

Executive order on fees payable for medicinal products, etc.

Fees mentioned in sections 11 and 20 have been adjusted at 1 January 2017 by the rate for the general price and wage index fixed by the Danish Ministry of Finance.

Table 1. Adjustment of fees in **section 11**:

Item number	Fee/Annual fee 2017
30369	DKK 7,344
30368	DKK 7,344

Table 2. Adjustment of fees in **section 20**:

Item number	Annual fee 2017
30371	DKK 4,761

Table 3. Adjustment of fees in **Schedule 1**.

Procedure	Group	Case type	Delimitation	Item no.	Application for		Annual fee
					MA	Renewal	
						Item no.	Item no.
National Procedure	All, excluding herbal medicinal products, vitamin and mineral preparations, traditional herbal medicinal products and homeopathic medicinal products	New application	New applications	30301	85,017	18,078 ¹⁾	9,523
National Procedure		New application	Bibliographic applications and fixed combination medicinal products	30303	85,017	18,078 ¹⁾	9,523
National Procedure		New application	Generic medicinal products (generic application, hybrid application and biological medicinal products analogous to already approved medicinal products)	30302	79,268	18,078 ¹⁾	9,523
National Procedure		New application	Application identical with already approved medicinal product	30304	24,286	18,078 ¹⁾	9,523
National Procedure		New application	Application refused by the Danish Medicines Agency or withdrawn by the applicant during the validation process	30306	14,063		
National Procedure		Extension	New indication or new target species	30309	18,078		
National Procedure		Extension	Additional pharmaceutical form	30310	18,078		9,523
National Procedure		Extension	Additional strength	30311	16,744		9,523
National Procedure		Parallel import	1st import country	30312	18,078		9,523
National Procedure		Parallel import	1st import country	30314		16,744 ⁴⁾	
National Procedure		Parallel import	2nd to 4th import country	30313	16,878		

National Procedure		Variation	Type IA and type IB	30315	1,822			
National Procedure		Variation	Administrative fee type IA and type IB	30316	839			
National Procedure		Variation	Reduced fee regardless of type	30317	456			
National Procedure		Variation	Type II, standard	30318	1,822			
National Procedure		Variation	Type II, complex	30319	1,822			
National Procedure		Periodic Safety Update Report	Periodic Safety Update Report	40101	7,028 ⁹⁾			
National Procedure		Variation	Refusal on the grounds of invalidity of a b-grouping comprising four variations or more	30415	5,569			
Procedure	Group	Case type	Delimitation	Item no.	Application for		Annual fee	
					MA	Renewal		
						Item no.	Item no.	
						30322	30323	
National Procedure	Natural medicinal products and strong vitamin and mineral preparations	New application	Bibliographic applications	30320	14,527	1,965	4,607	
National Procedure		New application	Application identical with already approved medicinal product	30321	13,235	1,965	4,607	
National Procedure		New application	Application refused by the Danish Medicines Agency or withdrawn by the applicant during the validation process	30413	2,396			
National Procedure		Extension	New indication or new target species	30324	4,216			
National Procedure		Extension	Additional pharmaceutical form	30325	1,955		4,607	
National Procedure		Extension	Additional strength	30326	1,955		4,607	
National Procedure		Variation	Type IA and type IB	30327	1,688			
National Procedure		Variation	Administrative fee type IA and type IB	30328	839			
National Procedure		Variation	Reduced fee regardless of type	30329	466			
National Procedure		Variation	Type II, standard	30330	1,822			
National Procedure		Variation	Type II, complex	30331	1,822			
Procedure		Group	Case type	Delimitation	Item no.	Application for		Annual fee
	MA					Renewal		
						Item no.	Item no.	
						30411	30323	
National Procedure	Traditional herbal medicinal products	New application	New application	30409	8,353	1,965	4,607	
National Procedure		New application	Application identical with already approved medicinal product	30410	7,033	1,965	4,607	
National Procedure		Extension	New indication, strength or pharmaceutical form	30418	1,955		4,607	
National Procedure		Variation	Type IA and type IB	30419	1,688			
National Procedure		Variation	Administrative fee type IA and type IB	30420	839			
National Procedure		Variation	Reduced fee regardless of type	30421	466			
National Procedure		Variation	Type II, standard	30422	1,822			

