Fees for submission application according to the Regulation of the Minister of Health of 16.06.2015 r. on the fees payable in relation to placing medicinal product on the market

Application for Marketing Authorisation

Application form:	Fee (PLN)				
	National procedure	CMS – MRP, DCP (100%)	RMS – MRP, DCP		
			MRP		DCP (150%)
			Preparation of Assessment Report (75%)	Update of Assessment Report (50%)	
full dossier: - art. 8(3) application (art. 10 PF / art. 8(3) EC) - fixed combination (art. 16 ust. 3 PF / 10b EC)	84 000	84 000	63 000	42 000	126 000
next strength	25 200	25 200	63 000	42 000	37 800
next pharmaceutical form	58 800	58 800	63 000	42 000	88 200
well -established use (art. 16 ust. 1 i 2 PF / art. 10a EC)	67 200	67 200	50 400	33 600	100 800
next strength	20 160	20 160	50 400	33 600	30 240
next pharmaceutical form	47 040	47 040	50 400	33 600	70 560
- generic application (art. 15 ust. 1 i 2 PF / art. 10(1) EC)	27 300	27 300	20 475	13 650	40 950
next strength	8 190	8 190	20 475	13 650	12 285
next pharmaceutical form	19 110	19 110	20 475	13 650	28 665
- hybrid application (art. 15 ust. 12 PF / art. 10(3) EC) - similar biological application (art. 15 ust. 7 PF / art. 10(4) EC) - informed consent (art. 16 ust. 5 PF / art. 10c EC)	43 680	43 680	32 760	21 840	65 520
next strength	13 104	13 104	32 760	21 840	19 656
next pharmaceutical form	30 576	30 576	32 760	21 840	45 864
herbal medicinal products other than these, referred to in Article 20a Pharmaceutical Law	27 300	27 300	20 475	13 650	40 950
next strength	8 190	8 190	20 475	13 650	12 285
next pharmaceutical form	19 110	19 110	20 475	13 650	28 665
medicinal products other than these, referred to in Article 20a Pharmaceutical Law, of which Community Monograph was prepared	10 080	10 080	7 560	5 040	15 120
next strength	3 024	3 024	7 560	5 040	4 536
next pharmaceutical form	7 056	7 056	7 560	5 040	10 584
traditional herbal medicinal products referred to in Article 20a Pharmaceutical Law	10 080	10 080	7 560	5 040	15 120
next strength	3 024	3 024	7 560	5 040	4 536
next pharmaceutical form	7 056	7 056	7 560	5 040	10 584

homeopathic medicinal products other than these, referred to in Article 21 Pharmaceutical Law	**27 300**	**Not applicable**			
next pharmaceutical form	**19 110**				
homeopathic medicinal products referred to in Article 21 Pharmaceutical Law:					
- **a list containing fewer than 50 products**	**14 280**	**14 280**	**10 710**	**7 140**	**21 420**
- **a list containing of 50 to 100 products**	**16 800**	**16 800**	**12 600**	**8 400**	**25 200**
- **a list containing the more than 100 products**	**25 200**	**25 200**	**18 900**	**12 600**	**37 800**
unprocessed pharmaceutical raw material used for medicinal purposes, vegetable raw material in a crumbled form, therapeutic mineral, medicinal product, manufactured with the use of industrial methods, pursuant to the provisions included in the Polish Pharmacopoeia	**4 200**	**Not applicable**			
pharmaceutical raw material, designated for manufacturing prescription and pharmaceutical medicines	**1 680**	**Not applicable**			
Any post approval change in the Marketing Authorization	**420**				
Any variation during procedure of granting marketing authorization must be paid according to the fees given in the table below.					

