

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 | 2500000 | 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 |

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| 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 | 250000 | 1000000 | 500000 | 250000 | 4500000 | 1800000 | 1800000 | 2250000 | 900000 | 225000 |
| 2.1. | Each subsequent pharmaceutical form and flavoring variety | 200000 | 800000 | 400000 | 200000 | 3600000 | 1440000 | 1440000 | 180000 | 720000 | 180000 |
| 2.2. | Each subsequent strength | 1000000 | 400000 | 200000 | 100000 | 1800000 | 720000 | 720000 | 900000 | 360000 | 144000 |

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| 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 | 36000000 | 1440000 | 1440000 | 180000 | 720000 | 180000 |
| 3.1. | Each subsequent pharmaceutical form and flavoring variety | 160000 | 640000 | 320000 | 160000 | 2880000 | 1152000 | 1152000 | 144000 | 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 | 6250000 | 2500000 | 100000 | 500000 | 900000 | 360000 | 360000 | 450000 | 180000 | 45000 |

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|------|---------------------------------------------------------------------------------------|---------------|---------------|---------------|--------------|---------------|---------------|---------------|---------------|---------------|--------------|
| 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 |

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| 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 |

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|------|-------------------------------------------------------------------------------------|--------------------------|--------------------------|--------------|--------------|---------------------------|------------|---------------------------|--------|--------|--------|
| 7.1. | Each subsequent pharmaceutical form | 1600000 | 640000 | 320000 | 160000 | 2880000 | 1152000 | 1152000 | 144000 | 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% | | | |

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|----|--------------------------------------------------------|-----|-----|--|--|-----|-----|-----|-----|-----|----|
| 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

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 | 140000 |

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 | 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 |