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Fee Regulation for the Authorisation and Registration of Medicinal Products by the Federal Institute for Drugs and Medical Devices and the Federal Office for Consumer Protection and Food Safety (AMG Fee Regulation - AMGKostV)

AMGKostV

Issued on: 10 December 2003

Full quote:

"AMG Fee Regulation of 10 December 2003 (Federal Law and Ordinance Gazette I P. 2510), amended by Article 1 of the Regulation of 3 March 2015 (Federal Gazette I P. 195)"

Regulation repealed by Art. 4 (13) G of 7 August 2013 I 3154 effective from 14 August 2018

Current status: Last amended by Art. 2 (26) G of 7 August 2013 I 3154

Note: Amended by Art. 1 V of 3 March 2015 I 195 (No. 8), passed but is not yet finally documented

Footnote

(+++ Wording as of 1 January 2004 +++)

Header: As amended by Art. 1 (1) V of 3 March 2015 I 195 effective from 7 March 2015

Preamble

On the basis of Section 33 (2) of the Medicinal Products Act as amended in the version of 11 December 1998 (Federal Gazette I P. 3586) in conjunction with the 2nd Part of the Administrative Costs Act of 23 June 1970 (Federal Gazette I S. 821), Section 1 of the Reassignment of Authority Act of 16 August 2002 (Federal Gazette I S. 3165), the Organisational Directives of 22 January 2001 (Federal Gazette I S. 127) and 22 October 2002 (Federal Law and Ordinance Gazette I S. 4206),
the Federal Ministry of Health and Social Security in coordination with the Federal Ministry of Economics and Labour provides as follows:

Section 1 Principles

(1) Based on the enclosed fee schedule, the Federal Institute for Drugs and Medical Devices and the Federal Office for Consumer Protection and Food Safety collect fees and charges for decisions on the authorisation of medicinal products, decisions on the registration of homoeopathic medicinal products and traditional herbal medicinal products, for the processing of applications, for activities within the scope of the collection and assessment of medicinal drug risks, for appeal proceedings against administrative acts issued in accordance with the Medicinal Products Act or against the determination of fees and charges in accordance with this Regulations as well as for any other individually attributable public services.

(2) No charges will be collected for publications in the Federal Gazette, where the authorisation expires or is suspended.

Section 2 Fees in the event of a rejection or withdrawal of an application

In the event that an application for an individually attributable service is rejected, for any other reason than lack of competence or if an application is withdrawn after its processing has commenced, a fee to the sum of 75 percent of the fee incurring for the individually attributable service shall become due; this fee can be reduced by a quarter or even waived according to reason and fairness.

Section 3 Reductions

(1) The fee can be reduced by half of the initially due amount, if the personnel and material costs associated with the individually attributable public service on the one hand and the significance, the economic value or the further benefits of the individually attributable public service received by the party owing the fee, justify this.

(2) The fees collectable in accordance with items 1 to 25 of the fee schedule, may be reduced upon application of the party owing the fee, except for in the cases set out in Section 2, to a maximum of one quarter of the relevant fee, if the applicant cannot expect an adequate economic benefit corresponding to the development and authorisation costs and

1. the placing of the medicinal product on the market is of interest for the public due to its area of application, or
2. if the application cases are rare or if the target group for which the medicinal product is determined is small.

Section 4 Offsetting of costs for experts

If one of the individually attributable public services set out in items 1 to 13 as well as 18 to 25 of the fee schedule is provided in the cases provided for by law and on the basis of the assessment of documents through independent experts, the costs incurring for this shall be offset against the relevant fee.

Section 5 Transitional provisions

(1) The AMG Cost Regulation shall continue to apply in the version of 10 December 2003 (Federal Gazette I P. 2510), which was last amended by Article 2 (26) of the Law of 7 August 2013 (Federal Gazette I P. 3154), where the underlying individually attributable public service has been applied for or started prior to 7 March 2015, but not yet completely provided. This shall not apply if a chargeable act already existed for the individually attributable public service in accordance with the AMG Cost Regulation of 10 December 2003, and as last amended by Article 2 (26) of the Law of 7 August 2013 (Federal Gazette I P. 3154), and if the fee incurring on this basis is higher than the fee specified in the AMG Cost Regulation as amended on 7 March 2015. In this case, further fees will be collected in accordance with the AMG Fee Regulation in the version of 7 March 2015.

(2) The Cost Regulation for the registration of homoeopathic medicinal products by the Federal Institute for Drugs and Medical Devices and the Federal Office for Consumer Protection and Food Safety shall continue to apply in the version of the publication of 24 October 2003 (Federal Gazette I P. 2157), and as amended by Article 2 (25) of the Law of 7 August 2013 (Federal Gazette I P. 3154), if the underlying individually attributable public service has been applied for or started prior to 7 March 2015, but not yet completely provided. This shall not apply if a chargeable act already existed for the individually attributable public service in the Cost Regulation as amended by the publication of 24 October 2003 (Federal Gazette I P. 2157), as amended by Article 2 (25) of the Law of 7 August 2013 (Federal Gazette I P. 3154), and if the fee incurring on this basis is higher than the fee specified in the AMG Cost Regulation in the version of 7 March 2015. In this case, fees will be collected in accordance with the AMG Cost Regulation in the version of 7 March 2015.

(3) Fees for individually attributable public services provided prior to 7 March 2015 can be charged on the basis of the AMG Cost Regulation as amended on 7 March 2015, provided that a decision as to costs has been expressly reserved for individually attributable public services with reference to the upcoming amendment of this regulation. Sentence 1 applies accordingly, provided that an individually attributable public service has been applied for or started prior to 7 March 2015, but has not yet been finally completed.

(4) The fees incurring in accordance with item 10 of the fee schedule shall be reduced by 50 percent if the underlying individually attributable public service has been applied for by 7 March 2016, provided that an application is required. The underlying individually fees incurring in accordance with item 10 of the fee schedule shall be reduced by 25 percent, where the attributable public service has been applied for by 7 March 2017, provided that an application is required.

Section 6 Entry into force, termination

This Regulation enters into force on 1 January 2004.

Annex (to Section 1) Glossary

Definition of terms

The terms used in the fee schedule are defined as follows: Known substance:

Medicinal products which meet the requirements of Section 22 (3) No. 1, 2 or 3 of Medicinal Products Act.

New substance:

Medicinal products which does meet the requirements of Section 22 (3) No. 1, 2 or 3 of the Medicinal Products Act.

Complete reference:

Reference of a second applicant to documents of the first applicant in accordance with Section 24b (1) of the Medicinal Products Act.

Partial reference:

Reference of a second applicant to parts of documents of the first applicant (with the exception of quality documents) and the submission of own documents.

Duplicate:

Complete reference of an applicant to an identical medicinal product of the same applicant, whereby the authorisation or registration of the product occurred no longer than five years ago.

Reference in accordance with Section 24a of the Medicinal Products Act:

Reference of the same applicant or another application with the consent of the first application to all documents including the quality documents of an authorised medicinal product in accordance with Section 24a of the Medicinal Products Act.

Series:

Several simultaneously submitted applications of the same applicant (in case of renewals: the same authorisation holder or registration holder) for medicinal products with an identical active substance, which differ in their pharmaceutical form, strength and, if applicable, indication.

