On approval of the Rules for regulation of prices for medicines

Invalidated Unofficial translation

Order of the acting Minister of Health of the Republic of Kazakhstan dated April 19, 2019 no. ҚР ДСМ-42. Registered with the Ministry of Justice of the Republic of Kazakhstan dated April 23, 2019 no. 18573. Abolished by the Order of the Minister of Health of the Republic of Kazakhstan dated December 11, 2020 No. KR DSM-247/ 2020

Unofficial translation

Footnote. Abolished by the Order of the Minister of Health of the Republic of Kazakhstan dated December 11, 2020 No. KR DSM-247/2020 (effective after ten calendar days after the date of its first official publication).

In accordance with subclause 112) of clause 1 of article 7 of the Code of the Republic of Kazakhstan dated September 18, 2009 "On public health and health care system" I HEREBY ORDER:

1. to approve the Rules for regulation of prices for medicines according to annex 1, to this order (hereinafter referred to as the Rules).

2. To declare to be no longer in force certain orders of the Ministry of Health of the Republic of Kazakhstan according to annex 2, to this order.

3. The Pharmacy Committee of the Ministry of Health of the Republic of Kazakhstan, in accordance with the procedure, established by the legislation 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 state registration of this order, direction of a copy of it in paper and electronic form in Kazakh and Russian languages to the Republican State Enterprise on the right of economic management “Institute of Legislation and Legal Information of the Republic of Kazakhstan” of the Ministry of Justice of the Republic of Kazakhstan for official publication and placement in the Reference Control Bank of the Regulatory Legal Acts of the Republic of Kazakhstan;

3) within ten calendar days from the date of state registration of this order, direction of a copy hereof for official publication in periodical printed media;

4) placement of this order on the Internet resource of the Ministry of Health of the Republic of Kazakhstan after its official publication;

5) within ten working days after the state registration hereof, submission to the Department of Legal Service of the Ministry of Health of the Republic of Kazakhstan of information about implementation of the measures, stipulated by subclauses 1), 2), 3) and 4) of this clause.

4. Control over execution hereof shall be entrusted to the vice-minister of health of the Republic of Kazakhstan Nadyrov K. T.

5. This order shall come into force upon expiry of ten calendar days from the date of its first official publication.

Acting Minister of Health
of the Republic of Kazakhstan *L. Aktayeva*

Annex to the order
of the Minister of Health
of the Republic of Kazakhstan
dated April 19, 2019
no. ҚР ДСМ-42

Rules for regulation of prices for medicines

Chapter 1. General provisions

1. These Rules shall establish the procedure for regulation of prices for medicines (hereinafter – medicines).

2. State regulation of prices shall be carried out by the authorized body in health care by formation and approval of marginal prices and markups.

3. In these Rules, the following general definitions shall be used:

1) price register - a system of accounting and systematization of information in electronic form about marginal prices for the brand name medicines for wholesale and retail sale, in chronological order, subject to changes and preservation of previous versions, with the possibility of open access to these data on the Internet resource of a state expert organization;

2) fixed price - the price of medicines, determined by the results of the purchase, at which the supplier agrees to supply medicines to a single distributor;

3) bio-analogous medicinal product (bio-analog, biosimilar medicinal product, biosimilar) - a biological medicinal product that contains a version of the active substance of a registered biological original medicinal product or reference medicinal product and which shows similarity (similarity) based on comparative studies in terms of quality, biological activity, safety and efficiency;

4) limit price for the trade name of medicines for retail sale - the price of the trade name of medicines above which its retail sale cannot be carried out;

5) retail margin - a premium to the price limit for the brand name medicines for wholesale on a regressive scale, including profit and costs associated with the retail

sale of medicines used to calculate the price limit for the brand name medicines for retail sale;

6) regressive scale of retail margin - a scale of retail margin in percentage terms, depending on the size of the price limit for the brand name medicines for wholesale;

7) original medicinal product - medicinal product with a new active ingredient, which was first registered and placed on the global pharmaceutical market, on the basis of a dossier containing the results of full preclinical (non-clinical) and clinical studies confirming its safety, quality and effectiveness;

8) international nonproprietary name of a medicine - the name of a medicine recommended by the World Health Organization;

9) an authorized body in health care (hereinafter referred to as the authorized body) – the state body providing guidance in the field of public health, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of the population, circulation of medicines, and medical devices (hereinafter referred to as MD), and control over the quality of medical services;

10) the state expert organization in the sphere of circulation of medicines and MD (hereinafter referred to as the state expert organization) – a republican state enterprise on the right of economic management, carrying out industrial and economic activities in the field of health care to ensure the safety, effectiveness and quality of medicines, as well as scientific research in the field of developing new original medicines, pharmacy, pharmacology;

11) the state register of medicines and MD – an information resource containing information about medicines and MD registered and approved for medical use in the Republic of Kazakhstan;

12) reference pricing for medicines - a price analysis system for the brand name of medicines based on the ex-works prices presented by the applicant of the same manufacturer of medicines with the same active substance, taking into account the dosage form, concentration and dosage in reference countries, as well as the actual price of deliveries to the Republic of Kazakhstan;

13) measuring unit of medicines (procurement unit) – a unit of dosed (divided) pharmaceutical formulation or limited primary packaging of the volume (mass) of non-dosed (undivided) pharmaceutical formulation for medicines;

14) registered price for wholesale and retail price – the estimated base price for the brand name of medicines for setting the price limit for the brand name of medicines for the wholesale and retail sale of medicines, consisting of the manufacturer’s price for the wholesale and retail sale, costs for assessment of safety and quality, marketing costs, and for imported medicines - transport costs from the manufacturer to the border of the Republic of Kazakhstan and customs costs;

15) marginal price for the brand name of medicines for wholesale is the price of the brand name of medicines above which its wholesale may not be carried out;

16) wholesale markup - a markup to the registered price for the wholesale and retail sale of medicines according to the regressive scale, including profits and expenses associated with the wholesale sale of medicines used to calculate the marginal price for the brand name of medicines for wholesale sales;

17) regressive wholesale markup scale - the wholesale markup scale in percentage terms, depending on the value of the registered price for the wholesale and retail sales of medicines;

18) reproduced medicinal product (generic) - a medicinal product that has the same quantitative and qualitative composition of active ingredients and the same dosage form as the original medicinal product, and whose bioequivalence to the original medicinal product is confirmed by appropriate bioavailability studies. Different salts, esters, isomers, mixtures of isomers, complexes or derivatives of the active substance are recognized as one and the same active substance, if their safety and effectiveness do not differ significantly. Different dosage forms for oral administration with immediate release of substances are recognized in the bioavailability studies of the same dosage form;

19) applicant - an individual or legal entity authorized to submit applications, documents and materials for registering the price or re-registering the registered price of medicines, which is the manufacturer, owner or holder of a registration certificate or who is an authorized representative of the manufacturer, owner or holder of a registration certificate on the basis of a power of attorney, as well as other entities in the area of circulation of medicines or MD, for medicines imported and (or) produced in the territory of the Republic of Kazakhstan before expiration of the registration certificate, the validity of the registration certificate medicines at the time of the application has expired;

20) reference countries - countries of the European and Central Asian region, macroeconomically comparable with Kazakhstan, belonging to the group of high, higher than middle or lower than middle income countries, according to the World Bank classification according to the estimated level of gross national income per capita , from the category credited by the International Bank reconstruction and development (Azerbaijan, Belarus, Bulgaria, Hungary, Greece, Latvia, Lithuania, Russia, Poland, Romania, Slovakia, Slovenia, Turkey, Croatia, Czech Republic, Estonia);

21) a limit price for the brand name of medicines or MD within the framework of the guaranteed volume of free medical care (hereinafter referred to as the GVoFMC) and in the system of compulsory social health insurance (hereinafter referred to as the

CSHI) - the price for the brand name of medicine or MD, above which procurement can be made within the framework of the guaranteed volume of medical care and in the CSHI system;

22) regressive markup scale within the framework of GVOFMC and in CSHI system – a markup scale the framework of GVOFMC and in CSHI system in percentage terms, depending on the size of the registered price for medicines the framework of GVOFMC and in CSHI system;

23) marginal price for the international nonproprietary name of medicines or technical specification MD within the framework of GVOFMC and in CSHI system - price for the international generic name medicines or technical specification MD above which the procurement within the framework of GVOFMC and in CSHI system cannot be performed;

24) registered price within the framework of GVOFMC and in CSHI system - the estimated base price for the brand name medicines to form the maximum price for the brand name within the framework of GVOFMC and in CSHI system, consisting of the manufacturer price within the framework of GVOFMC and in CSHI system, the cost of assessment of safety and quality, as well as for imported medicines - transport costs from the manufacturer to the border of the Republic of Kazakhstan and customs costs;

25) markup within the framework of GVOFMC and in CSHI system - a markup to the registered price within the framework of GVOFMC and in CSHI system medicines on a regressive scale, including profit and expenses associated with the acquisition, storage, transportation, sale of medicines within the framework of GVOFMC and in CSHI system used to calculate the maximum price for the brand name medicines within the framework of GVOFMC and in CSHI system;

26) DDP INCOTERMS 2010 is an international trade term for the standard terms of international sales contracts developed and defined by the International Chamber of Commerce.

