

**On fixation of prices for services implemented by a state monopoly entity**

***Invalidated***
***Unofficial translation***

Order of the Minister of Health of the Republic of Kazakhstan dated August 31, 2017 No. 671. It was registered with the Ministry of Justice of the Republic of Kazakhstan on November 21, 2017 No. 16002. Abolished by the order of the Acting Minister of Health of the Republic of Kazakhstan dated January 20, 2021 No. KR DSM-7

      *Unofficial translation*

      Footnote. Abolished by the order of the Acting Minister of Health of the Republic of Kazakhstan dated January 20, 2021 No. KR DSM-7 (effective ten calendar days after the date of its first official publication).

      In compliance with paragraph 2 of Article 63 and paragraph 2 of Article 63-1 of the Code of the Republic of Kazakhstan of September 18, 2009 "On Public Health and Healthcare System " I DO HEREBY ORDER:

      1. Establish:

      1) prices for services sold by the subject of the state monopoly for the examination during state registration, re-registration and amendments to the registration dossier of medicines and medical devices in accordance with the Rules for registration and examination of safety, quality and effectiveness of medical devices approved by the decision of the Eurasian Economic Commission of February 12, 2016 No. 46 and the Rules for registration and examination of medicinal products for medical use, approved by the decision of the Eurasian Economic Commission of November 3, 2016 No. 78, in accordance with Appendix 1 to this order;

      2) prices for services sold by a state monopoly entity for conducting an examination during state registration, re-registration and amendments to the registration dossier of drugs and medical devices in accordance with the legislation of the Republic of Kazakhstan, in accordance with Appendix 2 to this order;

      3) prices for services sold by a state monopoly entity for assessing the safety and quality of medicines and medical devices registered in the Republic of Kazakhstan, in accordance with Appendix 3 to this order.

      Footnote. Clause 1 as amended by the order of the Minister of Health of the Republic of Kazakhstan dated September 30, 2019 No. ҚР DSM-130 (shall be enforced upon expiry of ten calendar days after the day of its first official publication.

      2. In the manner prescribed by the law, the Department for Public Procurement and Assets of the Ministry of Healthcare of the Republic of Kazakhstan, shall ensure:

      1) state registration of this Order with the Ministry of Justice of the Republic of Kazakhstan;

      2) within ten calendar days from the date of the state registration of this order, sending a copy hereof in paper and electronic form in the state and Russian languages ​​to Republican State Enterprise on the Right of Economic Management “Republican Center of Legal Information of the Ministry of Justice of the Republic of Kazakhstan” for official publication and inclusion in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan, as well as sending a copy hereof for official publication in printed periodical publications;

      3) placement of this order on the official Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan;

      4) within ten working days after the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan, submission to the Department of Legal Services of the Ministry of Healthcare of the Republic of Kazakhstan of information on the implementation of measures provided for in subparagraphs 1), 2) and 3) of this paragraph.

      3. Order of the Minister of Health and Social Development of the Republic of Kazakhstan No. 771 dated September 30, 2015 “On Approval of Prices for Services Implemented by a State Monopoly Entity on Conducting Expert Examination during State Registration, Re-registration and Introduction of Amendments to the Registration Dossier of Medicines, Medical Devices and Medical Equipment and the Assessment of the Safety and Quality of Medicines and Medical Devices Registered in the Republic of Kazakhstan”, (registered in the Register of State Registration of Regulatory Legal Acts under No. 12179, published in Legal Information System“ Adilet ”on October 22, 2015) shall be deemed to have lost force.

      4. The control over the execution of this order shall be assigned to Vice Minister of Healthcare of the Republic of Kazakhstan Tsoi A. V.

      5. This order shall become effective ten calendar days after the day of its first official publication.

|  |
| --- |
|
*Minister of Healthcare*
 |
|
*of the Republic of Kazakhstan*
 |
*Y. Birtanov*
 |

      "AGREED"

      Minister of National Economy

      of the Republic of Kazakhstan

      \_\_\_\_\_\_\_\_\_\_\_\_\_T. Suleimenov

      October 27, 2017

|  |  |
| --- | --- |
|   | Appendix 1to the order of the Ministerhealth careRepublic of Kazakhstandated August 31, 2017 No. 671 |

 **Prices for services sold by the subject of the state monopoly for the examination during state**
**registration, re-registration and amendments to the registration dossier of medicines and**
**medical devices in accordance with the Rules for registration and examination of the safety,**
**quality and effectiveness of medical devices, approved by the decision of the Eurasian**
**Economic Commission of February 12 2016 No. 46 and the Rules for registration and**
**examination of medicines for medical use, approved by the decision of the**
**Eurasian Economic Commission of November 3, 2016 No. 78**

      Footnote. Appendix 1 as amended by order of the Minister of Health of the Republic of Kazakhstan dated September 30, 2019 No. ҚR DSM-130 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