Identical series:

Several simultaneously submitted applications of the same applicant (in case of renewals: the same authorisation holder or registration holder) for identical medicinal products.

Fee Schedule

The fees for individually attributable public services subject to charge shall be determined on the basis of the following fee schedule:

Fee item	Individually attributable public services subject to charge	Fee in euros
1.	**National marketing authorisation of a medicinal product**	
1.1	Marketing authorisation of a medicinal product / new substance	
1.1.1	Marketing authorisation of a medicinal product /new substance /no reference	
1.1.1.1	With assessment of potential environmental risks by the Federal Environment Agency	57 800
1.1.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	51 100
1.1.2	Marketing authorisation of a medicinal product /new substance with partial reference, where this results in a significant reduction of the personnel and material costs	
1.1.2.1	With assessment of potential environmental risks by the Federal Environment Agency	40 400
1.1.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	33 700
1.1.3	Marketing authorisation of a medicinal product / new substance / complete reference	
1.1.3.1	With assessment of potential environmental risks by the Federal Environment Agency	30 600
1.1.3.2	Without assessment of potential environmental risks by the Federal Environment Agency	23 900
1.2	Marketing authorisation of a medicinal product / known substance	
1.2.1	Marketing authorisation of a medicinal product / known substance / no reference	
1.2.1.1	With assessment of potential environmental risks by the Federal Environment Agency	28 200
1.2.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	21 500
1.2.2	Marketing authorisation of a medicinal product / known substance / with partial reference, where this results in a significant reduction of the personnel and material costs	
1.2.2.1	With assessment of potential environmental risks by the Federal Environment Agency	25 800
1.2.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	19 100
1.2.3	Marketing authorisation of a medicinal product / known substance / Complete reference	
1.2.3.1	with assessment of potential environmental risks by the Federal Environment Agency	22 300
1.2.3.2	without assessment of potential environmental risks by the Federal Environment Agency	15 600
1.2.4	Marketing authorisation of a duplicate and marketing authorisation with reference in accordance with Section 24a AMG	2 200
1.3	Marketing authorisation of a series or identical series, in addition to the fee for the first marketing authorisation, per marketing authorisation	

Fee item	Individually attributable public service subject to charge	Fee in euros
1.3.1	Marketing authorisation of a series	6 000
1.3.2	Marketing authorisation of an identical series	2 800
1.4	Marketing authorisation of a parallel imported medicinal product which is not considered authorised in accordance with Section 105 (1) AMG	
1.4.1	With one country of import	2 200
1.4.2	Every additional country of import in the application for marketing authorisation, in addition to the fee item 1.4.1	240
1.5	Marketing authorisation of a medicinal product, including duplicates, which is only subject to the marketing authorisation requirement because it has been treated with ionising radiation or marketing authorisation of a medicinal product, including duplicates, which is already considered authorised, provided that the treatment with ionising radiation is authorised	4 500
2	**Marketing authorisation of a medicinal product under the mutual recognition procedure (MRP)[1]**	
2.1	With Germany as reference member state (RMS), in addition to the fees in accordance with fee items 1.1 to 1.3	
2.1.1	Marketing authorisation of a medicinal product / new substance	
2.1.1.1	Marketing authorisation of a medicinal product / new substance / no reference	
2.1.1.1.1	With assessment of potential environmental risks by the Federal Environment Agency	56 100
2.1.1.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	47 400
2.1.1.2	Marketing authorisation of a medicinal product / new substance / partial reference	
2.1.1.2.1	With assessment of potential environmental risks by the Federal Environment Agency	46 500
2.1.1.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	37 800
2.1.1.3	Marketing authorisation of a medicinal product / new substance / Complete reference	
2.1.1.3.1	With assessment of potential environmental risks by the Federal Environment Agency	34 200
2.1.1.3.2	Without assessment of potential environmental risks by the Federal Environment Agency	25 500
2.1.2	Marketing authorisation of a medicinal product / known substance	
2.1.2.1	Marketing authorisation of a medicinal product / known substance / no reference	33 900
2.1.2.1.1	With assessment of potential environmental risks by the Federal Environment Agency	25 200
2.1.2.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	
2.1.2.2	Marketing authorisation of a medicinal product / known substance / partial reference	31 200
2.1.2.2.1	With assessment of potential environmental risks by the Federal Environment Agency	

Fee item	Individually attributable public services subject to charge	Fee in euros
2.1.2.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	22 500
2.1.2.3	Marketing authorisation of a medicinal product / known substance / Complete reference	
2.1.2.3.1	With assessment of potential environmental risks by the Federal Environment Agency	28 100
2.1.2.3.2	Without assessment of potential environmental risks by the Federal Environment Agency	19 400
2.1.3	Marketing authorisation of a medicinal product under the repeat use (further MRP after completion of a MRP in accordance with fee item 2.1 for additional EU member states)	
2.1.3.1	With new substance	
2.1.3.1.1	With assessment of potential environmental risks by the Federal Environment Agency	27 600
2.1.3.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	18 900
2.1.3.2	With known substance	
2.1.3.2.1	With assessment of potential environmental risks by the Federal Environment Agency	23 100
2.1.3.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	14 400
2.1.4	Marketing authorisation of a series or identical series, in addition to the fee for the first marketing authorisation, per marketing	
2.1.4.1	Marketing authorisation of a series	9 700
2.1.4.2	Marketing authorisation of an identical series	4 800
2.2	With Germany as concerned member state (CMS)	
2.2.1	Marketing authorisation of a medicinal product / new substance	
2.2.1.1	Marketing authorisation of a medicinal product / new substance / no or partial reference	
2.2.1.1.1	With assessment of potential environmental risks by the Federal Environment Agency	21 400
2.2.1.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	17 100
2.2.1.2	Marketing authorisation of a medicinal product / new substance / Complete reference	
2.2.1.2.1	With assessment of potential environmental risks by the Federal Environment Agency	19 000
2.2.1.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	14 700
2.2.2	Marketing authorisation of a medicinal product / known substance	
2.2.2.1	Marketing authorisation of a medicinal product / known substance / Complete reference	18 100
2.2.2.1.1	With assessment of potential environmental risks by the Federal Environment Agency	13 800
2.2.2.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	

Fee item	Individually attributable public services subject to charge	Fee in euros
2.2.2.2	Marketing authorisation of a medicinal product / known substance / Complete reference	
2.2.2.2.1	With assessment of potential environmental risks by the Federal Environment Agency	15 900
2.2.2.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	11 600
2.2.3	Marketing authorisation of a series or identical series, in addition to the fee for the first marketing authorisation, per marketing authorisation	
2.2.3.1	Marketing authorisation of a series	5 700
2.2.3.2	Marketing authorisation of an identical series	3 400
3	**Marketing authorisation of a medicinal product under the decentralised procedure in accordance with Section 25b (3) AMG**	
3.1	With Germany as reference member state (RMS)	
3.1.1	Marketing authorisation of a medicinal product / new substance	
3.1.1.1	Marketing authorisation of a medicinal product / new substance / no reference	
3.1.1.1.1	With assessment of potential environmental risks by the Federal Environment Agency	98 000
3.1.1.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	89 300
3.1.1.2	Marketing authorisation of a medicinal product / new substance / partial reference	
3.1.1.2.1	With assessment of potential environmental risks by the Federal Environment Agency	73 800
3.1.1.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	65 100
3.1.1.3	Marketing authorisation of a medicinal product / new substance / Complete reference	
3.1.1.3.1	With assessment of potential environmental risks by the Federal Environment Agency	53 600
3.1.1.3.2	Without assessment of potential environmental risks by the Federal Environment Agency	44 900
3.1.2	Marketing authorisation of a medicinal product / known substance	
3.1.2.1	Marketing authorisation of a medicinal product / known substance / no reference	51 200
3.1.2.1.1	With assessment of potential environmental risks by the Federal Environment Agency	42 500
3.1.2.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	
3.1.2.2	Marketing authorisation of a medicinal product / known substance / partial reference	
3.1.2.2.1	With assessment of potential environmental risks by the Federal Environment Agency	46 600
3.1.2.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	37 900

