On approval of the rules for assessment of quality of medicines and medical devices registered in the Republic of Kazakhstan

Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan dated December 20, 2020 No. ҚР ДСМ -282/2020. Registered in the Ministry of Justice of the Republic of Kazakhstan on December 22, 2020 No. 21836.

Unofficial translation

In accordance with subparagraph 44) of Article 7 of the Code of the Republic of Kazakhstan "On Public Health and Healthare System" **I HEREBY ORDER:**

Footnote. The preamble as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 14.09.2022 №ҚР ДСМ-99 (shall be enforced upon expiry of ten calendar days afer its first official publication).

1. To approve the rules for assessment of the quality of medicines and medical devices registered in the Republic of Kazakhstan in accordance with Appendix 1 to this order.

2. To recognize as invalid some orders of the Ministry of Health of the Republic of Kazakhstan in accordance with Annex 2 to this order.

3. The Committee for medical and pharmaceutical control of the Ministry of Health of the Republic of Kazakhstan, in accordance with the procedure established by the legislation of the Republic of Kazakhstan, to ensure:

1) state registration of this order in the Ministry of Justice of the Republic of Kazakhstan;

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

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

4. The supervising vice minister of health of the Republic of Kazakhstan is authorized to control the execution of this order.

5. This order comes into effect upon the expiration of ten calendar days after the day of its first official publication.

Minister of health of the Republic of Kazakhstan *A. Tsoi*

Appendix 1
to the order of the
Minister of health of the

Republic of Kazakhstan
dated December 20, 2020
№ ҚР ДСМ-282/2020

Rules for assessment of quality of medicines and medical devices registered in the Republic of Kazakhstan

Footnote. The Rules as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 14.09.2022 № ҚР ДСМ-99 (shall be enforced upon expiry of ten calendar days afer its first official publication).

Chapter 1. General provisions

1. These rules for assessment of quality of medicines and medical devices registered in the Republic of Kazakhstan (hereinafter referred to as the Rules) have been developed in accordance with subparagraph 44) of Article 7 of the Code of the Republic of Kazakhstan " On Public Health and Healthare System" (hereinafter referred to as the Кодекс) and shall determine the procedure for assessment of quality of medicines and medical devices registered in the Republic of Kazakhstan.

2. The following terms and definitions are used in these Rules:

1) a state body in the field of circulation of medicines and medical devices (hereinafter referred to as the state body) - a state body, carrying out management in the field of circulation of medicines and medical devices, control over the circulation of medicines and medical devices;

2) a state expert organization in the field of circulation of medicines and medical devices (hereinafter referred to as the expert organization) - a subject of a state monopoly that carries out production and economic activities in the field of healthcare to ensure the safety, effectiveness and quality of medicines and medical devices;

3) assessment of the quality of medicines and medical devices (hereinafter - product quality assessment) - determination of the compliance of the quality of medicines and medical devices with the data of the registration dossier, regulatory documents on quality, on the basis of which they were registered in the Republic of Kazakhstan;

4) document confirming the quality of a series of a medicine - manufacturer's document (quality certificate / certificate of analysis / series certificate / analytical passport / analysis report / test report) confirming the compliance of the quality of the declared medicinal product series with the quality indicators established in the regulatory document on quality;

5) document confirming the quality of a series of a medical device - manufacturer's document (quality certificate / certificate of analysis / series certificate / passport / analytical passport / analysis report / test report), confirming compliance of the medical device quality with the technical characteristics and parameters stated in the quality document;

6) products – medicines and medical devices, registered in the manner prescribed by paragraph 3 of Article 23 of the Code and permitted for medical use in the Republic of Kazakhstan;

7) applicant - an individual or legal entity carrying out pharmaceutical activities in the Republic of Kazakhstan, which provides products for quality assessment;

8) trend analysis – methods of discovering the hidden basic regularities of the behavior of a series of vaccines in a time sequence

9) registration dossier – a set of documents and materials submitted for examination of a medicine, medical device.

Footnote. Paragraph 2 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 21.02.2023 № 27 shall be enforced upon expiry of ten calendar days afer its first official publication).

3. Assessment of product quality in accordance with paragraph 2 of Article 241 of the Code refers to a state monopoly and is carried out by an expert organization for the purposes of:

1) determining the quality of registered products;

2) determining the quality of products sampled from the market taking into account the risk-based approach;

3) preventing the circulation of counterfeit products in the market of the Republic of Kazakhstan.

4. Payment for the services of assessment of the quality of products is made by the applicant to the account of the expert organization in accordance with the prices established by the authorized body in the field of healthcare in agreement with the antimonopoly body in accordance with the order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated January 20, 2021 № ҚР ДСМ-7 "On approval of prices for goods (works, services) produced and (or) sold by a subject of state monopoly" (hereinafter referred to as the Order № 7) (registered in the Register of State Registration of Regulatory Legal Acts under № 22096).

5. Assessment of the quality of products shall be carried out in the following types:

1) examination of documents when declaring products for each series (batch), which is the certain amount of a medicine, resulting from a technological process or a series of processes;

2) Examination of documents when declaring medical devices for each series (batch), which is an aggregate of a set number of medical devices produced according to a common technological process or enterprise standard;

3) examination of documents and laboratory testing of samples of medicines during serial assessment for manufacturers of the Republic of Kazakhstan;

4) examination of documents and laboratory testing of samples of medical devices during serial assessment for manufacturers of the Republic of Kazakhstan

5) examination of documents and laboratory testing of vaccines;

6) product sampling from the market taking into account the risk-based approach.

Medicines and medical devices that passed the quality assessment] in accordance with subparagraphs 1), 2), 3) and 4) of this paragraph, shall be subject to sampling from the market according to paragraph 5 of the Order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated December 24, 2020 № ҚР ДСМ-323/2020 "On approval of the rules for sampling from the market, including in medical organizations, of pharmaceuticals and medical devices subject to quality control taking into account a risk-based approach" (registered in the Register of State Registration of Regulatory Legal Acts under № 21923) (hereinafter referred to as the Order № 323).

Footnote. Paragraph 5 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 21.02.2023 № 27 shall be enforced upon expiry of ten calendar days afer its first official publication).

6. Assessment of the quality of products shall be carried out for each series (batch) of a medicine and for each series (batch) of a medical device, made in the Republic of Kazakhstan , or imported to the Republic of Kazakhstan before the expiry date of the registration certificate, issued in accordance with the Order of the Minister of Healthcare of the Republic of Kazakhstan dated February 9, 2021 № ҚР ДСМ-16 "On the approval of the rules for state registration, re-registration of a medicine or medical device, making changes to the registration dossier of a mediciny or medical device" (registered in the Register of State Registration of Regulatory Legal Acts under № 22175), registered in accordance with the decision of the Board of Eurasian Economic Commission dated November 3, 2016 № 78 "On the rules for registration and examination of medicines for medical use" and the decision of the Board of Eurasian Economic Commission dated February 12, 2016 № 46 "On the rules for registration and examination of safety, quality and effectiveness of medical devices".