4. Price regulation includes the following steps / activities:

1) for medicines, subject to wholesale and retail sale:

registration of a price or re-registration of the registered price for wholesale and retail sale for trade name of medicines;

establishment of wholesale markups;

calculation of marginal prices for trade name of medicines for wholesale sales;

approval of marginal prices for trade name of medicines for wholesale sales;

establishment of retail markups;

calculation of marginal prices for trade name of medicines for retail sales;

approval of marginal prices for trade name of medicines for retail sales;

entering the marginal prices for trade name of medicines for wholesale sales into the price register;

entering the marginal prices for trade name of medicines for retail sales into the price register;

2) for medicines, intended for provision of GVOFMC and CSHI:

registration of a price or re-registration of the registered price within the framework of GVOFMC and in CSHI system for a trade name of medicines;

establishment of markups within the framework of GVOFMC and in CSHI system;

calculation of marginal prices for a trade name of medicines within the framework of GVOFMC and in CSHI system;

approval of marginal prices for a trade name of medicines within the framework of GVOFMC and in CSHI system;

calculation of marginal prices for an international nonproprietary name of medicines;

approval of marginal prices for an international nonproprietary name of medicines.

5. Registration of a price or re-registration of registered prices and approval of marginal prices for a trade name of medicines shall be made in tenge. When converting the applicant's price into national currency, official foreign exchange rates shall be used on average for the month preceding the filing of the application (average exchange rate) of the National Bank of the Republic of Kazakhstan.

6. In the absence of an exchange rate at the National Bank of the Republic of Kazakhstan, reference price information shall be provided in United States dollars according to the estimated rate of operations for the previous month provided by the United Nations Treasury at www.treasury.un.org.

7. Information submitted by the applicant for price registration or re-registration of the registered price shall be confidential. Persons having access to confidential information as a result of their position, position or fulfillment of obligations, including during the audit, shall retain and take measures to protect it.

8. Price for medicinal products, manufactured in a pharmacy, shall be determined by the management of the pharmacy organization.

Chapter 2. Procedure for registration of a price or re-registration of a registered price for wholesale and retail sales for a trade name of medicines

9. Prices for medicines for wholesale and retail sales shall be registered or re-registered for consumer packaging separately for each trade name, taking into account the dosage form, dosage, concentration, volume and packaging of medicines.

10. To register the price or re-register the registered price for wholesale and retail sales for a trade name of medicines in the Republic of Kazakhstan, the applicant shall submit an application to the state expert organization to register the price or re-register the registered price for wholesale and retail sales (hereinafter referred to as the application) in the form, according to annex 1 to these Rules. Information about

medicines in the application shall be indicated in accordance with a registration certificate for medicines.

11. If within the framework of one registration certificate several variants of consumer packaging / dosages / dosage forms / prepackaging of medicines are registered, the applicant shall submit an application separately for each of the options. It shall be allowed to provide general accompanying documents for all medicines with different registration certificate numbers.

12. An electronic application form shall be submitted on the website of the state expert organization (www.ndda.kz) in online mode with further submission of documents on paper or shall be signed with an electronic digital signature, without provision of documents on paper.

13. The application shall be enclosed with the following documents:

1) a document confirming the applicant’s right to register prices or re-register the registered price for wholesale and retail sales (power of attorney, agreement, letter of authorization, etc.), including the right to provide information about ex works prices in reference countries and on actual delivery prices (for imported medicines);

2) manufacturer's price with a table of ex works prices in reference countries (for imported medicines), or manufacturer's price (for domestic manufacturers) for wholesale and retail sales on the applicant's letterhead, certified by the signature of the authorized person and the seal of the organization. In the table of ex works prices, for registering the price or re-registering the registered price for wholesale and retail sales, information on the number of medicines in consumer packaging in each country shall be displayed, calculated on the number registered in the Republic of Kazakhstan in the form, according to annex 2 to these Rules;

3) in the absence of state registration of medicines in reference countries - the manufacturer's price for wholesale and retail sales and information about an ex works price in the country of origin on the applicant's letterhead, certified by the signature of the authorized person and the seal of the organization;

4) copies of documents confirming the price of medicines (a copy of an invoice (way-bill) or pro-forma invoice) for the last 12 months (if the actual delivery was carried out), except in cases import on the grounds, stipulated by subclause 4) of article 80-1 of the Code of the Republic of Kazakhstan "On public health and health care system";

5) information on expenses for registration of a price or re-registration of a registered price for wholesale and retail sales on the applicant's letterhead, certified by the signature of the authorized person and the seal of the organization, of which:

a foreign manufacturer shall provide data on actual costs incurred from the manufacturer to the border of the Republic of Kazakhstan, customs costs, costs of assessment of safety and quality, as well as marketing costs. For medicines, the supply

of which to the territory of the Republic of Kazakhstan before the registration of the price for wholesale and retail sales was not carried out, data on projected costs shall be provided;

a domestic manufacturer shall provide the data on actual costs incurred for assessment of safety and quality and marketing costs. For medicines of a domestic manufacturer, the implementation of which on the territory of the Republic of Kazakhstan before the registration of prices for wholesale and retail sales was not carried out, data on projected costs;

6) a copy of the document confirming the valid or expired patent protection of the original medicinal product / biological original medicinal product with the expiration date of the patent protection and a copy of the document establishing the duration of patent protection;

7) for medicines, the registration certificate of which has expired at the time of application, imported or manufactured in the territory of the Republic of Kazakhstan before the expiration of the registration certificate of medicines, for registration of a price or re-registration of a registered price for wholesale and retail sales cuments confirming the import or manufacture of medicines shall be provided: a copy of the conclusion on the safety and quality of the goods, as well as for imported medicines - a copy of the cargo customs declaration;

14. In the absence of information about ex works prices for medicines in any reference country or the actual price of supplies to the Republic of Kazakhstan in the application, the applicant shall indicate in the appropriate column the justification for the reason for its absence.

15. Registration of a price or re-registration of a registered price for wholesale and retail sales for medicines of a domestic manufacturer shall be based on the manufacturer's price, as well as the costs of assessment of safety and quality and marketing costs.

16. Registration of a price or re-registration of a registered price for wholesale and retail sales for imported medicines shall be based on the manufacturer's price for wholesale and retail sales, as well as transport costs from the manufacturer to the border of the Republic of Kazakhstan, customs costs, expenses for assessment of safety and quality and marketing costs.

17. In the absence of an application for price registration for wholesale and retail sales no later than April 10 or October 10 of the current year for the corresponding reporting half-year (with the exception of submitting an application after the entry into force of these Rules in 2019 no later than May 20), registered the price for wholesale and retail sales medicines shall be determined on the basis of the maximum value of the actual price of supplies to the Republic of Kazakhstan according to the data of invoices (way-bills) or pro-forma invoices submitted to the state expert organization

for assessing security characteristics and quality of medicines for a period of at least 12 months.

18. When registering a price or re-registering a registered price for wholesale and retail sales, a currency adjustment shall be made to the price in national currency, in accordance with the price indicated in the documents confirming the actual price of deliveries, corresponding to the difference in exchange rates on the date of registration of the price or re-registration of the registered price for wholesale and retail sales.

19. If there is no supply to the territory of the Republic of Kazakhstan before the registration of the price or re-registration of the registered price for wholesale and retail sales, or if there is no sale in the territory of the Republic of Kazakhstan before the registration of the price for wholesale and retail sales medicines of a domestic manufacturer, the price for wholesale and retail sales shall be registered with the subsequent re-registration of the registered price for wholesale and retail sales no later than one year from the date of approval by the authorized body of marginal prices for a trade name of medicines with the provision of copies of documents confirming the price for medicines, as well as information on actual expenses. If re-registration of the registered price for wholesale and retail sales has not been made during the year, the state expert organization will notify the applicant of the need to re-register the registered price for wholesale and retail sales within one calendar month with the notification of the authorized body. If there is no re-registration of the registered price for wholesale and retail sales within the prescribed period, the state expert organization shall notify the authorized body.

