New marketing authorisation and renewal of marketing authorisation

The *Delimitation* column refers to the relevant articles of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use and Directive 2001/82/EC of 6 November 2001 on the Community code relating to veterinary medicinal products as amended.

Type of application	Type of medicinal product	Procedure – Denmark's role	Delimitation	Danish Medicines Agency's item number	Fee
New marketing authorisation and extensions	Ordinary medicinal products and vitamin and mineral preparations	National	Fully documented application (art. 8.3/12.3)	3001	191.548 kr.
			Fixed combination medicinal products (art. 10b/13b)	3002	191.548 kr.
			Bibliographic applications (art. 10a/13a)	3003	164.004 kr.
			Hybrid application (art. 10.3/13.3) with clinical studies concerning efficacy and/or safety.	3004	164.004 kr.
			Application concerning biological medicinal product analogous to already authorised medicinal products (art. 10.4/13.4).	3005	164.004 kr.
			Application concerning vitamin and mineral preparations, see the executive order on vitamin and mineral preparations	3006	164.004 kr.
			Hybrid application (art. 10.3/13.3) without clinical studies concerning efficacy and/or safety	3007	132.909 kr.
			Generics – veterinary, antibiotics (art. 13.1)	3008	154.779 kr.
			Generics – human (art. 10.1) Generics – veterinary, non- antibiotics (art. 13.1)	3009	132.909 kr.
			Generics - vetenary, non-antibiotika (art. 13.1)	3010	132.909 kr.
			Duplicate with same timetable as application subject to a full fee	3011	45.408 kr.
			Parallel registration (art. 10c/13c)	3012	43.563 kr.
			Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.	3013	17.294 kr.
			Future extension of marketing authorisation	3014	107.898 kr.
			Assessment of PSUR. A fee per D.sp.no.	3301/4001	7.510 kr.
		DCP, RMS	Fully documented application (art. 8.3/12.3)	3015	266.376 kr.
			Fixed combination medicinal products (art. 10b/13b)	3016	266.376 kr.
			Bibliographic application (art. 10a/13a)	3017	238.831 kr.
			Hybrid application (art. 10.3/13.3) with clinical studies concerning efficacy and/or safety.	3018	238.831 kr.
			Application concerning biological medicinal product analogous to already authorised medicinal products (art. 10.4/13.4).	3019	238.831 kr.
			Hybrid application (art. 10.3/13.3) without clinical studies concerning efficacy and/or safety	3020	207.738 kr.
			Generics – veterinary, antibiotics (art. 13.1)	3021	229.607 kr.
			Generics – human (art. 10.1)	3022	207.738 kr.
			Generics – veterinary, non-antibiotics (art 13.1)	3023	207.738 kr.
			Duplicate with same timetable as application subject to a full fee	3024	54.417 kr.
			Parallel registration (art. 10c/13c)	3025	52.572 kr.
			Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.	3026	33.178 kr.
			Future extension of marketing authorisation	3027	158.158 kr.
		DCP/MRP, RMS	Assessment of PSUR. A fee per D.sp.no.	3302/4002	7.510 kr.

		DCP/MRP, CMS	All applications for new marketing authorisation	3028/3029	27.380 kr.
			Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.	3030	28.513 kr.
			Future extension of marketing authorisation	3031	20.936 kr.
New marketing authorisation, registration and extension	Natural medicinal products, traditional herbal medicinal products or homeopathic medicinal products	National		3032	81.474 kr.
		DCP, RMS		3033	94.555 kr.
		DCP/MRP, CMS		3034	26.218 kr.
		All procedures	Assessment of PSUR. A fee per D.sp.no.	4003	7.510 kr.
		All procedures	Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.	3035	17.294 kr.
New marketing authorisation, registration and extension	All types	MRP/DCP/National, all roles	Rejection of new application for marketing authorisation after regulatory validation	3036	20.619 kr.
New marketing authorisation	All types	Parallel import	Per exporting country	3037	7.091 kr.
New mutual recognition procedure, MRP	All types	MRP, RMS	Full procedure, incl. Updating	3038	75.021 kr.
			Full procedure, incl. administrative updating	3039	30.911 kr.
			Day Zero procedure	3040	16.732 kr.
Renewal of marketing authorisation/registration	Ordinary medicinal products and vitamin and mineral preparations	National		3041	7.057 kr.
		MRP, CMS		3042	4.185 kr.
		MRP, RMS		3043	21.752 kr.
	All types	Parallel import	A fee per D.sp.no.	3044	4.105 kr.
	Natural medicinal products, traditional herbal medicinal products and homeopathic medicinal products	National		3045	11.283 kr.
Annual fee for medicinal products (general regulatory functions, supervision, control and analysis)	All types	All procedures	A fee per MT number/drug ID	3046	14.340 kr.

