

Member State	Directive 2004/27/EC	SPECIFICATIONS	National Currency resp. Euro	Fee in National Currency (if applicable)	Ratio National Euro/Currency (if applicable)	Fees in EURO
Austria	Art. 14	Simplified Registration (Single Remedy)	Euro			400
	Art. 16	Marketing Authorization (Single Remedy)	Euro			1000
		Marketing Authorization (Complex Remedy)	Euro			3500
Belgium	Art. 14	Simplified Registration (Single)	Euro			185
		Simplified Registration (Complex)	Euro			1590
		Simplified Registration (Complex maximum 5 stocks) - for every additional stock	Euro			27
		Additional Fee if no registration dossier as a single remedy exists	Euro			185
		Simplified Registration of a series of products derived from the same stock or stocks per pharmaceutical form	Euro			1060
		Simplified Registration of a series of products derived from the same stock or stocks per type of dilution	Euro			1060
	Art. 16	Simplified Registration to prove safety of each dilution which is lower than 1/10.000 or 1/100	Euro			106
		MRP/DCP Belgium as RMS	Euro			2x fee
		Market Authorisation (Single)	Euro			1325
		Marketing Authorisation (Complex)	Euro			2014
		Simplified Registration (Complex maximum 5 stocks) - for every additional stock	Euro			27
		Additional Fee if no registration dossier as a single remedy exists	Euro			185
Bulgaria	Art. 14	Simplified Registration (1-250 'packages')	Lev	6000	0,51	3060
		Simplified Registration (251-500 'packages')	Lev	8000	0,51	4080
		Simplified Registration (More than 500 'packages')	Lev	10000	0,51	5100
	MRP	RMS (Single Remedy)	Lev	4000	0,51	2040
		RMS (2 - 5 homeopathic stocks)	Lev	7000	0,51	3570
		RMS (More than 5 homeopathic stocks)	Lev	10000	0,51	5100
		CMS (Single Remedy)	Lev	2000	0,51	1020
		CMS (2 - 5 homeopathic stocks)	Lev	3500	0,51	1785
		CMS (More than 5 homeopathic stocks)	Lev	5000	0,51	2550
	Dcp	RMS (Single Remedy)	Lev	5000	0,51	2550
		RMS (2 - 5 homeopathic stocks)	Lev	8000	0,51	4080
		RMS (More than 5 homeopathic stocks)	Lev	11000	0,51	5610
		CMS (Single Remedy)	Lev	2500	0,51	1275
		CMS (2 - 5 homeopathic stocks)	Lev	4000	0,51	2040
		CMS (More than 5 homeopathic stocks)	Lev	5500	0,51	2805
	Art. 16	Marketing Authorisation (Single Remedy)	Lev	2000	0,51	1020
		Marketing Authorisation (2 - 5 homeopathic stocks)	Lev	3500	0,51	1785
		Marketing Authorisation (More than 5 homeopathic stocks)	Lev	5000	0,51	2550
Cyprus	Art. 14	Application Registration (simplified procedure)	CYP (Cyprus pound)	49,75	1,70854	85
	Art. 14	Fee for registration	CYP	49,75	1,70854	85
	Art. 14	Application Renewal	CYP	29,85	1,70854	51
	Art. 14	Registration Renewal	CYP	29,85	1,70854	51

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Czech Republic	Art. 14	Application for authorisation/registration	CZK (Czech koruna)	2000	0,035259	71
	Art. 14	Simplified Registration	CZK	99500	0,035259	3508
	MRP	RMS	CZK	98900	0,035259	3487
	MRP	RMS (application prior to 5 June 2003)	CZK	140600	0,035259	4957
	MRP	CMS	CZK	43900	0,035259	1548
	DcP	RMS	CZK	193400	0,035259	6819
	DcP	CMS	CZK	43900	0,035259	1548
	Art. 14	Renewal	CZK	33900	0,035259	1195
	Art. 16	Authorisation (Conventional)	CZK	88000	0,035259	3103
		Variations Type I A (Conventional)	CZK	2400	0,035259	85
		Variations Type I A (Conventional)	CZK	6700	0,035259	236
		Variations Type II (Conventional)	CZK	36700	0,035259	1294
Denmark	Art. 14	First pharmaceutical form and strength	DKK	2250	0,1341	302
	Art. 14	Additional pharmaceutical forms and strengths	DKK	500	0,1341	67
	Art. 14	Annual fee for each pharm form	DKK	910	0,1341	122
