This is a translation of the Danish fee list. In case of any discrepancies, the Danish text takes precedence.

Fees payable for applications for a new marketing authorisation, registration, extension and renewal and annual fees for medicinal products

The *Delimitation* column refers, if relevant, to the relevant articles of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

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/mineral preparations	National	Fully documented application (art. 8.3/8, 23, 25)	3001	DKK 365,912
			Fixed combination medicinal products (art. 10b/20)	3002	DKK 365,912
			Bibliographic applications (art. 10a/22)	3003	DKK 321,479
			Hybrid application (art. 10.3/19) with clinical studies concerning efficacy and/or safety.	3004	DKK 321,479
			Application concerning biological medicinal product analogous to already authorised medicinal products (art. 10.4).	3005	DKK 321,479
			Application concerning vitamin and mineral preparations, cf. the executive order on vitamin and mineral preparations	3006	DKK 321,479
			Hybrid application (art. 10.3/19) without clinical studies concerning efficacy and/or safety	3007	DKK 213,097
			Generics – veterinary, antibiotics (art. 18)	3008	DKK 213,097

			Generics – human (art. 10.1)	3009	DKK 211,974
			Generics – veterinary, non-antibiotics (art. 18)	3010	DKK 211,974
			Duplicate with same timetable as application subject to a full fee	3011	DKK 64,229
			Parallel registration (art. 10c/21)	3012	DKK 74,888
			Additional fee for assessment in addition to standard procedure due to complexity or the like of the submitted documentation	3013	DKK 47,697
			Future extension of marketing authorisation	3014	DKK 202,877
			Assessment of PSUR. One fee per D.sp.no.	4001	DKK 8,955
		DCP, RMS	Fully documented application (art. 8.3/8, 23, 25)	3015	DKK 423,859
			Fixed combination medicinal products (art. 10b/20)	3016	DKK 423,859
			Bibliographic application (art. 10a/22)	3017	DKK 416,813
			Hybrid application (art. 10.3/19) with clinical studies concerning efficacy and/or safety.	3018	DKK 416,813

			Application concerning biological medicinal product analogous to already authorised medicinal products (art. 10.4).	3019	DKK 416,813
			Hybrid application (art. 10.3/19) without clinical studies concerning efficacy and/or safety	3020	DKK 272,303
			Generics – veterinary, antibiotics (art. 18)	3021	DKK 271,325
			Generics – human (art. 10.1)	3022	DKK 269,921
			Generics – veterinary, non-antibiotics (art. 18)	3023	DKK 269,921
			Duplicate with same timetable as application subject to a full fee	3024	DKK 84,588
			Parallel registration (art. 10c/21)	3025	DKK 82,876
			Additional fee for assessment in addition to standard procedure due to complexity or the like of the submitted documentation	3026	DKK 55,971
		DCP/MRP, RMs	Future extension of marketing authorisation	3027	DKK 232,109
			Assessment of PSUR. One fee per D.sp.no.	4002	DKK 8,955

		DCP/MRP, CMS	All applications for new marketing authorisation	3028/3029	DKK 37,764
			Additional fee for assessment in addition to standard procedure due to complexity or the like of the submitted documentation	3030	DKK 5,246
			Future extension of marketing authorisation	3031	DKK 22,574
New marketing authorisation, registration and extension	Herbal medicinal products, traditional herbal medicinal products or homeopathic medicinal products	National		3032	DKK 130,616
		DCP, RMS		3033	DKK 123,499
		DCP/MRP, CMS		3034	DKK 36,349
		All procedures	Assessment of periodic safety update report (PSUR). One fee per D.sp.no.	4003	DKK 8,955
		All procedures	Additional fee for assessment in addition to standard procedure due to complexity or the like of the submitted documentation	3035	DKK 47,697
New marketing authorisation, registration and extension	All types	MRP/DCP/National, all roles	Rejection of new application for marketing authorisation upon regulatory validation	3036	DKK 27,860
New marketing authorisation	All types	Parallel import and parallel trade	Per exporting country	3037	DKK 11,080
New mutual recognition procedure, MRP	All types	MRP, RMS	Full procedure, incl. updating	3038	DKK 157,931