20. Registration of the price or re-registration of the registered price for wholesale and retail sales for imported medicines, the validity of the registration certificate of which at the time of submitting the application has expired, imported into the Republic of Kazakhstan before the expiration of the registration certificate shall be carried out on the basis of information on the prices of actual deliveries to the Republic of Kazakhstan for the last 12 months of the validity of the registration certificate.

21. Amendment of the registered price for wholesale and retail sales shall be allowed not more than one time in a reporting half-year.

22. For the purposes of re-registration of the registered price for wholesale and retail sales, the applicant shall submit an application and documents, and the state expert organization shall consider and shall re-register the registered price for wholesale and retail sales in accordance with the procedure and within the time period provided for in Chapter 2 of these Rules.

23. The state expert organization, within 10 working days from the date of the applicant’s request, shall monitor and shall analyze the reference pricing for a trade

name of medicines on the basis of the data submitted by the applicant and monitors the compliance of the proposed price for registration or re-registration of the registered price for wholesale and retail sales with the requirements of these Rules.

24. Based on the results of monitoring and analysis of reference pricing for a trade name of medicines, the state expert organization shall register the price or re-registers the registered price for wholesale and retail sales subject to the following criteria:

1) medicines for the Republic of Kazakhstan does not exceed the average value of ex works prices from the number of reference countries submitted in the application or, in the absence of state registration of medicines in reference countries, does not exceed of the value of an ex works price in the manufacturing country;

2) manufacturer price for wholesale and retail sales of imported medicines is not higher than the maximum price indicated in the submitted documents confirming the price of medicines (a copy of an invoice (way-bill) or pro-forma invoice);

3) marketing expenses indicated in the application for price registration or re-registration of the registered price for wholesale and retail sales do not exceed 50% of the manufacturer price for wholesale and retail sales for the Republic of Kazakhstan.

If the registered price for wholesale and retail sales does not meet the criteria specified in this clause, the state expert organization shall send a motivated refusal to register the price or re-register the registered price for wholesale and retail sales in the form, according to annex 3 to these Rules.

25. If an incomplete set of documents is provided, the required information is not available, or the information contained in the submitted documents needs to be clarified, the state expert organization will notify the applicant of the need to eliminate the above comments.

26. After receiving the notification, the applicant shall provide the state expert organization with relevant information in writing on the applicant's letterhead on-line (online) on the website of the state expert organization (www.ndda.kz) with further submission of documents in paper form or signed by electronic digital signature, without provision of paper documents in a period not exceeding 10 working days.

27. After providing additional information in accordance with clause 26 of these Rules, the state expert organization will re-examine the submitted documents in accordance with these Rules within 10 working days. In case of exceeding the deadline for providing the requested information or providing documents in incomplete volume and (or) incompleteness of the information contained in them in accordance with the requirements of these Rules, after the third notification on the elimination of comments , the state expert organization shall send the applicant a motivated refusal to register the price or re-register the registered price for Wholesale and retail sales by form, according to annex 3 to these Rules.

28. The applicant shall ensure the accuracy, completeness and content of the documents submitted in accordance with the current legislation of the Republic of Kazakhstan and these Rules. Provision of false data by the applicant shall be the basis for refusing to register the price or re-register the registered price for wholesale and retail sales. In case of revealing inaccurate data on the approved price limits for a trade name of medicines the state expert organization shall notify the authorized body about the need to exclude marginal prices on the corresponding medicines.

Chapter 3. Establishment of wholesale markups, calculation and approval of marginal prices for trade name of medicines for wholesale sales

29. Wholesale markups for wholesale sales for medicines are differentiated in accordance with regressive markup scale and shall be:

1) 21 % for medicines priced up to and including 350,00 tenge;

2) 20 % for medicines, priced above 350 tenge and up to and including 1000,00 tenge;

3) 19,5 % for medicines, priced above 1000 tenge and up to and including 3000,00 tenge

4) 19 % for medicines, priced above 3000 tenge and up to and including 5000,00 tenge;

5) 18,5 % for medicines, priced above 5000 tenge and up to and including 10000,00 tenge;

6) 18 % for medicines, priced above 10000 tenge and up to and including 20000,00 tenge;

7) 16 % for medicines, priced above 20000 tenge and up to and including 40000,00 tenge;

8) 14 % for medicines, priced above 40000 tenge and up to and including 100000,00 tenge;

9) 12 % for medicines, priced above 100000 tenge and up to and including 200000,00 tenge;

10) 11 % for medicines, priced above 200000 tenge and up to and including 500000,00 tenge;

11) 10 % for medicines, priced above 500000 tenge.

30. The calculation of marginal prices for trade name of medicines for wholesale sales shall be carried out by adding to the registered price for wholesale and retail sales a wholesale margin differentiated based on the value of the registered price for wholesale and retail sales for consumer packaging.

31. The state expert organization shall calculate the project of marginal prices for trade name of medicines for wholesale sales based on registered prices for wholesale and retail sales in accordance with applications for price registration or re-registration

of the registered price for wholesale and retail sales submitted no later than April 10 or October 10, respectively, for each reporting half-year (with the exception of filing an application after the entry into force of these Rules in 2019 no later than May 20) and shall send them to an authorized body for approval no later than 60 calendar days before the end of the reporting half-year (except for the first half of 2019).

32. The marginal price for the trade name of medicines for wholesale sales for the reproduced medicinal product (generic) or bio-analogous medicinal product shall be set below the value of the last price established for the patent name of the original / biological original medicinal product before the patent protection expires:

For a generic – at least 30 %;

For a bio-analogous medicinal product – at least 10 %.

33. In the absence of a limit price for the trade name of medicines for wholesale sales of the original / biological original medicine established before the patent protection expires, the marginal price for trade name of medicines for wholesale sales for the reproduced / bio-analogous medicine of the domestic manufacturer shall be set no higher than the maximum current limit prices for trade name of medicines for wholesale sales for medicines of other manufacturers with the same international non-proprietary name, taking into account the dosage, concentration, volume and packaging of medicines.

Chapter 4. Establishment of retail markups, calculation and approval of marginal prices for trade name of medicines for retail sales

34. Retail margin for retail sales for medicines are differentiated in accordance with the regressive markup scale and shall be:

1) 55 % for medicines priced up to and including 350,00 tenge;

2) 45 % for medicines, priced above 350 tenge and up to and including 1000,00 tenge;

3) 35 % for medicines, priced above 1000 tenge and up to and including 3000,00 tenge;

4) 33 % for medicines, priced above 3000 tenge and up to and including 5000,00 tenge;

5) 30 % for medicines, priced above 5000 tenge and up to and including 7500,00 tenge;

6) 27 % for medicines, priced above 7500 tenge and up to and including 10000,00 tenge;

7) 25% for medicines, priced above 10000 tenge up to and including 13500,00 tenge;

8) 22 % for medicines, priced above 13500 tenge and up to and including 20000,00 tenge;

9) 20 % for medicines, priced above 20000 tenge and up to and including 40000,00 tenge;

10) 15 % for medicines, priced above 40000 tenge and up to and including 100000,00 tenge;

11) 10 % for medicines, priced above 100000 tenge.

35. The calculation of marginal prices for trade name of medicines for retail sales shall be carried out by adding to the marginal price for trade name of medicines for wholesale sales a retail mark-up differentiated based on the marginal price for trade name of medicines for wholesale sales for consumer packaging.

36. Marginal price for trade name of medicines for retail sales in the first half of 2019 should not exceed the average value of market prices for the retail sale of medicines at the time of calculating the project of marginal prices for trade name of medicines for retail sales, taking into account the dosage form, by the state expert organization dosage, concentration, volume and packaging (according to open sources of information on retail prices).

37. The state expert organization shall calculate the project of marginal prices for trade name of medicines for retail sales based on of marginal prices for trade name of medicines for wholesale sales and sends them to an authorized body for approval no later than 60 calendar days before the end of the reporting six months (excluding the first half of 2019).

38. The marginal price for trade name of medicines for retail sales for the reproduced medicinal product (generic) or bio-analogous medicinal product shall be set below the value of the last price established for the patent name of the original / biological original medicinal product for trade name of medicines for retail sales:

For a generic - by 30 %;

For a bio-analogous medicinal product - by 10 %.

39. In the absence of a limit price for the trade name of medicines for retail sales of the original / biological original medicine established before the patent protection expires, the marginal price for trade name of medicines for retail sales for the reproduced / bio-analogous medicine of the domestic manufacturer shall be set no higher than the maximum current limit prices for trade name of medicines for retail sales for medicines of other manufacturers with the same international non-proprietary name, taking into account the dosage, concentration, volume and packaging of medicines.