Fee item	Individually attributable public services subject to charge	Fee in euros
3.1.2.3	Marketing authorisation of a medicinal product / known substance / Complete reference	
3.1.2.3.1	With assessment of potential environmental risks by the Federal Environment Agency	40 500
3.1.2.3.2	Without assessment of potential environmental risks by the Federal Environment Agency	31 800
3.1.3	Marketing authorisation of a series or identical series, in addition to the fee for the first marketing authorisation, per marketing authorisation	
3.1.3.1	Marketing authorisation of a series	14 400
3.1.3.2	Marketing authorisation of an identical series	7 000
3.2	With Germany as concerned member state (CMS)	
3.2.1	Marketing authorisation of a medicinal product / new substance	
3.2.1.1	Marketing authorisation of a medicinal product / new substance / no or partial reference	
3.2.1.1.1	With assessment of potential environmental risks by the Federal Environment Agency	24 100
3.2.1.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	19 500
3.2.1.2	Marketing authorisation of a medicinal product / new substance / Complete reference	
3.2.1.2.1	With assessment of potential environmental risks by the Federal Environment Agency	20 700
3.2.1.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	16 100
3.2.2	Marketing authorisation of a medicinal product / known substance	
3.2.2.1	Marketing authorisation of a medicinal product / known substance / Complete reference	20 500
3.2.2.1.1	With assessment of potential environmental risks by the Federal Environment Agency	15 900
3.2.2.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	
3.2.2.2	Marketing authorisation of a medicinal product / known substance / Complete reference	18 500
3.2.2.2.1	With assessment of potential environmental risks by the Federal Environment Agency	13 900
3.2.2.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	
3.2.3 fee for the	Marketing authorisation of a series or identical series, in addition to the first marketing authorisation, per marketing authorisation	
3.2.3.1	Marketing authorisation of a series	5 500
3.2.3.2	Marketing authorisation of an identical series	3 100
4	**Preparation or updating of an assessment report in accordance with Section 25 (5)a AMG, unless already covered by fee items 2 or**	
4.1	Preparation of an assessment report	

Fee item	Individually attributable public services subject to charge	Fee in euros
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 on a series or identical series, in addition to fee items 4.1 and 4.2	4 500
5	**Renewal of marketing authorisations in accordance with Section 105 (3) AMG**	
5.1	Chemically defined medicinal product	
5.1.1	Basic fee	12 600
5.1.2	Series or identical series, in addition to the first marketing authorisation fee, per marketing authorisation	2 700
5.2	Phytotherapeutic medicinal product	
5.2.1	Basic fee	9 600
5.2.2	Series or identical series, in addition to the first authorisation fee, per authorisation	2 700
5.3	Homoeopathic or anthroposophic medicinal product with Commission participation in accordance with Section 25 (7) AMG	
5.3.1	Basic fee	7 700
5.3.2	Series or identical series, in addition to the first authorisation fee, per authorisation	6 100
5.4	Homoeopathic or anthroposophic medicinal product without Commission participation in accordance with Section 25 (7) AMG	
5.4.1	Basic fee	6 900
5.4.2	Series or identical series, in addition to the first authorisation fee, per authorisation	5 400
5.5	Medicinal product in accordance with Section 109a AMG	
5.5.1	Basic fee	5 700
5.5.2	Series or identical series, in addition to the first authorisation fee, per authorisation	1 600
6	**Renewal of an marketing authorisation in acc. with Section 31 (3) AMG**	
6.1	Medicinal product with a new or known substance	
6.1.1	Basic fee	
6.1.1.1	With assessment of potential environmental risks by the Federal Environment Agency (only for medicinal products intended to be applied on animals)	13 300
6.1.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	6 200
6.1.2	Series or identical series, in addition to the fee for the first renewal, per renewal	3 100

	Individual attributable Fee item public service subject to charge	Fee in euros
6.2	Renewal entirely on the basis of a design published by the competent higher federal authority	
6.2.1	Basic fee	2 300
6.2.2	Series or identical series, in addition to the fee for the first renewal, per renewal	1 500
6.3	Renewal of a parallel imported medicinal product	
6.3.1	Basic fee	2 100
6.3.2	With variation of the marketing authorisation within the scope of the renewal procedure	2 600
7	**Renewal of an authorisation under the mutual recognition procedure (MRP)[2] or under a decentralised procedure (DCP)**	
7.1	With Germany as reference member state (RMS)	
7.1.1	Medicinal product with a new or known substance, basic fee	
7.1.1.1	With assessment of potential environmental risks by the Federal Environment Agency(only for medicinal products intended to be applied on animals)	18 300
7.1.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	9 600
7.1.2	Series or identical series, in addition to the fee for the first renewal, per renewal	4 200
7.2	With Germany as concerned member state (CMS)	
7.2.1	Medicinal product with a new or known substance, Basic fee	
7.2.1.1	With assessment of potential environmental risks by the Federal Environment Agency(only for medicinal products intended to be applied on animals)	8 400
7.2.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	4 000
7.2.2	Series or identical series, in addition to the fee for the first renewal, per renewal	2 000
8	**Examination of notifications in accordance with Section 29 AMG of the decision on the approval of notifications in accordance with Section 29 AMG**	
8.1	Variations in accordance with Section 29 (2)a Number 1 to 4 AMG with the exception of the variations set out in fee item 8.11	2 000
8.2	Variations in accordance with Section 29 (1) or (2)b as well as (2)a Number 5 AMG with the exception of the variations set out in the fee items 8.6 and 8.7, as well as the notification of any further import country for parallel imports, where authorisations have been granted for both the imported drugs in the country of origin as well as for the marketing authorisation within the scope of a procedure in accordance with fee item 2 (mutual recognition procedure) or fee item 3 (decentralised procedure).	300