|  |  |  |  |
| --- | --- | --- | --- |
|
No. |
Name of works |
unit of measurement |
Price in tenge without value added tax |
|
1 |
2 |
3 |
4 |
|
Expertise during state registration, re-registration and amendments to the registration dossier of medicines, medical devices, in accordance with the Rules for registration and expertise of safety, quality and effectiveness of medical devices, approved by the decision of the Eurasian Economic Commission dated February 12, 2016 No. 46 and the Rules for registration and expertise medicines for medical use, approved by the decision of the Eurasian Economic Commission of November 3, 2016 No. 78 (as a reference state and a state of recognition) |
|
1.1. Expertise in registration of medicines |
|
1 |
Original one-component drug |
1 drug |
1 579 541   |
|
1.1 |
In addition to each dose |
1 medicinal dose |
1 465 769   |
|
2 |
Original multicomponent drug |
1 drug |
1 702 488   |
|
2.1 |
In addition to each dose |
1 medicinal dose |
1 394 870   |
|
3 |
Original biological one-component drug |
1 drug |
1 671 615   |
|
3.1 |
In addition to each dose |
1 medicinal dose |
1 573 052   |
|
4 |
Original biological multicomponent drug |
1 drug |
1 772 301   |
|
4.1 |
In addition to each dose |
1 medicinal dose |
1 676 228   |
|
5 |
Reproduced one-component drug |
1 drug |
1 344 801   |
|
5.1 |
additionally each dose |
1 medicinal dose |
1 221 583   |
|
6 |
Reproduced multicomponent drug |
1 drug |
1 652 951   |
|
6.1 |
In addition to each dose |
1 medicinal dose |
1 419 127   |
|
7 |
Biosimilar single-component drug ( Biosimilar ) |
1 drug |
1 552 514   |
|
7.1 |
In addition to each dose |
1 medicinal dose |
1 466 365   |
|
8 |
Biosimilar multicomponent drug ( Biosimilar ) |
1 drug |
1 617 683   |
|
8.1 |
In addition to each dose |
1 medicinal dose |
1 545 254   |
|
9 |
Hybrid single-component drug |
1 drug |
1 302 132   |
|
9.1 |
In addition to each dose |
1 medicinal dose |
1 173 672   |
|
10 |
Hybrid multicomponent drug |
1 drug |
1 675 144   |
|
10.1 |
In addition to each dose |
1 medicinal dose |
1 420 957   |
|
11 |
Radiopharmaceutical Drug - Kit |
1 drug |
1 260 737   |
|
12 |
Radiopharmaceutical drug - precursor |
1 drug |
1 123 568   |
|
13 |
Homeopathic Medicine - Base Rate |
1 drug |
679 680  |
|
13.1 |
In addition to each dose |
1 medicinal dose |
631 674  |
|
14 |
Herbal Medicinal Product - Base Rate |
1 drug |
863 314  |
|
14.1 |
In addition to each dose |
1 medicinal dose |
788 373  |
|
15 |
Medicinal herbal raw materials - base rate |
1 drug |
827 694  |
|
1.2. Expertise during re-registration of medicinal products (confirmation of registration, bringing the registration dossier in accordance with the requirements of international treaties and acts constituting the law of the Eurasian Economic Union) |
|
16 |
Original one-component drug |
1 drug |
693346 |
|
16.1 |
In addition to each dose |
1 medicinal dose |
661,808 |
|
17 |
Original multicomponent drug |
1 drug |
757,022 |
|
17.1 |
In addition to each dose |
1 medicinal dose |
725 302 |
|
18 |
Original biological one-component drug |
1 drug |
734 662 |
|
18.1 |
In addition to each dose |
1 medicinal dose |
702,750 |
|
19 |
Original biological multicomponent drug |
1 drug |
917 840 |
|
19.1 |
In addition to each dose |
1 medicinal dose |
901,505 |
|
20 |
Reproduced one-component drug |
1 drug |
599349 |
|
20.1 |
In addition to each dose |
1 medicinal dose |
562746 |
|
21 |
Reproduced multicomponent drug |
1 drug |
801,307 |
|
21.1 |
In addition to each dose |
1 medicinal dose |
786 234 |
|
22 |
Biosimilar single-component drug ( Biosimilar ) |
1 drug |
855 233 |
|
22.1 |
In addition to each dose |
1 medicinal dose |
837 730 |
|
23 |
Biosimilar multicomponent drug ( Biosimilar ) |
1 drug |
877 224 |
|
23.1 |
In addition to each dose |
1 medicinal dose |
787 263 |
|
24 |
Hybrid single-component drug |
1 drug |
788169 |
|
24.1 |
In addition to each dose |
1 medicinal dose |
733,099 |
|
25 |
Hybrid multicomponent drug |
1 drug |
801,745 |
|
25.1 |
In addition to each dose |
1 medicinal dose |
782636 |
|
26 |
Radiopharmaceutical Drug - Kit |
1 drug |
794,009 |
|
27 |
Radiopharmaceutical drug - precursor |
1 drug |
749 692 |
|
28 |
Homeopathic Medicine - Base Rate |
1 drug |
581,161 |
|
28.1 |
In addition to each dose |
1 medicinal dose |
555 351 |
|
29 |
Herbal Medicinal Product - Base Rate |
1 drug |
630 238 |
|
29.1 |
In addition to each dose |
1 medicinal dose |
579,441 |
|
30 |
Medicinal herbal raw materials - base rate |
1 drug |
626,767 |
|
1.3. Expertise when making changes to the registration dossier of medicines |
|
31 |
Expertise when making changes to the registration dossier of medicinal products, without analytical expertise Type 1A |
1 drug |
126 954  |
|
32 |
Expertise when making changes to the registration dossier of medicinal products with analytical expertise Type 1B |
1 drug |
976 841 |
|
33 |
Expertise when making changes to the registration dossier of medicinal products, without analytical expertise Type 1B |
1 drug |
510,910 |
|
34 |
Expertise when making changes to the registration dossier of medicinal products with Type II analytical expertise |
1 drug |
1 135 006 |
|
35 |
Expertise when making changes to the registration dossier of medicinal products, without Type II analytical expertise |
1 drug |
651539 |
|
1.4. Expertise during registration (re-registration) of medical devices |
|
36 |
Class 1 - basic |
1 product |
308 335  |
|
37 |
Class 2A - basic rate |
1 product |
355 360 |
|
38 |
Class 2B - basic rate |
1 product |
396,928 |
|
39 |
Class 3 - basic rate |
1 product |
457,219 |
|
1.5. Laboratory tests (analytical expertise) during registration / re-registration of medical devices in accordance with the Rules for registration and expertise of safety, quality and effectiveness of medical devices, approved by the decision of the Eurasian Economic Commission dated February 12, 2016 No. 46 and the Rules for registration and expertise of medicines for medical use, approved by the decision of the Eurasian Economic Commission of November 3, 2016 No. 78 |
|
40 |
Class 1 - basic |
1 product |
264 213  |
|
40.1 |
Additionally for each modification |
1 product |
193 211 |
|
41 |
Class 2A - basic rate |
1 product |
371,027 |
|
41.1 |
Additionally for each modification |
1 product |
213,716 |
|
42 |
Class 2B - basic rate |
1 product |
405 693 |
|
42.1 |
Additionally for each modification |
1 product |
252 320 |
|
43 |
Class 3 - basic rate |
1 product |
519,780 |
|
43.1 |
Additionally for each modification |
1 product |
281521 |
|
1.6. Expertise when making changes to the registration dossier of medical devices |
|
44 |
Expertise when making changes to the registration dossier of a medical device |
1 product |
346,083 |

