Schedule 1

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 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 and mineral preparations	National	Fully documented application (art. 8.3/8, 23, 25)	3001	DKK 314,895
			Fixed combination medicinal products (art. 10b/20)	3002	DKK 314,895
			Bibliographic applications (art. 10a/22)	3003	DKK 276,657
			Hybrid application (art. 10.3/19) with clinical studies concerning efficacy and/or safety.	3004	DKK 276,657
			Application concerning biological medicinal product analogous to already authorised medicinal products (art. 10.4).	3005	DKK 276,657

			Application concerning vitamin and mineral preparations, cf. the executive order on vitamin and mineral preparations	3006	DKK 276,657
			Hybrid application (art. 10.3/19) without clinical studies concerning efficacy and/or safety	3007	DKK 183,386
			Generics – veterinary, antibiotics (art. 18)	3008	DKK 183,386
			Generics – human (art. 10.1)	3009	DKK 182,420
			Generics – veterinary, non-antibiotics (art. 18)	3010	DKK 182,420
			Duplicate with same timetable as application subject to a full fee	3011	DKK 55,274
			Parallel registration (10c/21)	3012	DKK 64,447

			Additional fee for assessment in addition to standard procedure due to complexity or the like of the submitted documentation	3013	41,047
			Future extension of marketing authorisation	3014	DKK 174,591
			Assessment of PSUR. One fee per D.sp.no.	4001	DKK 7,706
		DCP, RMS	Fully documented application (art. 8.3/8, 23, 25)	3015	DKK 364,763
			Fixed combination medicinal products (art. 10b/20)	3016	DKK 364,763
			Bibliographic application (art. 10a/22)	3017	DKK 358,700
			Hybrid application (art. 10.3/19) with clinical studies concerning efficacy and/or safety.	3018	DKK 358,700

			Application concerning biological medicinal product analogous to already authorised medicinal products (art. 10.4).	3019	DKK 358,700
			Hybrid application (art. 10.3/19) without clinical studies concerning efficacy and/or safety	3020	DKK 234,338
			Generics – veterinary, antibiotics (art. 18)	3021	DKK 233,496
			Generics – human (art. 10.1)	3022	DKK 232,288
			Generics – veterinary, non-antibiotics (art. 18)	3023	DKK 232,288
			Duplicate with same timetable as application subject to a full fee	3024	DKK 72,794
			Parallel registration (art. 10c/21)	3025	DKK 71,321
			Additional fee for assessment in addition to standard procedure due to complexity or the like of the submitted documentation	3026	DKK 48,167

			Future extension of marketing authorisation	3027	DKK 199,748
		DCP/MRP, RMS	Assessment of PSUR. One fee per D.sp.no.	4002	DKK 7,706
		DCP/MRP, CMS	All applications for new marketing authorisation	3028/3029	DKK 32,499
			Additional fee for assessment in addition to standard procedure due to complexity or the like of the submitted documentation	3030	DKK 4,515
			Future extension of marketing authorisation	3031	DKK 19,426
New marketing authorisation, registration and extension	Herbal medicinal products, traditional herbal medicinal products or homeopathic medicinal products	National		3032	DKK 112,405
		DCP, RMS		3033	DKK 106,280
		DCP/MRP, CMS		3034	DKK 31,281
		All procedures	Assessment of PSUR. One fee per D.sp.no.	4003	DKK 7,706
		All procedures	Additional fee for assessment in addition to standard procedure due to complexity or the like of the submitted documentation	3035	DKK 41,047

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 23,976
New marketing authorisation	All types	Parallel import and parallel trade	Per exporting country	3037	DKK 9,535
New mutual recognition procedure, MRP	All types	MRP, RMS	Full procedure, incl. updating	3038	DKK 135,911
			Full procedure, incl. administrative updating	3039	52,799
			Day Zero procedure	3040	DKK 14,461
Renewal of marketing authorisation/registration	Ordinary medicinal products and vitamin/mineral preparations	National		3041	DKK 5,684
		MRP, CMS		3042	DKK 1,455
		MRP, RMS		3043	DKK 9,294
	All types	Parallel import	A fee per D.sp.no.	3044	DKK 2,247
	Herbal medicinal products, traditional herbal medicinal products and homeopathic medicinal products	National		3045	DKK 9,135