Fee item	Individual attributable public services subject to charge	Fee in euros
8.3	Notification of any further import country for parallel imports, where authorisation has been granted for the marketing authorisation within the scope of a procedure in accordance with fee item I (national authorisation)	350
8.4	Variation of the marketing authorisation for parallel imported drugs or notification of an additional import country, where this results in a new overall assessment of the authorisation	560
8.5	Assignment to another pharmaceutical entrepreneur, notification of co-marketing or a local representative, notification of a parallel imported drug in accordance with Section 105 AMG, cancellation of effective substances	240
8.6	Variation of the address, telephone, fax number or email address of the authorisation holder, manufacturer, co-marketer or local representative, variation of the company name or legal form, per authorisation	140
8.7	Variation of the address, telephone, fax number or email address of the authorisation holder, variation of the company name or legal form of the authorisation holder, where this variation affects all authorisations of the authorisation holder simultaneously and is submitted in a notification separate from other variation notifications, regardless of the number of authorisations	140
8.8	Variation of name	500
8.9	Variation notifications in accordance with Section 29 (1)b and (1)c AMG	100
8.10	Notifications in accordance with Section 29 (1)e AMG	100
8.11	Variations subject to approval in accordance with Section 29 (2) a Number 1 and Number 6 AMG	
8.11.1	Variations in accordance with Section 29 (2)a Number 1 AMG, in case of the addition or variation of an indication in the same therapeutic area as well as variations in accordance with Section 29 (2)a Number 6 AMG	
8.11.1.1	With assessment of potential environmental risks by the Federal Environment Agency	8 500
8.11.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	2 400
8.11.2	Variation in accordance with Section 29 (2)a AMG, resulting in the determination of the new marketing authorisation requirement in accordance with Section 29 (3) AMG	2 400
8.12	Variation of the texts of package information leaflets and other product characteristics in adaptation of a text published by the competent highest federal authority or the European Commission, per marketing authorisation	430
8.13	Variations in accordance with Article 61 (3) of Directive 2001/83/EC, which are processed pursuant to the procedural instructions of CMDh for procedures in accordance with Article 61 (3) of Directive 2001/83/EC ("P"-Procedures)	
8.13.1	With Germany as reference member state (RMS)	560
8.13.2	With Germany as concerned member state (CMS)	300
8.14	If a notification simultaneously contains several submitted variations (with the exception of variations in accordance with	50 percent of

Fee item	Individually attributable public services subject to charge	Fee in euros
	the fee items 8.7 to 8.10, 8.13 as well as the notification of any further import country for parallel imports) for a medicinal product, in addition to the fee for the variation with the highest fee rate (basic fee), for each further variation. The fee in accordance with fee item 8.14 may in total not exceed the fee in accordance with fee item 1.2.3.2.	fee in accordance with fee items 8.1 to 8.6, 8.11 and 8.12
8.15	Where the variation in the adaptation of the package insert is based on the results gained from the consultation with patient target groups in accordance with Section 22 (7) Sentence 2 AMG, the fee can be reduced by 25 percent.	
9	**Examination of variations and decision on the approval of variations in accordance with Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334 of 12 December 2008, P. 7), as amended by Commission Regulation (EU) No 712/2012 (OJ L 209 of 4 August 2012, P. 4)**	
9.1	With Germany as reference member state (RMS) or reference authority in accordance with Article 7 or Article 20 of Commission Directive (EC) No 1234/2008	
9.1.1	Type I A	
9.1.1.1	For individual submission variation per marketing authorisation per notification/application	
9.1.1.2	For groups of variations in accordance with Article 7 (2) of Commission Directive (EC) No 1234/2008	370
9.1.1.2.1	For the first variation per notification	370
9.1.1.2.2	For each further variation per notification	300
9.1.1.3 variation,	Series, identical series and each further concerned marketing authorisation per notification, in addition to the fee for the first per variation	200
9.1.1.4 form of the pharmacovigilance	Variation of the address, telephone, fax number or email address of the marketing authorisation holder, variation of the company name or legal marketing authorisation holder, introduction or variation of the master data documentation, where submitted separate from other notifications in a notification in accordance with Article 72 Commission Directive (EC) No 1234/2008, per authorisation	140
9.1.2	Type I B	
9.1.2.1	In each case, for the first variation per notification	
9.1.2.1.1	With assessment of potential environmental risks by the Federal Environment Agency	6 100
9.1.2.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	1 800
9.1.2.2	For any further variation in accordance with Article 7 (2) of Commission Directive (EC) No 1234/2008	
9.1.2.2.1	With the assessment of potential environmental risks by the Federal Environment Agency	5 700

Fee item	Individually attributable public services subject to charge	Fee in euros
9.1.2.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	1 400
9.1.2.3	Series or identical series in addition to the fee for the first variation, per variation	900
9.1.3	Type II/simple variations or variations in accordance with Article 20 (1) of Commission Directive (EC) No 1234/2008	
9.1.3.1	In each case, for the first variation per application	4 300
9.1.3.2	For any further variation in accordance with Article 7 (2) of Commission Directive (EC) No 1234/2008	3 500
9.1.3.3	Series, identical series or any further concerned marketing authorisation per notification, in addition to the fee for the first variation, per variation	1 900
9.1.4	Type II/complex variations or variations in accordance with Article 20 (1) of Commission Directive (EC) No 1234/2008	
9.1.4.1	In each case, for the first variation per application	
9.1.4.1.1	With assessment of potential environmental risks by the Federal Environment Agency	15 600
9.1.4.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	7 500
9.1.4.2	For any further variation in accordance with Article 7 (2) of Commission Directive (EC) No 1234/2008	
9.1.4.2.1	With assessment of potential risks by the Federal Environment Agency	10 300
9.1.4.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	6 000
9.1.4.3	Series, identical series or any further concerned marketing authorisation per notification, in addition to the fee for the first variation, per variation	2 900
9.1.5	The fee incurring for variations submitted in accordance with Article 7 (2) Commission Directive (EC) No 1234/2008 or processed pursuant to the procedure in accordance with Article 20 of Commission Directive (EC) No 1234/2008, may in total not exceed the fee in accordance with fee item 2.1.2.3.2, per group of variations or per procedure in accordance with Article 20 of Commission Directive (EC) No 1234/2008	
9.2	With Germany as concerned member state (CMS) or as concerned member state in accordance with Article 7 or Article 20 of Commission Directive (EC) No 1234/2008	
9.2.1	Type I A	?
9.2.1.1	For individual submission Variation per marketing authorisation, per notification/application	190
9.2.1.2	For groups of variations in accordance with Article 7 (2I) of Commission Directive (EC) No 1234/2008	
9.2.1.2.1	For the first variation, per notification	190
9.2.1.2.2	For any further variation, per notification	150

Fee item	Individually attributable public services subject to charge	Fee in euros
9.2.1.3 authorisation	Series, identical series or any further concerned marketing per notification, in addition to the fee for the first variation, per variation	120
9.2.1.4 company introduction or	Variation of the address, telephone, fax number or email address of the marketing authorisation holder, variation of the name or legal form of the marketing authorisation holder, variation of the pharmacovigilance master data documentation, where submitted separate from other notifications in a notification in accordance with Article 72 Directive (EC) No 1234/2008, per authorisation	140
9.2.2	Type I B	
9.2.2.1	In each case, for the first variation per notification	
9.2.2.1.1	With assessment of potential environmental risks by the Federal Environment Agency	4 700
9.2.2.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	400
9.2.2.2	For any further variation in accordance with Article 7 (2) of Commission Directive (EC) No 1234/2008	
9.2.2.2.1	With assessment of potential environmental risks by the Federal Environment Agency	4 620
9.2.2.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	320
9.2.2.3	Series, identical series or any further authorisation concerned, per notification, in addition to the fee for the first variation, per variation	220
9.2.3	Type II/simple variations or Germany as concerned member state (CMS) in the procedure in accordance with Article 20 of Commission Directive (EC) No 1234/2008	
9.2.3.1	In each case for the first variation per application	1 700
9.2.3.2	for any further variation in accordance with Article 7 (2) of Commission Directive (EC) No 1234/2008	1 400
9.2.3.3	Series, identical series or any further authorisation concerned, per notification, in addition to the fee for the first variation, per variation	1 100
9.2.4	Type II/complex variations or Germany as concerned member state (CMS) in the procedure in accordance with Article 20 of Commission Directive (EC) No 1234/2008	
9.2.4.1	In each case for the first variation per application	
9.2.4.1.1	With assessment of potential environmental risks by the Federal Environment Agency	7 800
9.2.4.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	2 800
9.2.4.2	For any further variation in accordance with Article 7 (2) of Commission Directive (EC) No 1234/2008	
9.2.4.2.1	With assessment of potential environmental risks by the Federal Environment Agency	6 500