	Art. 14	Renewal	DKK	975	0,1341	131
	Art. 16	Identical fees as for ordinary pharmaceuticals	DKK	77050	0,1341	10332
	Art. 16	Renewal fee - Additional indication, strength, pharmaceutical form (as for ordinary drugs)	DKK	16385	0,1341	2197
	Art. 16	Annual fee as for ordinary drugs (+ additional pharmaceutical form/strength)	DKK	8630	0,1341	1157
Estonia	Art. 14	Simplified Registration	EEK	6000	0,0639115	383
	Art. 14	Renewal	EEK	5000	0,0639115	320
	MRP	RMS	EEK	56000	0,0639115	3579
	MRP	CMS	EEK	6000	0,0639115	383
	Art. 16	Authorisation (Conventional)	EEK	20000	0,0639115	1278
	Art. 16	Subsequent pharmaceutical form or strength	EEK	8000	0,0639115	511
	Art. 16	Renewal (Conventional)	EEK	10000	0,0639115	639
		Annual Fee	EEK	2500	0,0639115	160
		State fee for application for marketing authorisation / renewal	EEK	500	0,0639115	32
		State fee for application for variation	EEK	250	0,0639115	16
Finland	Art. 14	Simplified Registration (1-5 homeopathic stocks) /CMS	Euro			850
	Art. 14	Simplified Registration (more than 5 homeopathic stocks)/CMS	Euro			1100
	MRP/DCP	RMS (1-5 homeopathic stocks)	Euro			9850
	MRP/DCP	RMS (more than 5 homeopathic stocks)	Euro			10100
	Art. 16	Marketing authorisation (with indication)	Euro			9500
	Art. 16	Marketing authorisation including extensions (without indication)	Euro			1680
	Art. 16	Additional Strength/Pharmaceutical form	Euro			3800
	Art. 16	Extension (with indication)	Euro			3800
	Art. 16	Each additional strength and/or pharmaceutical form	Euro			3800
	Annual Fee	registered and authorised homeopathic and antroposophic products	Euro			100

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France						
	Art. 14	Single Remedy (NA after 18.01.1994)	Euro			1768
	Art. 14	Composition: 2 - 5 components (NA after 18.01.1994)	Euro			2478
	Art. 14	Composition: 6 or more components (NA after 18.01.1994)	Euro			7600
	Art. 14	Single Remedy (NA prior to 18.01.1994)	Euro			760
	Art. 14	Composition: 2 - 5 components (NA prior to 18.01.1994)	Euro			1256
	Art. 14	Composition: 6 or more components (MA prior to 18.01.1994)	Euro			3800
	Art. 14	Application for registration change	Euro			496
	Art. 14	5 year renewal of registration	Euro			380
	Art. 16	New application after the Law of 18.01.1994	Euro			10110
	Art. 16	Application for the medicinal products authorized prior to 18.01.1994	Euro			1011
	Art. 16	Modification of a Marketing Authorization	Euro			1011
	Art. 16	5 year renewal of a Marketing Authorization	Euro			674
NA (National Authorization) prior to / after 18.01.1994: products having / not having an Authorization on 18.01.1994						
Germany						
Registration (Nach- und Neu-Registrierung)						
	Art. 14	Single remedy	Euro			1080
	Art. 14	Complex remedy 2 to 4 components	Euro			1740
	Art. 14	Complex remedy 5 or more components	Euro			2350
	Art. 14	Additional fee for substances not mentioned in the German Homeopathic Pharmacopoeia	Euro			120
	Art. 14	Additional pharmaceutical form single remedy	Euro			1080
	Art. 14	Additional pharmaceutical form complex remedy 2 to 4 components	Euro			1420
	Art. 14	Additional pharmaceutical form complex remedy 5 or more components	Euro			2350
Authorisation (Nach- und Neu-Zulassung)						
Authorisation <i>without</i> Commission C or D Monograph						
	Art. 16	Basic Fee	Euro			7700
	Art. 16	25% Reduced Fee for products with a turnover between 76.690 und 127.800 Euro	Euro			5828
	Art. 16	50% Reduced Fee for products with a turnover between 25.560 und 76.690 Euro	Euro			3885