|  |  |
| --- | --- |
|   | Appendix 2to the order of the Minister ofHealth of theRepublic of Kazakhstandated August 31, 2017 No. 671 |

 **Prices for services sold by the subject of the state monopoly for the examination during state**
**registration, re-registration and amendments to the registration dossier of medicines and**
**medical devices in accordance with the legislation of the Republic of Kazakhstan**

      Footnote. Appendix 2 as amended by order of the Minister of Health of the Republic of Kazakhstan dated September 30, 2019 No. ҚР DSM-130 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |
No. |
Name of works |
unit of measurement |
Price in tenge without value added tax |
|
1 |
2 |
3 |
4 |
|
1. Expertise during state registration, re-registration and amendments to the registration dossier of medicines and medical devices imported into the Republic of Kazakhstan |
|
1.1. Expertise for state registration of medicines |
|
1 |
Multicomponent drug |
1 drug |
1 401 552 |
|
1.1 |
In addition to each dosage |
1 medicinal dose |
1 121 196 |
|
1.2 |
In addition to each packing |
1 packing |
29632 |
|
2 |
Multicomponent drug - bulk product |
1 drug |
1 350 891 |
|
2.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
1 095 386 |
|
3 |
One-component drug |
1 drug |
748,079 |
|
3.1 |
In addition to each dosage |
1 medicinal dose |
590 192 |
|
3.2 |
In addition to each packing |
1 packing |
14840 |
|
4 |
One-component drug - bulk product |
1 drug |
711 181 |
|
4.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
571,600 |
|
5 |
Medical multicomponent immunobiological preparation, Biosimilars |
1 drug |
1 648 097 |
|
5.1 |
In addition to each dosage |
1 medicinal dose |
1 272 695 |
|
5.2 |
In addition to each packing |
1 packing |
30,039 |
|
6 |
Medical multicomponent immunobiological preparation, Biosimilars - bulk product |
1 drug |
1 567 382 |
|
6.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
1 231 160 |
|
7 |
Medical one-component immunobiological preparation, Biosimilars |
1 drug |
1 234 878 |
|
7.1 |
In addition to each dosage |
1 medicinal dose |
993,047 |
|
7.2 |
In addition to each packing |
1 packing |
15208 |
|
8 |
Medical one-component immunobiological preparation, Biosimilars - bulk product |
1 drug |
1 161 950 |
|
8.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
956 600 |
|
9 |
Homeopathic remedy and herbal medicine |
1 drug |
323,762 |
|
9.1 |
In addition to each dosage |
1 medicinal dose |
275,088 |
|
10 |
Homeopathic remedy and herbal medicine -  bulk product |
1 drug |
301 307 |
|
10.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
264 397 |
|
11 |
Substances not manufactured in GMP conditions ( giempi ) \*, Premixes |
1 substance |
396,031 |
|
12 |
Medicinal plant raw materials |
1 drug |
315510 |
|
13 |
Parapharmaceuticals |
1 drug |
183 795 |
|
1.2. Expertise in the state re-registration of medicines |
|
14 |
Multicomponent drug |
1 drug |
1 266 959 |
|
14.1 |
In addition to each dosage |
1 medicinal dose |
929580 |
|
14.2 |
In addition to each packing |
1 packing |
19263 |
|
15 |
Multicomponent drug - bulk product |
1 drug |
1 233 180 |
|
15.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
912 352 |
|
16 |
One-component drug |
1 drug |
555 610 |
|
16.1 |
In addition to each dosage |
1 medicinal dose |
444,248 |
|
16.2 |
In addition to each packing |
1 packing |
9897 |
|
17 |
One-component drug - bulk product |
1 drug |
531,014 |
|
17.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
431,855 |
|
18 |
Medical multicomponent immunobiological preparation, Biosimilars |
1 drug |
1 224 339 |
|
18.1 |
In addition to each dosage |
1 medicinal dose |
1 062 538 |
|
18.2 |
In addition to each packing |
1 packing |
20,024 |
|
19 |
Medical multicomponent immunobiological preparation, Biosimilars - bulk product |
1 drug |
1 170 527 |
|
19.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
1 034 858 |
|
20 |
Medical one-component immunobiological preparation, Biosimilars |
1 drug |
1 003 929 |
|
20.1 |
In addition to each dosage |
1 medicinal dose |
882,980 |
|
20.2 |
In addition to each packing |
1 packing |
10145 |
|
21 |
Medical one-component immunobiological preparation, Biosimilars - bulk product |
1 drug |
955 316 |
|
21.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
858684 |
|
22 |
Homeopathic remedy and herbal medicine |
1 drug |
269257 |
|
22.1 |
In addition to each dosage |
1 medicinal dose |
223,595 |
|
23 |
Homeopathic remedy and herbal medicine - bulk product |
1 drug |
254,272 |
|
23.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
216,457 |
|
24 |
Substances not manufactured in GMP conditions ( giempy ), Premixes |
1 substance |
353,189 |
|
25 |
Medicinal plant raw materials |
1 drug |
239,933 |
|
26 |
Parapharmaceuticals |
1 drug |
154343 |
|
1.3. Expertise when making changes to the registration dossier of medicines |
|
27 |
Expert work when making changes to the registration dossier, with analytical expertise |
1 view |
194128 |
|
28 |
Expert work when making changes to the registration dossier, without analytical expertise |
1 view |
111 220 |
|