Annual fee for medicinal products (general regulatory functions, supervision, control and analysis)	All types	All procedures	A fee per MA number/drug ID	3046	**From 2023**	**Year 2022**
					DKK 18,065	DKK 16,959

Schedule 2

Variations – human medicines

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 1,999
		MRP-RMS	Type IA, type IB and type II	3102	DKK 6,479
		MRP-CMS	Type hk, type IB and type II	3103	DKK 1,466
	Quality	National	Type IB and type II, simple	3104	DKK 10,100
			Type IB and type II, complex	3105	DKK 37,831
		MRP-RMS	Type IB and type II, simple	3106	DKK 15,753
			Type IB and type II, complex	3107	DKK 42,873
		MRP-CMS	Type IB and type II, simple	3108	DKK 1,466
			Type IB and type II, complex	3109	DKK 1,466
	Regulatory/clinical	National	Type IB	3110	DKK 7,848
			Type II	3111	DKK 19,547
		MRP-RMS	Type IB	3112	DKK 8,539
			Type II	3113	DKK 15,107
		MRP-CMS	Type IB and type II	3114	DKK 4,569
Grouping and worksharing	Administrative and all types of IA and IAIN variations	National	Type IA, one D.sp.no.	3115	DKK 2,439
			Type IA, several D.sp.nos.	3116	DKK 3,098
		MRP-RMS	Type IA, one D.sp.no.	3117	DKK 8,249

			Type IA, several D.sp.nos.	3118	DKK 10,903
			Type IA, super grouping	3119	DKK 15,820
		MRP-CMS	Type IA, one D.sp.no.	3120	DKK 1,906
			Type IA, several D.sp.nos.	3121	DKK 2,566
	Quality	National	Type IB and type II, simple	3122	DKK 21,033
			Type IB and type II, complex	3123	DKK 42,389
		MRP-RMS	Type IB and type II, simple	3124	DKK 26,777
			Type IB and type II, complex	3125	DKK 49,734
		MRP, reference authority in case of worksharing	Type IB and type II, simple	3126	DKK 39,850
			Type IB and type II, complex	3127	DKK 77,989
		MRP-CMS	Type IB and type II, simple	3128/3129	DKK 2,566
			Type IB and type II, complex	3130/3131	DKK 5,194
	Regulatory/clinical	National	Type IB	3132	DKK 13,394
			Type II	3133	DKK 24,083
		MRP-RMS	Type IB	3134	DKK 13,439
			Type II	3135	DKK 23,295
		MRP, reference authority in case of worksharing	Type IB	3136	DKK 31,417
			Type II	3137	DKK 37,604
		MRP-CMS	Type IB and type II	3138/3139	DKK 7,204

Schedule 3

Variations – veterinary medicines

Type of application	Field	Procedure	Delimitation	Danish Medicines Agency's item number	Fee
Single	VNRA administrative and regulatory	National	VNRA administrative	3401	2,308
			VNRA regulatory	3402	5,685
		MRP-RMS	VNRA administrative	3403	7,482
			VNRA regulatory	3404	8,671
		MRP-CMS	VNRA administrative	3405	1,693
			VNRA regulatory	3406	3,484
	VRA Quality	National	VRA Reduced	3407	11,663
			VRA Standard Simple	3408	27,674
			VRA Standard Complex	3409	43,684
		MRP-RMS	VRA Reduced	3410	18,190
			VRA Standard Simple	3411	33,848
			VRA Standard Complex	3412	49,506
		MRP-CMS	VRA Reduced	3413	1,693
			VRA Standard Simple	3414	1,693
			VRA Standard Complex	3415	1,693
	VRA regulatory	National	VRA Reduced	3416	9,062
			VRA Standard	3417	22,572
		MRP-RMS	VRA Reduced	3418	9,860
			VRA Standard	3419	17,445

