Cabinet of Ministers Regulation No. 75
Riga, 29th January 2012 (prot. No.6, 26 §)

State Agency of Medicines Publicly Available Paid Service Price List

Issued in accordance with Article 5, Paragraph 1 of the Law on Public Agencies

1. This Regulation shall determine the price list of paid services provided by the State Agency of Medicines (hereinafter - price list) and the procedure for payment.

2. The State Agency of Medicines shall provide paid services in accordance with the price list (Annex).

3. Basing on an application from the marketing authorisation holder the State Agency of Medicines shall have the right to adopt a decision regarding exemption from the annual post-authorisation maintenance fee for medicinal products, if the following requirements have been fulfilled:

3.1. the realisation price of medicinal product is declared in the State Agency of Medicines in accordance with the normative acts regarding the principles for formation of prices of medicinal products;

3.2. the medicinal product is distributed in Latvia, but the turnover in the previous calendar year does not exceed 1500 lats;

3.3. the marketing authorisation holder has reported to the State Agency of Medicines the actual date of the beginning of distribution (marketing) of the medicinal product in Latvia or has reported the medicinal products that are (temporarily or permanently) no longer marketed in Latvia in accordance with the normative acts regarding procedure for distribution of medicinal products.

4. The payment for services provided shall be made in one of the following ways:

4.1. at the State Agency of Medicines by using a payment card;

4.2. at a credit institution or another finance institution that is entitled to perform financial transactions.

5. The service receiver shall make advance payment in full amount for the services mentioned in Section 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 13 of the Annex of this Regulation by using a non-cash transaction.

6. When submitting the documents necessary for receiving services to the State Agency of Medicines, the submitter shall supply one of the following documents verifying the transaction:

6.1. a payment order verified by the credit institution or a printout of the payment made via online banking of the credit institution verifying that the advance payment mentioned in Article 5 of this Regulation has been made (the name of the payer is clearly indicated in the payment printout and it is signed by the payer);

6.2. a check issued by the cash department of the State Agency of Medicines verifying a non-cash transaction with a payment card.

7. The service provision:

7.1. shall be initiated after receiving the payment verifying document mentioned in Article 6 of this Regulation and after the transaction of the appropriate sum in the payment account of the State Agency of Medicines;

7.2. may be discontinued:

7.2.1. if the State Agency of Medicines has adopted the appropriate decision in accordance with Section 31 of the Pharmaceutical Law and normative acts regarding procedure for marketing authorisation of medicinal products;

7.2.2. if the State Agency of Medicines has received an application declining services from the service receiver.

8. When discontinuing the provision of a service the State Agency of Medicines shall charge a fee for the services provided until the discontinuation of service provision from the advance payment mentioned in Article 5 of this Regulation in accordance with the following procedure:

8.1. if primary expertise of the application has been carried out determining the compliance of the marketing authorisation and renewal application with the requirements of the normative acts determining procedure for marketing authorisation of medicinal products - 10 percent of the fee stated.

8.2. if primary expertise of the application has been carried out determining the compliance of the marketing authorisation and renewal application with the requirements of the normative acts determining procedure for marketing authorisation of medicinal products and if the evaluation of the additional data and documentation (expertise on documentation) regarding the services mentioned in Section 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 13 of the Annex of this Regulation has been initiated - 50 percent of the fee stated.

8.3. if the evaluation of the additional data and documentation (expertise on documentation) regarding the services mentioned in Section 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 13 of the Annex of this Regulation has been carried out - 90 percent of the fee stated.

9. In the cases mentioned in Article 8 of this Regulation the State Agency of Medicines, basing on the application from the service receiver regarding return of payment, shall prepare a calculation of estimate expenses and shall return the appropriate sum via a credit institution transaction within 30 calendar days after the application from the service receiver has been received in the State Agency of Medicines. In the application regarding return of payment the service receiver shall provide requisites of the credit institution and the account number where the State Agency of Medicines shall transfer the appropriate sum.

10. The 17th January 2006 Cabinet of Ministers Regulation No. 61 "Regulations Regarding the State Agency of Medicines Publicly Available Paid Service Pricelist" (*"Latvijas Vēstnesis"*, 2006, No. 20; 2007, No. 80; 2008, No. 146; 2009, No. 200; 2010, No. 123, 206; 2011, No. 178, 205; 2012, No. 169) is repealed.

