2019: 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 extentions	Ordinary medicinal products and vitamin and mineral preparations	National	Fully documented application (art. 8.3/12.3)	3001	DKK 188,903
			Fixed combination medicinal products (art. 10b/13b)	3002	DKK 188,903
			Bibliographic applications (art. 10a/13a)	3003	DKK 161,740
			Hybrid application (art. 10.3/13.3) with clinical studies concerning efficacy and/or safety.	3004	DKK 161,740
			Application concerning biological medicinal product analogous to already authorised medicinal products (art. 10.4/13.4).	3005	DKK 161,740
			Application concerning vitamin and mineral preparations, see the executive order on vitamin and mineral preparations	3006	DKK 161,740
			Hybrid application (art. 10.3/13.3) without clinical studies concerning efficacy and/or safety	3007	DKK 131,074
			Generics – veterinary, antibiotics (art. 13.1)	3008	DKK 152,642
			Generics – human (art. 10.1)	3009	DKK 131,074
			Generics – veterinary, non-antibiotics (art. 13.1)	3010	DKK 131,074
			Duplicate with same timetable as application subject to a full fee	3011	DKK 44,781
			Parallel registration (art. 10c/13c)	3012	DKK 42,961
			Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.	3013	DKK 17,055
			Future extension of marketing authorisation	3014	DKK 106,408
			Assessment of PSUR. A fee per D.sp.no.	3301/4001	DKK 7,406
		DCP, RMS	Fully documented application (art. 8.3/12.3)	3015	DKK 262,698
			Fixed combination medicinal products (art. 10b/13b)	3016	DKK 262,698
			Bibliographic application (art. 10a/13a)	3017	DKK 235,534
			Hybrid application (art. 10.3/13.3) with clinical studies concerning efficacy and/or safety.	3018	DKK 235,534
			Application concerning biological medicinal product analogous to already authorised medicinal products (art. 10.4/13.4).	3019	DKK 235,534
			Hybrid application (art. 10.3/13.3) without clinical studies concerning efficacy and/or safety	3020	DKK 204,869
			Generics – veterinary, antibiotics (art. 13.1)	3021	DKK 226,437
			Generics – human (art. 10.1)	3022	DKK 204,869
			Generics – veterinary, non-antibiotics (art. 13.1)	3023	DKK 204,869
			Duplicate with same timetable as application subject to a full fee	3024	DKK 53,666
			Parallel registration (art. 10c/13c)	3025	DKK 51,846
			Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.	3026	DKK 32,720
			Future extension of marketing authorisation	3027	DKK 155,974
		DCP/MRP, RMS	Assessment of PSUR. A fee per D.sp.no.	3302/4002	DKK 7,406
		DCP/MRP, CMS	All applications for new marketing authorisation	3028/3029	DKK 27,002
			Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.	3030	DKK 28,120
			Future extension of marketing authorisation	3031	DKK 20,647
New marketing authorisation, registration and extension	Natural medicinal products, traditional herbal medicinal products or homeopathic medicinal products	National		3032	DKK 80,349
		DCP, RMS		3033	DKK 93,250
		DCP/MRP, CMS		3034	DKK 25,856
		All procedures	Assessment of PSUR. A fee per D.sp.no.	4003	DKK 7,406
		All procedures	Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.	3035	DKK 17,055
New marketing authorisation, registration and extension	All types	MRP/DCP/National, all roles	Rejection of new application for marketing authorisation after regulatory validation	3036	DKK 20,334
New marketing authorisation	All types	Parallel import	Per exporting country	3037	DKK 6,993
New mutual recognition procedure, MRP	All types	MRP, RMS	Full procedure, incl. updating	3038	DKK 73,985
			Full procedure, incl. administrative updating	3039	DKK 30,484
			Day Zero procedure	3040	DKK 16,501
Renewal of marketing authorisation/registration	Ordinary medicinal products and vitamin and mineral preparations	National		3041	DKK 6,959
		MRP, CMS		3042	DKK 4,127
		MRP, RMS		3043	DKK 21,451
	All types	Parallel import	A fee per D.sp.no.	3044	DKK 4,048
	Natural medicinal products, traditional herbal medicinal products and homeopathic medicinal products	National		3045	DKK 11,127
Annual fee for medicinal products (general regulatory functions, supervision, control and analysis)	All types	All procedures	A fee per MT number/drug ID	3046	DKK 14,142

