Eurasian Center for Accreditation
And Quality Assurance in
Higher Education and Health Care
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REPORT
OF THE EXTERNAL EXPERT COMMISSION ON THE RESULTS OF THE INSTITUTIONAL ASSESSMENT OF THE RSE ON REM "NATIONAL CENTER FOR THE EXAMINATION OF MEDICINES AND MEDICAL DEVICES" OF THE COMMITTEE FOR MEDICAL AND PHARMACEUTICAL CONTROL OF THE MINISTRY OF HEALTH OF THE REPUBLIC OF KAZAKHSTAN ON COMPLIANCE WITH THE STANDARDS OF INSTITUTIONAL ACCREDITATION OF ORGANIZATIONS OF ADDITIONAL AND NON-FORMAL EDUCATION (CONTINUING PROFESSIONAL DEVELOPMENT)

period of external expert evaluation: October 19-20, 2021

Almaty city, 2021

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LIST OF SYMBOLS AND ABBREVIATIONS

Abbreviation	Designation
DP	documented procedure
EAEU	Eurasian Economic Union
EEC	Eurasian Economic Commission
LS	medicines
MD	medical devices
REC	Scientific and educational center
NLA	Normative legal act
EP	Educational programme
TCL	Test center with laboratories
Company	RSE on REM "National Center for Expertise of Medicines and Medical Devices" of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan
TB	territorial branch
NCEM and MD	National Center for Expertise of Medicines and Medical Devices

1. Composition of the External Expert Commission

In accordance with ECAQA Order No. 29 dated October 4, 2021, an External Expert Commission (hereinafter referred to as EEC) was formed to conduct institutional accreditation of the RSE on PHV "National Center for Expertise of Medicines and Medical Devices" of the Committee of Medical and pharmaceutical control of the Ministry of Health of the Republic of Kazakhstan in the following composition:

P / p No.	Status in the EEC	Full name	Regalia, position, place of work / place of study, course, specialty
1	Chairperson	Dzhakova Gulzhanat Ertaevna	Candidate of Medical Sciences, Deputy Dean of the School of Medicine for Additional Education of the Pavlodar Branch of the NJSC "Semey Medical University" Independent accredited expert, Chairperson of the NGO "Independent Experts of Pavlodar".
2	Foreign expert	Urmambetova Zhumakan Samybekovna,	Candidate of Chemistry, Lecturer at the Department of Management and Economics of Pharmacy, Technology of Medicines named after Professor E.S. Matiev, Kyrgyz State Medical Academy named after I.K. Akhunbaeva.
3	Kazakhstan academic expert	Ustenova Gulbaram Omargazievna	Doctor of Pharmaceutical Sciences, Professor, Head of the Department of Pharmaceutical Technology, NJSC Asfendiyarov Kazakh National Medical University ".
4	Employers' representative	Eralieva Bibikhan Abdelievna,	Candidate of Medical Sciences, Clinical Pharmacologist of the SPE on REM "City Clinical

			Hospital No. 4", Almaty.
5	Listener Representative	Isaeva Nesibeli Kizatkyzy	Fifth year student with a degree in Pharmacy of the Kazakh-Russian Medical University.

Observer from ECAQA - Umarova Makpal Aldibekovna, Head of Accreditation and Monitoring Department...

The work of the EEC was carried out in accordance with the Regulation on the EEC (Order of the ECAQA Director general No. 4 dated February 13, 2017).

The EEC report contains an assessment of the RSE on REM "National Center for Expertise of Medicines and Medical Devices" of the Medical and Pharmaceutical Control Committee of the Ministry of Health of the Republic of Kazakhstan for compliance with the Standards of institutional accreditation of organizations of additional and non-formal education (Continuing Professional Development) (hereinafter - Accreditation Standards), recommendations of the EEC on further improving the activities of the above-mentioned organization and recommendations for the ECAQA Accreditation Council.

2. General part of the final report

2.1 Submission of the RSE to the REM "National Center for Expertise of Medicines and Medical Devices" of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan

Organization name, legal form of ownership, BIN	RSE on REM "National Center for Expertise of Medicines and Medical Devices" of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan BIN 980240003251
Full name of the first head	Dautbaev Erken Karimovich
date of creation	02.02.1998
Location and contact details	The Republic of Kazakhstan, Postal Code: 010000 City: Nur-Sultan Street: st. Imanova, 13, BC "Nursaulet" Phone: +7 (7172) 78-98-83 Email: **farm@dari.kz** Official website:www.ndda.kz
Information about branches, subsidiaries (if any)	4 branches (Almaty, Taraz, Karaganda, Ust-Kamenogorsk)

The total number of educational programmes, separately for additional and non-formal education	21
The total number of trainees trained since the beginning of the activity	600
Number of students with higher education	600
Number of students with specialized secondary education	-
Number of listeners since the beginning of the current year	121
Full-time teachers / part-time teachers	17

The Republican State Enterprise "National Center for Expertise of Medicines and Medical Devices" of the Committee for Quality Control and Safety of Goods and Services of the Ministry of Health of the Republic of Kazakhstan (hereinafter - the Enterprise) is a legal entity in the legal form of a state enterprise on the basis of the right of economic management.

The enterprise was established in accordance with the decree of the Government of the Republic of Kazakhstan dated October 2, 2002 No. 1081 "Certain issues of the Republican state enterprise" Center for medicines "Duri-durmek" of the Ministry of Health of the Republic of Kazakhstan ".

In accordance with the Decree of the Government of the Republic of Kazakhstan dated April 26, 2012 No. 527 "On the reorganization of the Republican state enterprise on the right of economic management" National Center for Expertise of Medicines, Medical Products and Medical Equipment "of the Ministry of Health of the Republic of Kazakhstan" The enterprise was reorganized by joining the following subsidiary state enterprises:

1) the subsidiary state enterprise "Center for expertise of medicines, medical devices and medical equipment in the Karaganda region" of the Republican state enterprise on the right of economic management "National center for expertise of drugs, medical devices and medical equipment" of the Ministry of Health of the Republic of Kazakhstan ";

2) the subsidiary state enterprise "Center for expertise of medicines, medical devices and medical equipment in the Kostanay region" of the Republican state enterprise on the right of economic management "National center for expertise of drugs, medical devices and medical equipment" of the Ministry of Health of the Republic of Kazakhstan ";

3) subsidiary state enterprise "Center for expertise of medicines, medical devices and medical equipment in Pavlodar region" of the Republican state enterprise on the right of economic management "National center for expertise of drugs, medical devices and medical equipment" of the Ministry of Health of the Republic of Kazakhstan;

4) the subsidiary state enterprise "Center for expertise of medicines, medical devices and medical equipment in the Zhambyl region" of the Republican state

enterprise on the right of economic management "National center for expertise of drugs, medical devices and medical equipment" of the Ministry of Health of the Republic of Kazakhstan;

5) the subsidiary state enterprise "Center for expertise of medicines, medical devices and medical equipment in the East Kazakhstan region" of the Republican state enterprise on the right of economic management "National center for expertise of drugs, medical devices and medical equipment" of the Ministry of Health of the Republic of Kazakhstan.

