

Translation of SAM public pricelist for marketing authorisation of veterinary medicinal products in Latvia (for reference only)

According to the Paragraph 4 of Cabinet Regulation No. 61 of 17 January 2006 as amended:

“State Agency of Medicines upon the evaluation of data provided in the application submitted by the marketing authorisation holder or applicant of the marketing authorisation is empowered to adopt the decision regarding to exemption from annual fees of post-marketing authorisation surveillance for the medicinal product or veterinary medicinal product if turnover of the medicinal product or the veterinary medicinal product in a previous calendar year not exceeded 1500 LVL, and the medicinal product is find necessary for maintenance of the treatment course” (refer to point 54 in the following table).

Extract from the pricelist

No.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
50.	Application and attached documentation expertise for authorisation of veterinary medicinal products in accordance with a national registration procedure				
50.1.	basic pharmaceutical form and strength	application	700.00	0.00	700.00
50.1.1.	each additional pharmaceutical form	application	300.00	0.00	300.00
50.1.2.	each additional strength	application	200.00	0.00	200.00
50.2.	homeopathic veterinary medicinal product	application	150.00	0.00	150.00
51.	Application and attached documentation expertise for renewal of veterinary medicinal products authorised in accordance with a national registration procedure				
51.1.	single pharmaceutical form and strength	application	300.00	0.00	300.00
51.1.1.	each additional pharmaceutical form	application	150.00	0.00	150.00
51.1.2.	each additional strength	application	90.00	0.00	90.00
51.2.	renewal of homeopathic veterinary medicinal product	application	90.00	0.00	90.00
52.	Approval of variations on documentation for authorisation of veterinary medicinal products				
52.1.	minor Type IA notification	application	100.00	0.00	100.00
52.2.	minor Type IB notification	application	150.00	0.00	150.00
52.3.	major type II variation requiring detailed scientific evaluation of documentation	application	300.00	0.00	300.00
52.4.	major type II variation not requiring detailed scientific evaluation of documentation	application	100.00	0.00	100.00

52.5.	major type II variation related to the change of the marketing authorisation holder (new marketing authorisation holder and current marketing authorisation holder are not the same person/entity)	application	100.00	0.00	100.00
52.6.	changes in package leaflet or labelling not connected to the summary of product characteristics	application	100.00	0.00	100.00
53.	Application and attached documentation expertise for authorisation of veterinary medicinal products in accordance with mutual recognition procedure where Latvia is a concerned Member State				
53.1.	basic pharmaceutical form	application	1200.00	0.00	1200.00
53.2.	each additional pharmaceutical form	application	600.00	0.00	600.00
53.3.	each additional strength or packaging volume, each application for veterinary medicinal product with identical authorisation documentation and with different invented names and the same or different Marketing Authorisation Holder (multiple applications) if submitted simultaneously	application	400.00	0.00	400.00
53. ¹	Application and attached documentation expertise for authorisation of veterinary medicinal products in accordance with decentralised procedure where Latvia is a concerned Member State				
53. ¹ 1.	basic pharmaceutical form	application	1200.00	0.00	1200.00
53. ¹ 2.	each additional pharmaceutical form	application	600.00	0.00	600.00
53. ¹ 3.	each additional strength or packaging volume, each application for veterinary medicinal product with identical authorisation documentation and with different invented names and the same or different Marketing Authorisation Holder (multiple applications) if submitted simultaneously	application	400.00	0.00	400.00
53. ²	Application and attached documentation expertise for renewal of veterinary medicinal products authorised in accordance with mutual recognition procedure or with decentralised procedure where Latvia				

	is the following:				
53. ² 1.	a reference Member State				
53. ² 1.1.	single pharmaceutical form	application	800.00	0.00	800.00
53. ² 1.2.	each additional pharmaceutical form	application	500.00	0.00	500.00
53. ² 1.3.	each additional strength or packaging volume, each application for veterinary medicinal product with identical authorisation documentation and with different invented names and the same or different Marketing Authorisation Holder (multiple applications) if submitted simultaneously	application	200.00	0.00	200.00
53. ² 1.4.	for procedure (additionally to sections 53. ² 1.1., 53. ² 1.2. and 53. ² 1.3.)	procedure number	1500.00	0.00	1500.00
53. ² 2.	a concerned Member State				
53. ² 2.1.	basic pharmaceutical form	application	800.00	0.00	800.00
53. ² 2.2.	each additional pharmaceutical form	application	500.00	0.00	500.00
53. ² 2.3.	each additional strength or packaging volume, each application for veterinary medicinal product with identical authorisation documentation and with different invented names and the same or different Marketing Authorisation Holder (multiple applications) if submitted simultaneously	application	200.00	0.00	200.00
54.	Annual fee for post-marketing authorisation surveillance of veterinary medicinal products (per year)				
54.1.	each pharmaceutical form and strength	marketing authorisation number	350.00	0.00	350.00
54.2.	each authorised homeopathic veterinary medicinal product	marketing authorisation number	100.00	0.00	100.00
58.	Application and attached documentation expertise for authorisation of veterinary medicinal products in accordance with mutual recognition procedure where Latvia is a reference Member State				
58.1.	basic pharmaceutical form	application	2000.00	0.00	2000.00
58.1.1.	each additional pharmaceutical form	application	1200.00	0.00	1200.00

58.1.2.	each additional strength or packaging volume, each application for veterinary medicinal product with identical authorisation documentation and with different invented names and the same or different Marketing Authorisation Holder (multiple applications) if submitted simultaneously	application	600.00	0.00	600.00
58.2.	Application and attached documentation expertise for authorisation of veterinary medicinal products in accordance with decentralised procedure where Latvia is a reference Member State				
58.2.1.	basic pharmaceutical form	application	2000.00	0.00	2000.00
58.2.2.	each additional pharmaceutical form	application	1200.00	0.00	1200.00
58.2.3.	each additional strength or packaging volume, each application for veterinary medicinal product with identical authorisation documentation and with different invented names and the same or different Marketing Authorisation Holder (multiple applications) if submitted simultaneously	application	600.00	0.00	600.00
90.	Issuing of marketing authorisation certificate	marketing authorisation certificate	50.00	0.00	50.00
92.	Issuing of duplicate of the marketing authorisation certificate	duplicate of the marketing authorisation certificate	30.00	0.00	30.00