Prime Minister *V. Dombrovskis*

Minister of Health *I. Circene*

Annex to
29th January 2013
Cabinet of Ministers
Regulation No. 75

State Agency of Medicines publicly available paid service price list

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
1	Expertise on documentation for marketing authorisation of medicinal products in the national procedure*				
1.1.	first submitted pharmaceutical form				
1.1.1.	new active substance (except sections 1.1.2. and 1.1.3. of this Annex)	application	4 000.00	0.00	4 000.00
1.1.2.	known active substance, fixed combination (new medicinal product containing at least 2 active substances in a combination that has not been authorised before as a medicinal product with a fixed composition), similar biological medicinal products or medicinal products with well-established medicinal use	application	3 000.00	0.00	3 000.00
1.1.3.	essentially similar medicinal products - generic medicinal products, hybrid application or other application, except applications mentioned in sections 1.4, 1.5, 1.6. and 1.7. of this Annex	application	3 000.00	0.00	3 000.00
1.2	each additional pharmaceutical form or substitution of active substance with a different salt, ester complex or isomer, if they do not differ significantly in properties with regard to safety and efficacy	application	2 000.00	0.00	2 000.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
1.3.	each additional strength or packaging of medicinal products, including substitution of active substance with a different salt, ester complex or isomer, if they do not differ significantly in properties with regard to safety and efficacy, as well as each application for medicinal products with identical authorisation documentation, but with different invented names and with the same or a different marketing authorisation holder (multiple applications, if notified simultaneously)	application	1 000.00	0.00	1 000.00
1.4.	traditional use herbal medicinal products (herbal medicinal products authorised in a simplified authorisation procedure)				
1.4.1.	composition of three or less active substances	application	1 000.00	0.00	1 000.00
1.4.2.	composition more than three active substances	application	1 500.00	0.00	1 500.00
1.5.	homeopathic medicinal products with therapeutic indications	application	1 000.00	0.00	1 000.00
1.6.	homeopathic medicinal products without therapeutic indications authorised in simplified authorisation procedure	application	400.00	0.00	400.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
1.7.	anthroposophic medicinal products described in the officially used pharmacopoeia and produced using the homeopathic method	application	400.00	0.00	400.00
2	Expertise on application and additional documentation for renewal of marketing authorisation of medicinal products authorised in the national procedure*				
2.1.	one pharmaceutical form	application	1 500.00	0.00	1 500.00
2.1.1.	each additional pharmaceutical form	application	800.00	0.00	800.00
2.1.2.	each additional strength or packaging of medicinal products, as well as each application for medicinal products with identical authorisation documentation, but with different invented names and with the same or a different marketing authorisation holder (multiple applications, if notified simultaneously)	application	500.00	0.00	500.00
2.2.	traditional use herbal medicinal products	application	600.00	0.00	600.00
2.3.	homeopathic medicinal products with therapeutic indications	application	500.00	0.00	500.00
2.4.	homeopathic medicinal products without therapeutic indications (authorised in simplified authorisation procedure)	application	200.00	0.00	200.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
3	Expertise on the Periodic Safety Update Report for nationally authorised medicinal products containing the same active substance(s) of one marketing authorisation holder*	report	300.00	0.00	300.00
4	Expertise on variation documentation for nationally authorised medicinal products*				
4.1.	minor Type I A variation	one variation**	100.00	0.00	100.00
4.2.	minor Type I B variation	one variation**	100.00	0.00	100.00
4.3.	major Type II variation requiring detailed scientific evaluation of documentation	one variation**	300.00	0.00	300.00
4.4.	major Type II variation not requiring detailed scientific evaluation of documentation	one variation**	150.00	0.00	150.00
4.5.	major Type II variation related to the change of the marketing authorisation holder (the new marketing authorisation holder and the current marketing authorisation holder are not the same person/entity)	one variation**	100.00	0.00	100.00
4.6.	changes in package leaflet or labelling that are not related to changes in the summary of product characteristics.	one variation**	100.00	0.00	100.00
5	Expertise on documentation for marketing authorisation of medicinal products in the mutual recognition procedure where Latvia is a Reference Member State*				
5.1.	first submitted pharmaceutical form	application	2 000.00	0.00	2 000.00
5.2.	each additional pharmaceutical form	application	1 200.00	0.00	1 200.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
5.3.	each additional strength or packaging of medicinal product, as well as each application for medicinal products with identical authorisation documentation, but with different invented names and with the same or a different marketing authorisation holder (multiple applications, if notified simultaneously)	application	600.00	0.00	600.00
5.4.	for procedure (in addition to sections 5.1., 5.2. and 5.3. of this Annex)				
5.4.1.	initial mutual recognition procedure	procedure number	5 000.00	0.00	5 000.00
5.4.2.	repeated mutual recognition procedure	procedure number	3 000.00	0.00	3 000.00
6	Expertise on application and additional documentation for marketing authorisation of medicinal products in the decentralised procedure where Latvia is a Reference Member State*				
6.1.	first submitted pharmaceutical form				
6.1.1.	new active substance	application	10 000.00	0.00	10 000.00
6.1.2.	known active substance, fixed combination, similar biological medicinal products or medicinal products with well-established medicinal use	application	4 000.00	0.00	4 000.00
6.1.3.	essentially similar medicinal products - generic medicinal products, hybrid application or other application	application	3 000.00	0.00	3 000.00
6.2.	each additional pharmaceutical form	application	2 000.00	0.00	2 000.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
6.3.	each additional strength or packaging of medicinal products, as well as each application for medicinal products with identical authorisation documentation, but with different invented names and with the same or a different marketing authorisation holder (multiple applications, if notified simultaneously)	application	1 00.00	0.00	1 00.00
6.4.	for procedure (in addition to sections 6.1., 6.2. and 6.3. of this Annex)	procedure number	9 000.00	0.00	9 000.00
7	Expertise on application and additional documentation for marketing authorisation of medicinal products in the mutual recognition procedure where Latvia is a Concerned Member State*				
7.1.	first submitted pharmaceutical form	application	2 000.00	0.00	2 000.00
7.1.1.	each additional pharmaceutical form	application	1 000.00	0.00	1 000.00
7.1.2.	each additional strength or packaging of medicinal product, as well as each application for medicinal products with identical authorisation documentation, but with different invented names and with the same or a different marketing authorisation holder (multiple applications, if notified simultaneously)	application	500.00	0.00	500.00
8	Expertise on application and additional documentation for marketing authorisation of medicinal products in the decentralised procedure where Latvia is a Concerned Member State*				
8.1.	first submitted pharmaceutical form	application	3 000.00	0.00	3 000.00
8.1.1.	each additional pharmaceutical form	application	2 000.00	0.00	2 000.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
8.1.2.	each additional strength or packaging of medicinal product, as well as each application for medicinal products with identical authorisation documentation, but with different invented names and with the same or a different marketing authorisation holder (multiple applications, if notified simultaneously)	application	1 000.00	0.00	1 000.00
9	Expertise on application and additional documentation for renewal of marketing authorisation of medicinal products in the mutual recognition and decentralised procedure where Latvia is				
9.1.	Reference Member State (RMS)*				
9.1.1.	single pharmaceutical form	application	2 000.00	0.00	2 000.00
9.1.2.	each additional pharmaceutical form	application	1 000.00	0.00	1 000.00
9.1.3.	each additional strength or packaging of medicinal product, as well as each application for medicinal products with identical authorisation documentation, but with different invented names and with the same or a different marketing authorisation holder (multiple applications, if notified simultaneously)	application	500.00	0.00	500.00
9.1.4.	for procedure (in addition to sections 9.1.1., 9.1.2. and 9.1.3. of this Annex)	procedure number	3 000.00	0.00	3 000.00
9.2.	Concerned Member State (CMS)*				
9.2.1.	first submitted pharmaceutical form	application	2 000.00	0.00	2 000.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
9.2.2.	each additional pharmaceutical form	application	1 000.00	0.00	1 000.00
9.2.3.	each additional strength or packaging of medicinal product, as well as each application for medicinal products with identical authorisation documentation, but with different invented names and with the same or a different marketing authorisation holder (multiple applications, if notified simultaneously)	application	500.00	0.00	500.00
10	Expertise on Periodic Safety Update Report for medicinal products authorised in the mutual recognition and decentralised procedure where Latvia is a Reference Member State*				
10.1.	medicinal products with one or several identical active substances	report	1 000.00	0.00	1 000.00
10.2.	for procedure (in addition to section 10.1. of this Annex)	procedure number	1 000.00	0.00	1 000.00
11	Expertise on variation documentation for medicinal products authorised in the mutual recognition and decentralised procedure*				
11.1.	minor Type I A variation	single variation**	100.00	0.00	100.00
11.2.	minor Type I B variation	single variation**	100.00	0.00	100.00
11.3.	major Type II variation requiring detailed scientific evaluation of documentation	single variation**	300.00	0.00	300.00
11.4.	major Type II variation not requiring detailed scientific evaluation of documentation	single variation**	150.00	0.00	150.00
11.5.	major Type II variation related to the change of the marketing authorisation holder	single variation**	100.00	0.00	100.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
11.6.	changes in package leaflet or labelling not related to changes in the summary of product characteristics.	single variation**	100.00	0.00	100.00
11.7.	for procedure, where Latvia is a Reference Member State				
11.7.1.	major Type II variation requiring detailed scientific evaluation of documentation	one procedure	600.00	0.00	600.00
11.7.2.	other changes, except changes mentioned in section 11.7.1. of this Annex	one procedure	300.00	0.00	300.00
12	Post-authorisation maintenance fee (annual)*				
12.1.	each authorised pharmaceutical form and strength (except medicinal products mentioned in the section 13 of this Annex)	marketing authorisation number	350.00	0.00	350.00
12.2.	traditional use herbal medical products and diagnostic medicinal products	marketing authorisation number	100.00	0.00	100.00
12.3.	homeopathic medicinal products with therapeutic indications	marketing authorisation number	100.00	0.00	100.00
12.4.	homeopathic medicinal products without therapeutic indications (authorised in simplified authorisation procedure) and anthroposophic medicinal products	marketing authorisation number	30.00	0.00	30.00
13	Evaluation of product (e.g. food supplement, cosmetics, biocide, medical device) compliance with the definition of a medicinal product*				
13.1.	product where evaluation of documentation does not require detailed scientific expertise	application	300.00	0.00	300.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
13.2.	detailed scientific expertise on product composition and pharmacological properties	application	600.00	0.00	600.00
14.	Expertise on application and documentation for distribution of and variations to parallel imported medicinal products in Latvia*	expertise	211.87	0.00	211.87
14.1.	variations to package leaflet	expertise	50.00	0.00	50.00
14.2.	variations to labelling	expertise	50.00	0.00	50.00
14.3.	variations to documentation (change of legal address of merchant)	expertise	50.00	0.00	50.00
15.	Expertise on application and documentation for distribution of unauthorised, individually approved medicinal products (in the case mentioned in Section 10, Paragraph 7(a) of the Pharmaceutical Law)*				
15.1.	first record of medicinal product in documentation	expertise	0.50	0.00	0.50
15.2.	each following record of medicinal product in documentation	expertise	0.50	0.00	0.50
16.	Expertise on application and documentation for distribution of unauthorised, individually approved medicinal products (in the cases described in Section 10, Paragraph 7(b) and 7(c) of the Pharmaceutical Law)*				
16.1.	first record of medicinal product in documentation	expertise	15.00	0.00	15.00
16.2.	each following record of medicinal roduct in documentation	expertise	4.75	0.00	4.75
17.	Expertise on application and documentation for import of medicinal product samples*				
17.1.	up to 5 records of a medicinal product	expertise	5.00	0.00	5.00
17.2.	each following record of medicinal product	expertise	1.00	0.00	1.00
18	Expertise on application and additional documentation of a pharmaceutical activity company in the following cases*				