Fee item	Individual attributable public services subject to charge	Fee in euros
9.2.4.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	2 200
9.2.4.3	Series, identical series or any further concerned authorisation in the procedure in accordance with Article 20 of Commission Directive (EC) No 1234/2008, in addition to the fee for the first variation, per variation	1 500
9.2.5	The fee incurring for variations, submitted in accordance with Article 7 (2) of Commission Directive (EC) No 1234/2008 or pursuant to the procedure in accordance with Article 20 of Commission Directive (EC) No 1234/2008, may in total not exceed the fee in accordance with fee item 2.2.2.2.2 per group of variations or per procedure in accordance with Article 20 of Commission Directive (EC) No 1234/2008.	
9.3	Variations of purely national authorisations	
9.3.1	Type IA	
9.3.1.1	For individual submission variation per authorisation, per notification/application	250
9.3.1.2	For groups of variations in accordance with Article 13d (2) of Commission Directive (EC) No 1234/2008	
9.3.1.2.1	For the first variation, per notification	250
9.3.1.2.2	For any further variation	200
9.3.1.3	Series, identical series or any further concerned authorisation per notification, in addition to the fee for the first variation, per variation	150
9.3.1.4	Variation of address, telephone, fax number or email address of the authorisation holder, change of the company name or legal form of the authorisation holder, introduction or variation of the pharmacovigilance master data documentation, where submitted separate from other notifications in form of a notification in accordance with Article (2) of Commission Directive (EC) No 1234/2008, per authorisation	140
9.3.2	Type IB	
9.3.2.1	In each case for the first variation per notification	
9.3.2.1.1	With assessment of potential environmental risks by the Federal Environment Agency	5 060
9.3.2.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	760
9.3.2.2	For any further variation in accordance with Article 13d (2) of Commission Directive (EC) No 1234/2008	
9.3.2.2.1	With assessment of potential environmental risks by the Federal Environment Agency	4 860
9.3.2.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	560
9.3.2.3	Series, identical series or any further authorisation concerned, per notification, in addition to the fee for the first variation, per variation	360

Fee item	Individually attributable public services subject to charge	Fee in euros
9.3.3	Type II/simple variations or variations in accordance with Article 20 (1) of Commission Directive (EC) No 1234/2008	
9.3.3.1	In each case, for the first variation per application	1 600
9.3.3.2	For any further variation in accordance with Article 13d (2) of Commission Directive (EC) No 1234/2008	1 300
9.3.3.3	Series, identical series or any further marketing authorisation concerned, per notification, in addition to the fee for the first variation, per variation	810
9.3.4	Type II/complex variations or variations in accordance with Article 20 (1) of Commission Directive (EC) No 1234/2008	
9.3.4.1	In each case, for the first variation per application	
9.3.4.1.1	With assessment of potential environmental risks by the Federal Environment Agency	8 750
9.3.4.1.2	Without assessment of potential environmental risks by the Federal Environment Agency	3 750
9.3.4.2	For any further variation in accordance with Article 13d (2) of Commission Directive (EC) No 1234/2008	
9.3.4.2.1	With assessment of potential environmental risks by the Federal Environment Agency	7 300
9.3.4.2.2	Without assessment of potential environmental risks by the Federal Environment Agency	3 000
9.3.4.3	Series, identical series or any further concerned marketing authorisation per notification, in addition to the fee for the first variation, per variation	1 900
9.3.5	The fee incurring for variations, submitted in accordance with Article 13d(2) of Commission Directive (EC) No 1234/2008 or pursuant to the procedure in accordance with Article 20 of Commission Directive (EC) No 1234/2008, may in total not exceed the fee in accordance with fee item 1.2.3.2 per group of variations or per procedure in accordance with Article 20 of Commission Directive (EC) No 1234/2008.	
10	**Registration of homoeopathic medicinal products**	
10.1	National registration procedure	
10.1.1	Registration/basic fee	6 400
10.1.2	Registration of a series, in addition to the fee for the first registration, per registration	2 100
10.1.3	Registration of a duplicate or identical series	1 600
10.1.4	Registration of a parallel imported medicinal product	1 600
10.2	Registration of a medicinal product under the mutual recognition procedure (MRP)	
10.2.1	with Germany as reference member state (RMS), in addition to the fees in accordance with fee items 10.1.1 to 10.1.4	
10.2.1.1	Registration/basic fee	11 800
10.2.1.2	Registration of a series, in addition to the fee for the first registration, per registration	5 900

Fee item	Individually attributable public services subject to charge	Fee in euros
10.2.1.3	Registration of an identical series, in addition to the fee for the first registration, per registration	2 900
10.2.2	With Germany as concerned member state (CMS)	
10.2.2.1	Registration/basic fee	7 100
10.2.2.2	Registration of a series, in addition to the fee for the first registration, per registration	3 500
10.2.2.3	Registration of an identical series, in addition to the fee for the first registration, per registration	2 100
10.3	Registration of a medicinal product under the decentralised procedure (DCP)	
10.3.1	With Germany as reference member state (RMS)	
10.3.1.1	Registration/basic fee	18 200
10.3.1.2	Registration of a series, in addition to the fee for the first registration, per registration	8 000
10.3.1.3	Registration of an identical series, in addition to the fee for the first registration, per registration	4 500
10.3.2	With Germany as concerned member state (CMS)	
10.3.2.1	Registration/basic fee	10 200
10.3.2.2	Registration of a series, in addition to the fee for the first registration, per registration	4 000
10.3.2.3	Registration of an identical series, in addition to the fee for the first registration, per registration	2 200
10.4	Renewal of a registration in accordance with Section 39 (2)c AMG	
10.4.1	Renewal of a registration/basic fee	2 700
10.4.2	Series or identical series, in addition to the fee for the first renewal, per renewal or parallel import	1 400
10.5	Renewal of a registration under the mutual recognition procedure (MRP) or a decentralised procedure (DCP)	
10.5.1	With Germany as reference member state (RMS)	
10.5.1.1	Renewal of a registration/basic fee	3 300
10.5.1.2	Series or identical series, in addition to the fee for the first renewal	1 700
10.5.2	With Germany as concerned member state (CMS)	
10.5.2.1	Renewal of a registration/basic fee	1 500
10.5.2.2	Series or identical series, in addition to the fee for the first renewal	800
10.6	Examination of the variations of a registration in accordance with Section 39 (2)b AMG and decision on the approval of the variations of a registration in accordance with Section 39 (2)b AMG	
10.6.1	Variations in accordance with Section 39 (2)b AMG in conjunction with Section 29 (2)a Number 1 to 4 AMG	2 000

