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	187.218 kr.
			Fixed combination medicinal products (art. 10b/13b)	3002	187.218 kr.
			Bibliographic applications (art. 10a/13a)	3003	160.297 kr.
			Hybrid application (art. 10.3/13.3) with clinical studies concerning efficacy and/or safety.	3004	160.297 kr.
			Application concerning biological medicinal product analogous to already authorised medicinal products (art. 10.4/13.4).	3005	160.297 kr.
			Application concerning vitamin and mineral preparations, see the executive order on vitamin and mineral preparations	3006	160.297 kr.
			Hybrid application (art. 10.3/13.3) without clinical studies concerning efficacy and/or safety	3007	129.905 kr.
			Generics – veterinary, antibiotics (art. 13.1)	3008	151.280 kr.
			Generics – human (art. 10.1) Generics – veterinary, non- antibiotics (art. 13.1)	3009	129.905 kr.
			Generics - vetenary, non-antibiotika (art. 13.1)	3010	129.905 kr.
			Duplicate with same timetable as application subject to a full fee	3011	44.382 kr.
			Parallel registration (art. 10c/13c)	3012	42.578 kr.
			Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.	3013	16.903 kr.
			Future extension of marketing authorisation	3014	105.459 kr.
			Assessment of PSUR. A fee per D.sp.no.	3301/4001	7.340 kr.
		DCP, RMS	Fully documented application (art. 8.3/12.3)	3015	260.355 kr.
			Fixed combination medicinal products (art. 10b/13b)	3016	260.355 kr.
			Bibliographic application (art. 10a/13a)	3017	233.433 kr.
			Hybrid application (art. 10.3/13.3) with clinical studies concerning efficacy and/or safety.	3018	233.433 kr.
			Application concerning biological medicinal product analogous to already authorised medicinal products (art. 10.4/13.4).	3019	233.433 kr.
			Hybrid application (art. 10.3/13.3) without clinical studies concerning efficacy and/or safety	3020	203.042 kr.
			Generics – veterinary, antibiotics (art. 13.1)	3021	224.417 kr.
			Generics – human (art. 10.1)	3022	203.042 kr.
			Generics – veterinary, non-antibiotics (art 13.1)	3023	203.042 kr.
			Duplicate with same timetable as application subject to a full fee	3024	53.187 kr.
			Parallel registration (art. 10c/13c)	3025	51.384 kr.
			Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.	3026	32.428 kr.
			Future extension of marketing authorisation	3027	154.583 kr.
		DCP/MRP, RMS	Assessment of PSUR. A fee per D.sp.no.	3302/4002	7.340 kr.
		DCP/MRP, CMS	All applications for new marketing authorisation	3028/3029	26.761 kr.
			Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.	3030	27.869 kr.
			Future extension of marketing authorisation	3031	20.463 kr.
New marketing authorisation, registration and extension	Natural medicinal products, traditional herbal medicinal products or homeopathic medicinal products	National		3032	79.632 kr.
		DCP, RMS		3033	92.418 kr.
		DCP/MRP, CMS		3034	25.625 kr.
		All procedures	Assessment of PSUR. A fee per D.sp.no.	4003	7.340 kr.
		All procedures	Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.	3035	16.903 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	20.153 kr.
New marketing authorisation	All types	Parallel import	Per exporting country	3037	6.931 kr.
New mutual recognition procedure, MRP	All types	MRP, RMS	Full procedure, incl. Updating	3038	73.325 kr.
			Full procedure, incl. administrative updating	3039	30.212 kr.

			Day Zero procedure	3040	16.354 kr.
Renewal of marketing authorisation/registration	Ordinary medicinal products and vitamin and mineral preparations	National		3041	6.897 kr.
		MRP, CMS		3042	4.090 kr.
		MRP, RMS		3043	21.260 kr.
	All types	Parallel import	A fee per D.sp.no.	3044	4.012 kr.
	Natural medicinal products, traditional herbal medicinal products and homeopathic medicinal products	National		3045	11.028 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	13.942 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	1.812 kr.
		MRP-RMS	Type IA, type IB and type II	3102	7.542 kr.
		MRP-CMS	Type IA, type IB and type II	3103	1.505 kr.
	Quality	National	Type IB and type II, simple	3104	9.628 kr.
			Type IB and type II, complex	3105	35.633 kr.
		MRP-RMS	Type IB and type II, complex	3106	15.359 kr.
			Type IB and type II, complex	3107	41.363 kr.
		MRP-CMS	Type IB and type II, simple	3108	1.505 kr.
			Type IB and type II, complex	3109	3.196 kr.
	Regulatory/clinical	National	Type IB	3110	8.978 kr.
			Type II	3111	11.403 kr.
		MRP-RMS	Type IB	3112	8.978 kr.
			Type II	3113	11.403 kr.
		MRP-CMS	Type IB and type II	3114	6.170 kr.
Grouping and worksharing	Administrative and all types of IA and IAIN variations	National	Type IA, one D.sp.no.	3115	2.264 kr.
			Type IA, several D.sp.nos.	3116	2.940 kr.
		MRP-RMS	Type IA, one D.sp.no.	3117	6.754 kr.
			Type IA, several D.sp.nos.	3118	8.985 kr.
			Type IA, super grouping	3119	13.324 kr.
		MRP-CMS	Type IA, one D.sp.no.	3120	1.956 kr.
			Type IA, several D.sp.nos.	3121	2.633 kr.
	Quality	National	Type IB and type II, simple	3122	16.620 kr.
			Type IB and type II, complex	3123	39.552 kr.
		MRP-RMS	Type IB and type II, simple	3124	22.665 kr.
			Type IB and type II, complex	3125	45.597 kr.
		MRP, reference authority in case of worksharing	Type IB and type II, simple	3126	33.537 kr.
			Type IB and type II, complex	3127	68.395 kr.
		MRP-CMS	Type IB and type II, simple	3128/3129	2.633 kr.
			Type IB and type II, complex	3130/3131	4.325 kr.
	Regulatory/clinical	National	Type IB	3132	13.381 kr.
			Type II	3133	15.574 kr.
		MRP-RMS	Type IB	3134	13.381 kr.
			Type II	3135	15.574 kr.
		MRP, reference authority in case of worksharing	Type IB	3136	20.071 kr.
			Type II	3137	23.361 kr.
		MRP-CMS	Type IB og type II	3138/3139	8.467 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	47.957 kr.	47.957 kr.

Wholesale distribution of medicinal products	Authorisation for wholesale distribution of medicinal products, see section 39(1) of the Danish Medicines Act.	5003/5004	14.800 kr.	14.800 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	1.111 kr.	1.111 kr.
Retail sale of medical gases	Authorisation for retail sale of medical gases, see section 39(1) of the Danish Medicines Act.	5007/5008	1.111 kr.	1.111 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	46.124 kr.	Administration fee amounts to 0.065 per cent of the distributor's total sale of medicinal products for production animals
Brokering of medicinal products	Registration of company engaging in brokering of medicinal products, see section 41b(1) of the Danish Medicines Act.	5011/5012	14.800 kr.	14.800 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	47.957 kr.	47.957 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	14.800 kr.	14.800 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	47.957 kr.	47.957 kr.
API inspection outside the EU	Inspection of company with API outside the EU, see section 10.	5019	79.648 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	143.869 kr.	143.869 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	1.596 kr.
Subscriptions	Subscription for Medicine Prices for companies	6002	1996 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	817 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	817 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	817 kr.