40. The Authorized body, not more than once every six months, no later than July 10 and January 10 of the corresponding reporting half-year, shall approve the maximum prices for trade name of medicines for retail sales of all medicines sold by pharmaceutical and MD entities.

Chapter 5. Maintenance of the Price Register

41. The price register is an information system containing information about marginal prices for a trade name of medicines for wholesale and retail sales.

42. The price register is maintained by the state expert organization in electronic form using automated system by entering information about marginal prices for a trade name of medicines into the register.

43. The registry entry contains the following information:

the name of the holder or owner of the registration certificate, the name of the manufacturers involved in the production process (if any);

name medicines (international non-proprietary, or grouping, or chemical and trade names);

code for anatomical and therapeutic chemical classification recommended by the World Health Organization;

number of the registration certificate of medicines (if any);

pharmaceutical formulation indicating the dosage, concentration and volume of medicines and its quantity in consumer packaging;

marginal price for trade name of medicines for wholesale sales for consumer packaging in tenge and the date it was established;

marginal price for trade name of medicines for retail sales for consumer packaging in tenge and the date it was established.

44. The entry in the register of prices of marginal prices for trade name of medicines for wholesale sales and retail sales shall be carried out on the basis of orders of the authorized body on the establishment of marginal prices for a trade name of medicines for wholesale and retail sales, within 10 working days from the date of state registration with the Ministry of Justice of the Republic of Kazakhstan.

45. In the absence of medicines in circulation in the territory of the Republic of Kazakhstan for 3 years, the applicant, within a period not exceeding 1 calendar month, shall submit to the authorized body an application to exclude information about of marginal prices for the indicated trade name medicines.

46. The price register shall be published on the official website of the state expert organization and shall be updated with all previous editions of the registry saved on the website.

47. Information about marginal prices for trade name of medicines for retail sales shall be placed in pharmacy organizations in a form accessible to all interested parties, taking into account the grouping of international non-proprietary names medicines.

48. The information contained in the price register shall be open and accessible to general use.

49. Information about marginal prices for a trade name of medicines for wholesale and retail sales shall be kept in the price register for five years starting from the year following the year of approval of marginal prices.

Chapter 6. Procedure for price registration or re-registration of registered price within the framework of GVOFMC and in CSHI system for a trade name of medicines

50. Prices for medicines within the framework of the GVOFMC and in CSHI system shall be registered or re-registered per unit of measure separately for each trade name, taking into account the dosage form, dosage, concentration, volume and packaging of medicines.

51. For registration of a price or re-registration of a registered price within the framework of GVOFMC and in CSHI system for a trade name of medicines in the Republic of Kazakhstan, the applicant shall submit to the state expert organization an application for registration of price or re-registration of the registered price within the framework of GVOFMC and in CSHI system in form, according to annex 4 to these Rules. Information about medicines in the application shall be indicated in accordance with a valid registration certificate for medicines.

52. If within the framework of one registration certificate several variants of consumer packaging / dosages / dosage forms / prepackaging of medicines are registered, the applicant shall provide an application separately for each of the options. It is allowed to provide general accompanying documents for all medicines with different registration certificate numbers.

53. An electronic application form shall be submitted on the website of the state expert organization (www.ndda.kz) in online (online) mode with further submission of documents on paper or shall be signed by electronic digital signature without providing documents on paper.

54. The application shall be enclosed with the following documents:

1) a document confirming the applicant’s right to register prices or re-register the registered price within the framework of the GVOFMC and in CSHI system (power of attorney, agreement, letter of authorization, etc.), including the right to provide information about ex works prices in reference countries and prices actual deliveries (for imported medicines);

2) manufacturer's price with a table of ex works prices in reference countries (for imported medicines), or manufacturer's price (for domestic manufacturers) within the framework of the guaranteed volume of medical care and the CSHI system on the applicant's letterhead, certified by the signature of the authorized person and the seal of the organization. The table of ex works prices for registration of a price or re-registration of a registered price within the framework of the GVOFMC and in CSHI system displays information on the number of medicines in consumer packaging

in each country, calculated per unit of measure of medicine in the form, according to annex 5 to these Rules;

3) in the absence of state registration of medicines in the reference countries - the manufacturer's price under the GVOFMC and CSHI system and information about an ex works price in the country of origin on the applicant's letterhead, certified with the signature of the authorized person and the seal of the organization;

4) copies of documents confirming the price of medicines (a copy of an invoice (way-bill) or pro-forma invoice) for the last 12 months (if the actual delivery was carried out), except for cases of importing on the grounds, stipulated by subclause 4) of article 80-1 of the Code of the Republic of Kazakhstan "On public health and health care system";

5) information on expenses for registration of a price or re-registration of a registered price within the framework of GVOFMC and in CSHI system on the applicant's letterhead, certified with the signature of the authorized person and the seal of the organization, of which:

a foreign manufacturer provides data on actual costs incurred from the manufacturer to the border of the Republic of Kazakhstan, customs costs and costs for assessment of safety and quality. For imported medicines, the delivery of which to the territory of the Republic of Kazakhstan before the registration of the price within the framework of the GVOFMC and in CSHI system, was not carried out, data on projected expenses;

a domestic manufacturer shall submit data on actually incurred costs for assessment of safety and quality;

6) copy of the document confirming the current or expired patent protection of the original medicinal product / biological original medicinal product with the expiration date of the patent protection and a copy of the document establishing the duration of patent protection;

7) for medicines, the registration certificate of which expired at the time of application, imported or produced in the territory of the Republic of Kazakhstan before the expiration of the registration certificate of medicines, for registration of a price or re-registration of a registered price within the framework of GVOFMC and in CSHI system documents are provided that confirm the import or production of medicines: a copy of the conclusion on the safety and quality of goods, as well as for imported medicines - a copy of the cargo customs declaration;

8) for medicines imported into the territory of the Republic of Kazakhstan that do not have a registration certificate - a copy of the permission of the authorized body to import and use the goods in the territory of the Republic of Kazakhstan, obtained through the e-government web portal.

55. In the absence of information about ex works prices for medicines in any reference country or the actual price of supplies to the Republic of Kazakhstan in the application, the applicant shall substantiate the reason for its absence in the corresponding column.

56. Registration prices or re-registration of the registered price within the framework of the GVOFMC and in CSHI system for medicines of a domestic manufacturer are based on the manufacturer price within the framework of GVOFMC and in CSHI system, as well as the costs of assessment of safety and quality.

57. Registration prices or re-registration of the registered price within the framework of the GVOFMC and in CSHI system for imported medicines is based on the manufacturer price within the framework of the GVOFMC and in CSHI system, as well as transport, customs and safety and quality assessment costs.

58. When registering a price or re-registering a registered price within the framework of GVOFMC and in CSHI system, a currency adjustment is made to the price indicated in the documents that confirm the price of medicines in national currency corresponding to the difference in exchange rates at the time of import and registration of the price or re-registration of the registered price within the framework of GVOFMC and in CSHI system.

59. In the absence of deliveries to the territory of the Republic of Kazakhstan over the past 12 months, the price within the framework of GVOFMC and in CSHI system shall be registered with the subsequent re-registration of the registered price within the framework of GVOFMC and in CSHI system no later than one year from the date of approval authorized body of the maximum price for a trade name of medicines within the framework of the GVOFMC and in CSHI system with the provision of copies of documents confirming the price of medicines, as well as information on actual costs. If re-registration of the registered price within the framework of GVOFMC and in CSHI system has not been performed during the year, the state expert organization will notify the applicant of the need to re-register the registered price within the framework of GVOFMC and in CSHI system within one calendar month from informing the authorized body. If there is no re-registration within the prescribed period, the state expert organization shall notify the authorized body.

60. Registration of the price or re-registration of the registered price within the framework of the GVOFMC and in CSHI system for imported medicines, the registration certificate of which expired at the time of application, imported into the territory of the Republic of Kazakhstan before the registration certificate expires shall be carried out based on information on the prices of actual deliveries to the Republic of Kazakhstan for the last 12 months of registration certificate validity.

61. Amendments to the registered price within the framework of GVOFMC and in CSHI system shall be allowed no more than once every six months. After the entry into

force of these Rules, until January 1, 2020, it is necessary to re-register the previously registered price within the framework of GVOFMC and in CSHI system in accordance with the requirements of these Rules. If the re-registration of the registered price within the framework of the GVOFMC and in CSHI system has not been completed within the specified time, the state expert organization informs the authorized body.