Fee item	Individually attributable public services subject to charge	Fee in euros
10.6.2	Variations in accordance with Section 39 (2)b Sentence 1 AMG as well as in accordance with Section 39 (2)b AMG in conjunction with Section 29 (2)a Number 5 AMG with the exception of the variations set out in fee items 10.6.5 and 10.6.6, in conjunction with Section 29 (2)b AMG as well as the parallel imports	300
10.6.3	Notification of an additional import country, where this leads to a new overall assessment of the registration	560
10.6.4	Assignment to another pharmaceutical entrepreneur, notification of co-marketing or a local representative, notification of a parallel imported drug in accordance with Section 105 AMG, cancellation of effective substances	240
10.6.5	Variation of the address, telephone, fax number or email address of the registration holder, manufacturer, co-marketer or local representative, variation of the company name or legal for, per registration	140
10.6.6	Variation of the address, telephone, fax number or email address of the registration holder, variation of the company name or legal form of the registration holder, where this variation simultaneously concerns all variations of the registration holder and is submitted in a notification separate from the other variation notifications, regardless of the number of registrations	140
10.6.7	Variation of name	500
10.6.8	Notifications in accordance with Section 39 (2)b in conjunction with Section 29 1e AMG	100
10.6.9	Variation in accordance with Section 39 (2)b AMG, resulting in the determination of the new registration requirement in accordance with Section 39 (2)b Sentence 4 AMG	2 400
10.6.10	Where several variations have been applied for simultaneously (with the exception of variations in accordance with fee items 10.6.6 and 10.6.7 and the notification of any further import country for parallel imports) for a medicinal product, in addition to the fee for the variation with the highest fee rate (basic fee), for any further variation The fee in accordance with fee item 10.6.10 may in total not exceed the fee in accordance with fee item 10.1.1.	50 percent of the fee in accordance with fee items 10.6.1 to 10.6.5 and 10.6.8
10.7	Order regarding the limited suspension of the registration in accordance with Section 39 (2)d AMG in conjunction with Section 30 (1) Sentence 3 and (2) Sentence 2 AMG, provided that the order is not based on the application of the pharmaceutical entrepreneur, depending on the personnel and material costs	30 to 5 000
10.8	Granting of an exemption in accordance with Section 39 (2)c Sentence 2 AMG in conjunction with Section 31 (1) Sentence 2 AMG, per registration	200
10.9	The basic fees collectable on the basis of the fee items 10.1.1 to 10.1.4, 10.2.1 to 10.3.2.3 as well as 10.4.1 to 10.5.2.2 of the fee schedule shall increase by 10 percent of the basic fee for homoeopathic medicinal products with more than one active substance for each medically active substance, however max. to twice the basic fee.	

Fee item	Individually attributable public services subject to charge	Fee in euros
11	**Registration of traditional herbal medicinal products in accordance with Sections 39a et seq. AMG**	
11.1	National registration procedure	
11.1.1	Procedure without lists / monographs	
11.1.1.1	Registration/basic fee	15 600
11.1.1.2	Registration of a series, in addition to the fee for the first registration, for every further registration	6 000
11.1.1.3	Registration of an identical series, in addition to the fee for the first registration, for every further registration and registration of duplicates	2 800
11.1.2	Procedure with lists / monographs	
11.1.2.1	Registration/basic fee	9 900
11.1.2.2	Registration of a series, in addition to the fee for the first registration, for every further registration	5 000
11.1.2.3	Registration of an identical series, in addition to the fee for the first registration, for every further registration and registration of duplicates	2 800
11.1.3	Registration of a parallel imported medicinal product	2 200
11.2	Registration of a medicinal product under the mutual recognition procedure	
11.2.1	With Germany as reference member state (RMS), in addition to the fees in accordance with fee item 11.1.2	
11.2.1.1	Registration/basic fee	19 400
11.2.1.2	Registration of a series, in addition to the fee for the first registration, for every further registration	9 700
11.2.1.3	Registration of an identical series, in addition to the fee for the first registration, for every further registration	4 800
11.2.2	With Germany as concerned member state (CMS)	
11.2.2.1	Registration/basic fee	11 600
11.2.2.2	Registration of a series, in addition to the fee for the first registration, for every further registration	5 700
11.2.2.3	Registration of an identical series, in addition to the fee for the first registration, for every further registration	3 400
11.3	Registration of a medicinal product under the decentralised procedure	
11.3.1	With Germany as reference member state (RMS)	
11.3.1.1	Registration/basic fee	31 800
11.3.1.2	Registration of a series, in addition to the fee for the first registration, for every further registration	14 400
11.3.1.3	Registration of an identical series, in addition to the fee for the first registration, for every further registration	7 000

Fee item	Individually attributable public services subject to charge	Fee in euros
11.3.2	With Germany as concerned member state (CMS)	
11.3.2.1	Registration/basic fee	13 900
11.3.2.2	Registration of a series, in addition to the fee for the first registration, for every further registration	5 500
11.3.2.3	Registration of an identical series, in addition to the fee for the first registration, for every further registration	3 100
11.4	Registration in the event of the implementation of a procedure in accordance with Section 39d (3) AMG, in addition to the fees in accordance with fee item 11.1.1, depending on the personnel and material costs	6 000 to 25 000
11.5	Registration in the event of the implementation of a procedure in accordance with Section 39d (4) AMG, in addition to the fees in accordance with fee item 11.1.1, depending on the personnel and material costs	6 000 to 25 000
11.6	Renewal of a registration in accordance with Section 39c (3) in conjunction with Section 31 (3) AMG	
11.6.1	Renewal of a registration/basic fee	6 200
11.6.2	Series or identical series, in addition to the fee for the first renewal, per renewal or parallel import	3 100
11.7	Renewal of a registration under the mutual recognition procedure (MRP) or a decentralised procedure (DCP)	
11.7.1	With Germany as reference member state (RMS)	
11.7.1.1	Renewal of a registration/basic fee	7 600
11.7.1.2	Series or identical series, in addition to the fee for the first renewal, per renewal	3 700
11.7.2	With Germany as concerned member state (CMS)	
11.7.2.1	Renewal of a registration/basic fee	3 400
11.7.2.2	Series or identical series, in addition to the fee for the first renewal, per renewal	1 700
11.8	Examination of variations of a registration in accordance with Section 39d (7) AMG and decision on the approval of variations of a registration in accordance with Section 39d (7) AMG	
11.8.1	Variations in accordance with Section 39d (7) AMG in conjunction with Section 29 (2)a Number 1 to 4 AMG	2 000
11.8.2	Variations in accordance with Section 39d (7) in conjunction with Section 29 (2)a Number 5 AMG with the exception of the variations specified notification of any further import country for parallel imports	300
11.8.3	Notification of an additional import country, where this leads to a new overall assessment of the registration	560
11.8.4	Assignment to another pharmaceutical entrepreneur, notification of co-marketing or a local representative, notification of a parallel imported drug in accordance with Section 105 AMG, cancellation of effective substances	240
11.8.5	Variation of the address, telephone, fax number or the email address of the registration holder,	140