			Full procedure, incl. administrative updating	3039	DKK 61,353	
			Day Zero procedure	3040	DKK 16,804	
Renewal of marketing authorisation/registration	Ordinary medicinal products and vitamin/mineral preparations	National		3041	DKK 6,605	
		MRP, CMS		3042	DKK 1,691	
		MRP, RMS		3043	DKK 10,799	
	All types	Parallel import	One fee per D.sp.no.	3044	DKK 2,611	
	Herbal medicinal products, traditional herbal medicinal products and homeopathic medicinal products	National		3045	DKK 10,615	
Annual fee for medicinal products (general regulatory functions, supervision, control and analysis)	All types	All procedures	A fee per MA number/drug ID	3046	2024	2025-
					DKK 20,978	DKK 20.255

Fees for variations – human 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	DKK 2,323
		MRP-RMS	Type IA, type IB and type II	3102	DKK 7,529
		MRP-CMS	Type IA, type IB and type II	3103	DKK 1,703
	Quality	National	Type IB and type II, simple	3104	DKK 11,736
			Type IB and type II, complex	3105	DKK 43,960
		MRP-RMS	Type IB and type II, simple	3106	DKK 18,305
			Type IB and type II, complex	3107	DKK 49,819

		MRP-CMS	Type IB and type II, simple	3108	DKK 1,703
			Type IB and type II, complex	3109	DKK 1,703
	Regulatory/clinical	National	Type IB	3110	DKK 9,119
			Type II variations	3111	DKK 22,713
		MRP-RMS	Type IB	3112	DKK 9,922
			Type II variations	3113	DKK 17,554
		MRP-CMS	Type IB and type II	3114	DKK 5,309
Grouping and worksharing	Administrative and all types of IA and IAIN variations	National	Type IA, one D.sp.no.	3115	DKK 2,834
			Type IA, several D.sp.nos.	3116	DKK 3,600
		MRP-RMS	Type IA, one D.sp.no.	3117	DKK 9,586
			Type IA, several D.sp.nos.	3118	DKK 12,669
			Type IA, super grouping	3119	DKK 18,383
		MRP-CMS	Type IA, one D.sp.no.	3120	DKK 2,214
			Type IA, several D.sp.nos.	3121	DKK 2,982
	Quality	National	Type IB and type II, simple	3122	DKK 24,440
			Type IB and type II, complex	3123	DKK 49,256
		MRP-RMS	Type IB and type II, simple	3124	DKK 31,115
			Type IB and type II, complex	3125	DKK 57,792
		MRP, reference authority in case of worksharing	Type IB and type II, simple	3126	DKK 46,306
			Type IB and type II, complex	3127	DKK 90,625
		MRP-CMS	Type IB and type II, simple	3128/3129	DKK 2,982
			Type IB and type II, complex	3130/3131	DKK 6,036
	Regulatory/clinical	National	Type IB	3132	DKK 15,564
			Type II variations	3133	DKK 27,984
		MRP-RMS	Type IB	3134	DKK 15,616
			Type II variations	3135	DKK 27,070

		MRP, reference authority in case of worksharing	Type IB	3136	DKK 36,507
			Type II variations	3137	DKK 43,697
		MRP-CMS	Type IB and type II	3138/3139	DKK 8,371