62. To re-register the registered price within the framework of the GVOFMC and in CSHI system, the applicant shall submit an application and documents to medicines, and the state expert organization considers and re-registers the registered price within the framework of the GVOFMC and in CSHI system in the manner and within the time period provided for in chapter 6 of these Rules.

63. The state expert organization, within 20 working days from the date of the applicant’s request, shall monitor and shall analyze the reference pricing for a trade name of medicines on the basis of the data submitted by the applicant and monitors the compliance of the proposed price for registration or re-registration of the registered price within the framework of GVOFMC and in CSHI system requirements of these Rules.

64. Based on the results of monitoring and analysis of reference pricing for a trade name of medicines, the state expert organization shall register the price or re-register the registered price within the framework of GVOFMC and in CSHI system, subject to the following criteria:

1) the manufacturer's price provided within the framework of the GVOFMC and in CSHI system for imported medicines for the Republic of Kazakhstan does not exceed the maximum value of three minimum of ex works prices from the number of reference countries submitted in the application, if the number of reference countries is less than three, the manufacturer's price within the framework of GVOFMC and in CSHI system does not exceed the maximum value of ex works prices represented by the number of reference countries. In the absence of state registration of medicines in reference countries, the manufacturer's price within the framework of GVOFMC and in CSHI system does not exceed of the value of an ex works price in the manufacturing country;

2) provided manufacturer’s price within the framework of the GVOFMC and in CSHI system for imported medicines is not higher than the maximum value of the three minimum prices specified in the submitted documents confirming the price of medicines (a copy of an invoice (way-bill) or pro-forma invoice);

3) transportation costs from the manufacturer to the border of the Republic of Kazakhstan specified in the statement do not exceed 15% of the value of the producer price within the framework of GVOFMC and in CSHI system.

If the registered price does not comply within the framework of GVOFMC and in CSHI system with the criteria specified in this clause, the state expert organization sends a motivated refusal to register the price or re-register the registered price within

the framework of GVOFMC and in CSHI system (in the form, according to annex 6 to these Rules).

65. If an incomplete set of documents is provided, the required information is not available, or the information contained in the submitted documents needs to be clarified, the state expert organization will notify the applicant of the need to eliminate the above comments.

66. After receiving the notification, the applicant shall provide the state expert organization with relevant information in writing on the applicant's letterhead on-line (online) on the website of the state expert organization (www.ndda.kz) with further submission of documents in paper form or signed by electronic digital signature, without provision of paper documents in a period not exceeding 10 working days.

67. After providing additional information in accordance with clause 66 of these Rules, the state expert organization will re-examine the submitted documents in accordance with these Rules within 10 working days. In case of exceeding the deadline for the provision of the requested information, as well as the submission of documents in incomplete volume and (or) incompleteness of the information contained in them in accordance with the requirements of these Rules, after the third notification on the elimination of comments, the state expert organization sends the applicant a motivated refusal to register the price or re-register the registered prices within the framework of GVOFMC and in CSHI system according to the form, according to annex 6 to these Rules.

68. The applicant shall ensure the accuracy, completeness and content of the documents submitted in accordance with the current legislation of the Republic of Kazakhstan and these Rules. Providing false data by the applicant shall be the reason for refusing to register the price or re-register the registered price within the framework of GVOFMC and in CSHI system in the form, according to annex 6 to these Rules. In case of revealing inaccurate data on the approved price limits for a trade name of medicines within the framework of GVOFMC and in CSHI, the state expert organization shall inform the authorized body about the need to exclude marginal prices for the corresponding medicines.

Chapter 7. Establishment of markups, calculation and approval of marginal prices for a trade name of medicines within the framework of GVOFMC and in CSHI system

69. The markups within the framework of GVOFMC and in CSHI system for medicines shall be differentiated in accordance with regressive markup scale and shall amount to:

1) 20 % for medicines priced up to and including 350,00 tenge;

2) 19,5 % for medicines, priced above 350 tenge and up to and including 1000,00 tenge;

3) 19 % for medicines, priced above 1000 tenge and up to and including 3000,00 tenge;

4) 18 % for medicines, priced above 3000 tenge and up to and including 5000,00 tenge;

5) 17 % for medicines, priced above 5000 tenge and up to and including 10000,00 tenge;

6) 16,5 % for medicines, priced above 10000 tenge and up to and including 20000,00 tenge;

7) 16 % for medicines, priced above 20000 tenge and up to and including 40000,00 tenge;

8) 15,5 % for medicines, priced above 40000 tenge and up to and including 100000,00 tenge;

9) 15 % for medicines, priced above 100000 tenge and up to and including 200000,00 tenge;

10) 14,5 % for medicines, priced above 200000 tenge and up to and including 500000,00 tenge;

11) 14 % for medicines, priced above 500000 tenge.

70. Calculation of marginal prices for a trade name of medicines within the framework of GVOFMC and in CSHI system shall be carried out by adding to the registered price within the framework of GVOFMC and in CSHI system margins within the framework of GVOFMC and in CSHI system, differentiated based on the value registered prices within the framework of GVOFMC and in CSHI system per unit of measure medicines.

71. The state expert organization shall calculate the project of marginal prices for a trade name of medicines within the framework of GVOFMC and in CSHI system in accordance with the registered prices within the framework of GVOFMC and in CSHI system in accordance with statements on price registration or re-registration of registered price within the framework of GVOFMC and in CSHI system, submitted no later than January 30, and shall send them to the authorized body for approval no later than 60 calendar days before approval by the authorized body of marginal prices for a trade name of medicines within the framework of GVOFMC and in CSHI system.

72. Marginal price for a trade name of medicines within the framework of the GVOFMC and in CSHI system for a reproduced medicinal product (generic) or bio-analogous medicinal product shall be set below the value of the last price established for patent protection for a trade name of medicines within the framework of GVOFMC and in CSHI system of the original / biological original medicinal product:

For a generic - by 30 %;

For a biological original medicinal product - by 10 %.

73. In case of the absence of the marginal price for a trade name of medicines within the framework of GVOFMC and in CSHI system for the original / biological original medicinal product, established before expiration of a patent protection, marginal price for a trade name of medicines within the framework of GVOFMC and in CSHI system of the domestic manufacturer of the reproduced/ biosimilar medicinal product shall be established not higher of maximum current marginal price for a trade name of medicines within the framework of GVOFMC and in CSHI system for medicines of other manufacturers, with similar international nonproprietary name, subject to dosage, concentration, volume, and prepackaging of medicines.

74. Authorized body in accordance with clause 3 of article 86-1 of the Code of the Republic of Kazakhstan "On public health and health care system" shall approve the marginal prices for a trade name of medicines within the framework of GVOFMC and in CSHI system not more frequently than once a year no later than May 1 of the reporting year.

Chapter 8. Calculation and approval of marginal prices for an international nonproprietary name of medicines within the framework of GVOFMC and in CSHI system

75. The marginal price for the international nonproprietary name for medicines should not exceed the maximum value of the three minimum of marginal prices for a trade name of medicines within the framework of GVOFMC and in CSHI system. In case of existence of approved in accordance with clauses 72 and 73 of these Rules of a marginal price for a trade name of medicines within the framework of GVOFMC and CSHI system of a domestic goods manufacturer, produced under the conditions of good manufacturing practice and delivered under long-term contracts, the marginal price for an international nonproprietary name is determined by the marginal price for a trade name of medicines within the framework of the GVOFMC and domestic system.

76. In the absence of three registered prices for the trade name within the framework of GVOFMC and in CSHI system, the marginal price for the international non-proprietary name for medicines should not exceed the maximum value of marginal prices for the trade name within the framework of GVOFMC and in CSHI system.

77. For orphan medicines, The marginal price for an international nonproprietary name shall be determined based on an analysis of the prices of the reference countries according to the international nonproprietary name. If the declared cost of annual use of orphan medicines exceeds 3,000 MCI and (or) there are registered medicines with similar indications, the marginal price for the international nonproprietary name shall be determined taking into account the clinical and economic characteristics of orphan medicines.

78. At the request of the authorized body, the state expert organization within 10 working days shall calculate the project of marginal prices for an international nonproprietary name of medicines within the framework of the GVOFMC and in CSHI system contained in the request, based on the approved of marginal prices or project of marginal prices (if there are no approved of marginal prices) for a trade name of medicines within the framework of GVOFMC and in CSHI system and sends them to an authorized body for approval.

79. If there is no limit price for an international nonproprietary name of medicines and (or) there is no limit price for a trade name of medicines within the framework of GVOFMC and CSHI, its purchase within the framework of GVOFMC and CSHI shall not be carried out until the price is set for medicines.