Fee item	Individually attributable public services subject to charge	Fee in euros
	manufacturer, co-marketer or local representative , variation of the company name or legal form, per registration	
11.8.6	Variation of the address, telephone, fax number or email address of the registration holder, variation of the company name or legal form, per registration, where this variation simultaneously concerns all registrations of the registration holder and is submitted in a notification separate from the other variation notifications, regardless of the number of registrations	140
11.8.7	Variation of name	500
11.8.8	Notifications in accordance with Section 39d (7) AMG in conjunction with Section 29 (1)e AMG	100
11.8.9	Variation in accordance with Section 39d (7) AMG, resulting in the new registration requirement in accordance with Section 39d (7) Sentence 3 AMG	2 400
11.8.10	Variations in accordance with Article 61 (3) of Directive 2001/83/EC, which are processed pursuant to the procedural instructions of CMDh for procedures in accordance with Article 61 (3) of Directive 2001/83/EC ("P"-Procedures)	
11.8.10.1	With Germany as reference members state (RMS)	560
11.8.10.2	With Germany as concerned member state (CMS)	300
11.8.11	Variations in accordance with Section 39d (7) AMG, also in conjunction with Section 29 (2)b AMG, with the exception of the fee items 11.8.1 to 11.8.10	300
11.8.12	For several simultaneously applied variations (with the exception of variations in accordance with fee items 11.8.6 and 11.8.7 as well as the notification of every further import country for parallel imports) for a medicinal product, in addition to the fee for the variation with the highest fee rate (basic rate), for each further variation The fee in accordance with fee item 11.8.12 may in total not exceed the fee in accordance with fee item 11.1.2.1.	50 percent of the fee in accordance with fee items 11.8.1 to 11.8.5 and 11.8.8 to 11.8.9
11.8.13	Where the variation in the adaptation of the package insert is based on the results gained from the consultation with patient target groups in accordance with Section 22 (7) Sentence 2 AMG, the fee can be reduced by 25 percent.	
11.9	Order regarding the limited suspension of the registration in accordance with Section 39 d (8) AMG in conjunction with Section 30 (1) Sentence 3 and (2) Sentence 2 AMG, provided that the order is not based on the application of the pharmaceutical entrepreneur, depending on the personnel and material costs	30 to 10 000
11.10	Granting of an exemption in accordance with Section 39 (2)c Sentence 2 AMGin conjunction with Section 31 (1) Sentence 2 AMG, per registration	200
12	**Examination of marketing authorisation-related information in accordance with Section 25(5) AMG, depending on the staff costs and operational expenditures**	5 000 to 25 000
13	**Individually attributable public services within the scope of clinical trials**	
13.1 Sentence 2	Marketing authorisation granted in accordance with Section 40 (1) AMG, Section 42 (2) AMG	

Fee item	Individually attributable public services subject to charge	Fee in euros
13.1.1	First submission of an trial plan for an investigational drug in Phase I, II or III	
13.1.1.1	Basic fee	3 800
13.1.1.2	For submission of an integrated study protocol with additional sub-studies in accordance with fee item 13.1.1 per additional sub-study, in addition to the basic fee	900
13.1.2	Follow-up study of an investigational drug assessed in accordance with fee item 13.1.1 in phase I, II or III	
13.1.2.1	Follow-up study without new assessment of documents	1 500
13.1.2.2	Follow-up study with new assessment of documents in phase I	
13.1.2.2.1	Basic fee	1 900
13.1.2.2.2	For submission of an integrated study protocol with additional sub-studies in accordance with fee item 13.1.2.2 per additional sub-study, in addition to the basic fee	800
13.1.2.3	Follow-up study with new assessment of documents in phase II or III	
13.1.2.3.1	Basic fee	2 100
13.1.2.3.2	For submission of an integrated study protocol with additional sub-studies in accordance with fee item 13.1.2.3 per additional sub-study, in addition to the basic fee	900
13.1.3	Approval of a clinical trial with an investigational drug which has a marketing authorisation in a EU member state at the time the application is filed; the application of the investigational drug occurs within or outside the authorised application conditions specified in the product characteristics.	
13.1.3.1	Basic fee	1 700
13.1.3.2	For submission of an integrated study protocol with additional sub-studies in accordance with fee item 13.1.3 per additional sub-study, in addition to the basic fee	900
13.1.4	Examination for proof of bioequivalence	2 100
13.1.5	Approval in accordance with Section 42 (3) conjunction with Section 9 (2) Sentence 2 and 3 GCP-V upon submission of additional documents which require a scientific processing	740
13.1.6	Approval of clinical trials with medicinal drugs which consist of or contain a genetically modified organism or a combination of genetically modified organisms	9 500
13.1.7	Approval of variations after start of a clinical trial in accordance with Section 42 (3) AMG in conjunction with Section 10 GCP-V	
13.1.7.1	Variations subject to approval, which require a scientific processing	
13.1.7.1.1	Basic fee	1 100
13.1.7.1.2	Variations subject to approval, which contains several variations subject to approval in accordance with fee item 13.1.7.1, per additional variation	700
13.1.7.2	Other variations	730

Fee item	Individual attributable public service subject to charge	Fee in euros
13.2	Assessment of annual reports on the safety of the participants in the trial in accordance with Section 42 ()3 AMG in conjunction with Section 13 (6) GCP-V	
13.2.1	Annual reports on monocenter clinical trials	500
13.2.2	Annual reports on multicentre clinical trials	1 000
13.2.3	Annual reports on more than five clinical trials with the same investigational drug	2 500
13.3	Examination of authorisation-related information in accordance with Section 42 (3) AMG in conjunction with Section 9 (5) GCP-V (GCP inspections), depending on the personnel and material costs	5 000 to 50 000
13.4	Examination, comparison and submission of the information for the EudraCT database in accordance with Section 14 (3) GCP-V, where not covered by fee item 13.1	250
14	**Assessment of reports in accordance with Section 63d and 63h (5) AMG and examinations in accordance with Section 62 (6), Section 63c (4) AMG in conjunction with Section 62 (6) AMG and Section 63h (6) AMG in conjunction with Section 62 (6) AMG**	
14.1	Report assessment under the national procedure	
14.1.1	Within ten years after the first authorisation of the medicinal product in Germany	1 400
14.1.2	More than ten years after the first marketing authorisation of the medicinal product in Germany	700
14.2	Report assessment under the mutual recognition procedure (MRP) or under a decentralised procedure in accordance with Section 25b (3) AMG	
14.2.1	With Germany as reference member state (RMS)	
14.2.1.1	Within ten years after the first marketing authorisation of the medicinal product in Germany	4 800
14.2.1.2	More than ten years after the first marketing authorisation of the medicinal product in Germany	1 400
14.2.2	With Germany as concerned member state (CMS)	
14.2.2.1	Within ten years after the first marketing authorisation of the medicinal product in Germany	1 400
14.2.2.2	More than ten years after the first marketing authorisation of the medicinal product in Germany	700
14.3	Where identical periodic reports in accordance with fee items 14.1 and 14.2 are simultaneously submitted and assessed, the fee in accordance with fee item 14.1 or 14.2 will be due only once. For every further identical periodic report, the fee will be reduced to	300
14.4	Examination of the collection and assessment of medicinal product risks and coordination of necessary measures in accordance with Section 62 (6) AMG, depending on the personnel and material costs	1 000 to 27 500