The company is the legal successor of all the rights and obligations of the said subsidiaries, transferred in accordance with the deeds of transfer. In accordance with the Resolution of the Government of the Republic of Kazakhstan dated September 23, 2014 No. 1005 "On some issues of the Ministry of Health and Social Development of the Republic of Kazakhstan" Ministry of Health and Social Development of the Republic of Kazakhstan.

In accordance with the Decree of the Government of the Republic of Kazakhstan dated February 17, 2017 No. 71 "On some issues of the ministries of health and the national economy of the Republic of Kazakhstan" Ministry of Health of the Republic of Kazakhstan.

In accordance with the Resolution of the Government of the Republic of Kazakhstan dated April 10, 2019 No. 177 "On some issues of the Ministry of Health of the Republic of Kazakhstan" services of the Ministry of Health of the Republic of Kazakhstan.

The enterprise is part of a unified system in the field of circulation of medicines and medical devices and, in accordance with the legislation of the Republic of Kazakhstan, is a state expert organization in the field of circulation of medicines and medical devices.

The staff of the NCLS and MD of all employees, according to the staffing table, is 428 units. The number of staff at the headquarters is 304. The number of staff in the territorial branch of Almaty - 119, Taraz - 24, Karaganda - 19, Ust-Kamenogorsk - 16.

Six doctors of sciences, including academicians, candidates of sciences - 30, doctors PhD - 8 work on the basis of the enterprise.

On the basis of the Territorial Branch of the RSE on REM "National Center for Expertise of Medicines and Medical Devices" of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan, in November 2020, a Scientific and Educational Center was opened.

Mission: to contribute to improving the health of the population of Kazakhstan by providing access to the market for high-quality, safe and effective drugs and medical devices through the implementation of training programmes in the field of circulation of drugs and medical devices.

Vision: Leading scientific and educational center in the Republic of Kazakhstan, the EAEU and Asian countries in terms of the quality of non-formal education in the field of circulation of medicines and medical devices

According to the Development Plan for 2020, 24 workshops were planned with the participation of 312 participants. 24 seminars were held, the total number of

listeners was 417 people, which is 105 listeners more than planned. In 2021, the number of trained students amounted to more than 200 people.

The most frequently requested training topics: Nomenclature of medical devices of the Republic of Kazakhstan; GMP; Pharmacovigilance, Clinical Research; Evidence-based medicine; Expertise MD, Advertising of drugs and medical devices; Regulation in the field of pharmacovigilance; Interaction with regulatory authorities, Assessment of safety and quality of drugs and medical devices, Counterfeit drugs, Expert examination of drugs in the EAEU, Formulary system, Pharmacopoeia, Generics, etc.

To provide educational services, REC employees have developed forms of educational programmes (EP), which are drawn up in accordance with the requirements and taking into account feedback from students and employers. Monitoring of EP and teaching materials to them is carried out by questioning external experts for compliance with priority areas in the field of circulation of medicines and medical devices, their scientific and innovative orientation. Thematic plans have been formed. Passports of educational programmes have been developed.

Assessment of the quality of training of students of a scientific educational center is carried out on the basis of the principles of objectivity and transparency.

Assessment of the quality of training of trainees consists of two stages: assessment of theoretical knowledge; assessment of practical skills.

The system for documenting the training process is reflected in F-DPA02-01-02 "Conducting training activities for the circulation of medicines and medical devices." F-DP-A02-01-25 Filled in “F-DP-A02-01-25” Certificate of actual training according to the documented procedure “DP-A02-01 Management of documented information”.

The Scientific and Educational Center has developed a strategy for further development, identified medium-term measures for 2022–2023, which include: training of full-time experts of the national regulator, including under the Bolashak programme (according to the Memorandum, training of 23 employees is planned in the specialties of pharmacy and pharmacology) and the construction of the Scientific and Educational Center of the National Center for ELECS in Nur-Sultan in order to create a scientific and practical base, including for students of pharmaceutical faculties.

2.2 Information on previous accreditation

Institutional accreditation of the RSE on the REM “National Center for Expertise of Medicines and Medical Devices” of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan as an organization implementing programmes of additional and non-formal education was not carried out.

2.3 Conclusion on the results of expert evaluation of the self-assessment report

Institutional self-assessment of RSE on REM "National Center for Expertise of Medicines and Medical Devices" of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan for compliance with the Standards of institutional accreditation of organizations of additional and non-formal education (Continuing Professional Development) was carried out on the basis

of order No. 113-Ө dated 28.07.2021 " On the establishment of an Internal Self-Assessment Commission in preparation for institutional accreditation. "

Report on institutional self-assessment RSE on REM "National Center for Expertise of Medicines and Medical Devices" of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan (hereinafter - the report) is presented on 73 pages of the main text, applications on 18 pages, electronic versions of 42 documents located by the link https://drive.google.com/drive/folders/11JxKjCWYkN2JFQ3IStMM87X6pVUI8LNW...

The report is characterized by the completeness, structuredness and internal unity of information provided by the accredited educational organization about its activities, the presence of links to tabular material, stylistically literate.

The report was drawn up in accordance with the Guidelines for self-assessment in the framework of institutional accreditation and fully complies with the Standards for institutional accreditation of continuing education organizations (Continuing Professional Development). There is a list of members of the internal self-assessment commission indicating the responsibility of each member of the internal commission (5 people in total), information about the representative of the Institution responsible for the institutional self-assessment - D.E. for preparation for institutional accreditation is Abdimanova B.Zh. director of the territorial branch of the city of Almaty (TB).

The working group on the preparation of the report and the staff of the Institution during the period of the self-assessment carried out certain work: collected the necessary information in accordance with the standards of institutional accreditation; a thorough analysis of the materials was carried out, their content is reflected in the report. The content of the Self-Assessment Report is structured in accordance with the ECAQA Institutional Accreditation Standards and includes a description of strengths, areas for improvement for each of the 9 standards.

The database and applications are presented in full, sequentially, and there are references to them in the text of the report. The report is written in competent language, wording for each standard is clear and understandable, tables contain references in the text and are consecutively numbered.

The report was reviewed by accreditation experts: Dzhakova G.E., Urmambetova Zh.S., Ustenova G.O., Eralieva B.A., Isaeva N.K. and the reviews highlight strengths and areas for improvement, as well as recommendations for additions and changes, including the following:

Standards	Reviewers' recommendations
1	No recommendation.
2	Introduce learning platforms for distance learning.
3	Introduction of an electronic journal to mark attendance and assess the educational achievement of students. Revise the scales for assessing the competencies of students (indicating the assessment criteria and points corresponding to the marks).

	Improve the base of test items for testing students with the validity of test items.
4	Develop and implement a "Code of Honor for the Listener" Develop a mechanism for determining the basic knowledge of the trainee to establish the level of training of a specialist in accordance with the sectoral qualifications framework of the RK (QF)
5	Expand cooperation with universities of the Republic of Kazakhstan near and far abroad
6	Inclusion of the journal "Pharmacy of Kazakhstan" in the list of journals included in the CCES.
7	No recommendation.
8	No recommendation.
9	No recommendation.