Chapter 9. The procedure for calculation of a price of the list price and margin of a single distributor for goods within the framework of GVOFMC and CSHI

80. The calculation of a price of a price list of a single distributor shall be made:

1) by adding the margin of a single distributor to the fixed price of goods delivered on the terms of DDP INCOTERMS 2010;

2) by adding the margin of the single distributor and the extra margin, in the amount established by the second part of paragraph 83 of these Rules, to the fixed price of goods delivered on conditions different from the terms of DDP INCOTERMS 2010;

3) by adding the margin of the single distributor to a fixed price in cases where the supplier reimburses the expenses of the single distributor related to the payment of customs duties and fees, and other expenses associated with the delivery of goods to the single distributor;

4) by adding the margin of the single distributor to the amount of costs per unit of goods for the payment of customs duties and fees, when delivering goods to the single distributor at zero price (free of charge);

5) in cases of delivery of goods at a zero price to a single distributor on the terms of DDP INCOTERMS 2010 or reimbursement by a supplier of expenses of a single distributor related to payment of customs duties and fees, and other expenses associated with the delivery of goods at a zero price to a single distributor, a price of the price list per unit shall be set at a rate of 0.01 tenge.

81. Prices of the price list of a single distributor for medicines shall not exceed the marginal prices for a trade name of medicines within the framework of GVOFMC and in CSHI system and marginal prices according to the international non-proprietary name medicines within the framework of GVOFMC and in CSHI system.

82. Markup for medicine prices shall be set in differentiated percentages on a regressive scale. In this case, the markup of a single distributor from a fixed price shall be set at the rate of:

1) 7 % for goods, priced at 100 000,00 tenge per measuring unit;

2) 6 % for goods, which price varies from 100 000,01 and up to 139 999, 99 tenge per measuring unit;

3) 5 % for goods, priced from 140 000,00 tenge per measuring unit.

83. When purchasing medicines from one source through international organizations established by the General Assembly of the United Nations, as well as from a foreign manufacturer (manufacturer) of medicines that do not have analogues registered in the Republic of Kazakhstan for the international non-proprietary name (composition) and (or) characteristics, the mark-up of a single distributor shall be accrued an additional markup in the amount of 3 (three) percent.

84. The single distributor shall calculate the allocated amount for the purchase in accordance with paragraph 82 of these Rules, in the following order: Purchase price = Marginal price minus markup. In this case, an additional markup is subtracted from the price limit when purchasing medicines from one source through international organizations established by the General Assembly of the United Nations, as well as from a foreign manufacturer (manufacturer) of medicines that have no analogues in the Republic of Kazakhstan with the international non-proprietary name (composition) and (or) characteristics, upon delivery of goods under conditions different from the conditions of DDP INCOTERMS 2010.

85. The purchase price shall be determined in tenge taking into account tiyns. When calculating the purchase price, rounding of tiyn shall be done down to hundredths.

86. The markup of a single distributor shall be made in accordance with subclause 20) of clause 1 of article 7 of the Code of the Republic of Kazakhstan dated September 18, 2009 "On public health and health care system".

87. The markup for a pharmaceutical service for the objects of retail sales of medicines shall not exceed 12 %.

Annex 1
to the Rules for regulation
of prices for medicines
Form

(name of state expert organization)

Application on registration of a price or re-registration of a registered price for wholesale and retail sales

We hereby provide information for registration of a price or re-registration of a registered price for wholesale and retail sales of medicine _____

1. Applicant

1.1. Manufacturer or medicine

Name		
Country		
Legal address		
Current address		
Telephone		
Fax		
e-mail		
Contact person	Surname, name, patronymic (if any)	
	Position	
	Telephone	
	Fax	
	e-mail	

1.2. Holder of the registration certificate

Name		
Country		
Legal address		
Current address		
Telephone		
Fax		
e-mail		
Surname, name, patronymic (if any) of the head		
Contact person	Surname, name, patronymic (if any)	
	Position	
	Telephone	
	Fax	
	e-mail	

1.3. An authorized representative / company, representative office of the applicant, authorized to carry out actions during the price registration procedure in the Republic of Kazakhstan

Name (or surname, name, patronymic (if any)	
Country	
Legal address	
Current address	
Telephone	
Fax	
e-mail	
Surname, name, patronymic (if any) of the head	

Authorization data	Authorization no.	
	Date of issue	
	Validity	

2. Information about medicine

1.	Trade name	
2.	Number and date of registration certificate in the Republic of Kazakhstan	
3.	The medicine is: (mark as necessary)	☐ Original medicinal product (under the patent protection) Patent term: _____ (specify the expiration date of the patent) ☐ Original medicinal product that has lost patent protection ☐ Original biological medicinal product (under the patent protection) Patent term: _____ (specify the expiration date of the patent) ☐ Original biological medicinal product, that has lost patent protection ☐ Reproduced medicinal product ☐ Biosimilar preparation ☐ Orphan
4.	International Nonproprietary Name(if any)	
5.	Composition	
6.	Pharmaceutical form	
7.	Dosage	
8.	Concentration	
9.	Volume	
10.	Quantity in a secondary (consumer) packaging	
11.	Code according to the Anatomical, Therapeutic, Chemical (ATC) classification system	
12.	Administration route	

13.	Previously registered price details for wholesale and retail sales							
	Date of registration of the registered price for wholesale and retail sales							
14.	Price of the domestic manufacturer for wholesale and retail sales (for consumer packaging)							
15.	Manufacturer's price for wholesale and retail sales for imported medicines (for consumer packaging)				Price for consumer packaging	Currency		Price for consumer packaging in tenge
		Data of documents confirming the price for medicines(for consumer packaging)			Price in the currency of the actual supply contract and / or invoice for consumer packaging	Currency		Price of the actual supply contract and / or invoice for consumer packaging in tenge
		Data of documents confirming the price for medicines(for consumer packaging)			Price in the currency of the actual supply contract and / or invoice for consumer packaging	Currency		Price of the actual supply contract and / or invoice for consumer packaging in tenge
		Data of documents confirming the price for medicines(for consumer packaging)			Price in the currency of the actual supply contract and / or invoice for consumer packaging	Currency		Price of the actual supply contract and / or invoice for consumer packaging in tenge
		Information about ex works price in the reference countries where there is state registration of the medicinal product or country of origin(for consumer packaging)						
	Country	Trade name	Quantity in consumer packaging in the reference country	Ex works price for consumer packaging	Ex works price, calculated on the number of medicines in consumer packaging registered in the Republic of Kazakhstan	Currency	Ex works price in tenge	Reason for absence

	Azerbaijan							
	Belarus							
	Bulgaria							
	Hungary							
	Greece							
	Latvia							
	Lithuania							
	Russia							
	Poland							
	Romania							
	Slovakia							
	Slovenia							
	Turkey							
	Croatia							
	Czech Republic							
	Estonia							
	(Manufacturing country)*							
16.	Cost data (for consumer packaging)							
	Name				Tenge, for consumer packaging			
	Transportation costs							
	Customs costs							
	Costs for assessment of safety and quality							
	Marketing costs							
17.	Registered price for wholesale and retail sales							

I guarantee the accuracy of the provided information about prices for medicines.

I undertake to inform about all changes in prices for medicines, as well as to submit an application and materials required for performance of reference pricing and registration of the registered price for wholesale and retail sales for medicines.

Date _____ surname, name, patronymic

* in the absence of state registration of a medicine with the reference countries

Annex 2
to the Rules for regulation
of prices for medicines
Form

Name of the authorized representative / company, representative office of the applicant authorized to conduct actions during the procedure of price registration in the Republic of Kazakhstan

Ref. no.____ dated _____

TABLE OF EX WORKS PRICES For registration of a price or re-registration of a registered price For wholesale and retail sales

Hereby, name of the authorized representative / company, representative office from the applicant authorized to conduct actions during the price registration procedure in the Republic of Kazakhstan ifor the purposes of registration of the price or re-register the registered price (underline as necessary) for wholesale and retail sales on the basis of the name of the document confirming the applicant's right to register the price or re-registration of the registered price for wholesale and retail sales, including the right to provide information about ex works prices in reference countries, the number and date provides ex works prices in countries of the medicinal product trade name, dosage, concentration, volume, pharmaceutical form, quantity in consumer packaging, manufacturer, RU number in the following reference countries:

Country	Trade name	Quantity in consumer packaging in the reference country	Ex works price for consumer packaging (currency)	Ex works price calculated for a minimum unit	Ex works price, calculated on the number of medicines in consumer packaging registered in the Republic of Kazakhstan (if necessary)
Azerbaijan					
Belarus					
Bulgaria					
Hungary					
Greece					
Latvia					
Lithuania					
Russia					
Poland					
Romania					
Slovakia					
Slovenia					
Turkey					
Croatia					
Czech Republic					
Estonia					
(Manufacturing country)*					

I guarantee the accuracy of the provided information about ex works prices in reference countries.