7. To perform product quality assessment by types, specified in subparagraphs 1), 2), 3), 4), 5) of paragraph 5 of these Rules, the applicant in accordance with the Civil Code of the Republic of Kazakhstan shall conclude a contract for the performance of work on the assessment of production quality with the expert organization.

When assessing quality by type, specified in subparagraph 6) пункта 5 of these Rules, the manufacturer (the holder of the registration certificate of the medicinal product, the authorized representative of the manufacturer of the medical product) or their authorized persons (hereinafter referred to as the manufacturer), in accordance with the Civil Code of the Republic of Kazakhstan shall conclude a contract with an expert organization to carry out work on the sampling of products from the market taking into account a risk-oriented approach for testing production samples.

8. Submission of the application and documents by the applicant, issuance of the certificate of product conformity shall be carried out electronically in the information system of the expert organization.

9. In case of natural or man-made emergencies, organization and implementation of sanitary and anti-epidemic and sanitary-preventive measures and related restrictive measures,

including quarantine, when submitting an application for product quality assessment and there is no notarization or apostilization of documents requiring certification, the applicant shall additionally provide a letter of guarantee (in free form) on provision of documents requiring notarization or apostilization, as well as copies of documents signed and sealed by the enterprise (if any) within sixty calendar days after the removal of restrictive measures.

When organizing and carrying out sanitary-epidemic and sanitary-preventive measures and related restrictive measures, including quarantine, assessment of the quality of products shall be carried out within a period of not more than three working days from the date of receipt of the application and documents.

10. The validity of product conformity certificates shall be suspended or revoked by an expert organization at the initiative of a state body or the owner of a product registration certificate in accordance with Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 24, 2020 № ҚР ДСМ-322/2020 "On the approval of the rules for suspension, prohibition or withdrawal from circulation or restriction of the use of medicines and medical devices" (hereinafter referred to as the Order № 322) (registered in the Register of State Registration of Regulatory Legal Acts under № 21906).

11. The expert organization shall draw up a decision on the suspension or withdrawal of the product conformity certificate in the form according to Appendix 1 to these Rules, and from receipt of the decision of the state body, within one working day, shall make the relevant entries in the information system of the expert organization and in the State Register of Medicines and Medical Devices.

Chapter 2. Procedure for assessment of quality of products

Section 1. Examination of documents when declaring products

12. To perform examination of documents when declaring products, the applicant shall submit:

1) an application for the assessment of quality of a medicine or a medical device in the form according to Appendix 2 to these Rules;

2) for imported medicines – a notarized or apostilled in accordance with requirements of the Hague Convention dated October 5, 1961 "List of states, recognizing the apostille" (hereinafter referred to as the the Hague Concention) copy of a Certificate of Good Manufacturing Practice (hereinafter referred to as the GMP), in a PDF format, existing at the time of production or Declaration from the manufacturer with the current GMP status on the website of the Food and Drug Administration (USA) (hereinafter referred to as the FDA (hereinafter referred to as the FDA)) without apostille, and the address of the website of the register of GMP certificates of conformity issued by the authorized body (if any) - with a translation into Kazakh or Russian language (when submitting a document in a foreign language), for medicines made in the territory of the Republic of Kazakhstan - a document

confirming compliance of the production site with the GMP requirements of the Republic of Kazakhstan and the address of the website of the register of the register of certificates of compliance with GMP requirements issued by the authorized body;

3) for imported medical devices – notarized or apostilled in accordance with the requirements of the Hague Convention copy of ISO (ISO) 13485, ISO 9001 or GMP certificate, in PDF format, except for medical devices of 1 and 2a class (non-sterile), valid at the time of production with a translation into Kazakh or Russian language (when submitting a document in a foreign language), and the official address of the electronic site of the register of the register of certificates of conformity to GMP requirements for domestic manufacturers issued by the authorized body (if any);

4) a copy of the document confirming the quality of the product series from the manufacturer with a translation into Kazakh or Russian (when presenting the document in a foreign language);

5) for imported products – a copy of the document on the origin of the goods, certifying the country of origin of the goods and issued by an authorized organization in accordance with the legislation of the given state or the state of export, if in the state of export the certificate is issued on the basis of summaries obtained from the country of origin of the goods;

6) for imported products – a copy of the bill of lading, invoice or invoice. For medicines or medical devices manufactured on the territory of the Republic of Kazakhstan, the applicant provides a certificate (optional form) on the availability of ready-to-sell medicines or medical devices specified in the application;

7) for imported products – a copy of customs declaration for products (electronic), except for products, set forth in the Resolution of the Government of the Republic of Kazakhstan dated July 21, 2018 № 441 "On the approval of the list of goods in respect of which conditional release is not allowed". When importing products manufactured and (or) imported from member states of the Eurasian Economic Union, a document confirming border crossing shall be provided.

Footnote. Paragraph 12 as amended by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated 07.06.2023 № 105 (shall be enforced upon expiry of ten calendar days afer its first official publication).

13. Expert organization within the period not exceeding five working days upon the date of receipt of application and documents, set forth in paragraph 12 of these Rules, shall check the submitted documents and verify yhe data indicated in them with information provided for in the State Register of Medicines and Medical Devices.

When submitting more than ten names of medicines or medical devices in one application , within the framework of one import document (invoice), the application review period is no more than ten working days.

14. When providing an incomplete package of documents, provided for in paragraph 12 of these Rules, inconsistency of the information in the presented documents with the data of the State Register of Medicines and Medical Devices, provision of unreliable information, the expert organization within five working days from the date of receipt of the documents shall send the applicant, through the information system of the expert organization, a notification of the need to eliminate the relevant comments. The applicant, within a period of no more than ten working days from the date of receipt of the notification, which are not part of the general period of quality assessment of medicines and medical devices, shall eliminate the relevant comments.

15. Based on the results of the examination of the documents, in the absence of any observations, the expert organization shall issue and register a certificate of product conformity in the information system of the expert organization within five working days in the form according to Appendix 3 to these Rules.

When specifying the products to which the product conformity certificate applies, an appendix to the product conformity certificate shall be drawn up in the form according to Appendix 4 to these Rules.

16. When providing an incomplete package of documents, provided for in paragraph 12 of these Rules, presence in them of discrepancies with the data of the registration dossier and the State Register of Medicines and Medical Devices, detection of inaccurate information, absence of data on the availability of the license on the elicence portal, as well as if the applicant fails to eliminate the remarks within the established time limits, the expert organization shall issue a decision to refuse to issue a product conformity certificate in the form according to Appendix 5 to these Rules.