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
18.1.	change of legal status or type merchant, or transfer of a constant part of the company of the merchant	expertise on documentation of 1 pharmaceutical activity company	50.00	0.00	50.00
18.2.	change of pharmacy director, responsible person for a wholesale distributor of medicinal products, qualified person of a company manufacturing or importing medicinal products, person responsible for manufacturing active pharmaceutical ingredients or controlled substances, head of the structural unit for quality control or manufacturing, person responsible for fulfilling requirements for special activity at a manufacturing or importing company (as well as change of surname)	expertise on documentation for 1 person	50.00	0.00	50.00
18.3.	change of name of an enterprise or a pharmaceutical activity company (if it differs from the name of the enterprise) of the merchant	expertise on documentation of 1 pharmaceutical activity company	50.00	0.00	50.00
18.4.	change of legal address of the merchant or change of pharmaceutcial activity company address	expertise on documentation of 1 pharmaceutical activity company	50.00	0.00	50.00
18.5.	change of surname of an individual merchant	expertise on documentation for 1 person	50.00	0.00	50.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
18.6.	regarding the closure of a pharmacy branch or a department of medicinal products wholesaler	expertise on documentation of 1 pharmaceutical activity company	30.00	0.00	30.00
18.7.	regarding the suspension of special permit (licence) for pharmaceutical activity	expertise on documentation of 1 pharmaceutical activity company	30.00	0.00	30.00
18.8.	regarding the suspension of operation of a pharmacy branch or medicinal products wholesaler	expertise on documentation of 1 pharmaceutical activity company	30.00	0.00	30.00
18.9.	regarding changes in the special permit (licence) for pharmaceutical activity (including ecpiration date) and its annexes, if evaluation of the compliance of pharmaceutical activity company is not required	expertise on documentation of 1 pharmaceutical activity company	30.00	0.00	30.00
18.10.	changes in documentation and information, if renewal of special permit (licence) for pharmaceutical activity is not required	expertise on documentation of 1 pharmaceutical activity company	30.00	0.00	30.00
18.11.	renewal of special permit (licence) for pharmaceutical activity, if evaluation of compliance of the pharmaceutical activity company is not required	1 expertise	50.00	0.00	50.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
18.12.	renewal of special permit (licence) for pharmaceutical activity or renewal of special activity requirements stated in the special permit (licence) for pharmaceutical activity, or renewal of manufacturing or import of specific medicinal products, if evaluation of compliance of the pharmaceutical activity company is not required	expertise on documentation of 1 pharmaceutical activity company	30.00	0.00	30.00
18.13.	expertise on documentation of a pharmaceutical activity company, if manufacturing or import of materials is being initiated (is carried out)	expertise on documentation of 1 pharmaceutical activity company	30.00	0.00	30.00
18.14.	Review of application from the merchant regarding approval of pharmaceutical activity site (address)	expertise on 1 pharmaceutical activity site (address)	50.00	0.00	50.00
19.	Evaluation of initiation of pharmacy operation, initiation of operation at a new pharmaceutical activity site (room), initiation of carrying out new special activity requirements and documentation (verification) on procedures for operation*				
19.1.	general type pharmacy				
19.1.1.	if the pharmacy is located in a city	expertise on documentation of 1 pharmacy	100.00	0.00	100.00
19.1.2.	if the pharmacy is located in a city and it has one branch	expertise on documentation of 1 pharmacy and 1 branch	80.00	0.00	80.00
19.1.3.	if the pharmacy is located in a city and it has more than one branch	expertise on documentation of 1 pharmacy and its branches	70.00	0.00	70.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
19.1.4.	if the pharmacy is located in rural area	expertise on documentation of 1 pharmacy	50.00	0.00	50.00
19.1.5.	if the pharmacy is located in a rural area and it has one branch	expertise on documentation of 1 pharmacy	40.00	0.00	40.00
19.1.6.	if the pharmacy is located in a rural area and it has more than one branch	expertise on documentation of 1 pharmacy and its branches	35.00	0.00	35.00
19.2.	closed type pharmacy	expertise on documentation of 1 pharmacy	45.00	0.00	45.00
19.3.	one pharmacy branch, if expertise on pharmacy documentation is not conducted	expertise on documentation of 1 pharmacy branch	35.00	0.00	35.00
20	Evaluation of compliance of pharmaceutical activity company (medicinal products wholesaler, medicinal products manufacturing company)*				
20.1.	medicinal products manufacturing or import company	expertise on documentation 1 medicinal products manufacturing or import company	400.00	0.00	400.00
20.2.	medicinal products manufacturing company	expertise on documentation 1 medicinal products manufacturing company	300.00	0.00	300.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
20.3.	medicinal products manufacturing (partial manufacturing process) company	expertise on documentation 1 medicinal products manufacturing company	300.00	0.00	300.00
20.4.	medicinal products manufacturing company that manufactures only investigational medicinal products	expertise on documentation 1 medicinal products manufacturing company	200.00	0.00	200.00
20.5.	medicinal products wholesaler	expertise on documentation of 1 medicinal products wholesaler	300.00	0.00	300.00
20.6.	department of medicinal products wholesaler	expertise on documentation of 1 department of medicinal products wholesaler	70.00	0.00	70.00
20.7.	company manufacturing active substances or controlled medicinal products	expertise on documentation of 1 medicinal products manufacturing company	300.00	0.00	300.00
20.8.	company carrying out only ethyl alcohol packaging	expertise on documentation of 1 medicinal products manufacturing company or wholesaler	200.00	0.00	200.00
21	Preparation and printing of submitted materials	1 page	0.85	0.18	1.03