1.4. Expert work during registration (re-registration) of medical devices |
|
29 |
bracket -system |
1 product |
6,028 |
|
Modification of the bracket -system |
1 product |
6 028 |
|
30 |
Hemocontainers ,
hemofilters ,
leukofilters ,
hemoconcentrators |
1 product |
408 601 |
|
Modification of hemocontainers ,
hemofilters ,
leukofilters ,
hemoconcentrators |
1 product |
188 330 |
|
31 |
Medical needles (except for surgical needles) |
1 product |
135,578 |
|
Modification of medical needles (except for surgical needles) |
1 product |
5998 |
|
32 |
Products for dentistry (excluding implantable) |
1 product |
48905 |
|
Modification of products for dentistry (except for implantable) |
1 product |
25672 |
|
33 |
Medical devices intended for use in dialysis procedures, patient life support systems, and anesthesia machines |
1 product |
270,306 |
|
Modification of medical devices intended for use in dialysis procedures, patient life support systems and anesthesia machines |
1 product |
45964 |
|
34 |
Prosthetic and orthopedic products |
1 product |
43770 |
|
Modification of prosthetic and orthopedic products |
1 product |
11,962 |
|
35 |
Products used for transfusion, perfusion and infusion , vascular catheters |
1 product |
257,174 |
|
Modification of products used for transfusions, perfusions and infusions , vascular catheters |
1 product |
33804 |
|
36 |
Medical products in the form of solutions, drops, sprays, gels, ointments, tablets, creams |
1 product |
303 448 |
|
Modification of medical devices in the form of solutions, drops, sprays, gels, ointments, tablets, creams |
1 product |
114194 |
|
37 |
Medical devices for in vitro (in vitro ) \*\* diagnostics |
1 product |
97123 |
|
Modification of medical devices for in vitro (in vitro ) diagnostics |
1 product |
83 121 |
|
38 |
Medical devices for in vitro (in vitro ) diagnostics, a set of up to 10 items |
1 set |
56,027 |
|
Modification of medical devices for in vitro (in vitro ) diagnostics, a set of up to 10 items |
1 set |
50 127 |
|
39 |
Medical devices for in vitro (in vitro ) diagnostics, a set of 11 to 20 items |
1 set |
98803 |
|
Modification of medical devices for in vitro (in vitro ) diagnostics, a set of 11 to 20 items |
1 set |
90934 |
|
40 |
Medical devices for in vitro (in vitro ) diagnostics, a set of over 20 items |
1 set |
154012 |
|
Modification of medical devices for in vitro (in vitro ) diagnostics, a set of over 20 items |
1 set |
131,365 |
|
41 |
Medical devices for birth control and protection against sexually transmitted infections |
1 product |
107,899 |
|
Modification of medical devices for birth control and protection against sexually transmitted infections |
1 product |
16361 |
|
42 |
Medical devices for in vitro fertilization service |
1 product |
213829 |
|
Modification of medical devices for in vitro fertilization service |
1 product |
34 482 |
|
43 |
Reusable sanitary and hygienic products |
1 product |
67,041 |
|
Modification of reusable sanitary and hygienic products |
1 product |
36416 |
|
44 |
Disposable sanitary and hygienic medical products |
1 product |
99,503 |
|
Modification of disposable medical products for sanitary and hygienic purposes |
1 product |
35,264 |
|
45 |
Medical devices for special purposes |
1 product |
426,040 |
|
Modification of medical devices for special purposes |
1 product |
8 008 |
|
46 |
Medical devices used for functional diagnostics |
1 product |
8 465 |
|
Modification of medical devices used for functional diagnostics |
1 product |
5745 |
|
47 |
Implantable devices |
1 product |
421,975 |
|
Modification of implantable devices |
1 product |
95571 |
|
48 |
Special purpose catheters |
1 product |
128,567 |
|
Modification of special purpose catheters |
1 product |
25705 |
|
49 |
Sets and sets of medical instruments (up to 50 components) |
1 set |
158,557 |
|
Modification of kits and sets of medical instruments (up to 50 components) |
1 set |
22,097 |
|
50 |
Kits and sets of medical instruments (from 101 to 500 components) |
1 set |
236,429 |
|
Modification of kits and sets of medical instruments (from 101 to 500 components) |
1 set |
47458 |
|
51 |
Kits and sets of medical instruments (from 501 to 1000 components) |
1 set |
303,689 |
|
Modification of kits and sets of medical instruments (from 501 to 1000 components) |
1 set |
82062 |
|
52 |
Kits and sets of medical instruments (from 51 to 100 components) |
1 set |
207,990 |
|
Modification of kits and sets of medical instruments (from 51 to 100 components) |
1 set |
43302 |
|
53 |
Sets and sets of medical instruments (over 1000 components) |
1 set |
372,479 |
|
Modification of kits and sets of medical instruments (over 1000 components) |
1 set |
132,763 |
|
54 |
Contact lenses |
1 product |
150 300 |
|
Contact lenses modification |
1 product |
5608 |
|
55 |
Spectacle lenses |
1 product |
7 720 |
|
Spectacle lens modification |
1 product |
4991 |
|
56 |
Medical instruments |
1 product |
82822 |
|
Modification of medical instruments |
1 product |
3821 |
|
57 |
Medical linen, means of protection of skin and mucous membranes |
1 product |
86898 |
|
Modification of medical underwear, means of protection of the skin and mucous membranes |