17. The validity period of a product conformity certificate shall be established until the end of the shelf life (operation) of the product, with the shelf life (operation) of the product being determined until the last day of the specified month (for medical equipment in accordance with the technical passport or certificate of quality, production or analysis issued by the manufacturer) inclusive.

Section 2. Examination of documents and laboratory testing of samples in serial assessment of medicines

18. For examination of documents and laboratory tests of samples of medicinal products in serial assessment for manufacturers of the Republic of Kazakhstan, with the exception of vaccines, the applicant shall submit on an electronic medium:

1) an application for the assessment of quality of medicines, manufactured by one manufacturer, in the form according to Appendix 2 to these Rules;

2) a notarized copy of the document confirming the compliance of the production site with GMP requirements and the website address of the register of certificates of compliance with GMP requirements issued by the authorized body (if any).

Production samples, including standard samples of chemical substances, standard samples of biological preparations, specific reagents for conducting tests in quantities sufficient for one-time tests taking into account the verification of methods by the laboratories of an expert organization with a final expiration date of at least three months with test certificates (test reports) for this series of drug samples, an act of acceptance and transfer of production samples shall be drawn up in the form according to Appendix 6 to these Rules. Sending of product samples to the expert organization in the absence of a territorial subdivision of the expert organization shall be carried out by the applicant, with observance of storage conditions during transportation.

Submission of the application and documents by the applicant shall be carried out electronically in the information system of the expert organization.

Testing samples shall be carried out in the laboratories of an expert organization.

Results of testing of product samples, sampled from the market shall be drawn up by a test report in the form according to Appendix 7 to these Rules.

When it is impossible to conduct laboratory tests of a medicine for certain indicators in the laboratories of an expert organization due to difficult accessibility of samples of medicinal products, standard samples, specific reagents, impossibility to comply with the conditions of transportation of these samples, as well as the lack of special equipment and consumables in the expert organization, tests shall be conducted in the presence of representatives of the expert organization in the manufacturer's quality control laboratory or in a contract laboratory used by the manufacturer, including by means of remote interaction, including audio or video communication in the organization and conduct of sanitary and anti-epidemic and sanitary and preventive measures and related restrictive measures, including quarantine.

A report of the laboratory test results shall be prepared by the manufacturer's quality control laboratory or by a contract laboratory used by the manufacturer according to the Appendix 8 to these Rules.

Footnote. Paragraph 18 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 21.02.2023 № 27 shall be enforced upon expiry of ten calendar days afer its first official publication).

19. The term of consideration of applications for examination of documents shall not exceed 5 working days from the date of their receipt.

Terms of laboratory tests of product samples shall be determined in accordance with the regulatory document on product quality. If the terms of testing are not provided in the normative documents, the tests are conducted within twenty-five working days from the day of receipt of samples to assess the quality of products in the accredited laboratory of the expert organization.

An additional twenty-five working days shall be granted for additional testing in case of disputed test results of samples of products taken from the market, which shall not include the time for the applicant to provide additional samples.

Footnote. Paragraph 19 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 21.02.2023 №27 shall be enforced upon expiry of ten calendar days afer its first official publication).

20. When providing an incomplete package of documents, provided for in paragraph 18 of these Rules, inconsistency of the information in the presented documents with the data of the State Register of Medicines and Medical Devices, provision of unreliable information, the expert organization within five working days from the date of receipt of the documents shall send to the applicant, through the information system of the expert organization, a notification on the need to eliminate the relevant comments. The applicant shall, within a period not exceeding ten working days from the date of receipt of the notification, eliminate the relevant comments.

21. In the absence of comments on the results of expert examination of documents and positive results of laboratory tests, the expert organization within two working days shall issue and register in the information system of the expert organization product conformity certificate in the form according to Appendix 9 to these Rules.

When specifying the products covered by a product conformity certificate, an annex to the product conformity certificate shall be drawn up in the form according to Appendix 10 to these Rules.

22. When providing an incomplete package of documents, provided for in paragraph 18 of these Rules, the presence of discrepancies in them with data from the registration dossier and the State Register of Medicines and Medical Devices, detection of inaccurate information, absence of data on the license availability on the elicence portal, failure of the applicant to eliminate remarks within the established timeframe, as well as in case of determination of nonconformities based on the results of laboratory tests, the expert organization shall issue a decision on refusal in issue of a product conformity certificate in the form according to Appendix 11 to these Rules.

23. If discrepancies in packaging and labeling are detected, the applicant shall apply for the procedure of amending the registration dossier in accordance with Order of the Minister of Healthcare of the Republic of Kazakhstan dated January 27, 2021 №ҚР ДСМ-10 " On approval of the rules for expert examination of medicines and medical devices " (hereinafter referred to as the Order № 10) (registered in the Register of State Registration of Regulatory Legal Acts under № 22144).

Based on the results of the changes made to the registration dossier, the applicant shall re-submit an application for serial assessment of the quality of the medicine.

If the applicant does not make changes to the registration dossier on packaging and labeling within six months in accordance with Order № 10, the expert organization shall send relevant information to the state body about the necessity of destruction (utilization) of production in the order provided for by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated February 16, 2021 № ҚР ДСМ-19 " On approval of the rules

for storage and transportation of medicines and medical products " (hereinafter referred to as the Order № 19) (registered in the Register of State Registration of Regulatory Legal Acts under № 22230).

24. The period of validity of a product conformity certificate during serial assessment shall be set for a period of no more than three years without specifying the series.

Section 3. Examination of documents and laboratory testing of samples in serial assessment of medical devices

25. To perform examination of documents and laboratory testing of samples of medical devices in serial assessment for manufacturers of the Republic of Kazakhstan, the applicant shall submit on an electronic medium:

1) an application for the assessment of quality of medical devices manufactured by one manufacturer, in the form according to Appendix 2 to these Rules;

2) a notarized copy of the document confirming the compliance of the production site with the requirements of ISO 13485, ISO 9001 or GMP.

Product samples, including standard samples of chemical substances, standard samples of biological preparations, specific reagents for testing in quantities sufficient for one-time tests taking into account verification of methods by laboratories of the expert organization with a residual shelf life of not less than three months with certificates of analysis (test reports) for this series of samples and test methods for medical devices for the indicators specified in the certificate of analysis (test report), shall be drawn up by the act of acceptance-transfer of product samples, in the form according to Appendix 6 to these Rules. Shipment of product samples to the expert organization in the absence of a territorial subdivision of the expert organization shall be carried out by the applicant with observance of storage conditions during transportation.

Submission of the application and documents by the applicant shall be carried out electronically in the information system of the expert organization.

Tests of samples shall be carried out in the laboratories of an expert organization.

The test results of samples of products sampled from the market shall be drawn up in a test reportin the form according to Appendix 7 to these Rules.

If it is impossible to carry out laboratory tests of a medical device for individual indicators , the tests shall be carried out in the presence of representatives of the expert organization in the manufacturer's quality control laboratory or in a contract laboratory used by the manufacturer, including using means of remote interaction, including audio or video communication in the organization and conduct of sanitary and anti-epidemic and sanitary and preventive measures and related restrictive measures, including quarantine.

