)	17 400
7.1.1.2	without assessment of potential ecological risks by the Federal Environment Agency	11 300
7.1.2	Series or identical series, in addition to the fees payable for the first renewal, per renewal	
7.1.2.1	including assessment of potential ecological risks by the Federal Environment Agency (only for medicines destined for use in animals)	11 100

Number	Official act subject to a fee	Fee in €
7.1.2.2	without assessment of potential ecological risks by the Federal Environment Agency	5 000
7.2	Germany acting as Concerned Member State (CMS)	
7.2.1	Medicinal product with a new or a known substance, basic fee	
7.2.1.1	including assessment of potential ecological risks by the Federal Environment Agency (only for medicines destined for use in animals)	10 800
7.2.1.2	without assessment of potential ecological risks by the Federal Environment Agency	4 700
7.2.2	Series or identical series, in addition to the fees payable for the first renewal, per renewal	
7.2.2.1	including assessment of potential ecological risks by the Federal Environment Agency (only for medicines destined for use in animals)	8 500
7.2.2.2	without assessment of potential ecological risks by the Federal Environment Agency	2 400
8	Processing of Variations pursuant to Section 29 AMG	
8.1	Variations pursuant to Section 29 sub-section 2a Nos. 1 to 4 AMG, except for variations referred to in Numbers 8.6	2 000
8.2	Variations pursuant to Section 29 sub-section 1 and sub-section 2a No. 5 AMG, except for the variations referred to in Number 8.4, as well as notification of any further import country in the case of parallel imports	310
8.3	Transfer to another pharmaceutical company, notification of co-marketing, notification of a parallel imported medicinal product pursuant to Section 105 AMG, change in the product name, deletion of active ingredients	250
8.4	Change in address, phone or fax number or email of the applicant, pharmaceutical company, manufacturer or local representative, registration or change of production or manufacturing facility, change of firm or of the legal form, irrespective of the number of marketing authorisations concerned	140

Number	Official act subject to a fee	Fee in €
8.5	Notification of variation pursuant to Section 29 sub-sections 1b and 1c AMG	100
8.6	Variations subject to approval pursuant to Section 29 sub-section 2a nos. 1 and 6 AMG	
8.6.1	Variations pursuant to Section 29 sub-section 2a No. 1 AMG, in case of the addition of or change in an indication within the same therapeutic area and variations pursuant to Section 29 sub-section 2a no. 6 AMG	
8.6.1.1	including assessment of potential ecological risks by the Federal Environment Agency	8 500
8.6.1.2	without assessment of potential ecological risks by the Federal Environment Agency	2 400
8.6.2	Processing of a variation pursuant to Section 29 sub-section 2a AMG, resulting in the decision that a new marketing authorisation pursuant to Section 29 sub-section 3 AMG is required	2 400
8.7	Change in the texts of the patient package leaflet and SPC/ <i>Fachinformation</i> to be harmonised with a core text published by the competent higher federal authority, per marketing authorisation	870
8.8	In case of several variations filed simultaneously for a medicinal product, in addition to the fee payable for the variation with the highest fee (basic fee) for each additional variation	50 % of the fee according to Numbers 8.1 to 8.3, 8.5 to 8.7
	The fee according to Number 8.8 must not exceed the fee according to Number 1.2.3.2.	
9	Processing of Variations pursuant to Article 3 Nos. 2 and 3 of Regulation (EC) No. 1084/2003 of the Commission of 3 June 2003 (Official Journal, EC No. L 159 p. 1)	
9.1	Germany acting as Reference Member State (RMS)	
9.1.1	Type IA, for the first and for each additional variation	410
9.1.2	Type IB, for the first and for each additional variation	1 900