1 product |
37,044 |
|
58 |
Medical underwear, means of protection of skin and mucous membranes, sets |
1 product |
98696 |
|
Modification of medical underwear, means of protection of skin and mucous membranes, sets |
1 product |
64248 |
|
59 |
Dental kits (up to 10 pieces) |
1 set |
44 325 |
|  |
Modification of sets of dental materials (up to 10 components) |
1 set |
20484 |
|
60 |
Sets of dental materials (over 10 components) |
1 set |
59 587 |
|
Modification of sets of dental materials (over 10 components) |
1 set |
28,003 |
|
61 |
Natural dressings |
1 product |
115659 |
|
Modification of natural-based dressings |
1 product |
39559 |
|
62 |
Polymer-based dressings |
1 product |
85,907 |
|
Modification of polymer-based dressings |
1 product |
11503 |
|
63 |
Medicated dressings |
1 product |
172,764 |
|
Modification of dressings with the addition of drugs |
1 product |
83,995 |
|
64 |
Plasters |
1 product |
79631 |
|
Modification of plasters |
1 product |
10 783 |
|
65 |
Medicinal patches |
1 product |
117,631 |
|
Modification of drug patches |
1 product |
60387 |
|
66 |
Fixing dressings, including contoured and elastic, tourniquets |
1 product |
42 586 |
|
Modification of fixing bandages, including contour and elastic bandages |
1 product |
23309 |
|
67 |
Consumables for taking blood samples, urine, stool, biopsy material |
1 product |
163349 |
|
Modification of consumables for sampling blood, urine, stool, biopsy material |
1 product |
94 381 |
|
68 |
Dental materials |
1 product |
50 788 |
|
Modification of dental materials |
1 product |
21368 |
|
69 |
Suture material |
1 product |
235,709 |
|
Suture modification |
1 product |
34190 |
|
70 |
Medical syringes |
1 product |
100 473 |
|
Modification of medical syringes |
1 product |
20744 |
|
1.5. Expertise when making changes (type 1) to the registration dossier of medical devices |
|
71 |
Making changes (type 1) to the registration dossier of medical devices, without analytical expertise |
1 view |
62,009 |
|
Modification when making changes (type 1) to the registration dossier of medical devices, without analytical expertise |
1 view |
62,009 |
|
72 |
Making changes (type 1) to the registration dossier of medical devices, with analytical expertise |
1 view |
132,400 |
|
Modification when making changes (type 1) to the registration dossier of medical devices, with analytical expertise |
1 view |
97436 |
|
1.6. Expert work in registration and re-registration of medical devices (medical equipment) |
|
73 |
Medical device (Medical equipment) - safety class 1 and 2a - registration |
1 view |
140864 |
|
Re-registration |
1 view |
70497 |
|
74 |
Medical device (Medical equipment) - safety class 2 b and 3 - registration |
1 view |
343 850 |
|
Re-registration |
1 view |
172,283 |
|
75 |
Medical complexes - registration |
1 view |
515 789 |
|
Re-registration |
1 view |
257 807 |
|
1.7. Expert work when making changes (type 1) to the registration dossier of a medical device (medical equipment) |
|
76 |
Making changes (type 1) to the registration dossier of a medical device (medical equipment), without analytical expertise |
1 view |
62,009 |
|
2. Expertise during state registration, re-registration and amendments to the registration dossier of medicines and medical devices for domestic manufacturers |
|
2.1. Expertise in registration of medicines |
|
77 |
Multicomponent drug |
1 drug |
235,574 |
|
77.1 |
In addition to each dosage |
1 medicinal dose |
154 818 |
|
77.2 |
In addition to each packing |
1 packing |
5738 |
|
78 |
Multicomponent drug - bulk product |
1 drug |
235,574 |
|
78.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
154 818 |
|
79 |
One-component drug |
1 drug |
190 956 |
|
79.1 |
In addition to each dosage |
1 medicinal dose |
117,038 |
|
79.2 |
In addition to each packing |
1 packing |
3468 |
|
80 |
One-component drug - bulk product |
1 drug |
190 956 |
|
80.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
117,038 |
|
81 |
Medical multicomponent immunobiological preparation, biosimilars |
1 drug |
199,400 |
|
81.1 |
In addition to each dosage |
1 medicinal dose |
121 520 |
|
81.2 |
In addition to each packing |
1 packing |
5738 |
|
82 |
Medical multicomponent immunobiological preparation, biosimilars - bulk product |
1 drug |
199 400 |
|
82.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
121 520 |
|
83 |
Medical one-component immunobiological preparation, biosimilars |
1 drug |
199,400 |
|
83.1 |
In addition to each dosage |
1 medicinal dose |
121 520 |
|
83.2 |
In addition to each packing |
1 packing |
3468 |
|
84 |
Medical one-component immunobiological preparation, biosimilars - bulk product |
1 drug |
199 400 |
|
84.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
121 520 |
|
85 |
Homeopathic remedy and herbal medicine |
1 drug |
179 756 |
|
85.1 |
In addition to each dosage |
1 medicinal dose |
126 046 |
|
86 |
Homeopathic remedy and herbal medicine - bulk product |
1 drug |
179 756 |
|
86.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
126 046 |
|
87 |
Substances not manufactured under conditions ( giempie ), premixes |
1 substance |
126 014 |
|
88 |