A report of the laboratory test results shall be prepared by the manufacturer's quality control laboratory or by a contract laboratory used by the manufacturer according to the Appendix 8 to these Rules.

Footnote. Paragraph 25 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 21.02.2023 № 27 shall be enforced upon expiry of ten calendar days afer its first official publication).

26. The term of consideration of applications for examination of documents shall not exceed 5 working days from the date of their receipt.

Terms of laboratory tests of product samples shall be determined in accordance with the document on product quality. If the terms of testing are not stipulated in the quality documents, the tests shall be conducted within twenty-five working days from the date of receipt of samples for assessment of product quality in the accredited laboratory of the expert organization.

An additional twenty-five working days shall be granted for additional testing in case of disputed test results of samples of products taken from the market, which shall not include the time for the applicant to provide additional samples.

Footnote. Paragraph 26 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 21.02.2023 № 27 shall be enforced upon expiry of ten calendar days afer its first official publication).

27. When providing an incomplete package of documents, provided for in paragraph 25 of these Rules, inconsistency of the information in the presented documents with the data of the State Register of Medicines and Medical Devices, provision of unreliable information, the expert organization within five working days from the date of receipt of the documents shall send to the applicant, through the information system of the expert organization, a notification on the need to eliminate the relevant comments. The applicant shall, within a period not exceeding ten working days from the date of receipt of the notification, eliminate the relevant comments.

28. In the absence of comments on the results of expert examination of documents and positive results of laboratory tests, the expert organization within two working days shall issue and register in the information system of the expert organization product conformity certificate in the form according to Appendix 9 to these Rules.

When specifying the products covered by a product conformity certificate, an annex to the product conformity certificate shall be drawn up in the form according to Appendix 10 to these Rules.

29. When providing an incomplete package of documents, provided for in paragraph 25 of these Rules, the presence of discrepancies in them with data from the registration dossier and the State Register of Medicines and Medical Devices, detection of inaccurate information, absence of data on the license availability on the elicence portal, failure of the applicant to eliminate remarks within the established timeframe, as well as in case of determination of nonconformities based on the results of laboratory tests, the expert organization shall issue a decision on refusal to issue of a product conformity certificate in the form according to Appendix 11 to these Rules.

30. If discrepancies in packaging and labeling are detected, the applicant shall apply for the procedure of amending the registration dossier in accordance with Order № 10.

Following the results of the changes made to the registration dossier, the applicant shall resubmit the application for serial quality assessment of the medical device.

If the applicant fails to make changes to the registration dossier on packaging and labeling within six months in accordance with the Order № 10, the expert organization shall send the relevant information to the state body on the need to destroy (dispose of) the products in the manner prescribed by the Order № 19.

31. The validity period of a product conformity certificate in case of serial assessment shall be set for a period not exceeding three years without specifying the series.

Section 4. Examinaiton of documents and laboratory testing of vaccines

32. To perform examination of documents and laboratory testing of vaccines, the applicant shall submit on an electronic medium:

1) an application for the assessment of quality of vaccines in the form according to Appendix 2 to these Rules;

2) a notarized copy of the document confirming the compliance of the production site with the requirements of GMP and the website address of the register of certificates of compliance with GMP requirements issued by the authorized body (if any);

3) summary protocol of the manufacturer for each series of vaccines in accordance with GMP requirements and the guidance of the World Health Organization (hereinafter referred to as the WHO) on the release of independent batches of vaccines by regulatory bodies, adopted at the 61st meeting of the WHO Expert Committee on Biological Standardization, 2010 with a translation into Kazakh or Russian language (when presenting a document in a foreign language). For vaccines that have undergone WHO prequalification, as well as those produced in the countries of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceutical Products for Human Use (The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) (hereinafter - ICH) the manufacturer's summary protocol shall not be provided;

4) a copy of the document confirming the quality of the production series from the manufacturer (certificate of analysis) with a translation into Kazakh or Russian (when presenting the document in a foreign language);

5) for vaccines imported into the Republic of Kazakhstan, a series quality certificate (release certificate) issued by the national regulatory body or quality control laboratory of the manufacturer's country or other official laboratory authorized by the regulatory body of the manufacturer's country to conduct quality control for the purpose of releasing the series to the market with a translation into Kazakh or Russian (if the document is submitted in a foreign language) shall be provided.

Laboratory tests shall be carried out for each series of vaccines produced in the Republic of Kazakhstan, as well as for vaccines imported into the Republic of Kazakhstan when:

1) adverse effects after immunization with a particular vaccine and manufacturer, according to the results of pharmacovigilance;

2) Information about problems with quality, safety or effectiveness of vaccines according to the results of pharmacovigilance.

The results of the trend analysis carried out by the expert organization shall be sent to the manufacturer within five working days for corrective and preventive measures, and the introduction of improvements to ensure the uniformity of the vaccine series.

Tests of vaccine samples shall be carried out in the laboratories of an expert organization. In this case, for laboratory testing, the applicant shall provide vaccine samples, in quantities sufficient for one-time testing with certificates of analysis (test reports) for this series of samples and a regulatory document on quality, including standard samples of chemical substances, standard samples of biological preparations, test strains of microorganisms, cell cultures and specific reagents for conducting tests in quantities sufficient for one-time tests taking into account the verification of methods by laboratories of an expert organization with a final expiration date of at least three months with certificates of analysis (test protocols) for this series of samples and vaccine test methods for indicators , specified in the certificate of analysis (test protocol), an act of acceptance and transfer of product samples shall be drawn up in the form according to Appendix 6 to these Rules.

Shipment of product samples to the expert organization in the absence of a territorial subdivision of the expert organization shall be carried out by the applicant with observance of storage conditions during transportation.

If it is impossible to carry out tests on individual indicators, vaccine tests shall be carried out in a subcontract laboratory on the basis of an agreement between an expert organization and a subcontract laboratory in accordance with the legislation of the Republic of Kazakhstan on public procurement.

Footnote. Paragraph 32 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 21.02.2023 № 27 shall be enforced upon expiry of ten calendar days afer its first official publication).

33. The term of consideration of applications for examination of documents shall not exceed 5 working days from the date of their receipt.

The terms of laboratory testing of vaccines shall be determined in accordance with the regulatory document on quality. If the test terms are not stipulated in the regulatory documents, then the tests shall be carried out within twenty-five working days from the date of receipt of vaccine samples for product quality assessment in the accredited laboratory of an expert organization.

An additional twenty-five working days shall be allowed for additional testing in the event of disputed test results for vaccine samples, which shall not include the time for the applicant to provide additional samples.

Footnote. Paragraph 33 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 21.02.2023 № 27 shall be enforced upon expiry of ten calendar days afer its first official publication).