Thus, in the process of feedback with a representative of an educational organization, experts received answers to the questions that arose, and appropriate changes and additions were made to the institutional self-assessment report based on the recommendations of the reviewers. The report is presented in ECAQA in its finalized form, with the correction of the data according to the above recommendations, it is written in a competent language, the wording for each standard is clear and understandable and described in accordance with the criterion of the standards, tables and contains references in the text and are consecutively numbered.

The quality of the self-assessment report served as the basis for the transition to the next stage of the accreditation procedure - external assessment. The experts planned the validation of the report data, the comparison of the information from the report with the information that will be obtained during a visit to the educational organization, that is, verification of quantitative and qualitative indicators.

3. Description of external expert evaluation

External expert work within the framework of the institutional assessment of the Republican State Enterprise at REM "National Center for Expertise of Medicines and Medical Devices" of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan was organized in accordance with the Guidelines for the external assessment of educational organizations and educational programmes of ECAQA (approved by order of the Director General of NJSC "Eurasian Center for Accreditation and Quality Assurance in Education and Health Care" No. 5 dated February 17, 2017) and according to the programme approved on September 28, 2021 by the Director General of ECAQA Sarsenbayeva S.S. and agreed with the Director general - Chairperson of the Management Board Dautbaev E.K. Dates of visit to the organization: October 19-20, 2021

An external assessment is aimed at validating the data of the self-assessment report and verifying indicators that indicate the degree of compliance with the criteria of accreditation standards.

The sequence of the visit within 2 days is detailed in the Visit Programme (hereinafter referred to as the programme), which is located in the documentation of the accreditation center and in Appendix 3 to this report. The programme is proof of the implementation of all planned activities within the framework of an external expert evaluation.

The participation of a foreign expert, Urmambetova Zhumakan Samybekovna, Republic of Kyrgyzstan, is provided offline.

To obtain objective information, the members of the EEC used the following methods and their results:

- interview with management and administrative staff - 5 people in total;
- interviews with listeners - 5 people;
- study website www.ndda.kz;
- interviewing 4 employees, 4 teachers;
- questioning of teachers and students - 12 and 15, respectively;
- review of resources in the context of the implementation of accreditation standards: visited the Test Center with laboratories RSE on REM "National Center for Expertise of Medicines and Medical Devices" of the Medical and Pharmaceutical Control Committee of the Ministry of Health of the Republic of Kazakhstan, where training is conducted on 21 educational programmes with the participation of 17 full-time teachers;
- study of educational and methodological documents in the amount of 21 units both before the visit to the organization and during the visit to the departments (the list of the studied documents is in Appendix 2).

On the part of the team of the accredited organization, the presence of all persons indicated in the visit programme and according to the lists of interview and interview sites is ensured (Table 1).

Table 1 - Information on the number and category of meeting participants, interviews, interviews with members of the EEC

No.	FULL NAME.	Position
1	Abdimanova B.Zh.	Director of the TB of Almaty
2	Kuzenbaeva R.S.	Head of the Scientific and Educational Center
3	Esbolatova D.E.	Specialist of the 1st category of the Scientific and Educational Center
4	Deryabin P.N.	Expert of the 1st category of the Department of Specialized Expertise medical devices
5	Satybaldieva Zh.A.	Expert of the 1st category of the Department of Specialized Expertise medical devices
	LISTENERS	
1	Mamarakhimov Farrukh Abduvalievich	listener
2	Ponomarenko Olesya Petrovna	listener

3	Budach Yaroslavna Mikhailovna	listener
4	Kuatova Aigerim Nurlanovna	listener
5	Zhakupova Gulnara Asanovna	listener

Mission RSE on REM "National Center for Expertise of Medicines and Medical Devices" (hereinafter - NCEM and MD) comply with the Charter of the organization, determines the main directions of activities, and is also defined in the Strategic Development Plan of the RSE on REM "National Center for Expertise of Medicines and Medical Devices" 2022-2026

Mission and vision of NCLES and MD are posted on the official website,

All participants in the educational process know the mission of the organization, took part in the formation of proposals for formulating the mission, while the mission was brought to the attention of potential listeners through the website, social networks, newsletters to medical organizations. Reviewed the strategic plan of the organization for a period of 5 years, including such directions as: conducting training activities on the circulation of medicines and medical devices, increasing the number of qualified specialists, by providing effective training services, to maintain the circulation of high-quality, effective and safe medicines and medical devices; leadership of the Republic of Kazakhstan, the EAEU and Asian countries in the field of non-formal training of healthcare and pharmacy specialists; dynamic development of exchange of experience with leading foreign strategic partners, which confirms compliance with the accreditation standard and demonstrates the goals, objectives and prospects of the organization.

Thus, during the implementation of programme activities, namely, following the results of an interview with the first head of the organization, members of the advisory body Quality Council, in interviews with students and teachers, compliance with the criteria of standard 1 was established.

Today NCEM and MD continues to provide informal education for public health personnel. Updating educational programmes and their relevance to the learning goal is important for obtaining specific learning outcomes and their effectiveness. From an interview with five students, it was found that before the start of classes, teachers inform about the mission, work plans of the educational organization, they say where to get the necessary information about the educational programme, teachers, training bases, the opportunity to draw up an individual training schedule. This indicates compliance with Standard 2 in terms of adapting training to the needs and wishes of individual students.

The organization's documents contain educational programmes where the goal is defined, the integration of practical and theoretical components, and independent work are taken into account. Compliance with standard requirements has been established.

Analyzing the provided documents of seminars on the topic "Regulation of pharmacovigilance", the volume of hours is 3, and on the topic "Rational use of drugs

in practical medicine", the volume of 42 hours, the experts received convincing data that the training is carried out according to the plan, before the beginning of the lesson, the students answer the tests, receive feedback from the teacher, have the opportunity to improve their skills in pharmacovigilance, the rational use of drugs in practical medicine. The organization ensures the observance of ethical aspects in the implementation of educational programmes, since the experts studied the code of ethics on September 05, 2016 No. 145 and during the interview, the listeners replied that they were informed about the content of this document.

There was no attendance at the practical lesson, due to the temporary suspension of training, for the period of passing the institutional accreditation of the scientific educational center RSE on REM "National Center for Expertise of Medicines and Medical Devices" of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan and in pursuance of the MoH RK Order No. 303 dated 20.12.

The analysis of educational activities showed that the scientific basis and all the achievements of science in the relevant disciplines were taken into account, additions were made to the bibliography, and teachers use them in the classroom.

The study of control and measuring instruments (tests) showed that the organization has implemented an appropriate assessment policy, which allows for a comprehensive assessment of the educational achievements of students.