Fee item	Individually attributable public services subject to charge	Fee in euros
15	**Individually attributable public services within the scope of non-interventional harmlessness tests**	
15.1	Non-interventional harmlessness tests conducted at own initiative	
15.1.1	Examination of notifications in accordance with Section 63f (1) AMG	260
15.1.2	Examination of requested documents in the case set out in Section 63f (1) Sentence 2 AMG, depending on the personnel and material costs	500 to 4 200
15.1.3	Examination of the final report	300 to 4 200
15.2	Requested non-interventional harmlessness tests, for implementation of the examination only nationally	
15.2.1	Approval of the draft examination notification in accordance with Section 63g (2) AMG, depending on the personnel and material costs	500 to 4 200
15.2.2	Approval of essential variations of the notification in accordance with Section 63g (3) AMG, per variation	250
15.2.3	Examination of the final report	300 to 4 200
16	**Examination of notifications in acc. with Section 67 (5) AMG**	100
17	**Examination of notifications in acc. with Section 67 (6) AMG**	260
18	**Imposing of conditions in accordance with Section 28, Section 30 (2)a, Section 39 (1) Sentence 4 to 6, Section 39 (2)d AMG in conjunction with Section 30 (2)a, Section 39c (1) Sentence 4 to 6, Section 39d (8) AMG in conjunction with Section 30 (2)a, Section 105 (5) AMG or a warning notice in accordance with Section 110 AMG or an incidental provision in accordance with Section 36 of the Administrative Procedure Act (VwVfG), depending on the personnel and material costs**	30 to 10 000
19	**Measures in accordance with Section 25c AMG, depending on the personnel and material costs**	30 to 10 000
20	**Measures in accordance with Section 30 (1) Sentence 4, (1)a Sentence 3, (2) Sentence 2, (2)a Sentence 1, Section 31 (4) Sentence 2, Section 42a (1) Sentence 2, (2) Sentence 2, (3) Sentence 3 and (5) AMG**	
20.1	Order of a limited suspension of an authorisation in accordance with Section 30 (1) Sentence 4, (1)a Sentence 3, (2) Sentence 2 AMG as well as measures in accordance with Section § 30 (2)a Sentence 1 AMG, with the exception of the measures set out in fee item 18 and in accordance with Section 31 (4) Sentence 2 AMG, depending on the personnel and material costs	30 to 10 000
20.2	Measures in accordance with Section 42a (1) Sentence 2, (2) Sentence 2, (3) Sentence 3 and (5) AMG, depending on the personnel and material costs	30 to 3 700
21	**Decisions in accordance with Section 21 (4) AMG**	
21.1	Decision on the authorisation requirement, depending on the personnel and material costs	900 to 6 000
21.2	Decision on the authorisation requirement of a clinical trial, authorisation requirement	900 to 3 700
22	**Granting of an exception in accordance with Section 31 (1) Sentence 2 AMG, per authorisation**	200

Fee item	Individually attributable public services subject to charge		Fee in euros
23	**Determination of an adequate waiting period in accordance with Section 59 (2) Sentence 2 AMG**		
23.1	For a medicinal product with a substance which does not correspond to the classification in accordance with Article 14 (2) lit. a, b or c of Regulation (EC) No 470/2009		4 300
23.2	For a medicinal product with a substance which corresponds to the classification in accordance with Article 14 (2) lit. a, b or c of Regulation (EC) No 470/2009		1 800
24	**Other individually attributable public services**		
24.1	Scientific opinions on the quality, therapeutic efficiency or harmlessness of a medicinal product		100 to 500
24.2	Decision on an application for restitution of the previous status in accordance with Section 32 VwVfG		260
24.3	Decision on an application for a reinstatement of the procedure in accordance with Section 51 VwVfG		260
24.4	Non-simple written information		50 to 500
24.5	Inspection of the authorisation records beyond the scope of a pending administrative procedure in accordance with fee items 1 to 12, 24.2 or 24.3		30 to 260
24.6	Advice to the applicant		200 to 10 000
24.7	Issuance of a certificate in accordance with Section 73a (2) AMG		100
24.8	Certifications with the exception of those specified in fee item 24.1 and authentications		10 to 150
25	**Appeal proceedings**		
25.1		Appeals against decisions on the merits	
25.1.1	Rejected as inadmissible	160; where a lower fee is due for the relevant decision, this one will be due; where lump-sum fees are due and their mean value is lower, this fee shall be due	
25.1.2	Partially or complete rejected as unfounded, where the appeal	max. the fee incurring in accordance with this Regulation for the decision on the merits to be investigated in the appeal proceedings; max. however, the maximum value.	

Fee item	Individually attributable public services subject to charge	Fee in euros
	is not successful, as the breach of a procedural or formal requirement in accordance with Section 45 VwVfG is irrelevant	however, min. 160; where a lower fee is set out for the decision on the merits under investigation
25.1.3	Upon withdrawal of an appeal after commencement of the processing of the case, however prior to its completion	max. 75 percent of the fee incurring in accordance with this Regulation for the decision on the merits to be investigated in the appeal proceedings; max. however, 75 percent of the max. value; however min. 160; where a lower fee than 160 is set out for the decision on the merits under investigation, this amount
25.2	Appeals against the assertion offers and charges	
25.2.1	Rejected as inadmissible	160; where the amount in dispute is lower;
25.2.2	Partially or complete rejected as unfounded, where the appeal is only not asserted as the breach of a procedural or formal requirement in accordance with Section 45 VwVfG is irrelevant	max. 10 percent of the amount in dispute; however at least 160; where the amount in dispute in lower than 160, this amount
25.2.3	Upon withdrawal of an appeal after commencement of the processing of the case, however prior to its completion	max. 75 percent of the amount in dispute; however at least 160; where the amount in dispute in lower than 160, this amount

1 Procedure in accordance with Title III Chapter 4 of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the creation of a community code for human medicinal products (OJ L 311 of 28 November 2001, P. 67), last amended by Regulation (EC) No 1901/2006 (OJ L 378 of 27 December 2006, P. 1), or in accordance with Title III Chapter 4 of Directive 2001/82/EC of the European Parliament and the Council of 6 November 2001 on the creation of a community code veterinary medicinal products (OJ L311 of 28 November 2001, P. 1), last amended by Regulation (EC) No. 596/2009 (OJ L 188 of 18 July 2009, P.14).

2 Procedure in accordance with Title III Chapter 4 of Directive 2001/83/EG EC of the European Parliament and the Council of 6 November 2001 on the creation of a community code for human medicinal products (OJ L 311 of 28 November 2001, P. 67), last amended by Regulation (EC) No 1901/2006 (OJ L 378 of 27 December 2006, P. 1), or in accordance with Title III Chapter 4 of Directive 2001/82/EC of the European Parliament and the Council of 6 November 2001 on the creation of a community code veterinary medicinal products (OJ L311 of 28 November 2001, P. 1), last amended by Regulation (EC) No. 596/2009 (OJ L 188 of 18 July 2009, P.14).