Number	Official act subject to a fee	Fee in €
9.1.3	Type II/variation as to the graduated plan officer	1 900
9.1.4	Type II/simple variations unless covered by Number 9.1.3	
9.1.4.1	First variation	4 700
9.1.4.2	Series or identical series, in addition to the fees payable for the first variation, per variation	2 100
9.1.5	Type II/Complex variations	
9.1.5.1	First variation	
9.1.5.1.1	including assessment of potential ecological risks by the Federal Environment Agency	16 100
9.1.5.1.2	without assessment of potential ecological risks by the Federal Environment Agency	8 000
9.1.5.2	Series or identical series, in addition to the fee for the first variation, per variation	3 100
9.2	Germany acting as Concerned Member State (CMS)	
9.2.1	Type IA, for the first and for each additional variation	230
9.2.2	Type IB, for the first and for each additional variation	500
9.2.3	Type II/variations regarding the graduated plan officer	500
9.2.4	Type II/simple variations unless covered by Number 9.2.3	
9.2.4.1	First variation	2 100
9.2.4.2	Series or identical series, in addition to the fees payable for the first variation, per variation	1 300
9.2.5	Type II/complex variations	
9.2.5.1	First variation	
9.2.5.1.1	including assessment of potential ecological risks by the Federal Environment Agency	8 400

Number	Official act subject to a fee	Fee in €
9.2.5.1.2	without assessment of potential ecological risks by the Federal Environment Agency	3 400
9.2.5.2	Series or identical series, in addition to the fee for the first variation, per variation	1 900
10	Registration of traditional plant products pursuant to Section 39a ff. AMG	
10.1	National registration procedure	
10.1.1	Procedure without lists/monographs	
10.1.1.1	Registration/basic fee	15 700
10.1.1.2	Registration of series, in addition to the fee for the first registration, per additional registration	6 000
10.1.1.3	Registration of identical series, in addition to the fees payable for the first registration, per additional registration and registration of duplicates	2 800
10.1.2	Procedure with lists/monographs	
10.1.2.1	Registration/basic fee	10 000
10.1.2.2	Registration of series, in addition to the fees payable for the first registration, per additional registration	5 000
10.1.2.3	Registration of identical series, in addition to the fees payable for the first registration, per additional registration, and registration of duplicates	2 800
10.2	Decentralised Procedure pursuant to Section 25b sub-section 3 AMG	
10.2.1	Germany acting as Reference Member State (RMS)	
10.2.1.1	Registration/basic fee	40 800
10.2.1.2	Registration of series, in addition to the fees payable for the first registration, per additional registration	18 600
10.2.1.3	Registration of identical series, in addition to the fees payable for the first registration, per additional registration	9 000

Number	Official act subject to a fee	Fee in €
10.2.2	Germany acting as Concerned Member State (CMS)	
10.2.2.1	Registration/basic fee	18 100
10.2.2.2	Registration of series, in addition to the fees payable for the first registration, per additional registration	7 100
10.2.2.3	Registration of identical series, in addition to the fees payable for the first registration, per additional registration	4 000
10.3	Registration of a medicinal product in a Mutual Recognition Procedure	
10.3.1	Germany acting as Reference Member State (RMS), in addition to the fees according to Numbers 10.1.2	
10.3.1.1	Registration/Basic fee	21 000
10.3.1.2	Registration of series, in addition to the fee for the first registration, per additional registration	10 500
10.3.1.3	Registration of identical series, in addition to the fees payable for the first registration, per additional registration	5 200
10.3.2	Germany acting as Concerned Member State (CMS)	
10.3.2.1	Registration/basic fee	12 600
10.3.2.2	Registration of series, in addition to the fees payable for the first registration, per additional registration	6 200
10.3.2.3	Registration of identical series, in addition to the fees payable for the first registration, per additional registration	3 700
10.4	Submission pursuant to Section 39d sub-section 3 AMG, in addition to the fee according to Item 10.1.1, depending on staff costs and operational expenditures	6 000 to 25 000
10.5	Submission pursuant to Section 39d sub-section 4 AMG, in addition to the fee according to Number 10.1.1, depending on staff costs and operational expenditures	6 000 to 25 000

