FEES RELATED TO MARKETING AUTHORISATION FOR VETERINARY MEDICINAL PRODUCTS according to the Regulation of the Minister of Health of 31 March 2023 on the determination and payment of fees related to the marketing authorisation of a veterinary medicinal product

Application for:	Fee (PLN)		
	National procedure	DCP, MRP, SRP where Poland is not a reference member state (CMS)	DCP, MRP, SRP where Poland is a reference member state (RMS)
Variation requiring assessment in accordance with Article 62 of Regulation (EU) 2019/6	16800	16800	20200
Variation requiring assessment in accordance with Article 62 of Regulation (EU) 2019/6, One-off alignment of the product information with version 9.0 of the QRD templates (G.I.18)	3500	3500	4200
Variation requiring assessment in accordance with Article 62 of Regulation (EU) 2019/6 for veterinary medicinal product intended for food-producing insects, farmed fish, fur animals or pigeons whose tissues or products are intended for human consumption	7500	7500	9000
Variation requiring assessment in accordance with Article 62 of Regulation (EU) 2019/6 for homeopathic veterinary medicinal products other than these, referred to in Article 85 of Regulation (EU) 2019/6	16800	16800	20200
Variation requiring assessment in accordance with Article 62 of Regulation (EU) 2019/6 for homeopathic veterinary medicinal products other than these, referred to in Article 85 of Regulation (EU) 2019/6 intended for food-producing insects, farmed fish, fur animals or pigeons whose tissues or products are intended for human consumption	7500	7500	9000
Variation in terms of registration of homeopathic veterinary medicinal products referred to in Article 87 of Regulation (EU) 2019/6	4400	Not applicable	

Variation in parallel trade authorisation referred to in Article 102 of Regulation (EU) 2019/6	1000	Not applicable
Transfer of a marketing authorisation to a new holder in accordance with Article 32 of Pharmaceutical Law	4400	Not applicable
Variation requiring assessment referred to in Article 62 in connection with articles 64 or 65 of Regulation (EU) 2019/6	If the MAH submits an application for several variations to the same marketing authorization for a veterinary medicinal product, the fee is 200% of the fee for a single variation.	
	If the MAH submits an application for the same variation to more than one marketing authorization for a veterinary medicinal product, the fee for the variation to the first authorisation mentioned in the application is 100% of the fee for the variation; the fee for the variation in the next marketing authorisation is 80% of the fee for the variation in the first marketing authorisation.	
	If the MAH submits an application for several of the same variations to more than one marketing authorisation for a veterinary medicinal product, the fee for all variations to the first authorisation shall be 200% of the variation fee; the fee for variations to the next marketing authorisation included in the application is 80% of the fee for the first marketing authorisation.	