Medicinal plant raw materials |
1 drug |
36 102 |
|
89 |
Parapharmaceuticals |
1 drug |
215 550 |
|
2.2. Expertise in the state re-registration of medicines |
|
90 |
Multicomponent drug |
1 drug |
209 692 |
|
90.1 |
In addition to each dosage |
1 medicinal dose |
138 644 |
|
90.2 |
In addition to each packing |
1 packing |
2546 |
|
91 |
Multicomponent drug - bulk product |
1 drug |
209,692 |
|
91.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
138644 |
|
92 |
One-component drug |
1 drug |
172,654 |
|
92.1 |
In addition to each dosage |
1 medicinal dose |
114 326 |
|
92.2 |
In addition to each packing |
1 packing |
2924 |
|
93 |
One-component drug - bulk product |
1 drug |
172,654 |
|
93.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
114 326 |
|
94 |
Medical multicomponent immunobiological preparation, biosimilars |
1 drug |
181862 |
|
94.1 |
In addition to each dosage |
1 medicinal dose |
116,074 |
|
94.2 |
In addition to each packing |
1 packing |
2546 |
|
95 |
Medical multicomponent immunobiological preparation, biosimilars - bulk product |
1 drug |
181862 |
|
95.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
116 074 |
|
96 |
Medical one-component immunobiological preparation, biosimilars |
1 drug |
181862 |
|
96.1 |
In addition to each dosage |
1 medicinal dose |
116 074 |
|
96.2 |
In addition to each packing |
1 packing |
2 924 |
|
97 |
Medical one-component immunobiological preparation, biosimilars - bulk product |
1 drug |
181 862 |
|
97.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
116 074 |
|
98 |
Homeopathic remedy and herbal medicine |
1 drug |
174618 |
|
98.1 |
In addition to each dosage |
1 medicinal dose |
123 866 |
|
99 |
Homeopathic remedy and herbal medicine - bulk product |
1 drug |
174618 |
|
99.1 |
In addition to each drug dose - bulk product |
1 medicinal dose |
123 866 |
|
100 |
Substances not manufactured in GMP conditions ( giempi ), Premixes |
1 substance |
123,776 |
|
101 |
Medicinal plant raw materials |
1 drug |
26200 |
|
102 |
Parapharmaceuticals |
1 drug |
195,016 |
|
2.3. Expertise when making changes (type 1) to the registration dossier of medicines |
|
103 |
Expertise when making changes (type 1) to the registration dossier, with analytical expertise |
1 view |
32748 |
|
104 |
Expertise when making changes (type 1) to the registration dossier, without analytical expertise |
1 view |
32748 |
|
2.4. Expertise for registration of medical devices \*\*\* |
|  |
105 |
bracket -system |
1 product |
39956 |
|  |
Modification of braces systems |
1 product |
6,665 |
|  |
106 |
Hemocontainers , hemofilters , leuco filters , hemoconcentrators |
1 product |
190 314 |
|  |
Modification hemocontainers , hemofilter , leuco filters hemoconcentrators |
1 product |
190314 |
|  |
107 |
Medical needles (except for surgical needles) |
1 product |
39956 |
|  |
Modification of medical needles (except for surgical needles) |
1 product |
6608 |
|  |
108 |
Products for dentistry (excluding implantable) |
1 product |
39 956 |
|  |
Modification of products for dentistry (except for implantable) |
1 product |
28 383 |
|  |
109 |
Medical devices intended for use in dialysis procedures, patient life support systems, and anesthesia machines |
1 product |
79 994 |
|  |
Modification of medical devices intended for use in dialysis procedures, patient life support systems and anesthesia machines |
1 product |
50 781 |
|  |
110 |
Prosthetic and orthopedic products |
1 product |
69166 |
|  |
Modification of prosthetic and orthopedic products |
1 product |
13,227 |
|  |
111 |
Products used for transfusion, perfusion and infusion , vascular catheters |
1 product |
79,994 |
|  |  |
Modification of products used for transfusions, perfusions and infusions , vascular catheters |
1 product |
37355 |
|  |
112 |
Medical products in the form of solutions, drops, sprays, gels, ointments, tablets, creams |
1 product |
190 956 |
|  |
Modification of medical devices in the form of solutions, drops, sprays, gels, ointments, tablets, creams |
1 product |
124 526 |
|  |
113 |
Medical devices for in vitro (in vitro ) diagnostics |
1 product |
70 546 |
|  |
Modification of medical devices for in vitro (in vitro ) diagnostics |
1 product |
70 546 |
|  |
114 |
Medical devices for in vitro (in vitro ) diagnostics, a set of up to 10 items |
1 set |
70 546 |
|  |
Modification of medical devices for in vitro (in vitro ) diagnostics, a set of up to 10 items |
1 set |
55 081 |
|  |
115 |
Medical devices for in vitro (in vitro ) diagnostics, a set of 11 to 20 items |
1 set |
70 546 |
|  |
Modification of medical devices for in vitro (in vitro ) diagnostics, a set of 11 to 20 items |
1 set |
70 546 |
|  |
116 |
Medical devices for in vitro (in vitro ) diagnostics, a set of over 20 items |
1 set |
70 546 |
|  |
Modification of medical devices for in vitro (in vitro ) diagnostics, a set of over 20 items |
1 set |
70 546 |
|  |
117 |
Medical devices for birth control and protection against sexually transmitted infections |
1 product |
79 994 |
|  |
Modification of medical devices for birth control and protection against sexually transmitted infections |
1 product |
