Fees for submission application according to the Regulation of the Minister of Health of 02.03.2011 amending Regulation on the fees payable in relation to placing medicinal product on the market (Journal of Laws of 2011 No 61, item 314)

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) - informed consent (art. 16 ust. 5 PF / art. 10c 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) - similar biological application (art. 15 ust. 7 PF / art. 10(4) 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)	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**	**7 560**
- **a list containing the more than 100 products**	**25 200**	**25 200**	**18 900**	**12 600**	**26 460**
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 in National Procedures

Application	Fee (PLN)
Variation type I	**4 200**
Variation type II	**16 800**
Transfer of a marketing authorisation to a new holder with Article 32 Pharmaceutical Law	**4 200**
Notification in accordance with Article 31.1c Pharmaceutical Law	**420**
Variation type I **herbal medicinal products other than these, referred to in Article 20a Pharmaceutical Law, and homeopathic medicinal products other than these, referred to in Article 21 Pharmaceutical Law**	**4 200**
Variation type II - **herbal medicinal products other than these, referred to in Article 20a Pharmaceutical Law, and homeopathic medicinal products other than these, referred to in Article 21 Pharmaceutical Law**	**16 800**
Variation type I - **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.**	**1 575**
Variation type II - **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.**	**4 200**
Variation type I - **homeopathic medicinal products referred to in Article 21 Pharmaceutical Law**	**2 100**
Variation type II - **homeopathic medicinal products referred to in Article 21 Pharmaceutical Law**	**8 400**
Variation type I - **antiseptic, referred to in art. 17 paragraph 3 of Pharmaceutical Law**	**1 575**
Variation type II - **antiseptic, referred to in art. 17 paragraph 3 of Pharmaceutical Law**	**4 200**
Variation type I and type II - **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**	**1 050**
Where several application forms including type II variations concerning changes in SmPC, labelling or PIL are submitted simultaneously and where the medicinal products included in these application forms differ only by the strength or pharmaceutical form, the fee for submission of subsequent application forms is 10% of the fee for submission of the single application form.	

Application for variation in European Procedure

<table>
<tr><th colspan="2" rowspan="2">Application</th><th colspan="3">Fee [PLN]</th></tr>
<tr><th>PL-CMS</th><th>PL-RMS</th><th>PL - Reference Authority for worksharing</th></tr>
<tr><td colspan="2">Type IA</td><td>4 200</td><td>5 040</td><td>5 460</td></tr>
<tr><td colspan="2">Type IB</td><td>4 200</td><td>5 040</td><td>5 460</td></tr>
<tr><td colspan="2">Type II</td><td>16 800</td><td>20 160</td><td>21 840</td></tr>
<tr><td colspan="2">Article 61(3) Notification– Directive 2001/83/EC</td><td colspan="3">420</td></tr>
<tr><td colspan="2">Variations to the existing Detailed Description of Pharmacovigilance System</td><td colspan="3">420</td></tr>
<tr><td colspan="2">Grouping of variations type IA
(Article 7(2a) of Regulation (EC) No 1234/2008)</td><td colspan="3">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.</td></tr>
<tr><td colspan="2">Grouping of variations from
Article 7(2b) of Regulation (EC) No 1234/2008</td><td colspan="3">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.</td></tr>
<tr><td rowspan="2">Worksharing</td><td>Single variation to the terms of several marketing authorizations</td><td colspan="3">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 variation to the terms of subsequent marketing authorizations included in the application form is 80% of the fee for a single variation.</td></tr>
<tr><td>Grouping of variations from
Article 7(2b) of Regulation (EC)
No 1234/2008</td><td colspan="3">The fee for all variations to the term of the first marketing authorization included in the application form 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.</td></tr>
<tr><td colspan="4">Where several application forms including type II variations concerning changes in SmPC, labelling or PIL are submitted simultaneously and where the medicinal products included in these application forms differ only by the strength or pharmaceutical form, the fee for submission of subsequent application forms is 10% of the fee for submission of the single application form.</td></tr>
</table>

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 other than these, referred to in Article 20a Pharmaceutical Law, and homeopathic medicinal products 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 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 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 antiseptic, referred to in art. 17 paragraph 3 of Pharmaceutical Law	4 200		
Renewal 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	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 other than these, referred to in Article 20a Pharmaceutical Law, and homeopathic medicinal products 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 medicinal products other than these, referred to in Article 20a Pharmaceutical Law, of which Community Monograph was prepared.	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	 622 1 226 1 898	 622 1 226 1 898	 808 1 594 2 468
Antiseptic, referred to in art. 17 paragraph 3 of Pharmaceutical Law	840		

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	**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	**3 108**
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