Fees for variations – veterinary medicinal products

Type of application	Field	Procedure	Delimitation	Danish Medicines Agency's item number	Fee
Single	VNRA administrative and regulatory	National	VNRA administrative	3401	DKK 2,682
			VNRA regulatory	3402	DKK 6,606
		MRP-RMS	VNRA administrative	3403	DKK 8,694
			VNRA regulatory	3404	DKK 10,076
		MRP-CMS	VNRA administrative	3405	DKK 1,967
			VNRA regulatory	3406	DKK 4,049
	VRA Quality	National	VRA Reduced	3407	DKK 13,553
			VRA Standard Simple	3408	DKK 32,157
			VRA Standard Complex	3409	DKK 50,762
		MRP-RMS	VRA Reduced	3410	DKK 21,137
			VRA Standard Simple	3411	DKK 39,332
			VRA Standard Complex	3412	DKK 57,527
		MRP-CMS	VRA Reduced	3413	DKK 1,967
			VRA Standard Simple	3414	DKK 1,967
			VRA Standard Complex	3415	DKK 1,967
	VRA regulatory	National	VRA Reduced	3416	DKK 10,530
			VRA Standard	3417	DKK 26,229
		MRP-RMS	VRA Reduced	3418	DKK 11,458
			VRA Standard	3419	DKK 20,271

		MRP-CMS	VRA Reduced	3420	DKK 6,131
			VRA Standard	3421	DKK 6,131
	VRA Extended	National	VRA Extended	3422	DKK 61,291
		MRP-RMS	VRA Extended	3423	DKK 68,984
		MRP-CMS	VRA Extended	3424	DKK 8,097
Grouping and worksharing	VRA Quality	National	VRA Reduced	3425	DKK 28,222
			VRA Standard Simple	3426	DKK 42,550
			VRA Standard Complex	3427	DKK 56,878
		MRP-RMS	VRA Reduced	3428	DKK 35,930
			VRA Standard Simple	3429	DKK 51,332
			VRA Standard Complex	3430	DKK 66,735
		MRP, reference authority in case of worksharing	VRA Reduced	3431	DKK 53,472
			VRA Standard Simple	3432	DKK 79,058
			VRA Standard Complex	3433	DKK 104,646
		MRP-CMS	VRA Reduced grouping	3434	DKK 3,444
			VRA Reduced worksharing	3435	DKK 3,444
			VRA Standard Simple grouping	3436	DKK 5,206
			VRA Standard Simple worksharing	3437	DKK 5,206
			VRA Standard Complex grouping	3438	DKK 6,970
			VRA Standard Complex worksharing	3439	DKK 6,970
	VRA regulatory	National	VRA Reduced	3440	DKK 17,971
			VRA Standard	3441	DKK 32,316
		MRP-RMS	VRA Reduced	3442	DKK 18,032
			VRA Standard	3443	DKK 31,257
		MRP, reference authority in case of worksharing	VRA Reduced	3444	DKK 42,156
			VRA Standard	3445	DKK 50,456

		MRP-CMS	VRA Reduced grouping	3446	DKK 9,665
			VRA Standard grouping	3447	DKK 9,665
			VRA Reduced worksharing	3448	DKK 9,665
			VRA Standard worksharing	3449	DKK 9,665
	VRA Extended	National	VRA Extended	3450	DKK 74,850
			VRA Extended Mix	3451	DKK 89,194
		MRP-RMS	VRA Extended	3452	DKK 84,766
			VRA Extended Mix	3453	DKK 97,991
		MRP, reference authority in case of worksharing	VRA Extended	3454	DKK 146,802
			VRA Extended Mix	3455	DKK 155,103
		MRP-CMS	VRA Extended grouping	3456	DKK 16,635
			VRA Extended Mix grouping	3457	DKK 16,635
			VRA Extended worksharing	3458	DKK 16,635
			VRA Extended Mix worksharing	3459	DKK 16,635

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, cf. section 39(1) of the Danish Medicines Act, and intermediate products, cf. section 39(2) of the Danish Medicines Act. If the company employs more than 500 employees at one location at the time of applying (with application fee) or on 1 January (with annual fee), an additional fee is charged, see item number 5021/5022.	5001/5002	DKK 70,146	2024	2025-
				DKK 70,989	DKK 70,116
Wholesale distribution of medicinal products		5003/5004	DKK 12,331	2024	2025-