Schedule 2
Variations – all types of medicinal products

Type of application	Field	Procedure – Denmark's role	Delimitation	Danish Medicines Agency's item number	Fee
Single	Administrative and all types of IA and IAIN variations	National	Type IA, type IB and type II	3101	1.854 kr.
		MRP-RMS	Type IA, type IB and type II	3102	7.716 kr.
		MRP-CMS	Type IA, type IB and type II	3103	1.540 kr.
	Quality	National	Type IB and type II, simple	3104	9.851 kr.
			Type IB and type II, complex	3105	36.457 kr.
		MRP-RMS	Type IB and type II, simple	3106	15.714 kr.
			Type IB and type II, complex	3107	42.320 kr.
		MRP-CMS	Type IB and type II, simple	3108	1.540 kr.
			Type IB and type II, complex	3109	3.270 kr.
	Regulatory/clinical	National	Type IB	3110	9.186 kr.
			Type II	3111	11.667 kr.
		MRP-RMS	Type IB	3112	9.186 kr.
			Type II	3113	11.667 kr.
		MRP-CMS	Type IB and type II	3114	6.313 kr.
	Administrative and all types of IA and IAIN variations	National	Type IA, one D.sp.no.	3115	2.316 kr.
			Type IA, several D.sp.nos.	3116	3.008 kr.
		MRP-RMS	Type IA, one D.sp.no.	3117	6.910 kr.
			Type IA, several D.sp.nos.	3118	9.193 kr.
			Type IA, super grouping	3119	13.632 kr.
		MRP-CMS	Type IA, one D.sp.no.	3120	2.001 kr.
			Type IA, several D.sp.nos.	3121	2.694 kr.
		National	Type IB and type II, simple	3122	17.004 kr.
			Type IB and type II, complex	3123	40.467 kr.
		MRP-RMS	Type IB and type II, simple	3124	23.189 kr.
			Type IB and type II, complex	3125	46.651 kr.

Grouping and worksharing	Quality	MRP, reference authority in case of worksharing	Type IB and type II, simple	3126	34.313 kr.
			Type IB and type II, complex	3127	69.977 kr.
		MRP-CMS	Type IB and type II, simple	3128/3129	2.694 kr.
			Type IB and type II, complex	3130/3131	4.425 kr.
	Regulatory/clinical	National	Type IB	3132	13.690 kr.
			Type II	3133	15.934 kr.
		MRP-RMS	Type IB	3134	13.690 kr.
			Type II	3135	15.934 kr.
		MRP, reference authority for worksharing	Type IB	3136	20.535 kr.
			Type II	3137	23.901 kr.
		MRP-CMS	Type IB og type II	3138/3139	8.663 kr.