34. When providing an incomplete package of documents, provided for in paragraph 32 of these Rules, inconsistency of the information in the presented documents with the data of the State Register of Medicines and Medical Devices, provision of unreliable information, the expert organization within five working days from the date of receipt of the documents shall send to the applicant, through the information system of the expert organization, a notification on the need to eliminate the relevant comments. The applicant shall, within a period not exceeding ten working days from the date of receipt of the notification, eliminate the relevant comments and provide a report on corrective and preventive actions.

Footnote. Paragraph 34 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 21.02.2023 № 27 shall be enforced upon expiry of ten calendar days afer its first official publication).

35. In the absence of comments on the results of expert examination of documents and positive results of laboratory tests, as well as the absence of potential rejects in the series of vaccine series, the expert organization within two working days shall issue and register in the information system of the expert organization product conformity certificate in the form according to Appendix 12 to these Rules.

36. When providing an incomplete package of documents, provided for in paragraph 32 of these Rules, presence of inconsistencies in them with the data of the registration dossier, detection of inaccurate information, absence of data on the license availability on the elicence portal, failure of the applicant to eliminate remarks within the established timeframe, as well as when identifying potential deviations in the sequence of the vaccine series and (or) inconsistencies according to the results of laboratory tests, the expert organization issues a decision to refuse to issue a product conformity certificate in the form according to Appendix 13 to these Rules.

37. The period of validity of the conformity certificate for a vaccine shall be established until the end of its shelf life, with the shelf life of the product being determined until the last day of the specified month.

38. The results of the assessment of the quality of vaccines shall be posted on the website of the expert organization.

Section 5. Sampling of products from the market taking into account a risk-based approach

39. Sampling of products from the market taking into account a risk-based approach, which is in circulation in the territory of the Republic of Kazakhstan, shall be carried out by an expert organization in accordance with Order № 323.

40. To carry out the sampling of products from the market, the expert organization annually, by November 1, shall form a plan for the sampling to assess the quality of medicines and medical devices in circulation in the territory of the Republic of Kazakhstan and places it freely available on the official website of the expert organization.

41. Testing of samples of products taken from the market shall be carried out at the expense of the manufacturer in accordance with the prices for services established by the authorized body in the field of healthcare in agreement with the antimonopoly body in accordance with Order № 7.

Reimbursement of the cost of product samples taken for testing to the subject from whom the sampling has been performed shall be made by the manufacturer in multiples of the sampling performed, depending on the number of subjects (objects) of sampling locations (by region, by the number of distributors, pharmacies and medical organizations).

42. Testing of samples of products taken from the market shall be carried out in testing laboratories of the expert organization accredited by in accordance with the Order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated October 27, 2020 № ҚР ДСМ-157/2020 "On approval of the Rules for accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines and medical devices" (registered in the Register of State Registration of Regulatory Legal Acts under № 21540).

43. Testing of products, sampled from the market taking into account the risk-oriented approach shall be conducted on the indicators of labeling and packaging in terms of determining its compliance with the layout (layouts) approved in the State Register of Medicines and Medical Devices with provision of one package.

In case of compliance of labeling and packaging with the State Register of Medicinal Products and Medical Devices, samples of medicinal products and medical devices sampled from the market shall be returned upon written request (in any form) of the applicant.

If nonconformities in labeling and packaging are identified, samples of the given name of the medicinal product or medical device circulating on the market shall be re-sampled and laboratory tests (except for labeling and packaging indicators) shall be performed for compliance with the requirements of the regulatory document on quality for medicines and quality document for medical devices.

For testing, samples of medicines or medical devices sampled from the market taking into account the risk-oriented approach, which do not meet the labeling and packaging indicators, shall be provided in quantities sufficient for a single test with a residual shelf life of at least

three months with certificates of analysis (test reports) for this series of samples of medicines and medical devices and test methods for medical devices for the indicators specified in the certificate of analysis (test report).

If it is impossible to reproduce certain quality indicators according to the regulatory document of a medicine or medical device quality document sampled from the market, the manufacturer shall provide a quality certificate or other similar document with the results of tests on these indicators for recognition of the results by an expert organization on these indicators.

To carry out testing of sampled products from the market and (or) in medical organizations according to paragraph 41 of these Rules the manufacturer shall provide standard samples of chemical substances, standard samples of biological preparations, specific reagents in quantities sufficient for a single test, taking into account the verification of methods by the laboratories of an expert organization for conducting tests on medicines and medical devices.

44. For technical errors related to the production process of putting information on the package (except for information on dosage form, dosage form, dosage, expiration date, storage conditions), which do not affect the quality and safety of the product and do not require changes to the product, subject to laboratory confirmation of product quality, except for the indicator labeling and packaging, the manufacturer shall provide a letter of guarantee to the state authority confirming the authenticity of the products, as well as the delivery of the following series in accordance with the approved product packaging layout.

45. The terms of laboratory tests of samples of products taken from the market shall be determined in accordance with the normative document on product quality. If the terms of testing are not stipulated in normative documents, the tests shall be carried out within twenty-five calendar days from the date of receipt of samples for assessment of product quality in the accredited laboratory of the expert organization.

An additional twenty-five working days shall be granted for additional testing in case of disputed test results of samples of products taken from the market, which shall not include the time for the applicant to provide additional samples.

46. Laboratory tests of medicines registered for the first time in the Republic of Kazakhstan, medicines requiring special storage conditions (stored at temperatures up to +15 (degree Celsius)), parenteral medicines (except for monoclonal antibodies)), as well as products with identified nonconformities based on the results of pharmaceutical control, inspection, pharmacovigilance, sampling from the market for the previous three years, sampled from the market taking into account the risk-based approach, shall be carried out according to critical indicators in accordance with the regulatory document on quality for medicines and the document on quality for medical devices.

Footnote. Paragraph 46 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 21.02.2023 № 27 shall be enforced upon expiry of ten calendar days afer its first official publication).

47. Test results of product samples taken from the market in serial assessment, as well as laboratory tests of vaccines shall be formalized in a test report in the form according to Appendix 7 to these Rules.

In case of positive results of tests of samples of products sampled from the market, the expert organization within two working days after the day of receipt of the test report shall notify (in any form) the manufacturer on compliance of products with regulatory documents on quality.

Footnote. Paragraph 47 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 21.02.2023 № 27 shall be enforced upon expiry of ten calendar days afer its first official publication).

48. In case of negative test results of product samples taken from the market, serial evaluation, as well as laboratory tests of vaccines, the expert organization shall draw up a negative conclusion on the quality of products within two working days after the day of receipt of the test report in the form according to Appendix 14 to these Rules. The results on the identified nonconformities of products shall be posted on the website of the expert organization.

Footnote. Paragraph 48 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 21.02.2023 № 27 shall be enforced upon expiry of ten calendar days afer its first official publication).

