

MARKETING AUTHORISATION FEES (in force since 3 of October, 2026)

(the reference to the original valid document: [Dėl Lietuvos Respublikos Vyriausybės 2000 m. gruodžio 15 d. nutarimo Nr. 1458 „Dėl Konkrečių valstybės rinkliavos dydžių sąrašo ir Valstybės rinkliavos mokėjimo ir grąžinimo taisyklių patvirtinimo“](#))

1. GRANTING MARKETING AUTHORISATION) (reference No 5749)													
		Application	NP ⁱ		MRP/CMS ⁱⁱ		DCP/CMS ⁱⁱⁱ		Update of the assessment report	MRP/RMS ^{iv}		DCP/RMS ^v	
			Validation	Evaluation of quality, safety and efficacy	Validation	Evaluation of quality, safety and efficacy	Validation	Evaluation of quality, safety and efficacy		Validation	Evaluation of quality, safety and efficacy	Validation	Evaluation of quality, safety and efficacy
4.38	1.1	Full application (2001/83/EB Article 8(3))	5 466 €		1060 €		1060 €		2 700 €	4 194 €		12 164 €	
			150 €	5 316 €	150 €	910 €	150 €	910 €		300 €	3 894 €	300 €	11 864 €
4.39	1.2	Well-established use application (2001/83/EB Article 10a)	5 516 €		1060 €		1060 €		2700 €	4 194 €		12 164 €	
			200 €	5 316 €	200 €	860 €	200 €	860 €		300 €	3894 €	300 €	11 864 €
4.40	1.3	Fixed combination application (2001/83/EB Article 10b)	5 529 €		1060 €		1060 €		2700 €	4 194 €		12 164 €	
			200 €	5 329 €	200 €	860 €	200 €	860 €		300 €	3894 €	300 €	11 864 €
4.41	1.4	Generic/hybrid application (2001/83/EB Article 10(1) ; 10(3) ; 10 (4))	3 302 €		620 €		620€		1700 €	3 055 €		8 882€	
			200 €	3 102 €	150 €	470 €	150 €	470 €		300 €	2755 €	300 €	8 582 €
4.42	1.5	Informed consent application (2001/83/EB Article 10c)	3 302 €		720 €		720 €		1700 €	3 055 €		8 882 €	
			200 €	3 102 €	150 €	570 €	150 €	570 €		300 €	2755 €	300 €	8 582 €
4.43	1.6	Additional strength form applied simultaneously	1198 €		375 €		375 €		300 €	921 €		2 143 €	
			200 €	998 €	150 €	225 €	150 €	225 €		200 €	721 €	300 €	1843 €
4.43-1	1.7	Additional pharmaceutical form applied simultaneously	1678 €		400 €		400 €		500 €	1324 €		5 399 €	
			200 €	1478 €	150 €	250 €	150 €	250 €		300 €	1024 €	300 €	5 099 €
4.44	1.8	Extension of Marketing Authorisation	2 681 €		590 €		590 €		1000 €	1858 €		3 496 €	
			200 €	2 481 €	150 €	440 €	150 €	440 €		300 €	1558 €	300 €	3 196 €
4.45	1.9	Marketing Authorisation of simplified registration procedure for homeopathic medicinal products (2001/83/EB Article 14)	890 €		380 €		380 €		200 €	871 €		2 252 €	
			150 €	740 €	150 €	230 €	150 €	230 €		200 €	671 €	300 €	1952 €
4.45.6	1.10	Marketing Authorisation of additional potency or pharmaceutical form applied simultaneously for simplified registration procedure for homeopathic medicinal products	434 €		198 €		198 €		200 €	464 €		1193 €	
			48 €	386 €	48 €	150 €	48 €	150 €		100 €	364 €	200 €	993 €
4.45.7	1.11	Extension of Marketing Authorisation of simplified registration procedure for homeopathic medicinal products	656 €		254 €		254 €		200 €	573 €		1589 €	
			150 €	506 €	69 €	185 €	69 €	185 €		100 €	473 €	200 €	1389 €
4.46	1.12	Marketing Authorisation of homeopathic medicinal products by other registration procedure (2001/83/EB Article 16)	1330 €		-		-		-	-		-	
			200 €	1130 €									
4.46.3	1.13	Marketing Authorisation of additional potency or pharmaceutical form applied simultaneously for homeopathic medicinal products authorized by other registration procedure	444 €		-		-		-	-		-	
			48 €	396 €									
4.46.4	1.14	Extension of Marketing Authorisation of homeopathic medicinal products authorized by other registration procedure	799 €		-		-		-	-		-	
			69 €	730 €									
4.47	1.15	Marketing Authorisation of simplified registration (Community herbal monograph) procedure for traditional herbal medicinal products (2001/83/EB Article 16(a))	1362 €		447 €		447 €		400 €	1087 €		5 658 €	
			200 €	1162 €	97 €	350 €	97 €	350 €		200 €	887 €	300 €	5 358 €
4.47.6	1.16	Marketing Authorisation of additional strengths or pharmaceutical form applied simultaneously of simplified registration procedure for traditional herbal medicinal products	644 €		215 €		215 €		200 €	549 €		801 €	
			100 €	544 €	48 €	167 €	48 €	167 €		100 €	449 €	100 €	701 €
4.47.7	1.17	Extension of Marketing Authorisation of simplified registration procedure for traditional herbal medicinal products	822 €		299 €		299 €		300 €	866 €		1116 €	
			69 €	753€	69 €	230 €	69 €	230 €		200 €	666 €	150 €	966 €
4.47-1	1.18	“Zero-day” procedure	-		300 €		-		-	-		-	