Schedule 2
Variations – all types of medicinal products

Type of application	Field	Procedure – Denmark's role	Delimitation	Danish Medicines Agency's item number	
Single	Administrative and all types of IA and IAIN variations	National	Type IA, type IB and type II	3101	DKK 1,828
		MRP-RMS	Type IA, type IB and type II	3102	DKK 7,610
		MRP-CMS	Type IA, type IB and type II	3103	DKK 1,519
	Quality	National	Type IB and type II, simple	3104	DKK 9,715
			Type IB and type II, complex	3105	DKK 35,954
		MRP-RMS	Type IB and type II, simple	3106	DKK 15,497
			Type IB and type II, complex	3107	DKK 41,735
		MRP-CMS	Type IB and type II, simple	3108	DKK 1,519
			Type IB and type II, complex	3109	DKK 3,225
	Regulatory/clinical	National	Type IB variations	3110	DKK 9,059
			Type II variations	3111	DKK 11,506
		MRP-RMS	Type IB variations	3112	DKK 9,059
			Type II variations	3113	DKK 11,506
		MRP-CMS	Type IB and type II	3114	DKK 6,226
Grouping and worksharing	Administrative and all types of IA and IAIN variations	National	Type IA, one D.sp.no.	3115	DKK 2,284
			Type IA, several D.sp.nos.	3116	DKK 2,966
		MRP-RMS	Type IA, one D.sp.no.	3117	DKK 6,815
			Type IA, several D.sp.nos.	3118	DKK 9,066
			Type IA, super grouping	3119	DKK 13,444
		MRP-CMS	Type IA, one D.sp.no.	3120	DKK 1,974
			Type IA, several D.sp.nos.	3121	DKK 2,657
	Quality	National	Type IB and type II, simple	3122	DKK 16,770
			Type IB and type II, complex	3123	DKK 39,908
		MRP-RMS	Type IB and type II, simple	3124	DKK 22,869
			Type IB and type II, complex	3125	DKK 46,007
		MRP, reference authority in case of worksharing	Type IB and type II, simple	3126	DKK 33,839
			Type IB and type II, complex	3127	DKK 69,011
		MRP-CMS	Type IB and type II, simple	3128/3129	DKK 2,657
			Type IB and type II, complex	3130/3131	DKK 4,364
	Regulatory/clinical	National	Type IB variations	3132	DKK 13,501
			Type II variations	3133	DKK 15,714
		MRP-RMS	Type IB variations	3134	DKK 13,501
			Type II variations	3135	DKK 15,714
		MRP, reference authority in case of worksharing	Type IB variations	3136	DKK 20,252
			Type II variations	3137	DKK 23,571
		MRP-CMS	Type IB and type II	3138/3139	DKK 8,543

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	48,389	DKK 48,389
Wholesale distribution of medicinal products	Authorisation for wholesale distribution of medicinal products, see section 39(1) of the Danish Medicines Act.	5003/5004	14,933	DKK 14,933
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	DKK 913	DKK 913
Retail distribution of medical gases	Authorisation for retail sale of medical gases, see section 39(1) of the Danish Medicines Act.	5007/5008	DKK 1,121	DKK 1,121
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	DKK 46,539	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	DKK 14,933	DKK 14,933

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	DKK 48,389	DKK 48,389
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	DKK 14,933	DKK 14,933
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	DKK 48,389	DKK 48,389
API inspection outside the EU	Inspection of company with API outside the EU, see section 10.	5019	DKK 80,365	-
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	DKK 145,165	DKK 145,165
Distribution and dispensing of medical chests and motion sickness tablets for lifeboats and life rafts	Authorisation to distribute and dispense medical chests with medicinal products for lifeboats and life rafts, see section 39(1) of the Danish Medicines Act.	5032/5033	14,933	14,933

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	DKK 1,611	
Subscribers	Subscription for Medicine Prices for companies	6002	DKK 2,015, incl. VAT	

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	Fees	
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	DKK 824	
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	DKK 824	
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	DKK 824	