During the interviews, the listeners also talked about the forms of assessment, about testing, interviews in the pre- and after the cycle period, pointed to the satisfaction of the forms of assessment of training. It was also noted about receiving regular feedback from teachers. Thus, the correspondence is established **standard 3.**

During a visit to the organization and during an interview with an employee Esbolatova D.E. specialist of the 1st category of the Scientific and Educational Center, the commission made sure that there is a documentation system that is transparent and accessible to all teachers and staff, and includes documents such as annual operational plans, annual reports, department regulations, contracts with teachers and students, and educational and methodological documentation (work programme, work curricula, journals), assessment tools (checklists, statements), certificates, certificates and licenses. A review of the website showed that its pages contain the documents necessary for the listeners: an agreement for conducting training events for the circulation of medicines and medical devices, an application for training, an application for payment, organization of the educational process, monitoring of educational programmes and teaching materials, assessment of the educational achievements of students, an appeal based on the results of the assessment of the educational achievements of students, about upcoming seminars and master classes, which is regularly updated. This information was obtained during an interview with D.E. Esbolatova - specialist of the 1st category of the Scientific and Educational Center.

Conversation with D.E. Esbolatova a specialist of the 1st category of the Scientific and Educational Center included such questions as: “Why are there a small number of hours in educational programmes? What number of hours do you plan in the future when implementing new cycles of professional development? The average volume of

hours for seminars? " And allowed experts to learn about approaches to attracting staff of clinical sites for teaching (in total there are 17 such teachers people), on the strategy and tactics of recruiting students, informational provision of additional and non-formal education, as well as to identify problems in the management and development of human resources.

The organization does not have clinical bases by the nature of its activity, and therefore, members of the external expert group visited the testing center with laboratories (TCL), where classes are held with the REC students.

During the visit to the TCL, it was established: the main tasks of the TCL are to conduct laboratory tests in order to confirm the compliance of safety and quality indicators of medicines (hereinafter - drugs) and medical devices (hereinafter - MD) during: examination of drugs and medical devices in the process of state registration and amendments to registration dossier, quality assessment of drugs and medical devices registered in the Republic of Kazakhstan; determining the quality of products selected from the market taking into account a risk-based approach; tests by way of doubt and arbitration tests; tests within the EAEU. The following types of tests are carried out at the TCL: physical and chemical (medicines and MD); biological (drugs, medical devices, vaccines, biological preparations), technical tests within the framework of the EAEU (MD). All laboratories of the TCL are accredited for compliance with the requirements of ISO / IEC 17025 - 2009 by National Accreditation Center LLP; TCL is an associate member of the GEON (General European OMCL Network) network since 2015; the status is maintained and the scope of accreditation is expanding; LFI is accredited by the Slovak National Accreditation Service (SNAS) for compliance with GLPOECD requirements. The only laboratory in the Republic of Kazakhstan for conducting bioequivalence studies. Pharmacological testing laboratory: provides a full range of services related to the proper conduct of pharmacokinetic studies in accordance with the international requirements of the GLP OECD (bioequivalence, bioavailability and pharmacokinetics of medicinal substances). The laboratory also performs a Comparative Dissolution Kinetics Test (CDKTS) to establish the equivalence of the dissolution profiles of the test drug and the reference drug. Additionally, the laboratory conducts preclinical in vitro / in vivo studies on the safety and pharmacological activity of drugs, substances, medical devices. Since 2018, the pharmacological testing laboratory of the Almaty TB is the first and only laboratory in Kazakhstan that has the status of international GLP accreditation in the field of pharmacokinetics. The experts obtained evidence of the fulfillment of standard 6, as well as the validation of the information in the self-assessment report. Additionally, the laboratory conducts preclinical in vitro / in vivo studies on the safety and pharmacological activity of drugs, substances, medical devices. Since 2018, the pharmacological testing laboratory of the Almaty TB is the first and only laboratory in Kazakhstan that has the status of international GLP accreditation in the field of pharmacokinetics. The experts obtained evidence of the fulfillment of standard 6, as well as the validation of the information in the self-assessment report. Additionally, the laboratory conducts preclinical in vitro / in vivo studies on the safety and pharmacological activity of drugs, substances, medical

devices. Since 2018, the pharmacological testing laboratory of the Almaty TB is the first and only laboratory in Kazakhstan that has the status of international GLP accreditation in the field of pharmacokinetics. The experts obtained evidence of the fulfillment of standard 6, as well as the validation of the information in the self-assessment report.

Interview with 5 teachers, including 5 full-time, showed that there are both successes and problems in the management of education, depending on the specific base (admission of students to the equipment, a sufficient number of thematic patients, time to maintain medical records, independent work). The experts received answers about the teacher training programme, the financing of this training, the availability of certification in teaching methods for teachers. The experts studied the materials on the admission of students and the selection of teachers and established compliance with standard 4.

In order to validate the performance of the data in the self-assessment report and to obtain evidence of the quality of the programmes, interviews were conducted with the trainees. The experts asked questions about satisfaction with training, sufficient time for hands-on training, and satisfaction with teaching methods and teacher qualifications. During the visit, the experts noted the strengths of the training process for students, such as equipment at a high level, which allows them to master key and professional competencies, constructively effective relationships between students and REC employees, thanks to which high-quality training is carried out.

Interview with 5 employers practice and business was conducted online and included questions such as:

- How do employers interact with REC employees?
- Do employers take part in the development of the EP?
- Is there feedback from employers after the training of trainees?
- Do employers provide post-training feedback to employees?

A review of the resources showed that they correspond to the goals and objectives of educational activities, so, visited testing center with laboratories (TCL), and employees of the educational organization ensure collegial and ethical relations with the medical staff, the leadership of the TCL to achieve the final results of the students.

On the last day of the visit to the organization, a meeting of the EEC members was held on the results of the external assessment. A final discussion of the results of external assessment, study of documents, results of interviews, interviews, questionnaires was held. The members of the EEC began to design the final report of the EEC. Generalizations of the results of the external assessment are made. The experts individually completed the "Quality profile and criteria for external assessment of the RSE on REM" National Center for Expertise of Medicines and Medical Devices "of the Medical and Pharmaceutical Control Committee of the Ministry of Health of the Republic of Kazakhstan to the Standards for Accreditation of Organizations of Continuing and Informal Education of ECAQA". No comments were made by the EEC members. Recommendations for improvement for the organization of education were discussed by the chairperson G.E.Dzhakova.

For the work of EEC, comfortable conditions were created, access to all necessary information and material resources was organized. The Commission notes the high level of corporate culture of the RSE on REM "National Center for Expertise of Medicines and Medical Devices" of the Medical and Pharmaceutical Control Committee of the Ministry of Health of the Republic of Kazakhstan, the high degree of openness of the team in providing information to members of the EEC.

At the end of the visit programme, the Chairperson of the EEC for the management and employees of the educational organization announced recommendations based on the results of an external assessment within the framework of institutional accreditation.

Conclusion: Within the framework of the visit and external assessment of the RSE to the REM “National Center for Expertise of Medicines and Medical Devices” (NCEM and MD) of the Medical and Pharmaceutical Control Committee of the Ministry of Health of the Republic of Kazakhstan for compliance with institutional ECAQA standards, members of the EEC carefully studied and assessed the main performance indicators of the educational organization.