Notes: * Fee indicated in point 1.6 have to be paid when simultaneously with the application to supplement marketing authorisation (registration) certificate additional application for other strength is being submitted
 *Fee indicated in points 1.10, 1.13, 1.16 have to be paid when simultaneously with the application to supplement marketing authorisation (registration) certificate additional application for other strength and/or other pharmaceutical form is being submitted.

2. RENEWAL OF MARKETING AUTHORISATION (reference No 5749, in force since <u>03 of October, 2026</u>)												
		Application	NP ⁱ		MRP/CMS ⁱⁱ		DCP/CMS ⁱⁱⁱ		MRP/RMS ^{iv}		DCP/RMS ^v	
4.48	2.1	Renewal of Marketing Authorisation	2170 €		770 €		770 €		3170 €		3170 €	
			170 €	2 000	170 €	600 €	170 €	600 €	170 €	3000 €	170 €	3000 €
4.49	2.2	Additional strengths or pharmaceutical forms applied simultaneously	620 €		420 €		420 €		1150 €		1150 €	
			120 €	500 €	120 €	300 €	120 €	300 €	150 €	1000 €	150 €	1000 €
4.50	2.3	Renewal of Marketing Authorisation of homeopathic medicinal products authorized by simplified registration procedure	680 €		300 €		300 €		1020 €		1020 €	
			130 €	550 €	130 €	170 €	130 €	170 €	170 €	850 €	170 €	850 €
4.50-6	2.4	Additional strengths or pharmaceutical forms applied simultaneously for Renewal of Marketing Authorisation of homeopathic medicinal products authorized by simplified registration procedure	350 €		270 €		270 €		620 €		620 €	
			100 €	250 €	70 €	200 €	70 €	200 €	120 €	500 €	120 €	500 €
4.51	2.5	Renewal of Marketing Authorisation of homeopathic medicinal products authorized by other registration procedure	970 €		-		-		-		-	
			170 €	800 €								
4.51.1	2.6	Additional strengths or pharmaceutical forms applied simultaneously for renewal of Marketing Authorisation of homeopathic medicinal products authorized by other registration procedure	620 €		-		-		-		-	
			120 €	500 €								
4.52	2.7	Renewal of Marketing Authorisation of traditional herbal medicinal products authorized by simplified registration procedure	970 €		520 €		520 €		1770 €		1770 €	
			170 €	800 €	120 €	400 €	120 €	400 €	170 €	1600 €	170 €	1600 €
4.52.6	2.8	Additional strengths or pharmaceutical forms applied simultaneously for renewal of Marketing Authorisation of traditional herbal medicinal products authorized by simplified registration procedure	550 €		290 €		290 €		920 €		920 €	
			100 €	450 €	70 €	220 €	70 €	220 €	120 €	800 €	120 €	800 €