49. In case of negative conclusion on results of laboratory tests of samples of products sampled from the market, at serial evaluation, as well as laboratory tests of vaccines in accordance with paragraph 48 of these Rules, the expert organization within five working days shall send information to the state body for taking measures to suspend the certificate of conformity and withdrawal from circulation of the medicinal product and medical device that do not meet the requirements of the legislation of the Republic of Kazakhstan in the field of health care, stipulated by the Order № 322.

Footnote. Paragraph 49 as amended by the order of the Minister of Healthcare of the Republic of Kazakhstan dated 21.02.2023 № 27 shall be enforced upon expiry of ten calendar days afer its first official publication).

Appendix 1
to the Rules for assessment of quality of
medicines and medical devices registered
in the Republic of Kazakhstan

Ministry of Healthcare of the Republic of Kazakhstan

Name and address of expert organization

Decision on suspension or revocation of a product conformity certificate
dated "____" _____ 20__ No_____

Product name: Medicine (with indication of dosage form, dosage, concentration and filling volume, number of doses in the package, № of registration certificate) Medical device (completeness, safety class, № of registration certificate)	
Series (batch) of products (serial number for medical devices, which are units, instruments and equipment), batch size Expiry date (operation - for medical devices, which are units, instruments and equipment)	
Name of manufacturing organization, country	

Validity of a product conformity certificate

_____

(Certificate №, date of issue) was suspended, revoked (specify as necessary)
in accordance with _____
(indicate documents, grounds) from "_____" _____ 20_____.
Signatures of the authorized persons:

_____ _____

signature surname, name, patronymic (if any)

_____ _____

signature surname, name, patronymic (if any)

Appendix 2
to the Rules for assessment of quality of
medicines and medical devices registered
in the Republic of Kazakhstan
"____" _____ 20___
(date of application)

_____

(name and address
of expert organization)

Application for assessment of quality of a medicine or a medical device

1	Name of the applicant	
2	Location of a legal entity	
3	Business address of the legal entity	
4	Bank details of the applicant	
5	Method of quality assessment	Examination of documents when declaring products Examination of documents and laboratory tests of samples of medicines during serial assessment Examination of documents and laboratory tests of samples of medical products during serial assessment Examination of documents and laboratory tests of vaccines

6	Information on the license to engage in pharmaceutical activities with the relevant annex (production, wholesale) to the license or notification of the commencement of activities (wholesale) in accordance with the Law of the Republic of Kazakhstan "On Permissions and Notifications", and a link to the license on elicense portal						
7	Information about declared products*						
№	Brand name	Series № (serial number for medical devices, which are units, instruments and equipment)	Manufacturing date	Expiry date (Useful lifetime)	Batch size	Manufacturer	Manufacturing country
8	The applicant, represented by_____ _____ (surname, name, patronymic (if any) of the head or authorized person, position) hereby guarantees the reliability of the information provided						
9	Date of filling in						
10	Signature, surname, name, patronymic (if any)						

Note

* Assessment of the quality of products shall not be carried out for separately imported (manufactured) components that are part of medical devices and are not used as an independent product or device, as well as for consumables for medical devices, specially designed by the manufacturer of a medical device for use with medical devices, capable of functioning only with these consumables.

Application for quality assessment shall be submitted: for producers of the Republic of Kazakhstan - within the framework of manufactured products; for imported products - within the framework of one import document.

Appendix 3
to the Rules for assessment of quality of
medicines and medical devices registered
in the Republic of Kazakhstan

Name and address of expert organization Product conformity certificate (in declaration)

"____" _____ 20___ № _____

Valid until "___" _____ 20___ under proper storage conditions

1. This product conformity certificate is to certify that the product_____
_____

(name and type of the product, according to the State Register of Medicines and Medical Devices, № of registration certificate, series

(serial № for medical devices, which are items, instruments and equipment

оборудованием), expiry date, batches quantity) made in

_____

(country, name of the manufacturer) submitted by

_____

(name, location of a legal entity, business address of the legal entity) passed the assessment of quality by declaration

2. Product conformity certificate is issued on the basis of certificates _____
_____

(GMP, №, date of issue, validity or ISO 13485, №, date of issue, shelf life)

_____

(manufacturer's quality certificate №, date of issue)

3. Additional information

_____

_____

(filled in if necessary)

Signatures of the authorized persons:

_____ _____

signature surname, name, patronymic (if any), position

_____ _____

signature surname, name, patronymic (if any), position

Appendix 4
to the Rules for assessment of quality of
medicines and medical devices registered
in the Republic of Kazakhstan
Form

_____

Name and address of expert organization

Appendix to product
Conformity certificate

№_____

List of specific products covered by the validity of a product conformity certificate (in declaration)

Product name in accordance with State Register of Medicines and		

Medical Devices, № of registration certificate, name of manufacturer, manufacturing country	Series (serial number for medical devices, which are units, instruments and equipment), expiry date, batch size	Validity of conformity certificate

Signatures of the authorized persons:

_____ _____

signature surname, name, patronymic (if any), position

_____ _____

signature surname, name, patronymic (if any), position

Appendix 5
to the Rules for assessment of quality of
medicines and medical devices registered
in the Republic of Kazakhstan
Form

_____

Name and address of expert organization

_____
Name of the applicant

_____
position, surname, name, patronymic
(if any)
of the head

_____
Location
of legal entity,
business address of the legal entity
dated "____" _____ №_____

Decision on refusal to issue a product conformity certificate (in declaration)

1. General information

Product name: Medicine (with indication of dosage form, dosage, concentration and filling volume, number of doses in the package, № of registration certificate) Medical device (completeness, safety class, № of registration certificate)	
Series (batch) of products (serial number for medical devices, which are units, instruments and equipment), batch size, expiry date (operation - for medical devices, which are units, instruments and equipment)	
Name of manufacturing organization, country	

2. Grounds for refusal (mark as necessary)

☐	provision of an incomplete package of documents according to the list provided for in paragraph 12 of the

	Rules for Quality Assessment of Medicines and Medical Devices Registered in the Republic of Kazakhstan
☐	provision of unreliable information
☐	discrepancy of information in the submitted documents with the data of the State Register of Medicines and Medical Devices of the Republic of Kazakhstan
☐	lack of information about the availability of a license on the e-license portal
☐	failure to eliminate the comments made by the expert organization in a timely manner

Signatures of the authorized persons:

_____ _____

signature surname, name, patronymic (if any), position

_____ _____

signature surname, name, patronymic (if any), position

Appendix 6
to the Rules for assessment of quality of
medicines and medical devices registered
in the Republic of Kazakhstan
Form

Acceptance and transfer certificate for product samples

dated "___" _____ 20___

Applicant: _____

(name of organization, address)

Address and place of sampling:

_____

The sampling was performed by:

_____

surname, name, patronymic (if any) of the person, who performed the sampling

The samples of the presented product were sampled in accordance with

_____

(name of the regulatory document)

for testing for the purposes of assessment of quality of products

The product was received under:

_____

(bill of lading; railroad receipt №,

_____

(under Contract №, date; Agreement №, date)
Manufacturer:

_____

(country, organization (individual entrepreneur), address
Supplier:

_____

_____

(Country organization (individual entrepreneur), address)
The samples were sampled from products, presented under the name:

Name of the samples of presented products	Measuring unit	Batch №	Batch size	Manufacturing date	Expiry date	Amount of the sampled products
1	2	3	4	5	6	7

Control samples in quantities equal to the number of selected samples are selected, sealed and stored in proper conditions during the validity period of a product conformity certificate at the subject in the sphere of circulation of medicines and medical devices.

