

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 via the general procedure	Registration via the simplified procedure	Re-registration	Renewal	EAEU first registration (reference country)	EAEU registration via the decentralized procedure (non first country)	Mutual recognition of the EAEU registration	Dossier compliance with the EAEU registration and assessment rules	EEU re-registration	Annual Fee for EAEU re-registered medicinal product
1A.	First pharmaceutical form and strength of the generic medicinal product	1250000	500000	250000	125000	2250000	900000	900000	1125000	450000	112500
1A.1.	Each subsequent pharmaceutical form and flavoring variety	1000000	400000	200000	100000	1800000	720000	720000	900000	360000	90000
1A.2.	Each subsequent strength	500000	200000	100000	50000	900000	360000	360000	450000	180000	72000
1A.3.	Each subsequent manufacturing site	500000	200000	100000	50000	900000	360000	360000	450000	180000	57600
1A.4.	Each subsequent presentation: quantitative changes of units included in the package	50000	20000	10000	5000	90000	36000	36000	45000	18000	46080

1B.	First pharmaceutical form and strength of a generic medicinal product with well-established medical use	750000	300000	150000	75000	1350000	540000	540000	675000	270000	67500
1B.1.	Each subsequent pharmaceutical form and flavoring variety	600000	240000	120000	60000	1080000	432000	432000	540000	216000	54000
1B.2.	Each subsequent strength	300000	120000	60000	30000	540000	216000	216000	270000	108000	43200
1B.3.	Each subsequent manufacturing site	300000	120000	60000	30000	540000	216000	216000	270000	108000	34560
1B.4.	Each subsequent presentation: quantitative changes of units included in the package	30000	12000	6000	3000	54000	21600	21600	27000	10800	27648
2	First pharmaceutical form, strength of original medicinal product, immunological medicinal product and new combinations	2500000	1000000	500000	250000	4500000	1800000	1800000	2250000	900000	225000
2.1.	Each subsequent pharmaceutical form and flavoring variety	2000000	800000	400000	200000	3600000	1440000	1440000	180000	720000	180000
2.2.	Each subsequent strength	1000000	400000	200000	100000	1800000	720000	720000	900000	360000	144000

2.3.	Each subsequent manufacturing site	1000000	400000	200000	100000	1800000	720000	720000	900000	360000	115200
2.4.	Each subsequent presentation: quantitative changes of units included in the package	100000	40000	20000	100000	180000	72000	72000	90000	36000	92160
3	First pharmaceutical form and strength of biosimilar, blood derived medicinal product, new combinations of well-known medicinal products and new pharmaceutical form and strength of generic medicinal product	2000000	800000	400000	200000	3600000	1440000	1440000	1800000	720000	180000
3.1.	Each subsequent pharmaceutical form and flavoring variety	1600000	640000	320000	160000	2880000	1152000	1152000	1440000	576000	144000
3.2.	Each subsequent strength	800000	320000	160000	80000	1440000	576000	576000	720000	288000	115200
3.3.	Each subsequent manufacturing site	800000	320000	160000	80000	1440000	576000	576000	720000	288000	92160
3.4.	Each subsequent presentation: quantitative changes of units included in the package	80000	32000	16000	8000	144000	57600	57600	72000	28800	73728
4	First pharmaceutical form and strength of veterinary medicinal product	625000	250000	100000	50000	900000	360000	360000	450000	180000	45000

4.1.	Each subsequent pharmaceutical form and flavoring variety	500000	200000	80000	40000	720000	288000	288000	360000	144000	36000
4.2.	Each subsequent strength	250000	100000	40000	20000	360000	144000	144000	180000	72000	28800
4.3.	Each subsequent manufacturing site	250000	100000	40000	20000	360000	144000	144000	180000	72000	23040
4.4.	Each subsequent presentation: quantitative changes of units included in the package	25000	10000	4000	2000	36000	14400	14400	18000	7200	18432
5	First pharmaceutical form and strength of the herbal medicinal products	500000	200000	100000	50000	900000	360000	360000	450000	180000	45000
5.1.	Each subsequent pharmaceutical form and flavoring variety	400000	160000	80000	40000	720000	288000	288000	360000	144000	36000
5.2.	Each subsequent strength	200000	80000	40000	20000	360000	144000	144000	180000	72000	28800
5.3.	Each subsequent manufacturing site	200000	80000	40000	20000	360000	144000	144000	180000	72000	23040
5.4.	Each subsequent presentation: quantitative changes of units included in the package	20000	8000	4000	2000	36000	14400	14400	18000	7200	18432
5.5.	First presentation form of packaged and labeled herbal substance in consumer packages	100000	40000	20000	10000	180000	72000	72000	90000	36000	9000