National Procedure		Variation	Type II, complex	30423	1,822		
Procedure	Group	Case type	Delimitation	Item no.	Application for		Annual fee
					MA	Renewal	
						Item no.	Item no.
						30334	30335
National Procedure	Homeopathic medicinal products, registration	New application	First pharmaceutical form and strength	30332	2,482	1,077	1,004
National Procedure		New application	Application identical with already approved medicinal product	30333	553	1,077	
National Procedure		Extension	Additional pharmaceutical forms and strengths	30336	553		1004
Procedure	Group	Case type	Delimitation	Item no.	Application for		Annual fee
					MA	Renewal	
						Item no.	Item no.
						30343	30308
Mutual Recognition Procedure, MRP, Concerned Member State	All, excluding traditional herbal medicinal products and homeopathic medicinal products	New application	New applications	30337	72,493	18,078 ²⁾ 10)	9,523 ³⁾
Mutual Recognition Procedure, MRP, Concerned Member State		New application	Bibliographic applications and fixed combination medicinal products	30339	72,493	18,078 ²⁾ 10)	9,523 ³⁾
Mutual Recognition Procedure, MRP, Concerned Member State		New application	Generic medicinal products (generic application, hybrid application and biological medicinal products analogous to already approved medicinal products)	30338	72,493	18,078 ²⁾ 10)	9,523 ³⁾
Mutual Recognition Procedure, MRP, Concerned Member State		New application	Application identical with already approved medicinal product	30340	17,980	18,078 ²⁾ 10)	9,523 ³⁾
Mutual Recognition Procedure, MRP, Concerned Member State		New application	Application refused by the Danish Medicines Agency or withdrawn by the applicant during the validation process	30342	14,063		
Mutual Recognition Procedure, MRP, Concerned Member State		Extension	New indication or new target species	30345	18,078		
Mutual Recognition Procedure, MRP, Concerned Member State		Extension	Additional pharmaceutical form	30346	16,613		9,523 ³⁾
Mutual Recognition Procedure, MRP, Concerned Member State		Extension	Additional strength	30347	16,613		9,523 ³⁾
Mutual Recognition Procedure, MRP, Concerned Member State		Variation	Type IA and type IB	30348	1,347		
Mutual Recognition Procedure, MRP,		Variation	Administrative fee type IA and type IB	30349	839		

Concerned Member State							
Mutual Recognition Procedure, MRP, Concerned Member State		Variation	Reduced fee regardless of type	30350	456		
Mutual Recognition Procedure, MRP, Concerned Member State		Variation	Type II, standard	30351	1,822		
Mutual Recognition Procedure, MRP, Concerned Member State		Variation	Type II, complex	30352	1,822		
Mutual Recognition Procedure, MRP, Concerned Member State		Veterinary SPC harmonisation	Fee for transfer of MA from National Procedure to MRP after completion of the relevant variations	30416	24,165		
Procedure	Group	Case type	Delimitation	Item no.	Application for		Annual fee
					MA	Renewal	
						Item no.	Item no.
					30354	303084)	
Mutual Recognition Procedure, MRP, Reference Member State	All, excluding traditional herbal medicinal products and homeopathic medicinal products	New application	Application where the Danish Medicines Agency's nationally granted marketing authorisation forms the basis of a Mutual Recognition Procedure. Includes new applications, bibliographic applications as well as generic medicinal products	30353	76,547 ⁵⁾	14,063 ³⁾	
Mutual Recognition Procedure, MRP, Reference Member State		New application	Application identical with already approved medicinal product	30355	35,226 ⁵⁾	14,063 ³⁾	
Mutual Recognition Procedure, MRP, Reference Member State		Extension	Application where the Danish Medicines Agency's nationally granted marketing authorisation forms the basis of a Mutual Recognition Procedure. Includes new additional form or strength	30414	35,226 ⁷⁾		
Mutual Recognition Procedure, MRP, Reference Member State		Variation The fee covers MRPs. For this scientific evaluation a national variation fee is charged	Type IA and type IB	30356	2,107		
Mutual Recognition Procedure, MRP, Reference Member State		Variation The fee covers MRPs. For this scientific evaluation a national variation fee is charged	Type II, standard	30357	8,425		
Mutual Recognition Procedure, MRP, Reference Member State		Variation The fee covers MRPs. For this scientific evaluation a national variation fee is charged	Type II, complex	30358	14,063		
Mutual recognition procedure. MRP, Reference Member State		Periodic Safety Update Report	Periodic Safety Update Report	40102	14,063		
Mutual Recognition Procedure, MRP,		Variation	Worksharing		Same fees as otherwise		