	Art. 16	75% Reduced Fee for products with a turnover less than 25.560 Euro	Euro			1943
	Art. 16	Additional strength/pharmaceutical form Standard Fee	Euro			3120
	Art. 16	Additional strength/pharmaceutical form 25% Reduced Fee	Euro			2340
	Art. 16	Additional strength/pharmaceutical form 50% Reduced Fee	Euro			1560
	Art. 16	Additional strength/pharmaceutical form 75% Reduced Fee	Euro			780
Authorisation <i>with</i> Commission C or D Monograph ('Kann-Bestimmung' = 60% reduction)						
	Art. 16	Basic Fee	Euro			3108
	Art. 16	25% Reduced Fee for products with a turnover between 76.690 und 127.800 Euro	Euro			2332
	Art. 16	50% Reduced Fee for products with a turnover between 25.560 und 76.690 Euro	Euro			1554
	Art. 16	75% Reduced Fee for products with a turnover less than 25.560 Euro	Euro			780
	Art. 16	Additional strength/pharmaceutical form Standard Fee	Euro			1248
	Art. 16	Additional strength/pharmaceutical form 25% Reduced Fee	Euro			936
	Art. 16	Additional strength/pharmaceutical form 50% Reduced Fee	Euro			624
	Art. 16	Additional strength/pharmaceutical form 75% Reduced Fee	Euro			312
	Art. 16	Renewal Authorisation with Commission C or D Monograph				8300
	Art. 16	Additional fee for a series of authorisations or a similar series Renewal Authorisation with Commission C or D Monograph per additional authorisation				6500
	Art. 16	Renewal Authorisation without Commission C or D Monograph				7500
	Art. 16	Additional fee for a series of authorisations or a similar series Renewal Authorisation without Commission C or D Monograph per additional authorisation				5700
	Art. 14/16	Publication	Euro			64

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Greece						
	Art. 14	Simplified Registration	Euro			6000
	Art. 14	MRP/DCP (Greece as reference Member State)	Euro			6000
	Art. 14	Renewal/Modification	Euro			1000
	Art. 16	Marketing Authorization New Substance (Half of the fees for conventional medicinal products)	Euro			12500
	Art. 16	Marketing Authorization 'Known' Substance (Half of the fees for conventional medicinal products)	Euro			10000
	Art. 16	Marketing Authorization Bibliographic Reference (Half of the fees for conventional medicinal products)	Euro			7500
	Art. 16	Each additional strength and/or pharmaceutical form	Euro			2500
	Art. 16	Renewal Marketing Authorization	Euro			2500
	Art. 16	Modification Marketing Authorization Type IA	Euro			250
	Art. 16	Modification Marketing Authorization Type IB	Euro			500
Hungary						
	Art. 14	Single remedies of which the active principle can be found in an official pharmacopoeia	HUF (Hungarian forint)	67500	0,00381316	257
		Single remedies of which the active principle cannot be found in an official pharmacopoeia	HUF	270000	0,00381316	1030
		Complex remedies of which the active principles can be found in an official pharmacopoeia	HUF	135000	0,00381316	515
		Complex remedies of which the active principles cannot be found in an official pharmacopoeia	HUF	180000	0,00381316	686
		Modification Single Remedy	HUF	9000	0,00381316	34
		Modification Complex Remedy	HUF	90000	0,00381316	343
		Renewal (every 5 years)	HUF	45000	0,00381316	172
		Annual Fee	HUF	9000	0,00381316	34
		Withdrawal authorisation/Cancellation of registration	HUF	27000	0,00381316	103
At the moment Hungary does not seem to distinguish between registration and authorisation. According to the law the regular fees for authorisation do not apply to homeopathic medicinal products. There does however not exist a special authorisation procedure for homeopathic medicinal products.						