		MRP-CMS	VRA Reduced	3420	5,276
			VRA Standard	3421	5,276
	VRA Extended	National	VRA Extended	3422	52,746
		MRP-RMS	VRA Extended	3423	59,366
		MRP-CMS	VRA Extended	3424	6,968
Grouping and worksharing	VRA Quality	National	VRA Reduced	3425	24,287
			VRA Standard Simple	3426	36,618
			VRA Standard Complex	3427	48,948
		MRP-RMS	VRA Reduced	3428	30,920
			VRA Standard Simple	3429	44,175
			VRA Standard Complex	3430	57,430
		MRP, reference authority in case of worksharing	VRA Reduced	3431	46,016
			VRA Standard Simple	3432	68,036
			VRA Standard Complex	3433	90,056
		MRP-CMS	VRA Reduced grouping	3434	2,963
			VRA Reduced worksharing	3435	2,963
			VRA Standard Simple grouping	3436	4,480
			VRA Standard Simple worksharing	3437	4,480
			VRA Standard Complex grouping	3438	5,998
			VRA Standard Complex worksharing	3439	5,998
	VRA regulatory	National	VRA Reduced	3440	15,466
			VRA Standard	3441	27,810

		MRP-RMS	VRA Reduced	3442	15,518
			VRA Standard	3443	26,899
		MRP, reference authority in case of worksharing	VRA Reduced	3444	36,278
			VRA Standard	3445	43,422
		MRP-CMS	VRA Reduced grouping	3446	8,318
			VRA Standard grouping	3447	8,318
			VRA Reduced worksharing	3448	8,318
			VRA Standard worksharing	3449	8,318
	VRA Extended	National	VRA Extended	3450	64,414
			VRA Extended Mix	3451	76,758
		MRP-RMS	VRA Extended	3452	72,948
			VRA Extended Mix	3453	84,329
		MRP, reference authority in case of worksharing	VRA Extended	3454	126,334
			VRA Extended Mix	3455	133,478
		MRP-CMS	VRA Extended grouping	3456	14,316
			VRA Extended Mix grouping	3457	14,316
			VRA Extended worksharing	3458	14,316
			VRA Extended Mix worksharing	3459	14,316

Schedule 4

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.	5001/5002	DKK 74,298	**From 2023**	**Year 2022**
				DKK 74,298	DKK 66,395
Wholesale distribution of medicinal products	Authorisation for wholesale distribution of medicinal products, cf. section 39(1) of the Danish Medicines Act.	5003/5004	DKK 25,915	**From 2023**	**Year 2022**
				DKK 25,915	DKK 22,456
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 598	**From 2023**	**Year 2022**
				DKK 598	DKK 686

Retail sale of medical gases	Authorisation for retail sale of medical gases, cf. section 39(1) of the Danish Medicines Act.	5007/5008	DKK 1,167	DKK 1,167	
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 commenced hour) and hourly rate: DKK 910		
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 48,425	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 15,538	DKK 15,538	
API manufacturing	Registration of company manufacturing active substances intended for use in the manufacturing of medicinal products, cf. section 50a(1) of the Danish Medicines Act.	5013/5014	DKK 74,298	**From 2023**	**Year 2022**
				DKK 74,298	DKK 68,311

API import and distribution	Registration of company import and distribute active substances intended for use in the manufacturing of medicinal products, cf. section 50a(1) of the Danish Medicines Act.	5015/5016	DKK 25,915	**From 2023**	**Year 2022**
				DKK 25,915	DKK 22,456
Toxicological and pharmacological trials (GLP)	Authorisation to conduct toxicological and pharmacological (non-clinical) trials, cf. section 85(1) of the Danish Medicines Act	5017/5018	DKK 74,298	**From 2023**	**Year 2022**
				DKK 74,298	DKK 68,311
API inspection outside the EU	Inspection of company with API outside the EU, cf. section 10.	5019	DKK 145,506	DKK 145,506	
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 1,112		

***) Additional fee for locations with more than 500 employees**	The additional fee is charged if the company employs more than 500 employees at one location at the time of applying (with application fee) or at 1 January (with annual fee)	5021/5022	DKK 151,048	DKK 151,048	
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 25,915	**From 2023**	**Year 2022**
				DKK 25,915	DKK 22,456

Schedule 5

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 2,409
Subscribers	Subscription for Medicine Prices for companies	6002	DKK 3,011, incl. VAT

Schedule 6

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 858
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 858

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	**From 2023**	**Year 2022**
			DKK 1,041	DKK 980