Reference Member State					charged for variations		
Mutual Recognition Procedure, MRP, Reference Member State		Veterinary SPC harmonisation	Fee for transfer of MA from National Procedure to MRP after completion of the relevant variations	30417	75,491		
Procedure	Group	Case type	Delimitation	Item no.	Application for		Annual fee
					MA	Renewal	
						Item no.	Item no.
						30354	30308
Decentralised Procedure, Concerned Member State	All, excluding traditional herbal medicinal products and homeopathic medicinal products	New application	New applications	30376	171,456 ⁹⁾		9,523
Decentralised Procedure, Concerned Member State		New application	Bibliographic applications and fixed combination medicinal products	30378	171,456 ⁹⁾		9,523
Decentralised Procedure, Concerned Member State		New application	Generic medicinal products (generic application, hybrid application and biological medicinal products analogous to already approved medicinal products)	30377	159,270 ⁹⁾		9,523
Decentralised Procedure, Concerned Member State		New application	Application identical with already approved medicinal product	30379	39,816 ⁹⁾		9,523
Decentralised Procedure, Concerned Member State		New application	Application refused by the Danish Medicines Agency or withdrawn by the applicant during the validation process	30381	14,063		
Decentralised Procedure, Concerned Member State		Extension	New indication or new target species	30382	39,412		
Decentralised Procedure, Concerned Member State		Extension	New pharmaceutical form	30383	39,412		9,523
Decentralised procedure, Concerned Member State		Extension	New strength	30384	36,500		9,523
Procedure	Group	Case type	Delimitation	Item no.	Application for		Annual fee
					MA	Renewal	
						Item no.	Item no.
						30402	30308
Decentralised Procedure, Reference Member State	All, excluding traditional herbal medicinal products and homeopathic medicinal products	New application	New applications	30392	269,585 ⁹⁾		9,523
Decentralised Procedure, Reference Member State		New application	Bibliographic applications and fixed combination medicinal products	30394	269,585 ⁹⁾		9,523
Decentralised Procedure, Reference Member State		New application	Generic medicinal products (generic application, hybrid application and biological medicinal products analogous to already approved medicinal products)	30393	250,216 ⁶⁾		9,523
Decentralised Procedure, Reference Member State		New application	Application identical with already approved medicinal product	30395	77,568		9,523
Decentralised Procedure,		New application	Application refused by the Danish Medicines Agency or	30397	14,063		

Reference Member State			withdrawn by the applicant during the validation process				
Decentralised Procedure, Reference Member State		Extension	New indication or new target species	30398	60,394		
Decentralised Procedure, Reference Member State		Extension	New pharmaceutical form	30399	60,394		9,523
Decentralised Procedure, Reference Member State		Extension	New strength	30400	55,926		9,523
		Variation	Worksharing		Same fees as otherwise charged for variations		
Decentralised Procedure, Reference Member State		Periodic Safety Update Report		40103	14,063		

¹⁾ Per D. sp. no.