Ireland						
	Art. 14	New National/Decentralised Application Standard Fee – single stock	Euro			646
	Art. 14	New National/Decentralised Application Standard Fee – 2 or more stocks	Euro			969
	Art. 14	New Mutual Recognition Incoming Application Standard Fee Single Stock	Euro			431
	Art. 14	New Mutual Recognition Incoming Application Standard Fee – 2 or more stocks	Euro			646
	Art. 14	Outgoing Mutual Recognition/Decentralised Supplement	Euro			538
	Art. 14	National Variation	Euro			323
	Art. 14	National variation – reduced rate	Euro			162
	Art. 14	Mutual Recognition incoming variation	Euro			215
	Art. 14	Mutual Recognition Incoming Variation – reduced rate	Euro			108
	Art. 14	Variation – Outgoing Mutual Recognition/Decentralised Supplement	Euro			162
		Annual maintenance fee	Euro			52
	Art. 16	National application for medicinal product (Reduced Standard Dossier)	Euro			7300
Italy						
	Art. 14 & Art. 16	Notification until 12/2008 **	Euro			25
	Art. 14	Single Remedy in one pharm. form	Euro			31
	Art. 14	Composition (2 - 8 comp.) in one pharm. form	Euro			155
	Art. 14	Composition (8 or more comp.) in one pharm. form	Euro			217
	Art. 14	per additional pharmaceutical form	Euro			6,00
	Art. 16	Marketing Autorization	Euro			not yet defined
		Authorization of the factory to the production	Euro			6290
	Art. 16	Modification Marketing Authorization (relating to the production process)	Euro			3145
	Art. 16	Modification Marketing Authorization (any other modification)	Euro			629

** Products on the market since 1995 are granted up to 31.12.2008 (notification status)

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Latvia	Art. 14	Registration	LVL (Latvian lats)	100	1,437	144
	Art. 14	Renewal	LVL	50	1,437	72
	Art. 14	Annual Fee without indication	LVL	30	1,437	43
	Art. 16	Authorisation with indication	LVL	170	1,437	244
	Art. 16	Renewal with indication	LVL	90	1,437	129
	Art. 16	New pharmaceutical form/strength	LVL	80	1,437	115
	Art. 16	Annual Fee with indication	LVL	100	1,437	144
Lithuania	Art. 14	Homeopathic product without special indications	LTL (Lithuanian litas)	2640	0,2895	764
	Art. 16	Homeopathic product with special indications	LTL	3520	0,2895	1019
		Renewal (MA)	LTL	1320	0,2895	382
Luxemburg	Art. 14	Simplified Registration	Euro			N.A.
