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** **- a list containing of 50 to 100 products** **- a list containing the more than 100 products**	 **10080** **14280** **16800**	 **10080** **14280** **16800**	 **7560** **10710** **12600**	 **15120** **21420** **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	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 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		
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	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 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**		
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**		

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 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**
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**		
Changes to a summary of pharmacovigilance system for veterinary medicinal products	**420**		
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	**420**		
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. 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.**		
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	**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**		

(according to § 9.1)	**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.**
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

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 - a list containing of 50 to 100 products - a list containing the more than 100 products	 2520 4200 8400	 2520 4200 8400	 3276 5460 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** **- a list containing of 50 to 100 products** **- a list containing the more than 100 products**	 **504** **840** **1680**	 **504** **840** **1680**	 **655,20** **1092** **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