²⁾ Per D. sp. no.

³⁾ An annual fee is charged for this procedure since no marketing authorisation has been granted in Denmark yet.

⁴⁾ For this type of procedure, the annual fee is charged for the marketing authorisation granted under the national procedure.

⁵⁾ For all pharmaceutical forms, strengths and indications covered by the procedure. One fee per procedure.

⁶⁾ Per D. sp. no.

⁷⁾ Per pharmaceutical form, strength and indication (one fee per procedure).

⁸⁾ For all pharmaceutical forms, strengths and indications covered by the procedure. One fee per procedure.

⁹⁾ Per D. sp. no.

¹⁰⁾ An application for renewal or variation of a medicinal product authorised under DCP is categorised as an MRP application

Procedure	Case type	Item no.	Application for		Annual fee
			MA	Renewal	
Centralised Procedure	Notifications of parallel distribution of centrally authorised medicinal products	30360	7,041		

Companies

Company	Case type	Delimitation	Item no.	Application fee	Annual fee
Companies	Handling of medicinal products and intermediate products	Manufacturing/import	50115	17,481	
Companies	Handling of medicinal products and intermediate products pursuant to sections 14(1) or 14(1) and (3)	Manufacturing/import	50109	13,220	
Companies	Handling of medicinal products and intermediate products pursuant to section 14(3)	Manufacturing/import	50110	13,746	
Companies	Handling of medicinal products and intermediate products	Manufacturing/import	50112		17,847
Companies	Manufacturing of active substances for use in medicinal products	Manufacturing	50150	36,020	
Companies	Manufacturing of active substances for use in medicinal products	Manufacturing	50151		36,020
Companies	Handling of medicinal products	Wholesale distribution	50116	4,261	
Companies	Handling of medicinal products	Wholesale distribution	50111		4,261
Companies	Import and distribution of active substances for use in medicinal products	Import/wholesale distribution	50152	12,618	
Companies	Import and distribution of active substances for use in medicinal products	Import/wholesale distribution	50153		12,618
Companies	Brokering of medicinal products	Brokering	50154	10,418	
Companies	Brokering of medicinal products	Brokering	50155		10,418
Companies	Distribution of HV marked products	Retail distribution	50114	3,668	
Companies	Distribution of HV marked products	Retail distribution	50136		3,689
Companies	Distribution of HV marked products, in conjunction with over-the-counter medicinal products	Retail distribution	50124	4,261	
Companies	Distribution of HV marked products, in conjunction with OTC medicines (reduced fee with existing authorisation for OTC medicines)	Retail distribution	50119	527	

Companies	Distribution of HV marked products, in conjunction with over-the-counter medicinal products	Retail distribution	50135		4,281
Companies	Distribution of medicinal products for production animals outside pharmacies	Retail distribution	50133	22,597	
Companies	Distribution of OTC medicines outside pharmacies	Retail distribution	50122	3,734	
Companies	Distribution of OTC medicines outside pharmacies	Retail distribution	50123		3,734
Companies	Distribution of smoking cessation products	Retail distribution	50129	332	
Companies	Distribution of smoking cessation products	Retail distribution	50130		332
Companies	Medicinal gases, distribution of medicinal gases	Retail distribution	50131	3,729	
Companies	Medicinal gases, distribution of medicinal gases	Retail distribution	50132		3,758
Companies	Change from OTC outlet to sales outlet pursuant to section 39(1) of the Danish Medicines Act	Retail distribution	50134	1,887	
Companies	GLP	All companies	50117	17,020	
Companies	GLP	All companies	50118		17,373
Raw material manufacturers	Inspection of raw material manufacturers	Countries outside the EU/EEA	50138	74,690	

Prices

	Product number	Fee
Notification of new or changed price of a package	60101	167
Withdrawal of pack size	60101	167
Annual fee, notification of consumer prices to pharmacies	60105	1,554
Subscription to Medicine Prices (Medicinpriser) for companies	60114	1,554 excluding VAT