Date_____

_____ _____ _____

_____

Position signature surname, name, patronymic

Seal (if any)

* in the absence of state registration with the reference countries

Annex 3
to the Rules for regulation
of prices for medicines
Form

_____

_____

Name of the authorized representative / company, representative office of the applicant authorized to conduct actions during the procedure of price registration in the Republic of Kazakhstan

MOTIVATED REFUSAL FROM REGISTRATION OF A PRICE OR RE-REGISTRATION OF A REGISTERED PRICE FOR WHOLESALE AND RETAIL SALES

Hereby, the Republican State Enterprise on the right of economic management " National Center for Expertise of Medicines and Medical Devices" reports the following . When considering applications for price registration or re-registration of the registered price for wholesale and retail sales of a medicinal product, in particular:

item no.	Unique code on pricing portal	Trade name of medicine
1		
2		

the employees of Expert Organization have revealed the following:

(mark as necessary

✓

)

Submission of documents in incomplete volume and (or) incompleteness of the information contained in them in accordance with the requirements of these Rules after the third notification on elimination of comments	
The deadline for the provision of information requested by a state expert organization exceeds 10 working days	
Provision of inaccurate information	
Manufacturer’s price for wholesale and retail sales of imported medicines for the Republic of Kazakhstan exceeds the average of ex works prices from the number of reference countries submitted in the application	

Manufacturer’s price for wholesale and retail sales of imported medicines for the Republic of Kazakhstan exceeds the value of the Franco-Factory price in the manufacturing country (In the absence of state registration of medicines in reference countries)	
Manufacturer’s price for wholesale and retail sales of imported medicines for the Republic of Kazakhstan exceeds the maximum value of the prices indicated in the submitted documents confirming the price of the medicine	
Marketing expenses exceed 50% of the producer price for wholesale and retail sales of imported medicines for the Republic of Kazakhstan	

Hereby, in accordance with clause 24, clause 27 as well as clause 28 "Rules for regulation of prices for medicines":

"24. Based on the results of monitoring and analysis of reference pricing for a trade name of medicines, the state expert organization registers the price or re-registers the registered price for wholesale and retail sales subject to the following criteria:

1) provided manufacturer’s price for wholesale and retail sales for imported medicines for of the Republic of Kazakhstan does not exceed the average of ex works prices from the number of reference countries submitted in the application or, in the absence of state registration of medicines in reference countries, does not exceed of the value of an ex works price in the manufacturing country;

2) provided manufacturer’s price for wholesale and retail sales of imported medicines is not higher than the maximum price indicated in the submitted documents confirming the price of medicines (a copy of an invoice (way-bill) or pro-forma invoice);

3) marketing expenses indicated in the application for price registration or re-registration of the registered price for wholesale and retail sales do not exceed 50% of the producer price for wholesale and retail sales for of the Republic of Kazakhstan.

If the registered price for wholesale and retail sales does not meet the criteria specified in this clause, the state expert organization shall send a motivated refusal to register the price or re-register the registered price for wholesale and retail sales (in the form, according to annex 3 to these Rules)."

" 27. After providing additional information in accordance with clause 26 of these Rules, the state expert organization will re-examine the submitted documents in accordance with these Rules within 10 working days. In case of exceeding the deadline for providing the requested information or submitting documents in incomplete volume and (or) incompleteness of the information contained in them in accordance with the requirements of these Rules, after the third notification on the elimination of comments , the state expert organization sends the applicant a motivated refusal to register the

price or re-register the registered price for wholesale and retail sales (in the form, according to annex 3 to these Rules)."

"28. The applicant shall ensure the accuracy, completeness and content of the submitted documents in accordance with the current Legislation of the Republic of Kazakhstan and these Rules. Providing false data by the applicant shall be the basis for refusing to register the price or re-register the registered price for wholesale and retail sales. In case of revealing inaccurate data on the approved price limits, the state expert organization informs the authorized body about the need to exclude marginal prices on the corresponding medicines."

The expert organization sends a motivated refusal to register the price or re-register the registered price for wholesale and retail sales to the above medicines.

_____ _____ _____

_____

Position signature Surname, name, patronymic (if any)

Annex 4
to the Rules for regulation
of prices for medicines
Form

_____

(name of state expert organization)

Application for registration of a price or re-registration of a registered price within the framework of GVOFMC and in CSHI system

We provide information for registration of a price or re-registration of a registered price within the framework of GVOFMC and in CSHI system of the medicine

_____

1. Applicant

1.1. Manufacturer or medicine

Name		
Country		
Legal address		
Current address		
Telephone		
Fax		
e-mail		
Contact person	Surname, name, patronymic (if any)	
	Position	
	Telephone	
	Fax	
	e-mail	

1.2. Holder of the registration certificate

Name		
Country		
Legal address		
Current address		
Telephone		
Fax		
e-mail		
Surname, name, patronymic (if any) of the head		
Contact person	Surname, name, patronymic (if any)	
	Position	
	Telephone	
	Fax	
	e-mail	

1.3. An authorized representative / company, representative office of the applicant, authorized to carry out actions during the price registration procedure in the Republic of Kazakhstan

Name (или Surname, name, patronymic (if any)		
Country		
Legal address		
Current address		
Telephone		
Fax		
e-mail		
Surname, name, patronymic (if any) of the head		
Authorization data	Authorization no.	
	Date of issue	
	Validity	

2. Information about medicine

1.	Trade name	
2.	Number and date of registration certificate in the Republic of Kazakhstan	
		☐ Original medicinal product (under the patent protection) Patent term: _____ (specify the expiration date of the patent) ☐ Original medicinal product that has lost patent protection ☐

3.	The medicine is: (mark as necessary)	Original biological medicinal product (under the patent protection) Patent term: _____ (specify the expiration date of the patent) ☐ Original biological medicinal product, that has lost patent protection ☐ Reproduced medicinal product ☐ Biosimilar preparation ☐ Orphan		
4.	International Nonproprietary Name(if any)			
5.	Composition			
6.	Pharmaceutical form			
7.	Dosage			
8.	Concentration			
9.	Volume			
10.	Quantity in a secondary (consumer) packaging			
11.	Code according to the Anatomical, Therapeutic, Chemical (ATC) classification system			
12.	Administration route			
13.	Information about previously registered price within the framework of GVOFMC and in CSHI system			
	Date of registration of the registered price within the framework of GVOFMC and in CSHI system			
14.	Price of the domestic manufacturer within the framework of GVOFMC and in CSHI system (per measuring unit)			
	Manufacturer's price within the framework of GVOFMC and in CSHI system for imported medicines (per measuring unit)	Price per measuring unit	Currency	Price per measuring unit in tenge
	Data of documents confirming the price for medicines(per measuring unit)	Price in the currency of the actual supply contract and / or invoice per measuring unit	Currency	Price of the actual supply contract and / or invoice per measuring unit in tenge

	Data of documents confirming the price for medicines(per measuring unit)				Price in the currency of the actual supply contract and / or invoice per measuring unit	Currency		Price of the actual supply contract and / or invoice per measuring unit in tenge
	Data of documents confirming the price for medicines(per measuring unit)				Price in the currency of the actual supply contract and / or invoice per measuring unit	Currency		Price of the actual supply contract and / or invoice per measuring unit in tenge
15.	Information about ex works price in the reference countries where there is state registration of the medicinal product or country of origin(per measuring unit)							
	Country	Trade name	Quantity in consumer packaging in the reference country	Ex works price for consumer packaging	Ex works price calculated per measuring unit	Currency	Ex works price in tenge	Reason for absence
	Azerbaijan							
	Belarus							
	Bulgaria							
	Hungary							
	Greece							
	Latvia							
	Lithuania							
	Russia							
	Poland							
	Romania							
	Slovakia							
	Slovenia							
	Turkey							
	Croatia							
	Czech Republic							
	Estonia							
	(Manufacturing country)*							
	Cost data(per measuring unit)							

16.	Name	Tenge, per measuring unit
	Transportation costs	
	Customs costs	
	Costs for assessment of safety and quality	
17.	Registered price within the framework of GVOFMC and in CSHI system	

I guarantee the accuracy of the provided information about prices for medicines.

I undertake to inform about all changes in prices for medicines, as well as to submit an application and materials required for performance of reference pricing or re-registration of the registered price within the framework of GVOFMC and in CSHI system for medicines.

