Non-official translation

DECREE OF THE GOVERNMENT OF THE REPUBLIC OF

ARMENIA

N166-N of February 28, 2019

«On adopting the fees in the Republic of Armenia for assessments in the field of medicinal products state regulation»

Taking into account Article 7, part 2 of the "Law on medicines" of the Republic of Armenia, the Government of the Republic of Armenia defines:

1. Establish:

1) Fees for the medicinal products registration, re-registration, renewal and variation assessment according to Appendix 1;
2) Fees for the expertise in order to issue import or export certificate of the imported to Republic of Armenia or exported from the Republic of Armenia medicinal products, substances, herbal substances, investigational pharmaceutical product according to Appendix 2;
3) Fee for the medicinal product manufacturing pre-licensing inspection according to Appendix 3;
4) Fee for medicinal products' wholesale distribution pre-licensing inspection in the Republic of Armenia according to Appendix 4;
5) Expertise fee for clinical trials (studies) authorization in the Republic of Armenia according to Appendix 5.

2. Current Decree enter into force on the tenth day following the day of official publication date.

Prime Minister of the Republic of Armenia

Nikol Pashinyan

March 7, 2019 Yerevan

APPENDIX 1

Decree of the Government of the Republic of
Armenia N 166-N of February 28, 2019

FEES
for the medicinal products registration, re-registration, renewal and variation assessment

N	Type of application	Assessment fee including VAT									
		1	2	3	4	5	6	7	8	9	10
		Registration under the standard procedure or EAEU regulations valid only for the the RA	Registration under the simplified procedure	Re-registration and renewal valid only for the RA	Registration under the EAEU regulations (reference country)	EAEU registration under the decentralized procedure (non-referent country) or mutual recognition	Dossier compliance with the EAEU registration and assessment regulations (reference country)	Dossier compliance with the EAEU registration and assessment regulations valid only for the the RA	Re-registration under the EAEU regulations	Annual Fee	Review for mutual recognition of medicinal product in other countries either registered under the EAEU regulations and valid only for the RA or medicinal product which dossier compliant with EAEU regulations and valid only for the RA
1A.	Generic medicinal product	1 100 000	500 000	500 000	2 100 000	1 500 000	1 200 000	900 000	1 000 000	100 000	1 000 000
1A.1.	Each subsequent pharmaceutical form and flavoring variety	1 100 000	500 000	500 000	2 100 000	1 500 000	1 200 000	900 000	1 000 000	100 000	1000 000
1A.2.	Each subsequent strength	500 000	250 000	250 000	1 100000	750 000	600 000	450 000	500 000	100 000	500 000
1A.3.	Each subsequent manufacturing site/variation	1 100 000	500 000	500 000	2 100000	1 500 000	1 200 000	900 000	1 000 000	100 000	1000 000
1A.4.	Each subsequent presentation form[1]	50 000	50 000	50 000	80 000	80 000	80 000	80 000	80 000	50 000	50 000

1B.	Generic medicinal product with well-established use	800 000	500 000	500 000	1 500 000	1 000 000	900 000	600 000	500 000	100 000	700 000
1B.1.	Each subsequent pharmaceutical form and flavoring variety	800 000	500 000	500 000	1 500 000	1 000 000	900 000	600 000	500 000	100 000	700 000
1B.2.	Each subsequent strength	400 000	250 000	250 000	750 000	500 000	450 000	300 000	250 000	100 000	350 000
1B.3.	Each subsequent manufacturing site/variation	800 000	500 000	500 000	1 500 000	1 000 000	900 000	600 000	500 000	100 000	700 000
1B.4.	Each subsequent presentation form[1]	50 000	50 000	50 000	80 000	80 000	80 000	80 000	80 000	50 000	50 000
2	Original medicinal product, immunological medicinal product or new combinations	2 400 000	1 000 000	1 000 000	3 500 000	2 500 000	2 100 000	1 400 000	1 500 000	200 000	1 100 000
2.1.	Each subsequent pharmaceutical form and flavoring variety	2 400 000	1 000 000	1 000 000	3 500 000	2 500 000	2 100 000	1 400 000	1 500 000	200 000	1 100 000
2.2.	Each subsequent strength	1 200 000	500 000	500 000	1 750 000	1 250 000	1 000 000	700 000	750 000	200 000	550 000
2.3.	Each subsequent manufacturing site/variation	2 400 000	1 000 000	1 000 000	3 500 000	2 500 000	2 100 000	1 400 000	1 500 000	200 000	1 100 000