	Authorisation for wholesale distribution of medicinal products, cf. section 39(1) of the Danish Medicines Act.			DKK 13,681	DKK 12,369
Retail sale of OTC medicines	Authorisation for retail sale of medicinal products, cf. 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 914	2024	2025-
				DKK 892	DKK 914
Retail sale of medical gases	Authorisation for retail sale of medical gases, cf. section 39(1) of the Danish Medicines Act.	5007/5008	DKK 1,266	DKK 1,266	
Retail sale of smoking cessation products	Authorisation for retail sale of smoking cessation products, cf. section 39(1) of the Danish Medicines Act.	5009	Calculated individually based on the time spent by the DKMA (per half hour commenced) and hourly rate: DKK 988		
Retail sale of medicinal products for production animals	Authorisation for retail sale of medicinal products for production animals, cf. section 39 of the Danish Medicines Act	5010	DKK 52,528	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, cf. section 41b(1) of the Danish Medicines Act	5011/5012	DKK 16,854	DKK 16,854	
API manufacturing	Registration of company manufacturing active substances	5013/5014	DKK 70,146	2024	2025-

	intended for use in the manufacturing of medicinal products, cf. section 50a(1) of the Danish Medicines Act. If the company employs more than 500 employees at one location at the time of applying (with application fee) or on 1 January (with annual fee), an additional fee is charged, see item number 5021/5022.			DKK 70,989	DKK 70,116
API import and distribution	Registration of company importing and distributing active substances intended for use in the manufacturing of medicinal products, cf. section 50a(1) of the Danish Medicines Act.	5015/5016	DKK 12,331	2024	2025-
				DKK 13,681	DKK 12,369
Toxicological and pharmacological trials (GLP)	Authorisation to conduct toxicological and pharmacological (non-clinical) trials, cf. section 85(1) of the Danish Medicines Act If the company employs more than 500 employees at one location at the time of applying (with application fee) or on 1 January (with annual fee), an additional fee is charged, see item number 5021/5022.	5017/5018	DKK 70,146	2024	2025-
				DKK 70,989	DKK 70,116
API inspection outside the EU	Inspection of company with API outside the EU, cf. section 10.	5019	DKK 157,833	DKK 157,833	

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, cf. section 10.	5020	Calculated individually and charged by hourly rate based on time consumption (per commenced hour) plus any other direct costs paid by the Danish Medicines Agency as part of the inspection. Hourly rate: DKK 1,206	
Additional fee for locations with more than 500 employees	The fee is charged in the case of manufacture and import of medicinal products and intermediates, API manufacturing and toxicological and pharmacological trials (GLP) if the company employs more than 500 employees at one location at the time of applying (with application fee) or on 1 January (with annual fee)	5021/5022	DKK 163,844	DKK 163,844
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, cf. section 39(1) of the Danish Medicines Act.	5032/5033	DKK 28,111	DKK 28,111

Fees for notification about prices etc.

Company	Explanation	Danish Medicines Agency's item number	Fee
Pharmacy	Notification of consumer prices, etc. of pharmacy-only medicinal products to the pharmacies	6001	DKK 2,767
Subscribers	Subscription for Medicine Prices for companies	6002	DKK 3,458, incl. VAT

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

Additional fee	Description	Danish Medicines Agency's item number	Fee
Additional fee for application for marketing authorisation, cf. section 16(1)	Additional fee for application for marketing authorisation if the medicinal product is manufactured outside the EU/EEA area, and the Danish Medicines Agency is obliged to inspect the company under current EU legislation	3049	DKK 996
Additional fee for application for variation of marketing authorisation, cf. section 16(2)	Additional 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 Danish Medicines Agency is obliged to inspect the company under current EU legislation.	3140	DKK 996
Additional fee to the annual fee for medicinal products, cf. section 16(3)	Additional fee to the annual fee for medicinal products manufactured outside the EU/EEA area if the Danish Medicines Agency is obliged to inspect the company under current EU legislation.	3048	DKK 1,130