Applicant: _____ _____
(signature) surname, name, patronymic(if any)
Samples accepted by:
Representative of the expert organization _____ _____
(signature) surname, name, patronymic (if any)
Date of acceptance of samples by the expert organization:
"_____" _____ 20__г.

Appendix 7
to the Rules for assessment of quality of
medicines and medical devices registered
in the Republic of Kazakhstan
Form

Place of the mark and (or) number of the Accreditation certificate _____
_____

Name and address of expert organization

_____

Accreditation certificate of the testing laboratory (№, validity period)

_____

Address, phone number of the expert organization (testing laboratory)

Протокол испытаний № _____ dated "____" _____ года
Страница ____ / Количество листов__

Subject (name, address):	_____ ___

Product name:	_____				
Type of testing:	_____				
Grounds:	_____				
Manufacturer, country:	_____				
Series, batch:	_____	Manufacturing date:_____ _____	_____ _____ _____ _____	Shelf life:_____	
Number of sampling:	_____	Date of receipt of sampling:	_____ _____		
Test start date and end date:	_____				
Designation of the regulatory document on product quality:	_____				
Designation of the regulatory document on quality for test methods:	_____ _____				

Test results

Name of indicators	Requirements of the regulatory document for products	t and humidity (%)	Actual results obtained	Brief description of conformity (non-conformity)
1	2	3	4	5

Conclusion:

The submitted samples conform (do not conform) to the requirements of the regulatory documents (underline as necessary)

Signatures of the authorized persons:

_____ _____ _____

(position) (signature) surname, name, patronymic(if any)

_____ _____ _____

(position) (signature) surname, name, patronymic(if any)

_____ _____ _____

(position) (signature) surname, name, patronymic(if any)

* The test report applies only to the samples tested.

Full or partial reprinting of the test report without written permission of the expert organization is prohibited.

Appendix 8
to the Rules for assessment of quality of
medicines and medical devices registered
in the Republic of Kazakhstan

Form

Report
on results of conducting laboratory tests at a contract laboratory, used by the manufacturer

_____

(Name of manufacturing organization)

_____

(Name of a quality control contract laboratory)

_____

(Name of a medicine, medical devices)

1. Resume

Name of a medicine (medical device) (hereinafter referred to as the M (MD))	
Name, address, details of production site	
Name, address, details of a quality control contract laboratory	
Grounds for laboratory tests	
Dates of laboratory tests	
surname, name, patronymic (if any) of experts (members of commission), position	

2. Observations and results of laboratory tests

Name of the M (MD)	
Link to the regulatory document	
Series №, manufacturing date	
Quality indicators, according to which the laboratory testing was performed	
Results	Conforms (does not conform) (underline as necessary)
Test report of the manufacturer	(number and date)

*Note

The report on the results of laboratory testing in the quality control laboratory at the production site shall be accompanied by a copy of the test report of the quality control laboratory. All annexes to the report are an integral part of it.

Members of the commission:

_____ _____

Signature surname, name, patronymic (if any)

_____ _____

Signature surname, name, patronymic (if any)

"_____" _____

Appendix 9
to the Rules for assessment of quality of
medicines and medical devices registered
in the Republic of Kazakhstan

_____

Name and address of expert organization

Product conformity certificate (in serial assessment)

"____" _____ 20___ № _____

Valid until "____" _____ 20___ under proper storage conditions

1. This product conformity certificate (in serial assessment) is to certify that products

_____

(name and type of product according to the State Register of Medicines and Medical Devices, № of registration certificate, series (serial number for medical devices, which are units, instruments and equipment), expiry date, batches quantity) made in

_____

(country, name of manufacturer)

submitted by

_____

(name, location of a legal entity, business address of the legal entity) passed the assessment of quality by examination of documents and laboratory testing of product samples in serial assessment

2. Product conformity certificate (in serial assessment) is issued based on certificates and test report

_____

_

(GMP, №, date of issue, validity or ISO 13485, №, date of issue, shelf life)

_____

_

(date of test report(s), name of acrredited laboratory, accreditation certificate №)

3. Additional information

_____

(filled in if necessary)

Signatures of the authorized persons:

_____ _____

signature surname, name, patronymic (if any), position

_____ _____

signature surname, name, patronymic (if any), position

Appendix 10
to the Rules for assessment of quality of
medicines and medical devices registered
in the Republic of Kazakhstan
Form

_____

Name and address of expert organization

Appendix to product conformity
certificate
№_____

List of particular products, which is covered by the validity of a product conformity certificate (in serial assessment)

Product name in accordance with State Register of Medicines and Medical Devices, № of registration certificate, name of manufacturer, manufacturing country	Series (serial number for medical devices, which are units, instruments and equipment), expiry date, batch size	Validity of conformity certificate

Signatures of the authorized persons:

_____ _____

signature surname, name, patronymic (if any), position

_____ _____

signature surname, name, patronymic (if any), position

Appendix 11
to the Rules for assessment of quality of
medicines and medical devices registered
in the Republic of Kazakhstan
Form

_____

Name and address of expert organization

_____
Name of the applicant

_____
position, surname, name, patronymic
(if any)
of the head

_____
Location of a legal entity,
business address of a legal entity
dated "____" _____ №_____

Decision on refusal to issue a product conformity certificate (in serial assessment)

dated "____" _____ 20__ № _____

_____

Name and address of expert organization hereby informs that:

1. According to your application dated "_____" _____ 20___ examination of documents and laboratory of the declared products

_____

_____

were performed.

(name and type of product according to the State Register of Medicines and Medical Devices, № of registration certificate, series (serial number for medical devices, which are units, instruments and equipment), expiry date, batches quantity)

2. Grounds for the refusal when determining discrepancies based on the results of document examination (mark as necessary)

☐	submission of an incomplete set of documents according to the list provided for by clauses 18 and 25 of the Rules for Quality Assessment of Medicines and Medical Devices Registered in the Republic of Kazakhstan
☐	provision of unreliable information
☐	non-conformity of information in the submitted documents with the data of the State Register of Medicines and Medical Devices of the Republic of Kazakhstan
☐	lack of license data on the elicence portal
☐	Failure to eliminate the remarks issued by the expert organization within the established timeframe

2. Grounds for refusal in determining nonconformities based on laboratory test results (to be filled in if there are nonconformities)

According to the test report(s) No _____ dated "_____" _____ 20___,

the presented products for quality assessment do not meet the requirements of_____

_____

(name and designation of a regulatory document for the declared products)

According to indicators

_____

3. Based on the determination of the above-mentioned non-conformities (one or more), you have been denied a product conformity certificate.

