

**Fees for submission application according to the Regulation of the Minister of Health
Of 08.07.2015 r. on the fees payable in relation to placing medicinal product on the market**

Application for Marketing Authorisation

Application for Marketing Authorisation	Fee (PLN)			
	National procedure	CMS – MRP, DCP (100%)	RMS – MRP, DCP	
			Preparation of Assessment Report MRP (75%)	DCP (150%)
original veterinary medicinal product art. 10(3) application (art. 10(2a,2b) PF / art. 12(3) EC), or fixed combination (art. 16a(4) PF / 13b EC)	58800	58800	44100	88200
original veterinary medicinal product art. 10(3) application (art. 10(2a,2b) PF / art. 12(3) EC), or fixed combination (art. 16a(4) PF / 13b EC) intended for food producing animals: fishes, insects, animals bred for fur, pigeons	15750	15750	11812,50	23625
well -established use (art. 16a(1) PF / art. 13a EC)	42000	42000	31500	63000
well -established use (art. 16a(1) PF / art. 13a EC) intended for food producing animals: fishes, insects, animals bred for fur, pigeons	10080	10080	7560	15120
generic application (art. 15a(1) PF / art. 13(1) EC)	22680	22680	17010	34020
generic application (art. 15a(1) PF / art. 13(1) EC) intended for food producing animals: fishes, insects, animals bred for fur, pigeons	7560	7560	5670	11340
- hybrid application (art. 15a(7) PF / art. 13(4) EC) - similar biological application (art. 15a(6) PF / art. 13(3) EC) - informed consent (art. 16a(3) PF / art. 13c EC)	33600	33600	25200	50400
- hybrid application (art. 15a(7) PF / art. 13(4) EC) - similar biological application (art. 15a(6) PF / art. 13(3) EC) - informed consent (art. 16a(3) PF / art. 13c EC) intended for food producing animals: fishes, insects, animals bred for fur, pigeons	9240	9240	6930	13860

herbal medicinal veterinary products other than these, referred to in Article 20a Pharmaceutical Law	27720	27720	20790	41580
herbal medicinal veterinary products other than these, referred to in Article 20a Pharmaceutical Law intended for food producing animals: fishes, insects, animals bred for fur, pigeons	7560	7560	5670	11340
homeopathic medicinal veterinary products other than these, referred to in Article 21 Pharmaceutical Law	27720	Not applicable		
homeopathic medicinal veterinary products other than these, referred to in Article 21 Pharmaceutical Law intended for food producing animals: fishes, insects, animals bred for fur, pigeons	7560	Not applicable		
homeopathic veterinary medicinal products referred to in Article 21 Pharmaceutical Law:				
- a list containing fewer than 50 products	10080	10080	7560	15120
- a list containing of 50 to 100 products	14280	14280	10710	21420
- a list containing the more than 100 products	16800	16800	12600	25200
Veterinary medicinal products referred to in Article 20 Pharmaceutical Law	2100	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			

For each additional pharmaceutical form, submitted at the same time as the initial application for authorisation, the fee is 70% of the first application fee.

For each additional strength, submitted at the same time as the initial application for authorisation, the fee is 30% of the first application fee.

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	2 318	2 318	3 246
Variation type IB	3 864	3 864	4 637
Variation type II	15 960	15 960	19 152
Variation type II for veterinary medicinal product for food producing animals: fishes, insects, animals bred for fur, pigeons	7140	7140	8 568
Worksharing	<p>Poland is RMS: Variation type IA – 3 516 Variation type IB – 5 023 Variation type II – 20 748 Variation type II for veterinary medicinal product for food producing animals: fishes, insects, animals bred for fur, pigeons - 9 282</p> <p>Poland is not RMS: Variation type IA – 2 318 Variation type IB – 3 864 Variation type II – 15 960 Variation type II for veterinary medicinal product for food producing animals: fishes, insects, animals bred for fur, pigeons - 7 140</p>		
Herbal veterinary medicinal products other than these, referred to in, Article 20a and Article 21 Pharmaceutical Law			
Variation type IA	2 318	2 318	3 246
Variation type IB	3 864	3 864	4 637
Variation type II	15 960	15 960	19 152
Variation type II for veterinary medicinal product for food producing animals: fishes, insects, animals bred for fur, pigeons	7140	7140	8 568
Worksharing	<p>Poland is RMS: Variation type IA – 3 516 Variation type IB – 5 023 Variation type II – 20 748 Variation type II for veterinary medicinal product for food producing animals: fishes, insects, animals bred for fur, pigeons - 9 282</p> <p>Poland is not RMS: Variation type IA – 2 318 Variation type IB – 3 864</p>		

	Variation type II – 15 960 Variation type II for veterinary medicinal product for food producing animals: fishes, insects, animals bred for fur, pigeons - 7 140		
Homeopathic veterinary medicinal products referred to in Article 21 Pharmaceutical Law			
Variation type IA	1 008	1 008	1411
Variation type IB	1 680	1 680	2 016
Variation type II	4 200	4 200	5 040
Worksharing	Poland is RMS: Variation type IA – 1 529 Variation type IB – 2 184 Variation type II – 5 460 Poland is not RMS: Variation type IA – 1 008 Variation type IB – 1 680 Variation type II – 4 200		
Veterinary medicinal products, referred to in, Article 20			
Variation type I	420	Not applicable	
Variation type II	1 680	Not applicable	
Pharmaceutical raw materials for the preparation of prescription and pharmaceutical medicines.			
Changing the data covered by the authorization and the change documentation as a basis for authorization	1 050	Not applicable	
Transfer of a marketing authorisation to a new holder with Article 32 Pharmaceutical Law (Acts. U. of 2008. No. 45, item. 271, as amended.)	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		
The fee for submitting the application for modification referred to in Art. 31 of the Act - changes in labelling packaging or in a leaflet without affecting the SPC	420		