Number	Official act subject to a fee	Fee in €
11.	Examination of information relating to the grant of marketing authorisation pursuant to Section 25 sub-section 5 AMG depending on staff costs and operational expenditures	5 000 to 25 000
12	Official acts in the context of Clinical Studies	
12.1	Grant of approval pursuant to Section 40 sub-section 1 sentence 2 in conjunction with Section 42 sub-section 2 AMG	
12.1.1	First presentation of a study protocol for an investigational product in Phase I, II or III	3 700
12.1.2	Follow-up study for an investigational product assessed according to Number 12.1.1 in Phase I, II or III	
12.1.2.1	Follow-up study without re-assessment of documents	1 500
12.1.2.2	Follow-up study with re-assessment of documents in Phase I	1 900
12.1.2.3	Follow-up study without re-assessment of documents in Phase II or III	2 100
12.1.3	Clinical study with an investigational product that has a marketing authorisation in an EU-Member State; use of the product in compliance with or without the conditions of use as authorised and laid down in the expert information (SPC)	1 700
12.1.4	Study to prove bioequivalence	2 100
12.1.5	Approval pursuant to Section 42 sub-section 3 AMG in conjunction with Section 9 sub-section 2 sentence 2 and 3 GCP-V if supplements are presented requiring scientific processing	730
12.1.6.	Approval of variations after the start of a clinical study pursuant to Section 42 sub-section 3 AMG in conjunction with Section 10 GCP-V	
12.1.6.1	Variations subject to approval requiring scientific processing	1 100
12.1.6.2	Other variations	720

Number	Official act subject to a fee	Fee in €
12.2	Assessment of annual reports on the safety of the study participants pursuant to Section 42 sub-section 3 AMG in conjunction with Section 13 sub-section 6 GCP-V	
12.2.1	Annual reports on mono-centre clinical studies	500
12.2.2	Annual reports on multi-centre clinical studies	1 000
12.2.3	Annual reports on more than five clinical studies with the same investigational product	2 500
12.3	Examination of information relating to approval pursuant to Section 42 sub-section 3 AMG in conjunction with Section 9 sub-section 5 GCP-V (GCP inspection), depending on staff costs and operational expenditures	5 000 to 25 000
12.4	Processing of data destined for the EudraCT data base pursuant to Section 14 sub-section 3 GCP-V, unless covered by Numbers 12.1	250
13	Official acts in connection with the processing of reports pursuant to Section 63b sub-section 5 and inspection pursuant to Section 63b sub-section 5a AMG	
13.1	Processing of reports in national procedures	
13.1.1	within ten years following the first authorisation of the medicinal substance in Germany	1 300
13.1.2	later than ten years following the first authorisation of the medicinal substance in Germany	650
13.2	Processing of reports in a Mutual Recognition Procedure or in a Decentralised Procedure pursuant to Section 25b sub-section 3 AMG	
13.2.1	Germany acting as Reference Member State (RMS)	
13.2.1.1	within ten years following the first authorisation of the medicinal substance in Germany	4 400
13.2.1.2	later than ten years following the first authorisation of the medicinal substance in Germany	1 300

Number	Official act subject to a fee	Fee in €
13.2.2	Germany acting as Concerned Member State (CMS)	
13.2.2.1	within ten years following the first authorisation of the medicinal substance in Germany	1 300
13.2.2.2	later than ten years following the first authorisation of the medicinal substance in Germany	650
13.3	If identical periodic reports according to Number 13.1 or 13.2 are simultaneously submitted and assessed, the fee according to Number 13.1 or 13.2 is charged only once. For each additional identical periodic report the fee is reduced to	280
13.4	Prolongation of the intervals for submission of the periodic safety update reports pursuant to Section 63b sub-section 5 AMG, per medicinal product	230
13.5	Examination of the collation and assessment of drug-associated risks and the coordination of necessary measures pursuant to Section 63b sub-section 5a AMG, depending on staff costs and operational expenditures	1 000 to 25 000
14	Imposing a condition pursuant to Section 28, Section 30 sub-section 2a, Section 105 sub-section 5 or of a warning pursuant to Section 110 AMG, or a collateral clause pursuant to Section 36 VwVfG (administrative procedural act), depending on staff costs and operational expenditures	80 to 380
15	Measures pursuant to Section 30 sub-sections 1, 1a and 2 and pursuant to Section 42a AMG	
15.1	Measures pursuant to Section 30 sub-sections 1, 1a and 2 AMG, unless the order for temporary suspension of the marketing authorisation is based on an application filed by the pharmaceutical company, depending on staff costs and operational expenditures	30 to 10 000
15.2	Measures pursuant to Section 42a AMG, depending on staff costs and operational expenditures	30 to 3 700