5.5.1.	Each subsequent presentation form	20000	6000	4000	2000	36000	14400	14400	18000	7200	1800
6	First pharmaceutical form and strength of the homeopathic medicinal product	500000	200000	100000	50000	900000	360000	360000	450000	180000	45000
6.1.	Each subsequent pharmaceutical form and flavoring variety	400000	160000	80000	40000	720000	288000	288000	360000	144000	36000
6.2.	Each subsequent strength	200000	80000	40000	20000	360000	144000	144000	180000	72000	28800
6.3.	Each subsequent manufacturing site	200000	80000	40000	20000	360000	144000	144000	180000	72000	23040
6.4.	Each subsequent presentation: quantitative changes of units included in the package	20000	8000	4000	2000	36000	14400	14400	18000	7200	18432
6.5.	First strength and pharmaceutical form of homeopathic medicinal product without therapeutic indications	100000	40000	20000	10000	180000	72000	72000	900000	36000	9000
6.5.1.	Each subsequent strength	20000	8000	4000	2000	36000	14400	14400	18000	7200	1800
7	Radiopharmaceuticals	2000000	800000	400000	200000	3600000	1440000	1440000	1800000	720000	180000

7.1.	Each subsequent pharmaceutical form	1600000	640000	320000	160000	2880000	1152000	1152000	1440000	576000	144000
7.2.	Each subsequent strength	800000	320000	160000	80000	1440000	576000	576000	720000	288000	115200
7.3.	Each subsequent manufacturing site	800000	320000	160000	80000	1440000	576000	576000	720000	288000	92160
7.4.	Each subsequent presentation form	80000	32000	16000	8000	144000	57600	57600	72000	28800	73728
8	Low-demanded, but vital medicinal product registered via the state order	375000	150000	75000	37500						
8.1.	Each subsequent pharmaceutical form	300000	120000	60000	30000						
8.2.	Each subsequent strength	150000	60000	30000	15000						
8.3.	Each subsequent manufacturing site	150000	60000	30000	15000						
8.4.	Each subsequent presentation form	15000	6000	3000	1500						
9	Type IA and IB variation including change of registration certificate holder	60000 each change	60000 each change			100000 each change		100000 each change			
9.1.	Type II	20%	20%			20%		20%			
10	Each new indication	30%	30%			30%	30%	30%			

11	Each new trade name	10%	30%			80%	40%	30%	50%	20%	5%
12	Inspections excluding inspection of manufacturing site	20%				80%					
13	Pre-registration consulting	10%				10%					

*% - The amount of the fee for the assessment is the specified percentage of fee established for the corresponding medicinal product in this table

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

N	Type of assessment	Assessment fee, including VAT (Armenian drams)
1	Expertise of documents	
	For one to five names	5000
	For 6 to 20 names	8000
	For 21 and more names	10000
2	Sampling	
	For one to five names	10000
	For 6 to 20 names	16000
	For 21 and more names	20000
3	Expertise on identity confirmation with registration sample	
	For one to five names	10000
	For 6 to 20 names	14000
	For 21 and more names	19000
4	Laboratory testing of medicinal product containing single active ingredient	48000
5	Laboratory testing of medicinal product containing more than one active ingredient	84000
6	Laboratory testing of substance	18000
7	Laboratory testing of herbal substances	44000
8	Preparing expert conclusion for export authorization	4000

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

N	Type of assessment	Assessment fee, including VAT (Armenian drams)
1	Medicinal product manufacturing pre-licensing inspection	280000

APPENDIX 4

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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	140000

APPENDIX 5
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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	95000
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 compassionate use authorisation given by the competent authority of ICH member country	50000
3	Expertise of changes in documents after obtaining clinical trial authorisation	50000
4	Annual fee that must be paid started from next year after receiving authorisation until the end of trials	50000