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
22	Review of clinical trial application and additional documentation*	1 expertise	1 000.00	0.00	1 000.00
23	Evaluation of compliance with good clinical practice of a clinical trial center or institutions related to clinical trials in a European Economic Area member state in connection with a marketing authorisation application*				
23.1.	one day (one inspector)	1 clinical trial center/ related institution	246.00	0.00	246.00
23.2.	two days (one inspector)	1 clinical trial center/ related institution	312.00	0.00	312.00
23.3.	three days (one inspector)	1 clinical trial center/ related institution	378.00	0.00	378.00
23.4.	four days (one inspector)	1 clinical trial center/ related institution	444.00	0.00	444.00
23.5.	five days (one inspector)	1 clinical trial center/ related institution	510.00	0.00	510.00
24	Evaluation of compliance with good clinical practice of a clinical trial center or institutions related to clinical trials not located in a European Economic Area member state in connection with a marketing authorisation application*				
24.1.	one day (one inspector)	1 clinical trial center/ related institution	450.00	0.00	450.00
24.2.	two days (one inspector)	1 clinical trial center/ related institution	570.00	0.00	570.00
24.3.	three days (one inspector)	1 clinical trial center/ related institution	690.00	0.00	690.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
24.4.	four days (one inspector)	1 clinical trial center/ related institution	780.00	0.00	780.00
24.5.	five days (one inspector)	1 clinical trial center/ related institution	910.00	0.00	910.00
25	Review of amendments to the clinical trial protocol*	1 amendment	150.00	0.00	150.00
26	Review of application and additional documentation for a non-interventional study proposed by a medicinal product manufacturer (its representative)*	1 expertise	200.00	0.00	200.00
27	Expertise on application and documentation for import or export of psychotropic and narcotic substances and medicinal products, as well as precursors*	expertise	15.00	0.00	15.00
28	Provision of medicinal products consumption data*	1 parameter	9.63	0.00	9.63
29	Expertise on medicinal product for distribution of remaining stock*				
29.1.	the medicinal product has not been renewed or their renewal has been denied	for 1 medicinal product	10.00	0.00	10.00
29.2.	variations to the marketing authorisation documentation	for 1 medicinal product	10.00	0.00	10.00
30	Expertise on application and documentation for distribution of unauthorised medicines*	expertise	500.00	0.00	500.00
31	Special expertise on application and documentation for operation with precursors*	expertise	50.00	0.00	50.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
32	Issuing Precursor Operator cards*	expertise	50.00	0.00	50.00
33	Expertise on application and documentation for use of plants included in lists I, II and III of narcotic, psychotropic substances and precursors controlled in Latvia, their substances and medicinal products in medical and veterinary medical scientific research, determining physical and chemical properties, as well as training*	expertise	50.00	0.00	50.00
34	Issue of authorisation for distribution of parallel imported medicinal products in Latvia*	authorisation	5.00	0.00	5.00
35	Issue of authorisation for import of medicinal product samples*	authorisation	5.00	0.00	5.00
36	Issue of authorisation for import or export of psychotropic and narcotic substances and medicinal products, as well as precursors*	authorisation	15.00	0.00	15.00
37	Issue of authorisation for distribution of remaining stock of medicinal product, if the medicinal product has not been renewed or their renewal has been denied*	authorisation	50.00	0.00	50.00
38	Issue of licence for operation with precursors*	licence	50.00	0.00	50.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
39	Annual fee for receiving information from the database of the Drug Register of the Republic of Latvia	1 year subscription	182.60	40.17	222.77
40	Medicinal products quality control*				
40.1.	determination of medicinal product identity				
40.1.1.	using a chemical reaction	1 test	10.40	0.00	10.40
40.1.2.	using instrumental methods and thin layer chromatography (TLC)	1 test	26.65	0.00	26.65
40.2.	determination of clarity	1 test	4.42	0.00	4.42
40.3.	determination of colour compliance	1 test	4.42	0.00	4.42
40.4.	determination of solubility	1 test	4.42	0.00	4.42
40.5.	determination of pH	1 test	8.97	0.00	8.97
40.6.	determination of density	1 test	9.88	0.00	9.88
40.7.	determination of refractive index	1 test	4.42	0.00	4.42
40.8.	determination of melting point (temperature)	1 test	10.92	0.00	10.92
40.9.	determination of optical rotation	1 test	12.09	0.00	12.09
40.10.	determination of particulate contamination				
40.10.1.	visually	1 test	7.93	0.00	7.93
40.10.2.	instrumentally	1 test	12.09	0.00	12.09
40.11.	determination of impurities				
40.11.1.	using limiting test methods	1 test	8.71	0.00	8.71