Application for variation

Application	Fee (PLN)		
	Procedure		
	National	EUR-CMS	EUR-RMS
Variation type IA	**2 500**	**2 500**	**3 500**
Variation type IB	**4 200**	**4200**	**5 400**
Variation type II	**16 800**	**16 800**	**20 160**
Worksharing	**Poland is RMS:** **Variation type IA – 3 500** **Variation type IB – 5 460** **Variation type II – 21 840** **Poland is not RMS:** **Variation type IA – 2 500** **Variation type IB – 4 260** **Variation type II – 16 800**		
Herbal medicinal products other than these, referred to in Article 10, Article 16.1, Article 20a and Article 21a Pharmaceutical Law			
Variation type IA	**937**	**Not applicable**	
Variation type IB	**1 575**		
Variation type II	**4 200**		
Worksharing	**Poland is RMS:** **Variation type IA – 1 312** **Variation type IB – 2 047** **Variation type II – 5 460** **Poland is not RMS:** **Variation type IA – 937** **Variation type IB – 1 575** **Variation type II – 4 200**		
Traditional herbal medicinal products referred to in Article 20a Pharmaceutical Law, and medicinal products other than these, referred to in Article 20a Pharmaceutical Law, of which Community Monograph was prepared.			
Variation type IA	**937**	**Not applicable**	
Variation type IB	**1 575**		
Variation type II	**4 200**		
Homeopathic medicinal products referred to in Article 21 Pharmaceutical Law			
Variation type IA	**1 250**	**Not applicable**	

Variation type IB	**2 100**		
Variation type II	**8 400**		
- Unprocessed pharmaceutical raw material used for medicinal purposes, vegetable raw material in a crumbled form, therapeutic mineral, medicinal product, manufactured with the use of industrial methods, pursuant to the provisions included in the Polish Pharmacopoeia - pharmaceutical raw material, designated for manufacturing prescription and pharmaceutical medicines: variation type IA, IB, II	**1 050**	**Not applicable**	
Transfer of a marketing authorisation to a new holder with Article 32 Pharmaceutical Law	**4200**	**Not applicable**	
The fee for other variations resulting from administrative activities which are a consequence of the issued marketing authorisation, including issuing a duplicate	**420**		
Notification in accordance with Article 31.1c Pharmaceutical Law	**420**		
Article 61(3) Notification– Directive 2001/83/EC	**Not applicable**	**420**	
Variation in accordance with art. 31.1b Pharmaceutical Law when Poland is not RMS: - change in the name or address of the marketing authorisation holder in other than Poland countries participating in the procedure; - change in the name of the medicinal product in other than Poland countries participating in the procedure; - change in summary of pharmacovigilance system for medicinal products in other than Poland countries participating in the procedure	**Not applicable**	**420**	**Not applicable**
Changes to a summary of pharmacovigilance system for medicinal products	**420**		
Administrative variations which are results of the decisions or acts of local law issued by other bodies irrespective of the will of the marketing authorisation holder	**420**		
Minor type IA variation concerning new, updated or deletion of European Pharmacopoeial TSE Certificate of suitability for an active	**420**		

substance/starting material/reagent/intermediate/or excipient irrespective of number of certificates	
Application form containing the same type IA variation to more than one marketing authorization (according to § 7.1)	**The fee for each variation to the terms of the first marketing authorization included in the application form is 100% of the fee for a single variation, the fee for each variation to the terms of subsequent marketing authorizations included in the application form is 80% of the fee for a single variation.**
Application form containing the same type IB or type II variation to more than one marketing authorization (according to § 7.2)	**The fee for each variation to the terms of the first marketing authorization included in the application form is 100% of the fee for a single variation, the fee for each variation to the terms of subsequent marketing authorizations included in the application form is 80% of the fee for a single variation.**
Application form containing several type IA, type IB or type II variations to one marketing authorization (according to § 8.1)	**The fee for all variations to the terms of one marketing authorization is 200% of the fee for a single variation, for which the highest fee is charged, but not more than the total amount charged for variations included in the application form.**
Application form containing only type IA, variations to one marketing authorization (according to § 8.2)	**The application fee is a sum fee for each change in a proposal**
Application form containing several type IA, type IB or type II variations to more than one marketing authorization (according to § 9.1)	**The fee for all variations to the terms of one marketing authorization is 200% of the fee for a single variation, for which the highest fee is charged, but not more than the total amount charged for variations included in the application form. The fee for all variations to the terms of subsequent marketing authorizations included in the application form is 80% of the fee for all variations to the terms of the first marketing authorization included in the application form.**
If application form includes the same type II variation concerning changes in SmPC, labelling or PIL and the medicinal products included in these application form differ only by the strength or pharmaceutical form, the fee for variation to the terms of the first marketing authorization included in the application form is 100% of the fee for a single variation, the fee for each variation to the terms of subsequent marketing authorizations included in the application form is 10% of the fee for a single variation (according to § 10).	