Schedule 3
Fees for application for authorisation or registration of companies as well as annual fee for authorised or registered companies

Company	Explanation	Danish Medicines Agency's item number	Application fee	Annual fee
Manufacturing and import of medicinal products and intermediate products	Authorisation to manufacture and import medicinal products, see section 39(1) of the Danish Medicines Act, and intermediate products, see section 39(2) of the Danish Medicines Act.	5001/5002	49.066 kr.	49.066 kr.
Wholesale distribution of medicinal products	Authorisation for wholesale distribution of medicinal products, see section 39(1) of the Danish Medicines Act.	5003/5004	15.142 kr.	15.142 kr.
Retail sale of OTC medicines	Authorisation for retail sale of medicinal products, see section 39(1) of the Danish Medicines Act. See below about fees for retail sale of medical gases and smoking cessation products.	5005/5006	926 kr.	926 kr.
Retail sale of medical gases	Authorisation for retail sale of medical gases, see section 39(1) of the Danish Medicines Act.	5007/5008	1.137 kr.	1.137 kr.
Retail sale of smoking cessation products	Authorisation for retail sale of smoking cessation products, see section 39(1) of the Danish Medicines Act.	5009	Calculated individually based on the time spent by the DKMA (per commenced half hour) and hourly rate: DKK 900	-
Retail sale of medicinal products for production animals	Authorisation for retail sale of medicinal products for production animals, see section 39 of the Danish Medicines Act.	5010	47.191 kr.	Administration fee amounts to 0.065 per cent of the distributor's total sale of medicinal products
Brokering of medicinal products	Registration of company engaging in brokering of medicinal products, see section 41b(1) of the Danish Medicines Act.	5011/5012	15.142 kr.	15.142 kr.
API manufacturing	Registration of company engaging in the manufacturing of active substances intended for use in the manufacturing of medicinal products, see section 50a(1) of the Danish Medicines Act.	5013/5014	49.066 kr.	49.066 kr.
API import and distribution	Registration of company engaging in import and distribution of active substances intended for use in the manufacturing of medicinal products, see section 50a(1) of the Danish Medicines Act.	5015/5016	15.142 kr.	15.142 kr.
Toxicological and pharmacological trials (GLP)	Authorisation to conduct toxicological and pharmacological (non-clinical) trials, see section 85(1) of the Danish Medicines Act.	5017/5018	49.066 kr.	49.066 kr.
API inspection outside the EU	Inspection of company with API outside the EU, see section 10.	5019	81.490 kr.	-

Inspection of the manufacturing of products or data, for which import authorities require a GMP or GLP statement	Inspection of company in Denmark not covered by an authorisation or registration, see section 10.	5020	Calculated individually based on the time spent by the DKMA (per commenced hour) and hourly rate as well as other direct costs paid by the DKMA as part of the inspection. Hourly rate: DKK 1,100	-
***) Additional fee for locations with more than 500 employees**	The additional fee will be charged if the company employs more than 500 employees at one location on the application date (application fee) or at 1 January (annual fee).	5021/5022	147.197 kr.	147.197 kr.

Schedule 4
Fees for notification about prices etc.

Company	Explanation	Danish Medicines Agency's item number	Annual fee
Pharmacy	Notification of consumer prices, etc. of pharmacy-only medicinal products to the pharmacies.	6001	1.618 kr.
Subscriptions	Subscription for Medicine Prices for companies	6002	2.042 kr. inkl moms

Schedule 5
Special fees for medicinal products manufactured at a company outside the EU/EEA area

Additional fee	Description	Danish Medicines Agency's item number	Fee
Addition to fee for application for marketing authorisation, see section 16(1)	Addition to fee for application for marketing authorisation if the medicinal product is manufactured outside the EU/EEA area, and the DKMA is obliged to inspect the company under current EU legislation.	3049	836 kr.
Addition to fee for application for variation of marketing authorisation, see section 16(2).	Addition to fee for application for variation of marketing authorisation if the manufacturing site of the medicinal product is changed to a company outside the EU/EEA area, and the DKMA is obliged to inspect the company under current EU legislation.	3140	836 kr.
Addition to the annual fee for medicinal products, see section 16(3)	Addition to the annual fee for medicinal products manufactured outside the EU/EEA area if the DKMA is obliged to inspect the company under current EU legislation.	3048	836 kr.