The information received by external experts during visits to the NCEM and MD, during meetings with management and employees was analyzed, more than 40 documents were studied, during questioning of students and teachers, interviews with employers, students and compared with the data of the self-assessment report, which made it possible to make sure of the reliability and validation the information provided by NCEM and MD for compliance with the standards of institutional accreditation of organizations of additional and non-formal education. Despite the fact that the NCEM and MD described their best practice in the self-assessment report, during the visit by external experts, additional information and documents were requested (strategic plan, agreements with trainees, a journal for issuing a certificate of advanced training, educational and methodological complexes of specialties, tests, questionnaires,

On the last day of the visit, the EEC members assessed the compliance of the accredited educational organization for compliance with the standards of institutional accreditation of organizations of additional and non-formal education, developed by ECAQA. The above document was individually completed by each member of the EEC. All Standards are met. No comments were made by the EEC members.

Thus, the analysis of the institutional self-assessment report and the expert assessment of the EEC allowed us to obtain strong evidence of the compliance of educational activities NCEM and MD Accreditation standards and develop recommendations for improvement.

The accreditation procedure was carried out in full in accordance with the Regulation on the External Expert Commission, the Guidelines for external evaluation of the ECAQA medical education organization.

4. Results of the survey.

Observer for ECAQA from 19-20 October 2021... an online survey was carried out on the resource https://webanketa.com/.

The audience survey includes 22 questions...

A total of 15 people answered (a total of 15 listeners for the current year). Work experience in the specialty of students - up to 5 years -26.7%, more than 10 years - 33.3%.

As a result of the survey, it was noted that 80% of respondents are satisfied with the conditions and equipment of classrooms and classrooms of the educational center, 66.7% note the availability of conditions for rest and meals for students, the availability of office equipment, access to electronic resources, the use of active and interactive teaching methods.

60% are completely satisfied with the library fund of the center, 6.7% are not satisfied.

80% of respondents noted the provision of methodological and didactic materials for classes and satisfaction with training in this particular organization.

86.7% of the respondents noted that they acquired the necessary special knowledge at the scientific and educational center and applied them in their work.

93.3% are satisfied with the teaching methods. 73.3% of respondents are fully satisfied with the schedule of training sessions, 26.7% of respondents partially disagree with the schedule. Fully agree with the methods of assessing knowledge 73.3%, no answer - 26.7%.

Thus, based on the results of the survey, the following conclusions can be drawn: the highest percentage of 93.3% are satisfied with the teaching methods and 86.7% noted the acquisition of the necessary special knowledge at the scientific educational center of the National Center for Scientific and Technical Education and the MD.

The survey of teachers included 21 questionnaire questions. A total of 12 people answered (17 in total), while 33.3% had a teaching experience of up to 5 years, 0% for up to 10 years, and 66.7% for over 10 years.

As a result of the survey, it was noted that 83.3% of respondents are satisfied with the organization of the educational process, 100% note the observance of ethics and subordination in relations between colleagues, teachers, and management. 83.3% of respondents are satisfied with the organization of work and workplace in this educational organization. 91.7% of the respondents noted that there is an opportunity for career growth and the development of the teacher's competence. Only 66.7% of respondents are satisfied with the salary and work of the HR service. On professional development courses (programmes)less than 1 year ago 33.3% studied, during this year - 50%, more than 3 years ago 16.7% respondents. 83.3% respondents arrange microclimate in the team. 91.7% of respondents noted that they have the opportunity to realize themselves as a professional in their specialty. 50% of respondents are satisfied with the level of prior training of trainees upon admission to training programmes. 66.7% of respondents note that the educational organization implements programmes of social support for teachers.

Thus, based on the results of the survey, the following conclusions can be drawn: the highest percentage - 100% of the teaching staff note the observance of ethics and subordination in relations between colleagues, teachers, management, and 91.7% of respondents noted that there is an opportunity for career growth and the development

of teacher's competence, they have the opportunity to realize themselves as a professional in their specialty in the scientific educational center of the National Center for Education and Science of the Republic of Belarus and MD.

5. Analysis for compliance with accreditation standards based on the results of external appraisals RSE on REM "National Center for Expertise of Medicines and Medical Devices" of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan.

Standard 1: MISSION AND OUTCOMES

Evidence of Compliance:

1.1 Mission

The developed and approved mission, vision, goals and strategic directions for the development of the NCEM and MD activities comply with the Charter of the organization and determine the main areas of activity. The uniqueness of NCEM and MD lies in the implementation of important monopoly and technologically related activities. Bringing the Policy (the mission is given in the policy) to the employees of the Enterprise and its explanation is carried out:

1) when conducting training in SM;
2) when drawing up labor contracts;
3) by the method of visual agitation.

The strategic plan of the Enterprise is a long-term strategic document of the Enterprise at the top level. Its implementation is carried out through a three-year low-level document - the Operational Plan of the Enterprise, updated on a rolling basis as the implementation of short-term and new operational tasks.

There is a stable organizational, functional and staffing structure. The activities of the qualified personnel of the organization are regulated

In order to form positive motivation and attractiveness of non-formal education programmes, the following is applied: 1) Obtaining information from the primary source, 2) Availability of highly qualified personnel, 3) Application of innovative technologies and active teaching methods.

1.2 Professionalism and professional autonomy

The company considers professionalism as the ability to effectively train, organize and conduct scientific and applied research on topical issues of the healthcare system. The programmes of the Enterprise are aimed at teaching strategies and tactics for independent acquisition of knowledge, formation of skills and development of skills, that is, to promote the development of educational autonomy of students in mastering information.

1.3 Learning outcomes

Evaluation of the final learning outcomes is carried out by teachers at the end of a seminar or a series of seminars. Informing students about the learning outcomes is carried out in the following ways: through the website, e-mail, official correspondence.

1.4 Participation in the formulation of mission and learning outcomes

The management actively involves associations in this process, because for the further development of the domestic pharmaceutical industry, it is necessary not only to train specialists in the universities of our country, but also to provide them with Continuing Professional Development through advanced training in the type of activity. In addition to the main stakeholders (government agencies, business representatives, public associations, manufacturers, etc.), REC consults in defining the mission and developing the final learning outcomes with an international organization - a working group with the US Pharmacopeial Convention, the Promoting the Quality of Medicines Plus programme (PQM +) Programme

Conclusions of the EEC on the criteria. Out of 10 standards conform: completely - 10, significantly - 0, partially - 0, do not correspond - 0.

Standard 1: The implementation of this standard complies with the requirements of the ECAQA Institutional Accreditation Standards.

Recommendations for improvement identified during the external visit: not defined.

Standard 2: EDUCATIONAL PROGRAMME

Evidence of Compliance:

2.1 Model of educational programmes of additional and non-formal education

Goals, objectives, competencies, learning outcomes, EP assessment methods meet the requirements of the TEP. Training in educational programmes is carried out in accordance with the RLA RK on Continuing Professional Development. The additional programmes include theoretical knowledge, the development of practical skills and methods of self-study. The educational programme uses a variety of teaching and learning methods.