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
40.11.2.	using thin layer chromatography (TLC)	1 test	34.45	0.00	34.45
40.12.	determination of nominal volume	1 test	1.56	0.00	1.56
40.13.	determination of average mass and deviations from average mass	1 test	5.46	0.00	5.46
40.14.	determination of amount of sulphated ash	1 test	10.27	0.00	10.27
40.15.	determination of heavy metal content	1 test	10.27	0.00	10.27
40.16.	determination of loss of mass on drying	1 test	7.67	0.00	7.67
40.17.	determination of water	1 test	11.44	0.00	11.44
40.18.	disintegration determination	1 test	11.05	0.00	11.05
40.19.	friability determination	1 test	4.68	0.00	4.68
40.20.	dissolution test (without further quantitative analysis)	1 test	33.15	0.00	33.15
40.21.	determining hardness of solid pharmaceutical forms	1 test	5.98	0.00	5.98
40.22.	determination of size of solid pharmaceutical forms	1 test	5.98	0.00	5.98
40.23.	determination of osmolality	1 test	5.20	0.00	5.20
40.24.	determination of viscosity	1 test	16.50	0.00	16.50
40.25.	determination of uniformity of active substance content				
40.25.1.	using titration	1 test	72.28	0.00	72.28
40.25.2.	using spectrophotometry	1 test	79.43	0.00	79.43
40.25.3.	using polarimetry	1 test	50.70	0.00	50.70

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
40.25.4.	using high performance liquid chromatography (HPLC)	1 test	116.48	0.00	116.48
40.25.5.	using gas chromatography (GC)	1 test	81.25	0.00	81.25
40.25.6.	using atomic absorption spectrometry (AAS)	1 test	116.35	0.00	116.35
40.26.	determining quantitative composition:				
40.26.1.	using titration	1 test	29.12	0.00	29.12
40.26.2.	using spectrophotometry	1 test	44.59	0.00	44.59
40.26.3.	using polarimetry	1 test	21.06	0.00	21.06
40.26.4.	using high performance liquid chromatography (HPLC)	1 test	81.38	0.00	81.38
40.26.5.	using gas chromatography (GC)	1 test	47.32	0.00	47.32
40.26.6.	using atomic absorption spectrometry (AAS)	1 test	75.14	0.00	75.14
40.27.	sterility test	1 test	19.50	0.00	19.50
40.28.	test for microbiological contamination	1 test	58.50	0.00	58.50
41.	Translation and formatting of medicinal product quality control analysis protocol in English	1 protocol	19.50	4.29	23.79
42.	Quality control of herbal drugs*				
42.1.	determination of identity				
42.1.1.	macroscopic description (of a herbal drug)	1 analysis	2.20	0.00	2.20