Application for Renewal or Withdrawal of Marketing Authorisation

Renewal in European Procedures	National procedure	CMS	RMS
	10 500	10 500	13 650
Renewal **herbal medicinal products referred to in Article 10 and Article 16.1 Pharmaceutical Law, other than these, referred to in Article 20a Pharmaceutical Law, and homeopathic medicinal products referred to in Article 10 and Article 16.1 Pharmaceutical Law, other than these, referred to in Article 21 Pharmaceutical Law**	10 500	10 500	13 650
Renewal **traditional herbal medicinal products referred to in Article 20a Pharmaceutical Law, and herbal medicinal products other than these, referred to in Article 20a Pharmaceutical Law, of which Community Monograph was prepared**	4 200	4 200	5 460
Renewal **herbal medicinal products other than these, referred to in Article 10, Article 16.1, Article 20a and Article 21 Pharmaceutical Law**	4 200	4 200	5 460
Renewal **homeopathic medicinal products referred to in Article 21 Pharmaceutical Law** **- a list containing fewer than 50 products** **- a list containing of 50 to 100 products** **- a list containing the more than 100 products**	 **3 108** **6 132** **9 492**	 **3 108** **6 132** **9 492**	 **4 040** **7 972** **12 340**
Renewal **unprocessed pharmaceutical raw material used for medicinal purposes, vegetable raw material in a crumbled form, medicinal product manufactured with the use of industrial methods, pursuant to the provisions included in the Polish Pharmacopoeia**	2 100	Not applicable	
Renewal **pharmaceutical raw material, designated for manufacturing prescription and pharmaceutical medicines**	1 050	Not applicable	
Withdrawal of marketing authorisation	420		

Annual fees

Annual fee (each MA)	National procedure	CMS	RMS
	2 100	2 100	2 730
Herbal medicinal products referred to in Article 10 and Article 16.1 Pharmaceutical Law, other than these, referred to in Article 20a Pharmaceutical Law, and homeopathic medicinal products referred to in Article 10 and Article 16.1 Pharmaceutical Law, other than these, referred to in Article 21 Pharmaceutical Law	2 100	2 100	2 730
Traditional herbal medicinal products referred to in Article 20a Pharmaceutical Law, and herbal medicinal products other than these, referred to in Article 20a Pharmaceutical Law, of which Community Monograph was prepared	840	840	1 092
Herbal medicinal products other than these, referred to in Article 10, Article 16.1, Article 20a and Article 21 Pharmaceutical Law	840	840	1 092
Homeopathic medicinal products referred to in Article 21 Pharmaceutical Law - a list containing fewer than 50 products - a list containing of 50 to 100 products - a list containing the more than 100 products	 621,60 1226,40 1898,40	 621,60 1226,40 1898,40	 808 1594,40 2468
Unprocessed pharmaceutical raw material used for medicinal purposes, vegetable raw material in a crumbled form, medicinal product manufactured with the use of industrial methods, pursuant to the provisions included in the Polish Pharmacopoeia	420	Not applicable	
Pharmaceutical raw material, designated for manufacturing prescription and pharmaceutical medicines	210	Not applicable	

Application for the authorisation in accordance with the provisions of art 21a of the Pharmaceutical Law

Application for parallel import	6 132
Variations for parallel import	1 594
Renewal for parallel import	5 250
Other variations resulting from the administrative activities connected with the granted parallel import licence	420

Application in accordance with the provisions of art. 33a par. 2 of the Pharmaceutical Law (exception from sunset clause)

Granting the decision on exception from sunset clause (each MA)	4 200

Applications for authorisation of a clinical trial on a medicinal product for human use according to the regulation of the Minister of Health of 02.05.2012 (journal of laws of 2012, item 491)

Phase I-III	**8 000**
Bioequivalence trials	**7 000**
Phase IV	**4 000**
Non-commercial trials	**2 000**

* PF - the Pharmaceutical Law of 6 September 2001 as amended (Journal of Laws of 2008 No 45, item 271, as amended.)
* EC - 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