18,073 |
|  |
118 |
Medical devices for in vitro fertilization service |
1 product |
79,994 |
|  |
Modification of medical devices for in vitro fertilization service |
1 product |
38 094 |
|  |
119 |
Medical products for sanitary and hygienic purposes, reusable |
1 product |
33 270 |
|  |
Modification of reusable medical products for sanitary and hygienic purposes |
1 product |
33 270 |
|  |
120 |
Disposable sanitary and hygienic medical products |
1 product |
33 270 |
|  |  |
Modification of disposable medical products for sanitary and hygienic purposes |
1 product |
33 270 |
|  |
121 |
Medical devices for special purposes |
1 product |
55,594 |
|  |
Modification of medical devices for special purposes |
1 product |
8 851 |
|  |
122 |
Medical devices used for functional diagnostics |
1 product |
9,360 |
|  |
Modification of medical devices used for functional diagnostics |
1 product |
6 352 |
|  |
123 |
Implantable devices |
1 product |
69166 |
|  |
Modification of implantable devices |
1 product |
69166 |
|  |
124 |
Special purpose catheters |
1 product |
55,594 |
|  |
Modification of special purpose catheters |
1 product |
28408 |
|  |
125 |
Sets and sets of medical instruments (up to 50 components) |
1 set |
190314 |
|  |
Modification of kits and sets of medical instruments (up to 50 components) |
1 set |
24,425 |
|  |
126 |
Kits and sets of medical instruments (from 101 to 500 components) |
1 set |
190314 |
|  |
Modification of kits and sets of medical instruments (from 101 to 500 components) |
1 set |
52 464 |
|  |
127 |
Kits and sets of medical instruments (from 501 to 1000 components) |
1 set |
190314 |
|  |
Modification of kits and sets of medical instruments (from 501 to 1000 components) |
1 set |
90,724 |
|  |
128 |
Kits and sets of medical instruments (from 51 to 100 components) |
1 set |
190314 |
|  |
Modification of kits and sets of medical instruments (from 51 to 100 components) |
1 set |
47 870 |
|  |
129 |
Sets and sets of medical instruments (over 1000 components) |
1 set |
190314 |
|  |
Modification of kits and sets of medical instruments (over 1000 components) |
1 set |
146,774 |
|  |
130 |
Contact lenses |
1 product |
95642 |
|  |
Contact lenses modification |
1 product |
6,200 |
|  |
131 |
Spectacle lenses |
1 product |
95642 |
|  |
Spectacle lens modification |
1 product |
5 518 |
|  |
132 |
Medical instruments |
1 product |
39956 |
|  |
Modification of medical instruments |
1 product |
4223 |
|  |
133 |
Medical linen, means of protection of skin and mucous membranes |
1 product |
79,994 |
|  |
Modification of medical underwear, means of protection of the skin and mucous membranes |
1 product |
40945 |
|  |
134 |
Medical underwear, means of protection of skin and mucous membranes, sets |
1 product |
79,994 |
|  |
Modification of medical underwear, means of protection of skin and mucous membranes, sets |
1 product |
71,024 |
|  |
135 |
Dental kits (up to 10 pieces) |
1 set |
39956 |
|  |
Modification of sets of dental materials (up to 10 components) |
1 set |
22642 |
|  |
136 |
Sets of dental materials (over 10 components) |
1 set |
39956 |
|  |
Modification of sets of dental materials (over 10 components) |
1 set |
30955 |
|  |
137 |
Natural dressings |
1 product |
39956 |
|  |
Modification of natural-based dressings |
1 product |
39956 |
|  |
138 |
Polymer-based dressings |
1 product |
39956 |
|  |
Modification of polymer-based dressings |
1 product |
12 748 |
|  |
139 |
Medicated dressings |
1 product |
39 956 |
|  |
Modification of dressings with the addition of drugs |
1 product |
39956 |
|  |
140 |
Plasters |
1 product |
39 956 |
|  |
Modification of plasters |
1 product |
11,922 |
|  |
141 |
Medicinal patches |
1 product |
39956 |
|  |
Modification of drug patches |
1 product |
39956 |
|  |
142 |
Fixing dressings, including contoured and elastic, tourniquets |
1 product |
39 956 |
|  |
Modification of fixation dressings, including contour and elastic tourniquets |
1 product |
25 771 |
|  |
143 |
Consumables for taking blood samples, urine, stool, biopsy material |
1 product |
55,594 |
|  |
Modification of consumables for sampling blood, urine, stool, biopsy material |
1 product |
55,594 |
|  |
144 |
Dental materials |
1 product |
39956 |
|  |
Modification of dental materials |
1 product |
23620 |
|  |
145 |
Suture material |
1 product |
82382 |
|  |
Suture modification |
1 product |
37774 |
|  |
146 |
Medical syringes |
1 product |
100 306 |
|  |
Modification of medical syringes |
1 product |
22916 |
|  |
2.5. Expertise when making changes (type 1) to the registration dossier of medical devices |
|  |
147 |
Making changes (type 1) to the registration dossier of medical devices, without analytical expertise |
1 view |
32 748 |
|  |
Modification when making changes (type 1) to the registration dossier of medical devices, without analytical expertise |
1 view |
32748 |
|  |
148 |
Making changes (type 1) to the registration dossier of medical devices, with analytical expertise |
1 view |
32748 |
|  |
Modification when making changes (type 1) to the registration dossier of medical devices, with analytical expertise |
1 view |
32748 |