In order to provide quality training services focused on national and international standards, training of specialists is carried out according to a list of non-formal education programmes. REC applies the basic principles of integrated learning, designed to ensure the relationship between the fundamental and clinical sciences, which is very important for the formation of students' motivation and interest in the topics studied through the prism of applying the knowledge gained to solving a specific problem or problem. In 2020, the State Programme for the Development of Healthcare for 2020-2024 was adopted (hereinafter referred to as the State Programme). The state programme sets goals for the formation of the population's commitment to a healthy lifestyle, the development of public health services, improving the quality of medical care, and sustainable development of the health care system.

2.2 Scientific method

The specifics of EP within the framework of non-formal training in REC covers the main issues in the field of circulation of drugs and medical devices on the territory of the Republic of Kazakhstan and the EAEU. When developing EP and teaching materials for them, teachers take into account the achievements of science, scientific concepts on the topic. Teachers and students have the opportunity to use the information system "Library", which allows you to store, search for legal acts,

international documents, conference materials, etc. Ethical aspects are observed in the implementation of CPD programmes, distance learning technologies are introduced). Access to electronic resources is open - Clarivate Analytics, Medline, Scopus, Google Scholar, Elsevier, RSCI. Students not only get acquainted with regulations, basic terms and definitions in the field of evaluating advertising materials for medicines and medical devices,

2.3 The content of programmes of additional and non-formal education and their relationship with the provision of medical care

The enterprise has provided a variety and individuality of the content of training programmes. Characteristics of non-formal education programmes, consists of 18 seminars and 3 training cycles. 1) Educational programmes; 2) Passports of training programmes; 3) Study materials for educational programmes (presentations).

Not applicable to the functionality of the Enterprise, due to the lack of functions for organizing practical (clinical) training.

In 2020, REC carried out consultations on the development of individual self-development plans for students based on the 2020 thematic plan. The consultations were carried out through oral counseling. An assessment of the knowledge, skills, attitudes and management capacity gaps of trainees prior to training is carried out by counseling trainees prior to applying for training.

Conclusions of the EEC on the criteria. Out of 13 standards conform: completely - 12, significantly - 1, partially - 0, do not correspond - 0.

Standard 2: The implementation of this standard is generally in line with the requirements of the ECAQA Institutional Accreditation Standards.

Recommendations for improvement identified during the external visit:

1) Introduce learning platforms for distance learning.

Standard 3: ASSESSMENT AND DOCUMENTATION

Evidence of Compliance:

3.1 Assessment methods

The assessment of the educational achievements of students is carried out in accordance with the requirements of the Order of the Minister of Health of the Republic of Kazakhstan dated December 11, 2020 No. as well as F-DP-A02-01-02 "Conducting training activities on the circulation of drugs and medical devices" Based on the results of the oral thematic survey, the teacher should describe the work of each responding student; point out mistakes, as well as identify the most competent and correct answers of the listeners and give marks.

3.2 Documentation of continuing and non-formal education

REC developed passports of EP, including brief information on seminars or seminar cycles. The programme passports are displayed on the website of the Enterprise and are freely available. Monitoring of the educational process and documentation is carried out, methods for assessing students of CPD programmes have been developed. The training of trainees is based on improving their competencies, the results of this training are positive feedback and comments from the trainees. NCEM and MD introduced distance learning format (Unicraff moodle).

Feedback is provided with trainees on the relevance and quality of CPD programmes. At the end of the programme, NCEM and MD conduct a survey.

Conclusions of the EEC on the criteria. Out of 11 standards conform: completely - 9, significantly - 2, partially - 0, do not correspond - 0.

Standard 3: The implementation of this standard is generally in line with the requirements of the ECAQA Institutional Accreditation Standards.

Recommendations for improvement identified during the external visit:

1) Introduce an electronic journal to mark attendance and assess the educational achievements of students.
2) Revise the scales for assessing the competencies of students (indicating the assessment criteria and points corresponding to the marks).
3) Improve the base of test items for testing students with the validity of test items.

Standard 4: THE HEALTH CARE PROFESSIONALS

Evidence of Compliance:

4.1 Motivation

In NCEM and MD, training in various areas of training is regulated, employees of NCEM and MD are trained in domestic and foreign organizations on an ongoing basis.

Also, employees of the NCEM and MD participate in international scientific and practical conferences, congresses, seminars, master classes in conjunction with universities, provide advisory assistance to listeners on an ongoing basis.

The following applies to the mechanisms for stimulating the participation of students in training on the basis of the Enterprise: 1) Obtaining information from the primary source, 2) Availability of highly qualified personnel, 3) Application of innovative technologies and active teaching methods.

In turn, the system of incentives and remuneration for trainees is not provided for at the Enterprise. In accordance with the decision of the Board of the RSE on REM "NCEM and MD" KM and FC MoH RK "dated January 25, 2021 No. 2, the Price List for technological activities related to services carried out by a state monopoly entity was approved, the prices for services are the same for all layers of listeners. ...

4.2. Learning strategies

To plan the training, students have the opportunity to familiarize themselves with the Thematic Plan. To document the training, the Enterprise issues handouts during seminars or seminar cycles, and provides a registered certificate of completion of non-formal training. Depending on the type of training seminar or a series of seminars, training takes place in: classrooms or conference rooms. Classrooms and conference rooms are equipped with information and communication technologies (hereinafter - ICT), such as: computer equipment, software, multimedia, as well as the Internet, which makes it possible to conduct training seminars online.

4.3 Participation and influence of trainees in continuing and non-formal education programmes

REC cooperates with associations of pharmaceutical and medical activities. Together with the associations, work was carried out to form an EP for students, according to the existing training needs in the field of circulation of medicines and medical devices in the Republic of Kazakhstan and the EAEU.

4.4 Working conditions

Accounting for the working conditions and employment of trainees in relation to the main practice is carried out by maintaining the Database. Thematic plan for holding seminars in the Scientific and Educational Center of the TB Almaty for 2021–2022. and announcements of upcoming workshops are published and communicated in advance, allowing trainees to allocate time and other necessary resources to participate in informal learning.

Conclusions of the EEC on the criteria. Out of 13 standards conform: fully - 11, significantly - 2, partially - 0, do not correspond - 0

Standard 4: The implementation of this standard is generally in line with the requirements of the Institutional ECAQA Standards.

Recommendations for improvement identified during the external visit:

1) Develop and implement a "Code of Honor for the Listener";
2) Develop a mechanism for determining the basic knowledge of the trainee to establish the level of training of a specialist in accordance with the sectoral qualifications framework of the RK (QF).

Standard 5: CPD PROVISION

Evidence of Compliance:

5.1 Recognition policy and educators

NCEM and MD submitted an application to the NJSC "Eurasian Center for Accreditation and Quality Assurance in Education and Health Care" for institutional accreditation to verify programmes.

The commission found that CPD programmes meet government-mandated quality education requirements. NCEM and MD has highly qualified personnel capable of training. As well as the possibility of regulating conflicts of interest

The organization works closely with universities, pharmaceuticals and other organizations to conduct joint scientific and practical conferences, trainings, master classes, etc.