<p>Variation in accordance with art. 31.1b Pharmaceutical Law when Poland is not RMS:</p> <ul style="list-style-type: none"> - 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 veterinary 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
<p>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</p>	420		
<p>Changes to a summary of pharmacovigilance system for veterinary medicinal products</p>	420		
<p>Minor type IA variation concerning new, updated or deletion of European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient irrespective of number of certificates</p>	420		
<p>Application form containing the same type IA variation to more than one marketing authorization (according to § 7.1)</p>	<p>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.</p>		
<p>Application form containing the same type IB or type II variation to more than one marketing authorization (according to § 7.2)</p>	<p>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.</p>		
<p>Application form containing several type IA, type IB or type II variations to one marketing authorization (according to § 8.1)</p>	<p>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. Where fees for all variation to the terms of one marketing authorisation are equal, the fee is 200% of the fee for a single variation.</p>		
<p>Application form containing only type IA, variations to one marketing authorization (according to § 8.2)</p>	<p>The application fee is a sum fee for each change in a proposal</p>		
<p>Application form containing several type IA, type IB or type II variations to more than one marketing authorization</p>	<p>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</p>		

<p>(according to § 9.1)</p>	<p>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. Where fees for all variation to the terms of one marketing authorisation are equal, the fee is 200% of the fee for a single variation.</p>
<p>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).</p>	

Application for renewal or withdrawal of Marketing Authorisation

Application form	Fee (PLN)		
	National procedure	CMS	RMS
Renewal for veterinary medicinal product	10500	10500	13650
Renewal for veterinary medicinal product intended for food producing animals: fishes, insects, animals bred for fur, pigeons	5250	5250	6825
Renewal for herbal veterinary medicinal product other than these, referred to in Article 20a Pharmaceutical Law or for homeopathic veterinary medicinal product other than these, referred to in Article 21 Pharmaceutical Law	10500	10500	13650
Renewal for herbal veterinary medicinal product other than these, referred to in Article 20a Pharmaceutical Law or for homeopathic veterinary medicinal product other than these, referred to in Article 21 Pharmaceutical Law intended for food producing animals: fishes, insects, animals bred for fur, pigeons	5250	5250	6825
Renewal for homeopathic veterinary medicinal product referred to in Article 21 Pharmaceutical Law			
- a list containing fewer than 50 products	2520	2520	3276
- a list containing of 50 to 100 products	4200	4200	5460
- a list containing the more than 100 products	8400	8400	10920
Renewal for veterinary medicinal product referred to in Article 20 Pharmaceutical Law	1050	Not applicable	
Renewal pharmaceutical raw material, designated for manufacturing prescription and pharmaceutical medicines	1050	Not applicable	
Withdrawal of Marketing Authorisation	420		

Annual fees

Annual fee	Fee (PLN)		
	National procedure	CMS	RMS
To Marketing Authorisation for veterinary medicinal product	2100	2100	2730
To Marketing Authorisation for veterinary medicinal product for food producing animals: fishes, insects, animals bred for fur, pigeons	1050	1050	1365
To Marketing Authorisation for herbal veterinary medicinal product other than these, referred to in Article 20a Pharmaceutical Law and homeopathic veterinary medicinal product other than these, referred to in Article 21 Pharmaceutical Law	2100	2100	2730

To Marketing Authorisation for herbal veterinary medicinal product other than these, referred to in Article 20a Pharmaceutical Law or for homeopathic veterinary medicinal product other than these, referred to in Article 21 Pharmaceutical Law intended for food producing animals: fishes, insects, animals bred for fur, pigeons	1050	1050	1365
To Marketing Authorisation for homeopathic veterinary medicinal product referred to in Article 21 Pharmaceutical Law			
- a list containing fewer than 50 products	504	504	655,20
- a list containing of 50 to 100 products	840	840	1092
- a list containing the more than 100 products	1680	1680	2184
To Marketing Authorisation for veterinary medicinal product referred to in Article 20 Pharmaceutical Law	210	Not applicable	
To Marketing Authorisation 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	6132 PLN
Variations for parallel import	1594 PLN
Renewal for parallel import	5250 PLN
Other variations resulting from the administrative activities connected with the granted parallel import authorisation	420 PLN

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)	4200 PLN
--	-----------------

Applications for authorisation of veterinary clinical trial according to the regulation of the Minister of Health of 21.11.2012 (Journal of Laws of 2012, item 1363)

For veterinary clinical trials of:	Fee (PLN)
1) Tested veterinary medicinal product not authorised in Poland	7 000
2) Tested veterinary medicinal product authorised in Poland	4 000
3) Residues of veterinary medicinal product in the tissues	4 000

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

* EC - Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use