      Note:

      \* GMP ( giempi ) - Good Pharmaceutical Practices in the Circulation of Medicines - Health standards that apply to all stages of the life cycle of medicines: good manufacturing practice

      \*\* in vitro (in vitro ) - studies in which not multicellular whole organisms are used as test systems, but microorganisms or material isolated from whole organisms, or their imitation.

      \*\*\* Expertise upon re-registration of medical devices manufactured in the Republic of Kazakhstan (for domestic manufacturers) due to the expiration of the registration certificate is paid in the amount of 50% of the registration cost.

|  |  |
| --- | --- |
|   | Appendix 3to the order of the Minister ofHealth of theRepublic of Kazakhstandated August 31, 2017 No. 671 |

 **Prices for services sold by a state monopoly entity for assessing the safety and quality of**
**medicines and medical devices registered in the Republic of Kazakhstan**

      Footnote. Appendix 3 as amended by order of the Minister of Health of the Republic of Kazakhstan dated September 30, 2019 No. ҚR DSM-130 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

|  |  |  |  |
| --- | --- | --- | --- |
|
No. |
Service (work) name |
unit of measurement |
Price in tenge without value added tax |
|
1 |
2 |
3 |
4 |
|
1.1. Assessment of the safety and quality of drugs and medical devices by declaration |
|
1 |
Assessment of the safety and quality of drugs and medical devices by declaration |
1 drug / 1 product |
10,983 |
|  |
Documentary expertise at: |  |  |
|
2 |
Extension of the validity period of the conclusion on safety and quality without testing |
1 conclusion |
3969 |
|
3 |
Making a copy of the conclusion on safety and quality |
1 copy |
219 |
|
4 |
Making a duplicate of the conclusion on safety and quality |
1 duplicate |
1 438 |
|
1.2. Assessment of the safety and quality of medicines and medical devices of each batch (batch) |
|
five |
Evaluation of safety and quality of medicinal products of a batch (batch) - multicomponent medicinal product |
1 drug |
71,545 |
|
6 |
Evaluation of safety and quality of medicinal products of a batch (batch) - one-component medicinal product |
1 drug |
59555 |
|
7 |
Evaluation of safety and quality of medicinal products of a batch (batch) - multicomponent biological medicinal product |
1 drug |
97152 |
|
eight |
Assessment of safety and quality of medicinal products in a batch (batch) - one-component biological medicinal product |
1 drug |
69899 |
|
nine |
Assessment of the safety and quality of medicinal products in a batch (batch) - homeopathic medicinal product |
1 drug |
29868 |
|
ten |
Evaluation of safety and quality of medicinal products of a batch (batch) - herbal medicinal product |
1 drug |
33,191 |
|
eleven |
Evaluation of safety and quality of batch (batch) drugs - bulk- product |
1 drug |
62,276 |
|
12 |
Assessment of the safety and quality of medicinal products in a batch (batch) - medicinal plant raw materials |
1 drug |
32244 |
|
13 |
Evaluation of safety and quality of batch (batch) medical devices - Class 1 |
1 product |
55 335 |
|
fourteen |
Assessment of safety and quality of batch (batch) medical devices - Class 2A |
1 product |
68175 |
|
fifteen |
Assessment of safety and quality of medical devices of a batch (batch) - Class 2B |
1 product |
84 122 |
|
sixteen |
Evaluation of safety and quality of medical devices batch (batch) - Class 3 |
1 product |
115,967 |
|
1.3. Serial assessment of the safety and quality of medicines and medical devices |
|  |
Assessment of production conditions for: |
|
17 |
Serial assessment of safety and quality of medicines and medical devices - 1 production workshop |
1 examination |
480,546 |
|  |
Laboratory tests at: |
|
18 |
Serial assessment of safety and quality of medicinal products - multicomponent medicinal product |
1 drug |
59550 |
|
nineteen |
Serial assessment of safety and quality of medicinal products - single-component medicinal product |
1 drug |
47560 |
|
20 |
Serial assessment of safety and quality of medicinal products - multicomponent biological medicinal product |
1 drug |
85156 |
|
21 |
Serial assessment of safety and quality of medicinal products - single-component biological medicinal product |
1 drug |
57902 |
|
22 |
Serial assessment of safety and quality of medicines - homeopathic medicinal product |
1 drug |
17873 |
|
23 |
Serial assessment of safety and quality of medicines - herbal medicinal product |
1 drug |
21196 |
|
24 |
Serial assessment of safety and quality of medicines - bulk -product |
1 drug |
50281 |
|
25 |
Serial assessment of the safety and quality of medicines - medicinal plant raw materials |
1 drug |
20249 |
|
26 |
Serial Assessment of Safety and Quality of Medical Devices - Class 1 |
1 product |
43340 |
|
27 |
Serial Assessment of Safety and Quality of Medical Devices - Class 2A |
1 product |
56180 |
|
28 |
Serial assessment of safety and quality of medical devices - Class 2B |
1 product |
72127 |
|
29 |
Serial assessment of safety and quality of medical devices - Class 3 |
1 product |
103,972 |
|  |
1.4. Laboratory testing of samples of medicines and medical devices withdrawn from the market |
|
30 |
Laboratory testing of drug samples withdrawn from the market - multicomponent drug |
1 drug |
59550 |
|
31 |
Laboratory testing of drug samples withdrawn from the market - one-component drug |
1 drug |
47560 |
|
32 |
Laboratory testing of drug samples withdrawn from the market - multicomponent biological medicinal product |
1 drug |
85156 |
|
33 |
Laboratory testing of samples of medicinal products withdrawn from the market - one-component biological medicinal product |
1 drug |
57902 |
|
34 |
Laboratory testing of drug samples withdrawn from the market - homeopathic medicinal product |
1 drug |
17873 |
|
35 |
Laboratory testing of drug samples withdrawn from the market - herbal medicinal product |
1 drug |
21196 |
|
36 |
Laboratory testing of drug samples withdrawn from the market - bulk- product |
1 drug |
50281 |
|
37 |
Laboratory tests of samples of medicines withdrawn from the market - medicinal plant raw materials |
1 drug |
20249 |
|
38 |
Laboratory testing of medical device samples taken from the market - Class 1 |
1 product |
43340 |
|
39 |
Laboratory testing of medical device samples taken from the market - Class 2A |
1 product |
56180 |
|
40 |
Laboratory testing of samples of medical devices withdrawn from the market - Class 2B |
1 product |
72127 |
|
41 |
Laboratory testing of medical device samples taken from the market - Class 3 |
1 product |
103,972 |

 © 2012. «Institute of legislation and legal information of the Republic of Kazakhstan» of the Ministry of Justice of the Republic of Kazakhstan