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 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) Fixed combination medicinal products (art. 10b/13b)		DKK 182,296
			Bibliographic applications (art. 10a/13a) Hybrid application (art. 10.3/13.3) with clinical studies concerning efficacy and/or safety. Application concerning biological medicinal product analogous to already authorised medicinal products (art. 10.4/13.4). Application concerning vitamin and mineral preparations, see the executive order on vitamin and mineral preparations		DKK 156,083
			Hybrid application (art. 10.3/13.3) without clinical studies concerning efficacy and/or safety		DKK 126,490
			Generics – veterinary, antibiotics (art. 13.1)		DKK 147,303
			Generics – human (art. 10.1) Generics – veterinary, non-antibiotics (art. 13.1)		DKK 126,490
			Duplicate with same timetable as application subject to a full fee		DKK 43,215
			Parallel registration (art. 10c/13c)		DKK 41,459
			Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.		DKK 16,459
			Future extension of marketing authorisation		DKK 102,686
			Assessment of PSUR. A fee per D.sp.no.		DKK 7,147
		DCP, RMS	Fully documented application (art. 8.3/12.3) Fixed combination medicinal products (art. 10b/13b)		DKK 253,510
			Bibliographic application (art. 10a/13a) Hybrid application (art. 10.3/13.3) with clinical studies concerning efficacy and/or safety. Application concerning biological medicinal product analogous to already authorised medicinal products (art. 10.4/13.4).		DKK 227,296
			Hybrid application (art. 10.3/13.3) without clinical studies concerning efficacy and/or safety		DKK 197,704
			Generics – veterinary, antibiotics (art. 13.1)		DKK 218,517

			Generics – human (art. 10.1) Generics – veterinary, non-antibiotics (art 13.1)		DKK 197,704
			Duplicate with same timetable as application subject to a full fee		DKK 51,789
			Parallel registration (art. 10c/13c)		DKK 50,033
			Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.		DKK 31,575
			Future extension of marketing authorisation		DKK 150,519
		DCP/MRP, RMS	Assessment of PSUR. A fee per D.sp.no.		DKK 7,147
		DCP/MRP, CMS	All applications for new marketing authorisation		DKK 26,057
			Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.		DKK 27,136
			Future extension of marketing authorisation		DKK 19,925
New marketing authorisation, registration and extension	Natural medicinal products, traditional herbal medicinal products or homeopathic medicinal products	National			DKK 77,538
		DCP, RMS			DKK 89,988
		DCP/MRP, CMS			DKK 24,951
		All procedures	Assessment of PSUR. A fee per D.sp.no.		DKK 7,147
		All procedures	Additional fee for assessment in addition to standard procedure due to complexity of the submitted documentation.		DKK 16,459
New marketing authorisation, registration and extension	All types	MRP/DCP/National, all roles	Rejection of new application for marketing authorisation after regulatory validation		DKK 19,623
New marketing authorisation	All types	Parallel import	Per exporting country		DKK 6,749
New mutual recognition procedure, MRP	All types	MRP, RMS	Full procedure, incl. updating		DKK 71,397
			Full procedure, incl. administrative updating		DKK 29,418
			Day Zero procedure		DKK 15,924
Renewal of marketing authorisation/registration	Ordinary medicinal products and vitamin and mineral preparations	National			DKK 6,716
		MRP, CMS			DKK 3,982
		MRP, RMS			DKK 20,701
	All types	Parallel import	A fee per D.sp.no.		DKK 3,907
	Natural medicinal products, traditional herbal medicinal products and homeopathic medicinal products	National			DKK 10,738
Annual fee for medicinal products (general regulatory functions, supervision, control and analysis)	All types	All procedures	A fee per MT number/drug ID		DKK 13,575

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		DKK 1,764
		MRP-RMS	Type IA, type IB and type II		DKK 7,344
		MRP-CMS	Type IA, type IB and type II		DKK 1,465
	Quality	National	Type IB and type II, simple		DKK 9,375
			Type IB and type II, complex		DKK 34,696
		MRP-RMS	Type IB and type II, simple		DKK 14,955
			Type IB and type II, complex		DKK 40,276
		MRP-CMS	Type IB and type II, simple		DKK 1,465
			Type IB and type II, complex		DKK 3,112
	Regulatory/clinical	National	Type IB		DKK 8,742
			Type II		DKK 11,103
		MRP-RMS	Type IB		DKK 8,742
			Type II		DKK 11,103
		MRP-CMS	Type IB and type II		DKK 6,008
Grouping and worksharing	Administrative and all types of IA and IAIN variations	National	Type IA, one D.sp.no.		DKK 2,204
			Type IA, several D.sp.nos.		DKK 2,863
		MRP-RMS	Type IA, one D.sp.no.		DKK 6,576
			Type IA, several D.sp.nos.		DKK 8,749
			Type IA, super grouping		DKK 12,974
		MRP-CMS	Type IA, one D.sp.no.		DKK 1,905
			Type IA, several D.sp.nos.		DKK 2,564
	Quality	National	Type IB and type II, simple		DKK 16,183
			Type IB and type II, complex		DKK 38,512
		MRP-RMS	Type IB and type II, simple		DKK 22,069
			Type IB and type II, complex		DKK 44,398
		MRP, reference authority in case of worksharing	Type IB and type II, simple		DKK 32,655
			Type IB and type II, complex		DKK 66,597
		MRP-CMS	Type IB and type II, simple		DKK 2,564
			Type IB and type II, complex		DKK 4,211
	Regulatory/clinical	National	Type IB		DKK 13,029
			Type II		DKK 15,165
		MRP-RMS	Type IB		DKK 13,029
			Type II		DKK 15,165
		MRP, reference authority in case of worksharing	Type IB		DKK 19,543
			Type II		DKK 22,747
		MRP-CMS	Type IB and type II		DKK 8,244

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.		DKK 46.696*	DKK 46.696*
Wholesale distribution of medicinal products	Authorisation for wholesale distribution of medicinal products, see section 39(1) of the Danish Medicines Act.		DKK 14,411	DKK 14,411
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.		DKK 1,082	DKK 1,082
Retail sale of medical gases	Authorisation for retail sale of medical gases, see section 39(1) of the Danish Medicines Act.		DKK 1,082	DKK 1,082
Retail sale of smoking cessation products	Authorisation for retail sale of smoking cessation products, see section 39(1) of the Danish Medicines Act.		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.		DKK 44,911	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.		DKK 14,411	DKK 14,411
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.		DKK 46.696*	DKK 46.696*
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.		DKK 14,411	DKK 14,411
Toxicological and pharmacological trials (GLP)	Authorisation to conduct toxicological and pharmacological (non-clinical) trials, see section 85(1) of the Danish Medicines Act.		DKK 46.696*	DKK 46.696*
API inspection outside the EU	Inspection of company with API outside the EU, see section 10.		DKK 77,554	-

Schedule 3

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.		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).		DKK 140,087	DKK 140,087

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.		DKK 1,554
Subscriptions	Subscription for Medicine Prices for companies		DKK 1,943, 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	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.		DKK 796
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.		DKK 796
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.		DKK 796