2.4.	Each subsequent presentation form[1]	50 000	50 000	50 000	80 000	80 000	80 000	80 000	80 000	50 000	50 000
3	Biosimilar, blood product, new combinations of well-known medicinal products or hybrid medicinal product[2]	2 100 000	900 000	900 000	3 100 000	2 200 000	2 000 000	1 400 000	1 500 000	200 000	1 000 000
3.1.	Each subsequent pharmaceutical form and flavoring variety	2 100 000	900 000	900 000	3 100 000	2 200 000	2 000 000	1 400 000	1 500 000	200 000	1 000 000
3.2.	Each subsequent strength	1 000 000	500 000	500 000	1 500 000	1 000 000	1 000 000	700 000	750 000	200 000	500 000
3.3.	Each subsequent manufacturing site/variation	2 100 000	900 000	900 000	3 100 000	2 200 000	2 000 000	1 400 000	1 500 000	200 000	1 000 000
3.4.	Each subsequent presentation[1]	50 000	50 000	50 000	80 000	80 000	80 000	80 000	80 000	50 000	50 000
4	Veterinary medicinal product	800 000	500 000	500 000	1 500 000	1 000 000	900 000	600 000	500 000	100 000	700 000
4.1.	Each subsequent pharmaceutical form and flavoring variety	800 000	500 000	500 000	1 500 000	1 000 000	900 000	600 000	500 000	100 000	700 000
4.2.	Each subsequent strength	400 000	250 000	250 000	750 000	500 000	450 000	300 000	250 000	100 000	350 000

4.3.	Each subsequent manufacturing site/variation	800 000	500 000	500 000	1 500 000	1 000 000	900 000	600 000	500 000	100 000	700 000
4.4.	Each subsequent presentation form[1]	50 000	50 000	50 000	80 000	80 000	80 000	80 000	80 000	50 000	50 000
5	Herbal medicinal product	800 000	500 000	500 000	1 500 000	1 000 000	900 000	600 000	500 000	100 000	700 000
5.1.	Each subsequent pharmaceutical form and flavoring variety	800 000	500 000	500 000	1 500 000	1 000 000	900 000	600 000	500 000	100 000	700 000
5.2.	Each subsequent strength	400 000	250 000	250 000	750 000	500 000	450 000	300 000	250 000	100 000	350 000
5.3.	Each subsequent manufacturing site/varition	800 000	500 000	500 000	1 500 000	1 000 000	900 000	600 000	500 000	100 000	700 000
5.4.	Each subsequent presentation form[1]	50 000	50 000	50 000	80 000	80 000	80 000	80 000	80 000	50 000	50 000
5.5.	Packaged and labeled herbal raw material in consumer packages	250 000	250 000	50 000	500 000	300 000	250 000	200 000	100 000	50 000	250 000
5.5.1.	Each subsequent presentation form[1]	50 000	50 000	50 000	80 000	80 000	80 000	80 000	80 000	50 000	50 000
6	Homeopathic medicinal product	800 000	500 000	500 000	1 500 000	1 000 000	900 000	600 000	500 000	100 000	700 000

6.1.	Each subsequent pharmaceutical form and flavoring variety	800 000	500 000	500 000	1 500 000	1 000 000	900 000	600 000	500 000	100 000	700 000
6.2.	Each subsequent strength	400 000	250 000	250 000	750 000	500 000	450 000	300 000	250 000	100 000	350 000
6.3.	Each subsequent manufacturing site/variation	800 000	500 000	500 000	1 500 000	1 000 000	900 000	600 000	500 000	100 000	700 000
6.4.	Each subsequent presentation form[1]	50 000	50 000	50 000	80 000	80 000	80 000	80 000	80 000	50 000	50 000
6.5.	Homeopathic medicinal product without therapeutic indications	400 000	250 000	250 000	750 000	500 000	450 000	300 000	250 000	100 000	350 000
6.5.1.	Each subsequent strength	200 000	125 000	125 000	375 000	250 000	225 000	150 000	125 000	50 000	50 000
7	Radiopharmaceu-ticals	2 100 000	900 000	900 000	3 100 000	2 200 000	2 000 000	1 400 000	1 500 000	200 000	1 000 000
7.1.	Each subsequent pharmaceutical form	2 100 000	900 000	900 000	3 100 000	2 200 000	2 000 000	1 400 000	1 500 000	200 000	1 000 000
7.2.	Each subsequent strength	1 000 000	500 000	500 000	1 500 000	1 000 000	1 000 000	700 000	750 000	200 000	500 000
7.3.	Each subsequent manufacturing site/variation	2 100 000	900 000	900 000	3 100 000	2 200 000	2 000 000	1 400 000	1 500 000	200 000	1 000 000
7.4.	Each subsequent presentation form[1]	50 000	50 000	50 000	80 000	80 000	80 000	80 000	80 000	50 000	50 000