5.2 Obligations and development of organizations of additional and non-formal education

Educational programmes comply with the requirements established by the state for the quality of non-formal education, namely, clauses 18-21 of the Order of the Minister of Health of the Republic of Kazakhstan dated December 21, 2020 No. to organizations that implement educational programmes for additional and non-formal education in the field of health care, as well as the rules for recognizing learning outcomes obtained by health professionals through additional and non-formal education. "The Company has introduced control and monitoring mechanisms for the use of effective and efficient teaching methods by employees and teachers through monitoring of educational programmes and teaching materials.

Conclusions of the EEC on the criteria. Out of 11 standards conform: completely - 10, significantly - 1, partially - 0, do not correspond - 0.

Standard 5: The implementation of this standard is generally in line with the requirements of the ECAQA Institutional Accreditation Standards.

Recommendations for improvement identified during the external visit:

1) Expand cooperation with universities of the Republic of Kazakhstan near and far abroad.

Standard 6: EDUCATIONAL AND CPD ACTIVITIES

Evidence of Compliance:

6.1 Material and technical base

Workrooms - 37.3 and 12.5 sq.m. respectively. Three auditoriums with a total area of 84.6 sq.m. Conference rooms (large and small): 174.1 and 56.9 sq.m. respectively. Classrooms, large and small conference rooms are equipped with information and communication technologies (hereinafter - ICT), such as: computer equipment, software, multimedia, and the Internet.

The total occupancy of the large conference room is 148 people and 6 people on the podium, the total occupancy of the small conference room is 40 people.

6.2 Learning bases

Not applicable, due to the lack of practice at the Enterprise of conducting seminars on clinical (practical) bases. The organization conducts non-formal education.

The company guarantees that MTB contributes to the effective implementation of Continuing Professional Development programmes. At the moment, REC is equipped with all the necessary resources and information systems.

6.3 Information technology

The company uses its own and external electronic resources. The policy of the Company regarding the use of information and communication technologies is aimed at increasing the efficiency and quality of training for students. Training of students is carried out on the basis of NCEM and MD, within the framework of concluded agreements. Training is conducted in well-equipped classrooms with high-quality hardware equipment. Highly qualified personnel are involved in training, as well as full-time IT specialists. Throughout the NCEM and MD there is access to the Internet.

6.4 Interaction with colleagues

The main areas of educational programmes for non-formal education at REC are issues of admission to the market of drugs and medical devices in the Republic of Kazakhstan and the EAEU. An important area is the development of regulatory legal acts in the field of drugs and medical devices circulation. Within the framework of the EAEU, working groups have been created to formulate common approaches to regulating the circulation of drugs and medical devices. Our students and teachers are also members of the working groups.

Staff reviews ethical issues in non-clinical and clinical research.

6.5 Formalized and non-formalized learning

During the seminars, an active discussion is held with the listeners about the changes in the normative legal acts, our teachers invite the listeners to actively

participate in the work of working groups on the development of the normative legal acts in the Republic of Kazakhstan and the EAEU.

Activities for the development of programmes and regulations for international cooperation, with the participation of students in regional, national and international programmes of Continuing Professional Development are included in the strategic development plan of the organization, the operational plan for the academic year.

6.6 Research and scientific advances

The REC carries out constant and systematic work in the field of policy to ensure the quality of education. Since the founding of the center, the first place has been on the implementation of a quality management system (ISO), quality policies are being developed and constantly updated. The company closely cooperates with public and international organizations in order to establish and develop bilateral relations in the field of improving the health care system in terms of quality, safety and efficiency, as well as registration of medicines, medical devices and medical equipment, training of specialists, harmonization of regulatory legal acts. As part of regulatory activities, it interacts on an ongoing basis with the Global Medical Device Nomenclature (GMDN) Agency on the nomenclature of medical devices. Experts of the NCEM take part in the working groups of the International Medical Device Regulators Forum (IMDRF) and the Asian Working Group on Harmonization (AHWP), etc.

6.7 Education in alternative educational institutions

International cooperation is carried out at the Enterprise by the Department for Harmonization of Legislation and Strategy, at the moment the Enterprise has more than 23 concluded Memorandums with national and international organizations, and also participates as a member or observer in 6 international organizations.

Conclusions of the EEC on the criteria. Conforms out of 15 standards: fully - 14, significantly - 1, partially - 0, do not comply - 0

Standard 6: The implementation of this standard is generally in line with the requirements of the ECAQA Institutional Accreditation Standards.

Recommendations for improvement identified during the external visit:

1) Inclusion of the journal "Pharmacy of Kazakhstan" in the list of journals included in the CCES

Standard 7: EVALUATION OF CPD ACTIVITIES

Evidence of Compliance:

7.1.1Mechanisms for monitoring and evaluating educational programmes

The Scientific and Educational Center develops educational programmes, carries out an examination of educational programmes. The EP is submitted for agreement with the teachers for the relevant cycles and with stakeholders. According to DR-A02-01 "Management of the documented procedure", the EP is approved by the director of the TB of Almaty. The thematic plan for non-formal learning is formed by REC and approved by the Director general - Chairperson of the Management Board. Assessment of the quality of educational programmes and discussion of the required changes are carried out at the level of teachers, professional associations, applicants, heads of pharmaceutical organizations. Based on monitoring the development of educational

programmes, teachers make changes to the content of the programme, teaching methods and methods of assessing knowledge. Monitoring and analysis of data on the assessment of EP is carried out by the Council for Quality, which provides for such measures as the approval of educational programmes, analysis of student surveys, amendments and additions to educational programmes, which contributes to professional development, the most objective assessment of the level of qualifications and improvement of the quality of pharmaceutical care to the population ... In order to assess the effectiveness of educational programmes, constant monitoring of students' opinions (questionnaires) about the EP, the relevance of the thematic content, and the compliance of the expected learning outcomes with market requirements is carried out. The opinion of students is considered as an assessment of experts who are able to objectively assess the EP according to the proposed criteria (indicators). as the approval of educational programmes, analysis of the questionnaire of students, making changes and additions to educational programmes, which contributes to professional development, the most objective assessment of the level of qualifications and improvement of the quality of pharmaceutical care for the population. In order to assess the effectiveness of educational programmes, constant monitoring of students' opinions (questionnaires) about the EP, the relevance of the thematic content, and the compliance of the expected learning outcomes with market requirements is carried out. The opinion of students is considered as an assessment of experts who are able to objectively assess the EP according to the proposed criteria (indicators). as the approval of educational programmes, analysis of the questionnaire of students, making changes and additions to educational programmes, which contributes to professional development, the most objective assessment of the level of qualifications and improvement of the quality of pharmaceutical care for the population. In order to assess the effectiveness of educational programmes, constant monitoring of students' opinions (questionnaires) about the EP, the relevance of the thematic content, and the compliance of the expected learning outcomes with market requirements is carried out. The opinion of students is considered as an assessment of experts who are able to objectively assess the EP according to the proposed criteria (indicators). the most objective assessment of the level of qualifications and improvement of the quality of pharmaceutical care for the population. In order to assess the effectiveness of educational programmes, constant monitoring of students' opinions (questionnaires) about the EP, the relevance of the thematic content, and the compliance of the expected learning outcomes with market requirements is carried out. The opinion of students is considered as an assessment of experts who are able to objectively assess the EP according to the proposed criteria (indicators). the most objective assessment of the level of qualifications and improvement of the quality of pharmaceutical care for the population. In order to assess the effectiveness of educational programmes, constant monitoring of students' opinions (questionnaires) about the EP, the relevance of the thematic content, and the compliance of the expected learning outcomes with market requirements is carried out. The opinion of students is considered as an assessment of experts who are able to objectively assess the EP according to the proposed criteria (indicators).