Number	Official act subject to a fee	Fee in €
16	Decision on the marketing authorisation obligation pursuant to Section 21 sub-section 4 AMG, depending on staff costs and operational expenditures	900 to 6 000
17	Processing of applications as defined in Section 31 sub-section 1 sentence 2 AMG, per marketing authorisation	200
18	Determination of an appropriate waiting time pursuant to Section 59 sub-section 2 sentence 2 AMG	
18.1	for a medicinal product with a substance not contained in Annex I, II or III of Regulation (EEC) no. 2377/90	3 000
18.2	for a medicinal product with a substance contained in Annex I, II or III of Regulation (EEC) no. 2377/90	1 500
19	Other official acts	
19.1	Scientific comments on quality, therapeutic efficacy or safety of a medicinal product	100 to 500
19.2	Processing of an application for restoration to the previous condition pursuant to Section 32 VwVfG	260
19.3	Processing of an application for resumption of the procedure pursuant to Section 51 VwVfG	260
19.4	non-simple written information	50 to 500
19.5	Inspection of marketing authorisation files outside of a pending administrative procedure pursuant to Numbers 1 to 11, 19.2 or 19.3	30 to 260
19.6	Advice to applicant	200 to 8 800

Number	Official act subject to a fee	Fee in €
20	Processing of appeals	
20.1	Appeal to decisions on the merits	
20.1.1	Rejection as inadmissible	160; or where a lower fee is specified for the substantive decision to be reviewed, the lower one
20.1.2	Partial or complete rejection as unjustified, unless the appeal is only without success because the violation of a procedural or formal requirement pursuant to Section 45 VwVfG is disregarded	not more than the fee specified in this Ordinance for the substantive decision to be reviewed in the appeal procedure; where a framework of fees is specified not more than its maximum fee; but not less than 160; where a lower fee is specified for the decision to be reviewed, the lower one
20.1.3	Withdrawal of an appeal after the beginning of its substantive processing but before its completion	not more than 75 % of the fee specified in this Ordinance for the substantive decision to be reviewed in the appeal procedure; where a framework of fees is specified not more than 75 % of its maximum fee; but not less than 160; where a lower fee than 160 is specified for the decision to be reviewed, the lower one
20.2	Appeal to decisions on fees and expenses	
20.2.1	Rejection as inadmissible	160; if the disputable sum is lower, the lower one

Number	Official act subject to a fee	Fee in €
20.2.2	Partial or complete rejection as inadmissible, unless the appeal is only without success because the violation of a procedural or formal requirement pursuant to Section 45 VwVfG is disregarded	not more than 10 % of the disputable sum; yet not less than 160; where the disputable sum is lower than 160, the lower one
20.2.3	Withdrawal of an appeal after the beginning of its substantive processing but before its completion	not more than 7.5 % of the disputable sum; yet not less than 160; where the disputable sum is lower than 160, the lower one

*) Procedure pursuant to Title III Chapter 4 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code for Human Medicinal Products (Official Journal, EC No. L 311 p. 67) or pursuant to Title III Chapter 4 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code for Medicinal Products for Veterinary Use (Official Journal, EC No. L 311 p. 1).