8	Medicinal product registered within the framework of the state order	500 000	250 000	250 000							
8.1.	Each subsequent pharmaceutical form	500 000	250 000	250 000							
8.2.	Each subsequent strength	200 000	100 000	100 000							
8.3.	Each subsequent manufacturing site/variation	500 000	250 000	250 000							
8.4.	Each subsequent presentation form[1]	50 000	50 000	50 000							
9	Type IA and IB variation, each change	60 000 and also fee for each laboratory test, if required	60 000		100 000 and also fee for each laboratory test, if required	50 000					
9.1.	Type II, each change except for the manufacturing site, in case of which the payment is made in the amount defined for each medicinal product above	300 000 and also fee for each laboratory test, if required	150 000		700 000 and also fee for each laboratory test, if required	350 000					

1 Each subsequent presentation is considered only as a change in the number of units included in the package or the amount of medicinal herbal raw materials; in case of other changes of the presentation, payment is made in the amount defined for each subsequent pharmaceutical form

2 For hybrid medicinal products which do not differ from the original medicinal product by the active ingredient(s), strength and pharmaceutical form, the payment should be made in accordance with the amounts defined in point 1A of this appendix.

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APPENDIX 2

Decree of the Government of the Republic
of Armenia N 166-N of February 28, 2019

FEES

for the expertise in order to issue import or export certificate of the imported to Republic of Armenia or exported from the Republic of Armenia medicinal products, substances, herbal substances, investigational pharmaceutical product

	Type of assessment	Assessment fee, including VAT (Armenian drams)
1	**Expertise of documents**	
	For one to five names	10 000
	For 6 to 20 names	20 000
	For 21 and more names	1000
2	**Sampling**	
	For one to five names	12 000
	For 6 to 20 names	20 000
	For 21 and more names	1000

3	**Expertise on identity confirmation with registration sample**	
	For one to five names	12 000
	For 6 to 20 names	20 000
	For 21 and more names	1000
4	**Laboratory testing of medicinal product, active substance (API), herbal raw material or investigational medicinal product**	According to each laboratory test fee
5	**Expertise of the documents for export authorization (per each product name)**	1000

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APPENDIX 3

Decree of the Government of the Republic
of Armenia N 166-N of February 28, 2019

Fee for the medicinal product manufacturing pre-licensing inspection

	Type of assessment	Assessment fee, including VAT (Armenian drams)
1	Medicinal product manufacturing pre-licensing inspection	280 000

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APPENDIX 4
Decree of the Government of the
Republic of Armenia N 166-N of
February 28, 2019

Fee for medicinal products' wholesale distribution pre-licensing inspection in the Republic of Armenia

N	Type of assessment	Assessment fee, including VAT (Armenian drams)
1	Medicinal products' wholesale distribution pre-licensing inspection	140 000

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APPENDIX 5
Decree of the Government of the
Republic of Armenia N 166-N of
February 28, 2019

Expertise fee for clinical trials (studies) authorization in the Republic of Armenia

N	Type of assessment	Assessment fee, including VAT (Armenian drams)
1	Expertise for clinical trials authorisation in the Republic of Armenia	500 000
2	Expertise of bioequivalence studies and in cases when the investigational pharmaceutical product is registered in the Republic of Armenia or has a clinical trial or conpasionate use authorisation given by the competent authority of ICH member country	250 000
3	Expertise of changes in documents after obtaining clinical trial authorisation	100 000
4	Annual fee that must be paid started from next year after receiving authorisation until the end of trials	100 000

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