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
42.1.2.	microscopic description (of a herbal drug)	1 analysis	9.36	0.00	9.36
42.2.	determination of foreign matter in herbal drugs	1 analysis	8.19	0.00	8.19
42.3.	determination of quantitative components				
42.3.1.	determination of extractive substances in herbal drugs	1 analysis	32.11	0.00	32.11
42.3.2.	determeination of essential oils herbal drugs	1 analysis	32.11	0.00	32.11
42.4.	degree of fragmentation of herbal drugs	1 analysis	4.29	0.00	4.29
43.	Quality control of purified water (in pharmacies)	1 sample	19.50	4.10	23.60
44.	Preparation of volumetric solutions, indicators and reactants for pharmacies*	1 name	3.90	0.00	3.90
45.	Microbiological contamination control of water	1 analysis	6.50	1.43	7.93
46.	Travel expenses for selection of water samples from pharmacies	1 km	0.20	0.04	0.24
47.	Formulation of an expert opinion after an official request*	1 expert opinion	50.00	0.00	50.00
48	Good manufacturing practice inspection at a medicinal product manufacturing or import company or a laboratory carrying out quality control under contract* and the inspection lasts for				
48.1.	one day (one inspector)	1 manufacturing company	246.00	0.00	246.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
48.2.	two days (one inspector)	1 manufacturing company	312.00	0.00	312.00
48.3.	three days (one inspector)	1 manufacturing company	378.00	0.00	378.00
48.4.	four days (one inspector)	1 manufacturing company	444.00	0.00	444.00
48.5.	five days (one inspector)	1 manufacturing company	510.00	0.00	510.00
49	Good manufacturing practice inspection in a country not included in the European Economic Area at a medicinal product manufacturing company or a laboratory carrying out quality control under contract* and the inspection lasts for				
49.1.	one day (one inspector)	1 manufacturing company	369.00	0.00	369.00
49.2.	two days (one inspector)	1 manufacturing company	468.00	0.00	468.00
49.3.	three days (one inspector)	1 manufacturing company	567.00	0.00	567.00
49.4.	four days (one inspector)	1 manufacturing company	666.00	0.00	666.00
49.5.	five days (one inspector)	1 manufacturing company	765.00	0.00	765.00
50	Good manufacturing practice inspection performed following a request from a medicinal product manufacturer at a company manufacturing or importing materials* and the inspection lasts for				

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
50.1.	one day (one inspector)	1 manufacturing company	305.00	0.00	305.00
50.2.	two days (one inspector)	1 manufacturing company	381.00	0.00	381.00
50.3.	three days (one inspector)	1 manufacturing company	460.00	0.00	460.00
50.4.	four days (one inspector)	1 manufacturing company	522.00	0.00	522.00
50.5.	five days (one inspector)	1 manufacturing company	610.00	0.00	610.00
51	Good manufacturing practice inspection performed following a request from a medicinal product manufacturer at a company manufacturing materials* in a country not included in the Europea Economic Area and the inspection lasts for				
51.1.	one day (one inspector)	1 manufacturing company	450.00	0.00	450.00
51.2.	two days (one inspector)	1 manufacturing company	570.00	0.00	570.00
51.3.	three days (one inspector)	1 manufacturing company	690.00	0.00	690.00
51.4.	four days (one inspector)	1 manufacturing company	780.00	0.00	780.00
51.5.	five days (one inspector)	1 manufacturing company	910.00	0.00	910.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
52	Evaluation of compliance of education and professional experience of the qualified person at a medicinal product manufacturing or import company with the normative acts regarding requirements of medicinal product manufacturing*	1 person	70.00	0.00	70.00
53	Evaluation of good manufacturing practice documentation of a medicinal product manufacturing company not located in any of the EU Member States - evaluation of submitted site master file and procedures*	1 manufacturing company	150.00	0.00	150.00
54	Sampling of medicinal product for testing*	1 medicinal product sample	3.00	0.00	3.00
55	Evaluation of compliance, inspection of good distribution practice of a medicinal products wholesaler*, if the inspection lasts for				
55.1.	half a day (one inspector)	1 medicinal products wholesaler	61.71	0.00	61.71
55.2.	one day (one inspector)	1 medicinal products wholesaler	123.41	0.00	123.41
55.3.	two days (one inspector)	1 medicinal products wholesaler	156.32	0.00	156.32
56	Copying documentation	1 page	0.13	0.03	0.16
57	Official edition of the Drug Register of the Republic of Latvia	1 book	7.85	1.65	9.50

