

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

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. 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
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		651539

	products, without Type II analytical expertise	1 drug	
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 2
to the order of the Minister of
Health of the
Republic of Kazakhstan
dated 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
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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		254,272

	and herbal medicine - bulk product	1 drug		
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
	Reusable sanitary and hygienic products	1 product	67,041

43	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
	Medical underwear, means of protection of skin and mucous membranes, sets	1 product	98696
58	Modification of medical underwear, means of protection of skin and mucous membranes, sets	1 product	64248
	Dental kits (up to 10 pieces)	1 set	44 325
60	Modification of sets of dental materials (up to 10 components)	1 set	20484
	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
		Medical devices for in vitro (in vitro) diagnostics, a set of over 20 items	1 set	70 546

	116	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 3
to the order of the Minister of
Health of the
Republic of Kazakhstan
dated 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. ҚР 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		85156

	products - multicomponent biological medicinal product	1 drug	
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		85156

	the market - multicomponent biological medicinal product	1 drug	
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