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)	87 500	87 500	65 625	43 750	131 250
next strength	26 250	26 250	65 625	43 750	39 375
next pharmaceutical form	61 250	61 250	65 625	43 750	91 875
well -established use (art. 16 ust. 1 i 2 PF / art. 10a EC)	70 000	70 000	52 500	35 000	105 000
next strength	21 000	21 000	52 500	35 000	31 500
next pharmaceutical form	49 000	49 000	52 500	35 000	73 500
- 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)	28 438	28 438	21 328	14 219	42 656
next strength	8 531	8 531	21 328	14 219	12 797
next pharmaceutical form	19 906	19 906	21 328	14 219	29 859
hybrid application (art. 15 ust. 12 PF / art. 10(3) EC)	45 500	45 500	34 125	22 750	68 250
next strength	13 650	13 650	34 125	22 750	20 475
next pharmaceutical form	31 850	31 850	34 125	22 750	47 775
herbal medicinal products other than these, referred to in Article 20a Pharmaceutical Law	28 438	28 438	21 328	14 219	42 656
next strength	8 531	8 531	21 328	14 219	12 797
next pharmaceutical form	19 906	19 906	21 328	14 219	29 859
medicinal products other than these, referred to in Article 20a Pharmaceutical Law, of which Community Monograph was prepared	10 500	10 500	7 875	5 250	15 750
next strength	3 150	3 150	7 875	5 250	4 725
next pharmaceutical form	7 350	7 350	7 875	5 250	11 025

traditional herbal medicinal products referred to in Article 20a Pharmaceutical Law	**10 500**	**10 500**	**7 875**	**5 250**	**15 750**
next strength	**3 150**	**3 150**	**7 875**	**5 250**	**4 725**
next pharmaceutical form	**7 350**	**7 350**	**7 875**	**5 250**	**11 025**
homeopathic medicinal products other than these, referred to in Article 21 Pharmaceutical Law	**28 438**	**Not applicable**			
next pharmaceutical form	**19 906**				
homeopathic medicinal products referred to in Article 21 Pharmaceutical Law:					
- **a list containing fewer than 50 products**	**14 875**	**14 875**	**11 156**	**7 438**	**22 313**
- **a list containing of 50 to 100 products**	**17500**	**17 500**	**13 125**	**8 750**	**7 875**
- **a list containing the more than 100 products**	**26 250**	**26 250**	**19 688**	**13 125**	**27 563**
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	**4 375**	**Not applicable**			
pharmaceutical raw material, designated for manufacturing prescription and pharmaceutical medicines	**1 750**	**Not applicable**			
Any post approval change in the Marketing Authorization	**438**				
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	**4 375**
Variation type II	**17 500**
Transfer of a marketing authorisation to a new holder with Article 32 Pharmaceutical Law	**4 375**
Notification in accordance with Article 31.1c Pharmaceutical Law	**438**
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**	**4 375**
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**	**17 500**
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.**	**1 641**
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.**	**4 375**
Variation type I - **homeopathic medicinal products referred to in Article 21 Pharmaceutical Law**	**2 188**
Variation type II - **homeopathic medicinal products referred to in Article 21 Pharmaceutical Law**	**8 750**
Variation type I - **antiseptic, referred to in art. 17 paragraph 3 of Pharmaceutical Law**	**1 641**
Variation type II - **antiseptic, referred to in art. 17 paragraph 3 of Pharmaceutical Law**	**4 375**
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**	**1 094**
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>4 375</td><td>5 250</td><td>5 688</td></tr>
<tr><td colspan="2">Type IB</td><td>4 375</td><td>5 250</td><td>5 688</td></tr>
<tr><td colspan="2">Type II</td><td>17 500</td><td>21 000</td><td>22 750</td></tr>
<tr><td colspan="2">Article 61(3) Notification– Directive 2001/83/EC</td><td colspan="3">438</td></tr>
<tr><td colspan="2">Variations to the existing Detailed Description of Pharmacovigilance System</td><td colspan="3">438</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
	10 938	10 938	14 219
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**	**10 938**	**10 938**	**14 219**
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.**	**4 375**	**4 375**	**5 688**
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**	**3 238** **6 388** **9 888**	**3 238** **6 388** **9 888**	**4 209** **8 304** **12 854**
Renewal **antiseptic, referred to in art. 17 paragraph 3 of Pharmaceutical Law**	**4 375**		
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**	**2 188**	**Not applicable**	
Renewal **pharmaceutical raw material, designated for manufacturing prescription and pharmaceutical medicines**	**1 094**	**Not applicable**	
Withdrawal of marketing authorisation	**438**		

Annual fees

Annual fee (each MA)	National procedure	CMS	RMS
	2 188	2 188	2 844
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	2 188	2 188	2 844
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.	875	875	1 138
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	 648 1 278 1 978	 648 1 278 1 978	 842 1 661 2 571
Antiseptic, referred to in art. 17 paragraph 3 of Pharmaceutical Law	875		
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	438	Not applicable	
Pharmaceutical raw material, designated for manufacturing prescription and pharmaceutical medicines	219	Not applicable	

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

Application for parallel import	6 388
Variations for parallel import	3 238
Renewal for parallel import	5 469
Other variations resulting from the administrative activities connected with the granted parallel import licence	438

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)	4 375

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