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
58	Official electronic edition of the Drug Register of the Republic of Latvia containing summaries of product characteristics and package leaflets	1 USB flash memory card	4.55	0.95	5.50
59	Issue of marketing authorisation*	marketing authorisation	50.00	0.00	50.00
60	Issue of a marketing authorisation duplicate*	marketing authorisation duplicate	30.00	0.00	30.00
61	Issue of good manufacturing practice certificate for medicinal products*	certificate	65.00	0.00	65.00
62	Issue of Certificate of Pharmaceutical Product*	certificate	65.00	0.00	65.00
63	Issue of an abridged product certificate (Certificate of Pharmaceutical Product or Free Sales certificate)*	certificate	40.00	0.00	40.00
64	Issue of authorisation for conduct of clinical trial*	authorisation	20.00	0.00	20.00
65	Expertise on medical devices documentation				
65.1.	Expertise on documentation of medical devices manufactured in Latvia*				
65.1.1.	expertise on documentation of class I medical devices (except medical devices mentioned in section 65.1.2. of this Annex)	1 expertise	90.00	0.00	90.00
65.1.2.	expertise on documentation of class I medical devices in sterile packaging and class I medical devices with a measuring function	1 expertise	95.00	0.00	95.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
65.1.3.	expertise on documentation of class II A medical devices	1 expertise	100.00	0.00	100.00
65.1.4.	expertise on documentation of class II B medical devices	1 expertise	110.00	0.00	110.00
65.1.5.	expertise on documentation of class III medical devices	1 expertise	120.00	0.00	120.00
65.1.6.	expertise on documentation of IVD (*in vitro* diagnostics) medical devices included in Appendix 2, List A of the 2.08.2005. Cabinet of Ministers Regulation No. 581 "Procedures for authorisation, evaluation of compliance, distribution, exploitation and technical supervision of medical devices"	1 expertise	120.00	0.00	120.00
65.1.7.	expertise on documentation of IVD (*in vitro* diagnostics) medical devices included in Appendix 2, List B of the 2.08.2005. Cabinet of Ministers Regulation No. 581 "Procedures for authorisation, evaluation of compliance, distribution, exploitation and technical supervision of medical devices"	1 expertise	110.00	0.00	110.00
65.1.8.	expertise on documentation of IVD (*in vitro* diagnostics) self-testing medical devices	1 expertise	100.00	0.00	100.00
65.1.9.	expertise on documentation of other IVD (*in vitro* diagnostics) medical devices	1 expertise	90.00	0.00	90.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
65.1.10.	expertise on documentation submitted by the manufacturer of a medical device and included information on variations to samples or manufacturing technologies of types of medical devices authorised and manufactured in Latvia, as well as supplementation of the medical devices database of Latvia (LATMED)	1 expertise	45.00	0.00	45.00
65.2.	expertise on quality certifying documentation of medical devices without a CE mark*				
65.2.1.	expertise on quality certifying documentation of class I medical devices (except medical devices mentioned in section 65.2.2. of this Annex)	1 expertise	250.00	0.00	250.00
65.2.2.	expertise on quality certifying documentation of class I medical devices in sterile packaging and class I medical devices with a measuring function	1 expertise	280.00	0.00	280.00
65.2.3.	expertise on quality certifying documentation of class II A medical devices	1 expertise	300.00	0.00	300.00
65.2.4.	expertise on quality certifying documentation of class II B medical devices	1 expertise	320.00	0.00	320.00
65.2.5.	expertise on quality certifying documentation of class III medical devices	1 expertise	350.00	0.00	350.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
65.2.6.	expertise on quality certifying documentation of IVD (*in vitro* diagnostics) medical devices included in Appendix 2, List A of the 2.08.2005. Cabinet of Ministers Regulation No. 581 "Procedures for authorisation, evaluation of compliance, distribution, exploitation and technical supervision of medical devices"	1 expertise	350.00	0.00	350.00
65.2.7.	expertise on quality certifying documentation of IVD (*in vitro* diagnostics) medical devices included in Appendix 2, List B of the 2.08.2005. Cabinet of Ministers Regulation No. 581 "Procedures for authorisation, evaluation of compliance, distribution, exploitation and technical supervision of medical devices"	1 expertise	320.00	0.00	320.00
65.2.8.	expertise on quality certifying documentation of IVD (*in vitro* diagnostics) self-testing medical devices	1 expertise	300.00	0.00	300.00
65.2.9.	expertise on quality certifying documentation of other IVD (in vitro diagnostics) medical devices	1 expertise	250.00	0.00	250.00
66	Expertise on documentation of specially supplied medical devices or their accessories*				