	Art. 16	Marketing Authorization of a product not yet authorised in another member state	Euro			2479
		Marketing Authorization of a product already authorised in another member state	Euro			124
Malta	Art. 126a	Issue of authorisation	MTL (Maltese lira)			116
	Art. 126a	Renewal of authorisation (every 5 years)				116
	Art. 14	New Product (single stock)				233
	Art. 14	New Product (for 2 or more stocks)				466
	Art. 14	Variations Administrative				35
	Art. 14	Variations Technical				70
	MRP/DCP	RMS (Outgoing supplement over the fee for National applications)				20%
	MRP/DCP	Mutual Recognition Procedure/Decentralised Procedure CMS				116
	Annual fee (for each form and strength, for all marketing authorisations)				116	
The Netherlands	Art. 14	New applications (Art 4. Regulation concerning homeopathic products = Article 14 Directive 2001/83/EC)	Euro			1200
	Art. 14	MRP/DCP (The Netherlands as reference Member State)	Euro			4000
	Art. 16	With Indications	Euro			2400
	Art. 16	Without indications (oral or external only)	Euro			1200
		Variations	Euro			600
		Annual contribution per dossier	Euro			30
Poland	Art. 14	Simplified registration - Group application for:				
	Art. 14	a) up to 50 products	PLN (Polish zloty)	7004	0,258158	1808
	Art. 14	b) more than 50 products	PLN	8240	0,258158	2127
	Art. 14	Changes after registration	PLN	1030	0,258158	266
	Art. 14	Renewal - Group application for:				
	Art. 14	a) up to 50 products	PLN	1524	0,258158	394
	Art. 14	b) more than 50 products	PLN	3008	0,258158	776
	Art. 16	Marketing Authorization	PLN	4944	0,258158	1276
	Art. 16	Type I Variation	PLN	773	0,258158	199
	Art. 16	Type II Variation	PLN	2060	0,258158	532
Portugal	Art. 14	Single Remedy	Euro			250
	Art. 14	and for each pharm. form	Euro			50
	Art. 16	Marketing Authorization ident. to ordinary drugs	Euro			2500
	Art. 16	Supplem. for each other administration form	Euro			500

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Romania		To be established				
Slovakia	Art. 14	Simplified Registration	SKK (Slovakian koruna)	5000	0,0274455	137
	Art. 14	Renewal	SKK	4000	0,0274455	110
	Art. 14	Variations	SKK	2000	0,0274455	55
Slovenia	Art. 14	Up to 3 stocks in 1 pharmaceutical form				900
	Art. 14	More than 3 stocks in 1 pharmaceutical form				1150
	Art. 14	Additional pharmaceutical form				300
	Art. 14	Variations***				150
	Art. 14	Renewal***				150
	MRP/DCP	CMS up to 3 stocks in 1 pharmaceutical form				250
	MRP/DCP	CMS more than 3 stocks in 1 pharmaceutical form				300
	MRP/DCP	Additional pharmaceutical form				100
	MRP/DCP	CMS Variations***				150
	MRP/DCP	CMS Renewal***				150
	MRP/DCP	RMS up to 3 stocks in 1 pharmaceutical form				20000
	MRP/DCP	RMS more than 3 stocks in 1 pharmaceutical form				22000
	MRP/DCP	Additional pharmaceutical form				8750
	MRP/DCP	RMS Variations****				5000
	MRP/DCP	RMS Renewal****				5000
		*** In case there are additional pharmaceutical forms in one application, the limit of € 1500,- could be paid beside basic fee)				1500
		**** In case there are additional pharmaceutical forms in one application, the limit of € 15000,- could be paid beside basic fee)				15000
Spain	Art. 14	Simplified Registration	Euro			573
	Art. 14	Renewal fees (five year)	Euro			287
	Art. 16	Marketing Authorization	Euro			7868
	Art. 16	Renewal fees (five year)	Euro			1464
	Art. 16	Variation	Euro			1165
	Art. 14 & Art. 16	Annual fees	Euro			86
Sweden	Art. 14	Single Remedies (per product or product group)	SEK	2250	0,108598	244
	Art. 14	Complex Remedies	SEK	???	0,108598	???
	Art. 14	MRP (per product or product group)	SEK	10000	0,108598	1086
	Art. 14	DCP (per product or product group)	SEK	15000	0,108598	1629
	Art. 14	Renewal	SEK	5000	0,108598	543
	Art. 14	Annual Fee (per product or product group)	SEK	225	0,108598	24
	Art. 16	National Registr. Without RMS	SEK	40000	0,108598	4344
	Art. 16	National Registr. With RMS	SEK	15000	0,108598	1629
		Based on a government decision fees for 2008 are cut by 20% for medicinal products. In case this cut also applies to HAMPS a 20% reduction applies to the mentioned fees.				-20%