3. VARIATIONS AND OTHER CHANGES (reference No 5749)

		Variation / Change	NP ⁱ			MRP/CMS ⁱⁱ DCP/CMS ⁱⁱⁱ		MRP/RMS ^{iv} DCP/RMS ^v	
			Validation	Evaluation of quality, safety and efficacy	additional fee for each additional variation code	Evaluation of quality, safety and efficacy	additional fee for each additional variation code	Evaluation of quality, safety and efficacy	additional fee for each additional variation code
4.53	3.1	Variation Type IA	-	121 €	12 €▼	73 €	30 €▼	200 €	30 €▼
4.54	3.2	Variation Type IB	217 €			215 €	30 €▼	800 €	40 €▼
			97 €	120 €	12 €▼				
4.55	3.3	Variation Type II (except new indication; B.I.a.1(b); B.I.a.1(c); B.I.a.1(d); B.I.a.1(e); B.I.a.1(g); B.I.a.1(j); B.I.a.2(b); B.I.a.2(c); B.I.a.2(d); B.I.a.3(c); B.I.b.2(d); B.I.e.2; B.II.a.3(b2); B.II.a.3(b3); B.II.a.3(b4); B.II.a.3(b5); B.II.b.1(c); B.II.b.1(d); B.II.b.3(b); B.II.b.3(c); B.II.b.3(d); B.II.b.3(e); B.II.c.4(b); B.II.c.4(c); B.II.h.1(a); B.II.h.1(b1); B.V.a.1(a); B.V.a.2(a); B.II.g.1(a); B.II.g.1(b); B.IV.1(a)3)	613 €		515 €	30 €▼	2 000 €	50 €▼	
			97 €	516 €					12 €▼
4.56	3.4	Variation Type II (new indication; B.I.a.1(b); B.I.a.1(c); B.I.a.1(d); B.I.a.1(e); B.I.a.1(g); B.I.a.1(j); B.I.a.2(b); B.I.a.2(c); B.I.a.2(d); B.I.a.3(c); B.I.b.2(d); B.I.e.2; B.II.a.3(b2); B.II.a.3(b3); B.II.a.3(b4); B.II.a.3(b5); B.II.b.1(c); B.II.b.1(d); B.II.b.3(b); B.II.b.3(c); B.II.b.3(d); B.II.b.3(e); B.II.c.4(b); B.II.c.4(c); B.II.h.1(a); B.II.h.1(b1); B.V.a.1(a); B.V.a.2(a); B.II.g.1(a); B.II.g.1(b); B.IV.1(a)3)	845 €		700 €	30 €▼	3 000 €	50 €▼	
			97 €	748 €					12 €▼
4.57	3.5	Change of labeling and package leaflet ▼▼	162 €			158 €		404 €	
4.58	3.6	Change of classification	738 €						
			97 €	641 €					
4.59	3.7	Transfer of Marketing Authorisation ▼▼	284 €						

▼ When the application is being submitted for grouping of variations, **additional fee (12 € or 30 € or 50 €) has to be paid for each additional variation code** not depending on the number of medicine products/strengths/pharmaceutical forms.

▼▼ One State fee has to be paid for several strengths and / or pharmaceutical forms when at the same time the application (-s) is/are being submitted for identical variation of terms to marketing authorisation or transfer of marketing authorisation rights and when the documentation is common.

3a. VARIATIONS (*WORKSHARING*) (reference No 5749)

			LTL/CMS			LTL/RMS		
			Validation	Evaluation of quality, safety and efficacy	additional fee for each additional medicinal product's name*	Validation	Evaluation of quality, safety and efficacy	additional fee for each additional medicinal product's name*
4.54-1.1	3a.1	Worksharing (IB) -	350 €		12 €▲	897 €		50 €▲
			97 €	253 €		97 €	800 €	
4.54-1.2	3a.2	Worksharing (II) -	697 €		12 €▲	2 097 €		50 €▲
			97 €	600 €		97 €	2 000 €	

▲ When the application is being submitted for group of medicines products, **additional fee (12 € or 50 €) has to be paid for each additional invented name** of medicinal product not depending on the number of strengths and (or) pharmaceutical forms.

5. PARALLEL IMPORT (reference No 5749, in force since 03 of October, 2026)				
			Validation	Evaluation of documents
4.63	5.1.	Application for licence of parallel import	110 €	550 €
4.64	5.2.	Application for change of parallel import conditions*		300 €
* One State fee has to be paid for several strengths and / or pharmaceutical forms when at the same time the application (-s) is/are being submitted for identical variation of terms to marketing authorisation and when the documentation is common.				

ⁱ NP – *national procedure*
ⁱⁱ MRP / CMS – *mutual recognition procedure; CMS – LT as Concerned Member State*
ⁱⁱⁱ DCP / CMS – *decentralized procedure; CMS – LT as Concerned Member State*
^{iv} MRP/RMS – *mutual recognition procedure; RMS – LT as Reference Member State*
^v DCP/RMS – *decentralized procedure; RMS – LT as Reference Member State*