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
66.1.	medical devices manufactured in Latvia without a CE mark and for which the compliance evaluation procedures mentioned in the 2.08.2005. Cabinet of Ministers Regulation No. 581 “Procedures for authorisation, evaluation of compliance, distribution, exploitation and technical supervision of medical devices” have not been performed				
66.1.1.	single expertise on documentation of class I medical devices (except medical devices mentioned in section 66.1.2. of this Annex)	1 expertise	50.00	0.00	50.00
66.1.2.	single expertise on documentation of class I medical devices in sterile packaging and class I medical devices with a measuring function	1 expertise	50.00	0.00	50.00
66.1.3.	single expertise on documentation of class II A medical devices	1 expertise	55.00	0.00	55.00
66.1.4.	single expertise on documentation of class II B medical devices	1 expertise	60.00	0.00	60.00
66.1.5.	single expertise on documentation of class III medical devices	1 expertise	70.00	0.00	70.00
66.1.6.	single expertise on documentation of IVD (*in vitro* diagnostics) medical devices included in Appendix 2, List A of the 2.08.2005. Cabinet of Ministers Regulation No. 581 “Procedures for authorisation, evaluation of compliance, distribution, exploitation and technical supervision of medical devices”	1 expertise	70.00	0.00	70.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
66.1.7.	single expertise on documentation of IVD (*in vitro* diagnostics) medical devices included in Appendix 2, List B of the 2.08.2005. Cabinet of Ministers Regulation No. 581 "Procedures for authorisation, evaluation of compliance, distribution, exploitation and technical supervision of medical devices"	1 expertise	60.00	0.00	60.00
66.1.8.	single expertise on documentation of IVD (*in vitro* diagnostics) self-testing medical devices	1 expertise	55.00	0.00	55.00
66.1.9.	single expertise on documentation of other IVD (in vitro diagnostics) medical devices	1 expertise	50.00	0.00	50.00
66.2.	medical devices without a CE mark and for which the compliance evaluation procedures mentioned in the 2.08.2005. Cabinet of Ministers Regulation No. 581 "Procedures for authorisation, evaluation of compliance, distribution, exploitation and technical supervision of medical devices" have not been performed (except medical devices manufactured in Latvia)				
66.2.1.	single expertise on quality certifying documentation of class I medical devices (except medical devices mentioned in section 66.2.2. of this Annex)	1 expertise	120.00	0.00	120.00
66.2.2.	single expertise on quality certifying documentation of class I medical devices in sterile packaging and class I medical devices with a measuring function	1 expertise	140.00	0.00	140.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
66.2.3.	single expertise on quality certifying documentation of class II A medical devices	1 expertise	150.00	0.00	150.00
66.2.4.	single expertise on quality certifying documentation of class II B medical devices	1 expertise	170.00	0.00	170.00
66.2.5.	single expertise on quality certifying documentation of class III medical devices	1 expertise	180.00	0.00	180.00
66.2.6.	single expertise on quality certifying documentation of IVD (*in vitro* diagnostics) medical devices included in Appendix 2, List A of the 2.08.2005. Cabinet of Ministers Regulation No. 581 "Procedures for authorisation, evaluation of compliance, distribution, exploitation and technical supervision of medical devices"	1 expertise	180.00	0.00	180.00
66.2.7.	single expertise on quality certifying documentation of IVD (*in vitro* diagnostics) medical devices included in Appendix 2, List B of the 2.08.2005. Cabinet of Ministers Regulation No. 581 "Procedures for authorisation, evaluation of compliance, distribution, exploitation and technical supervision of medical devices"	1 expertise	170.00	0.00	170.00
66.2.8.	single expertise on quality certifying documentation of IVD (*in vitro* diagnostics) self-testing medical devices	1 expertise	150.00	0.00	150.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
66.2.9.	single expertise on quality certifying documentation of other IVD (in vitro diagnostics) medical devices	1 expertise	120.00	0.00	120.00
67	Documentation processing*				
67.1.	Issue of marketing authorisation certificate statement for a medical device	marketing authorisation certification	20.00	0.00	20.00
67.2.	Issue of marketing authorisation certificate duplicate for a medical device	marketing authorisation duplicate	10.00	0.00	10.00
67.3.	Issue of marketing authorisation certificate for a medical device	marketing authorisation	50.00	0.00	50.00
67.4.	Issue of authorisation for placing specially supplied medical devices on the market	authorisation	20.00	0.00	20.00
67.5.	Issue of authorisation duplicate for placing specially supplied medical devices on the market	authorisation duplicate	10.00	0.00	10.00
68	Annual fee for using 1st and 2nd safety group medical device register of the Medical device database of Latvia (LATMED)*	1 year subscription	50.00	0.00	50.00
69	Assessment of conformity of blood, tissues, cells and organ centers and procurement organisations and documentation processing*				
69.1.	assessment of conformity of blood center, blood establishments and hospital blood banks and issue of certificate	certificate	450.00	0.00	450.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
69.1.1.	evaluation of documentation for changes in operating conditions for blood center, blood establishments and hospital blood banks	1 expertise	50.00	0.00	50.00
69.1.2.	issue of conformity certificate duplicate for blood center, blood establishments and hospital blood banks	certificate duplicate	10.00	0.00	10.00
69.2.	assessment of conformity of tissues, cells and organ centers and procurement organizations and issue of authorisation	authorisation	450.00	0.00	450.00
69.2.1.	evaluation of documentation for changes in activities or changes in standart operating procedures of tissues, cells and organ centers and procurement organizations	1 expertise	50.00	0.00	50.00
69.2.2.	issue of authorisation duplicate for use of tissues, cells and organs	authorisation duplicate	10.00	0.00	10.00
70	Assessment of conformity of site for use of tissues, cells, organs and dead human bodies for the implementation of medical studies program at a higher education institution and documentation processing*				
70.1.	assessment of conformity of site for use of tissues, cells, organs and dead human bodies and issue of authorisation	authorisation	450.00	0.00	450.00
70.2.	evaluation of documentation for changes in activities or changes in standart operating procedures of site for use of tissues, cells, organs and dead human bodies	1 expertise	50.00	0.00	50.00

Nr.	Service	Unit	Fee (LVL)	VAT (LVL)	Total (LVL)
70.3.	issue of authorisation duplicate for use of tissues, cells, organs and dead human bodies	authorisation duplicate	10.00	0.00	10.00
71	Expertise on documentation for clinical trials with medical devices*	1 expertise	1 000.00	0.00	1 000.00
72	Expertise on documentation submitted for receiving authorisation for amendments to clinical trial with medical devices*	1 expertise	600.00	0.00	600.00
73	Renewal of authorisation for conduct of clinical trial with medical devices after suspension of the authorisation*	1 expertise	600.00	0.00	600.00
74	Issue of authorisation for conduct of clinical trial with medical devices*	authorisation	20.00	0.00	20.00

Notes

1. *The value added tax is not applied in accordance with Section 3, Paragraph 8 of the “Law On Value Added Tax”.

2. **The State Agency of Medicines:

2.1. shall apply a 70 percent discount to the fee stated for evaluation of variations to authorised medicinal products for each additional marketing authorisation number that is included in the group of variations within one variation, if the application for variations is submitted simultaneously in a single application;

2.2. shall apply a 70 percent discount to the fee stated for evaluation of variations to authorised medicinal products for each additional marketing authorisation number within one variation, if the application for variations is submitted simultaneously in a single application;

2.3. shall not apply fee for related variations that are clearly consequential to the primary variation that has been submitted in accordance with the Section 4 or Section 11 of this Annex, if the application for variations is submitted simultaneously in a single application and the relation between all consequential variations is indicated.

Minister of Health *I.Circene*