Date _____ surname, name, patronymic

*in the absence of state registration with the reference countries

Annex 5
to the Rules for regulation
of prices for medicines
Form

Name of the authorized representative / company, representative office of the applicant authorized to conduct actions during the procedure of price registration in the Republic of Kazakhstan

Ref. no.____ dated _____

TABLE OF EX WORKS PRICES FOR REGISTRATION OF THE PRICE OR RE-REGISTRATION OF THE REGISTERED PRICE WITHIN GVOFMC AND CSHI SYSTEM

Hereby, the name of the authorized representative / company, representative office of the applicant authorized to act during the price registration procedure in the Republic of Kazakhstan for the purposes of registration of the price or re-registration of the registered price (underline as necessary) within the framework of GVOFMC and in CSHI system based on the name of the document confirming the right Applicant to register prices or re-register registered prices within the framework of GVOFMC and in CSHI system, including the right to provide information about ex works prices in reference countries, the number and date provides ex works prices in reference countries for the medicine trade name, dosage, concentration, volume, pharmaceutical form, quantity in consumer packaging, manufacturer, RC number in the following reference countries:

Country	Trade name	Quantity in consumer packaging in the reference country	Ex works price for consumer packaging (currency)	Ex works price calculated per measuring unit

Azerbaijan				
Belarus				
Bulgaria				
Hungary				
Greece				
Latvia				
Lithuania				
Russia				
Poland				
Romania				
Slovakia				
Slovenia				
Turkey				
Croatia				
Czech Republic				
Estonia				
(Manufacturing country)*				

I hereby guarantee the accuracy of provided information about ex works prices in the reference countries.

Date_____

_____ _____ _____

_____

Position signature surname, name, patronymic

Seal (if any)

* In case of the absence of registration in reference countries

Annex 6
to the Rules for regulation of
prices for medicines
Form

_____

Name of the authorized representative / company, representative office of the applicant authorized to conduct actions during the procedure of price registration in the Republic of Kazakhstan

MOTIVATED REFUSAL FROM REGISTRATION OF A PRICE OR RE-REGISTRATION OF A REGISTERED PRICE WITHIN GVOFMC AND IN CSHI SYSTEM

Hereby, the Republican State Enterprise under the right of economic management " National Center for Expertise of Medicines and Medical Devices" reports the following . When considering applications for price registration or re-registration of the

registered price of a medicinal product within the framework of GVOFMC and in CSHI system, in particular:

item no.	Unique code on pricing portal	Trade name of medicine
1		
2		

The employees of the Expert Organization have revealed the following: (mark as necessary

✓

)

Submission of documents in incomplete volume and (or) incompleteness of the information contained in them in accordance with the requirements of these Rules after the third notification on elimination of comments	
The deadline for the provision of information requested by a state expert organization exceeds 10 business days	
Provision of inaccurate information	
Manufacturer’s price within the framework of GVOFMC and in CSHI system of imported medicines for of the Republic of Kazakhstan exceeds the maximum value of three minimum of ex works prices from the number of reference countries submitted in the application	
Manufacturer’s price within the framework of the GVOFMC and in CSHI system of imported medicines for of the Republic of Kazakhstan exceeds the maximum value of ex works prices from the number of reference countries submitted in the application (if the number of reference countries is less than three)	
Manufacturer’s price within the framework of GVOFMC and in CSHI system of imported medicines for of the Republic of Kazakhstan exceeds the value of the ex works price for the manufacturing country. (In the absence of state registration of medicines with reference countries)	
Manufacturer’s price within the framework of the GVOFMC and in CSHI system of imported medicines for of the Republic of Kazakhstan exceeds the maximum value of the three minimum prices indicated in the submitted documents confirming the price of the medicine	
Transportation costs from the manufacturer to the border of the Republic of Kazakhstan exceed 15% of the manufacturer's price value within the framework of GVOFMC and in CSHI system for of the Republic of Kazakhstan	

Hereby, in accordance with clause 64, clause 67, as well as clause 68 of the "Rules for regulation of prices for medicines":

"64. Based on the results of monitoring and analysis of reference pricing for a trade name of medicines, the state expert organization shall register prices or re-registers the registered price within the framework of GVOFMC and in CSHI system, subject to the following criteria:

1) provided by the manufacturer's price within the framework of the GVOFMC and in CSHI system for imported medicines for of the Republic of Kazakhstan does not exceed the maximum value of three minimum of ex works prices from the number of reference countries submitted in the application, if the number of reference countries is less than three, manufacturer's price within the framework of GVOFMC and in CSHI system does not exceed the maximum value of ex works prices represented by the number of reference countries. In the absence of state registration of medicines in reference countries, the manufacturer’s price within the framework of GVOFMC and in CSHI system does not exceed of the value of an ex works price in the manufacturing country;

2) provided by the manufacturer’s price within the framework of the GVOFMC and in CSHI system for imported medicines is not higher than the maximum value of the three minimum prices indicated in the submitted documents confirming the price of medicines (a copy of an invoice (way-bill) or pro-forma invoice);

3) transportation costs from the manufacturer to the border of the Republic of Kazakhstan specified in the statement do not exceed 15% of the value of the manufacturer's price within the framework of GVOFMC and in CSHI system

If the registered price does not comply within the framework of the GVOFMC and in CSHI system with the criteria specified in this clause, the state expert organization shall send a motivated refusal to register the price or re-register the registered price within the framework of GVOFMC and in CSHI system in the form, according to annex 6 to these Rules."

"67. After providing additional information in accordance with paragraph 66 of these Rules, the state expert organization will re-examine the submitted documents in accordance with these Rules within 10 working days. In case of exceeding the deadline for providing the requested information, as well as providing documents in incomplete volume and (or) incompleteness of the information contained in them in accordance with the requirements of these Rules, after the third notification on the elimination of comments, the state expert organization shall send the applicant a motivated refusal to register the price or re-registration of the registered price within the framework of GVOFMC and in CSHI system in the form, according to annex 6 to these Rules."

"68. The applicant shall ensure the accuracy, completeness and content of the submitted documents in accordance with the current Legislation of the Republic of Kazakhstan and these Rules. Provision of false data by the applicant shall be the reason for refusing to register the price or re-register the registered price within the framework

of GVOFMC and in CSHI system in the form, according to annex 6 to these Rules. In case of revealing inaccurate data on the approved price limits for a trade name of medicines within the framework of GVOFMC and in CSHI, the state expert organization shall inform the authorized body about the need to exclude marginal prices for the corresponding medicines."

The expert organization shall send a motivated refusal to register the price or re-register the registered price within the framework of GVOFMC and in CSHI system to the medicines listed above.

_____ _____ _____

_____

Position signature Surname, name, patronymic (if any)

Annex 2
to the order of the
Minister of Health
of the Republic of Kazakhstan
dated April 19, 2019
no. ҚР ДСМ-42

List of cancelled orders:

1. Order of the acting Minister of Health and Social Development of the Republic of Kazakhstan dated July 30, 2015 no. 639 "Rules for formation of marginal prices and markups for medicines and medical devices, procured within the guaranteed volume of free medical care and in the system of compulsory social medical insurance" (registered with the Register of state registration of normative legal acts under no.93075 , published on August 25, 2015 in "Adilet" Information Reference System);

2. Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated October 23, 2015 no. 820 "On amendments and additions to the order of the acting Minister of Health and Social Development of the Republic of Kazakhstan dated July 30, 2015 no. 639 "Rules for formation of marginal prices and markups for medicines and medical devices, procured within the guaranteed volume of free medical care and in the system of compulsory social medical insurance" (registered with the Register of state registration of normative legal acts under no.94814 , published on November 4, 2015 in "Adilet" Information Reference System);

3. Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated June 8, 2016 no. 485 "On amendments and additions to the order of the acting Minister of Health and Social Development of the Republic of Kazakhstan dated July 30, 2015 no. 639 "Rules for formation of marginal prices and markups for medicines and medical devices, procured within the guaranteed volume of free medical

care and in the system of compulsory social medical insurance" (registered with the Register of state registration of normative legal acts under no.03652, published on July 4, 2016 in "Adilet" Information Reference System);

4. Order of the Minister of Health of the Republic of Kazakhstan dated February 8, 2018 no. 53 " On amendments and additions to the order of the acting Minister of Health and Social Development of the Republic of Kazakhstan dated July 30, 2015 no. 639 "Rules for formation of marginal prices and markups for medicines and medical devices, procured within the guaranteed volume of free medical care and in the system of compulsory social medical insurance" (registered with the Register of state registration of normative legal acts under no.3075, published on August 25, 2015 in " Adilet" Information Reference System).