Signatures of the authorized persons:

_____ _____

signature surname, name, patronymic (if any), position

_____ _____

signature surname, name, patronymic (if any), position

Appendix 12
to the Rules for assessment of quality of
medicines and medical devices registered
in the Republic of Kazakhstan

_____

Name and address of expert organization

Vaccine conformity certificate

"____" _____ 20___ № _____

Valid until "___" _____ 20___ under proper storage conditions

1. This product conformity certificate is to certify that vaccine

_____

_____

(product name according to the State Register of Medicines and Medical Devices of the Republic of Kazakhstan, № of registration certificate, series, expiry date, batches quantity, № of registration certificate) made in

_____

_____

_____

(country, name and address of the manufacturer, production site)

submitted by

_____

(name, location of a legal entity, business address of the legal entity) conform the requirement of assessment and quality, set forth in _____

_____

(regulatory document(s)

2. Vaccine conformity certificate is issued based on certificates and test report

_____

(GMP, №, date of issue, validity or ISO 13485, №, date of issue, shelf life)

_____

(date of test report(s), name of accredited laboratory, accreditation certificate №)

3. Additional information (storage conditions)

_____

_____

(filled in if necessary)

The above vaccine has been quality assessed for release of the series (batch) into circulation. This certificate is based on the manufacturer's summary protocol (except for vaccines prequalified by WHO and produced in the ICH region), the certificate of release of the series issued by the national regulatory authority or the manufacturer's country quality control laboratory or other official laboratory authorized by the regulatory authority of the manufacturer's country to perform quality control for the purpose of placing the series on the market, as well as full (for vaccines produced in the Republic of Kazakhstan) or selective (for imported vaccines) independent laboratory testing in the laboratory of the state expert organization in the sphere of circulation of medicines and medical devices.

Signatures of the authorized persons:

_____ _____

signature surname, name, patronymic (if any), position

_____ _____

signature surname, name, patronymic (if any), position

Appendix 13
to the Rules for assessment of quality of
medicines and medical devices registered
in the Republic of Kazakhstan
Form

_____

Name and address of expert organization

_____
Name of the applicant

_____
position, surname, name, patronymic
(if any)
of the head

_____
Location of a legal entity,
business address of a legal entity
dated "____" _____ №_____

Decision on refusal to issue a vaccine conformity certificate

dated "____" _____ 20__ № _____

_____

Name and address of expert organization hereby informs that:

1. According to yout application dated "_____" _____ 20___ examination of documents and laboratory tests of the declared series of vaccine_____

_____

(product name according to the State Register of Medicines and Medical Devices of the Republic of Kazakhstan, № of registration certificate, series, shelf life, batches quantity, № of registration certificate) made in

_____

__

_____

__

_____

__

(country, name and address of the manufacturer, production site)

submitted by

_____were performed.

(name, location of a legal entity, business address of a legal entity)

2. Grounds for the refusal when determining discrepancies based on the results of document examination (mark as necessary)

☐	submission of an incomplete package of documents according to the list stipulated in paragraph 32 of the Rules for Quality Assessment of Medicines and Medical Devices Registered in the Republic of Kazakhstan
☐	provision of unreliable information
☐	Inconsistency of information in the submitted documents with the data in the registration dossier
☐	lack of license data on the elicence portal
☐	Failure to eliminate the remarks issued by the expert organization within the established timeframe
☐	Identification of potential deviations in the sequence of vaccine series

2. Grounds for refusal in determining non-conformities according to the results of laboratory tests (to be filled in if there are non-conformities) According to the test report (s) No ____ dated "_____" _____ 20___, the submitted products for quality assessment do not meet the requirements

_____

(name and designation of a regulatory documents for the declared products)

According to indicators

_____

3. Based on the determination of the above-mentioned discrepancies (one or more), you are denied a vaccine conformity certificate

Signatures of the authorized persons:

_____ _____

signature surname, name, patronymic (if any), position

_____ _____

signature surname, name, patronymic (if any), position

Appendix 14
to the Rules for assessment of quality of
medicines and medical devices registered
in the Republic of Kazakhstan
Form

_____

Name and address of expert organization

"____" _____ 20 __

_____

Name, surname, name, patronymic (if any) of the subject

_____

position, surname, name, patronymic (if any) of the head

_____

Location of a legal entity, business address of the legal entity

Negative conclusion on the quality of products

Laboratory testing was performed:

_____

product name

1. _____

№ of registration certificate, Series №, expiry date, batch size,

name of the manufacturing enterprise, country

_____

2. According to test report No

_____

dated "__" _____ 20__, the sampled products do not meet the requirements _____

_____

name and designation of the regulatory document for the declared product_____

_____

Signatures of the authorized persons:

_____ _____

signature surname, name, patronymic (if any)

_____ _____

signature surname, name, patronymic (if any)

Annex 2 to the order

List of some orders of the Ministry of Health of the Republic of Kazakhstan that have become invalid

1. Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated November 26, 2014 № 269 "On approval of the Rules for 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 № 10003, published on January 8, 2015 in the information and legal system "Adilet");

2. Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated June 28, 2016 № 569 "On amendments to the order of the Minister of Health and Social Development of the Republic of Kazakhstan dated November 26, 2014 № 269 "On approval of the Rules for assessment of the safety and quality of medicines and products of medical purpose, registered in the Republic of Kazakhstan" (registered in the Register of state

registration of regulatory legal acts under № 13881, published on August 9, 2016 in the information and legal system "Adilet");

3. Order of the Minister of Health of the Republic of Kazakhstan dated May 17, 2019 № ҚР ДСМ -82 "On amendments to the order of the Minister of Health and Social Development of the Republic of Kazakhstan dated November 26, 2014 № 269 "On approval of the Rules for assessment of the safety and quality of medicines and products of medical purpose, registered in the Republic of Kazakhstan" (registered in the Register of state registration of regulatory legal acts under № 18699, published on May 27, 2019 in the Reference Control Bank of regulatory legal acts of the Republic of Kazakhstan);

4. Order of the Minister of Health of the Republic of Kazakhstan dated July 6, 2020 № ҚР ДСМ -79/202 "On amendments to the order of the Minister of Health and Social Development of the Republic of Kazakhstan dated November 26, 2014 № 269 "On approval of the Rules for 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 № 20937, published on July 6, 2020 in the Reference Control Bank of regulatory legal acts of the Republic of Kazakhstan).