7.2 Feedback

The Scientific and Educational Center under appropriate conditions conducts consultations, collecting feedback and suggestions from listeners through the Applicant Service Center, questionnaires, associations of pharmaceutical and medical activities and directly by phone by REC employees. A Guide blog has been created on the Enterprise website. The feedback form is freely available on the Enterprise website in the REC "Contacts" tab. The analysis of the feedback questionnaires is carried out by the REC staff using an automated programme and the results of the analysis of the questionnaires are provided by the Director general-Chairperson of the Management Board, Supervisory Board, Quality Council in semi-annual and annual reports on the work done by the Enterprise for further submission to the authorized body. Based on the results of the survey, appropriate measures and recommendations are developed to improve educational programmes and the educational process.

Conclusions of the EEC on the criteria. Out of 10 standards conform: completely -10, significantly - 0, partially -0, do not correspond - 0

Standard 7: fully complies with the ECAQA Institutional Accreditation Standards.

Recommendations for improvement identified during the external visit: not defined.

Standard 8: ORGANISATION

Evidence of Compliance:

8.1 Documentation and needs for planning further and non-formal education

Scientific and educational center is a structural unit within the Territorial Branch of the city of Almaty. Within the framework of the WHO Global Benchmarking Mission, the Mission and Strategic Development Plans of the Enterprise have been developed. Taking into account the key values and principles of the Enterprise, procedures have been developed in the field of training events. As part of regulatory activities on an ongoing basis, the Enterprise interacts with the Global Medical Device Nomenclature (GMDN) Agency on the nomenclature of medical devices. Within the framework of quality standardization (GF RK), the Enterprise is a full member of the US Pharmacopoeia Convention, an official observer in the European Pharmacopoeia Commission. A Memorandum was signed with the British Pharmacopoeia and the Chinese Pharmacopoeia Commission.

The REC has 17 employees headed by Academician, Professor R.S. Kuzdenbaeva. The teaching staff of the REC consists of 16 leading experts of the Republic of Kazakhstan, the EAEU, including: 3 doctors of medical sciences, 1 doctor of pharmaceutical sciences, 4 candidates of sciences, 1 PhD. Experts are members of the E11 Pediatric extrapolation and E9 Statistical Principles for Clinical Trials working groups and also participate in ICH meetings. Regulatory documents of the Republic of Kazakhstan and the EAEU in the field of circulation of drugs and medical devices are developed by employees participating in the training process. Since 2020, the Scientific and Educational Center has been maintaining the journal "Pharmacy of Kazakhstan",

which is publicly available on the website of the Enterprise. It generalizes scientific and practical achievements in the field of pharmacy and medicine, improves the scientific and practical qualifications of workers in the pharmaceutical and medical fields through the publication of a journal. The enterprise has an appropriate material and technical base for the implementation of effective training of students. As you can see, REC applies the basic principles of integrated learning, which help specialists in the field of drugs and medical devices to collect facts in a single chain in order to get a complete picture of the current situation and develop a holistic approach to the main issues of the profile.

8.2 Academic leadership

Direct management and coordination of non-formal education is carried out by the Scientific and Educational Center. As part of informal training, RECs developed, approved and implemented documents that ensure the functioning of the quality assurance system for training programmes: regulations on REC, job descriptions, thematic training plan, documented procedure. The transparency of the management of non-formal learning is carried out through the discussion of training documentation at working meetings with associations of medical and pharmaceutical activities and, after their agreement, is approved in accordance with the established procedure. The Company periodically analyzes its activities by hearing public reports at meetings of collegial management bodies, surveys of listeners' satisfaction,

8.3 Allocation of budget and resources for training

The financial security of the Enterprise allows it to fully finance all existing educational programmes. For this, the Company has sufficient amounts of its own income and budgetary funds. The main source of the formation of financial resources for the educational process are funds under contracts for the provision of services related to a technologically related type of activity with the services of the state monopoly "conducting training events for the circulation of medicines and medical devices" in accordance with the approved price list. The price list is publicly available on the website of the Company.

8.4. Administration

The responsible subdivision for the QMS at the Enterprise is the Department for the provision of the management system. The main purpose of the UOSM is to work on the implementation of policies and goals in the field of ensuring, functioning and continuous improvement of the management system at the Enterprise, including the integrated one, as well as conducting internal audits to maintain and improve the management system and its processes at the Enterprise. The entire life process of documentation of the RSE on RK "NCEM and MD" KM and FC MoH RK is controlled by a documented procedure. The quality council approves documents describing educational processes. The Quality Council is a collegial body of the Enterprise, acting in order to coordinate work on the implementation of the Policy and the Goals, as well as planning, ensuring, monitoring the proper functioning and improvement of the QMS, He is also endowed with other rights aimed at effective planning, ensuring control over the proper functioning and improvement of the QMS at the Enterprise in accordance with the Regulation on the Quality Council approved by the Supervisory

Board. The management of the Enterprise has a sufficient level of managerial competence, assumes responsibility for the implementation of all processes that ensure the achievement of the mission.

Conclusions of the EEC on the criteria. Out of 8 standards conform: fully - 8.

Standard 8: fully meets the criteria of the ECAQA Institutional Accreditation Standards.

Recommendations for improvement identified during the external visit: not defined.

Standard 9: CONTINUOUS RENEWAL

Evidence of Compliance:

Most of REC teachers are leaders The divisions of the Enterprise responsible for the functioning of the quality management system in the Enterprise have extensive experience not only in expert work, but also in the development of regulatory legal acts in the field of circulation of drugs and medical devices and in the implementation of state drug policy. Accordingly, students, receiving information and knowledge from primary sources, have the opportunity to discuss problematic issues, build a constructive dialogue with teachers to improve processes, formulate proposals for improving professional performance. At the Enterprise, the QMS is constantly being improved, the proof is the certificate №19.2508.026, issued by the certification body "Association for Certification" Russian Register ". The testing center with laboratories of TB in Almaty is a full member, The Official Laboratories Network of the European Directorate for Quality Control of Medicines of the Council of Europe (EDQM) and is an associate member of the Official Laboratories Network (OMCL) (accreditation certificate EDQM / MJA-093). The Pharmacological Research Laboratory of the TB in Almaty is accredited by the Slovak National Accreditation Service (SNAS) for compliance with the GLP OECD requirements. As part of regulatory activities, it interacts on an ongoing basis with the Global Medical Device Nomenclature (GMDN) Agency on the nomenclature of medical devices. Enterprise experts take part in the working groups of the International Medical Device Regulators Forum (IMDRF) and the Asian Harmonization Working Group (AHWP). Since November 2016, the Company has been awarded the official status of an observer country in the International Conference on the Harmonization of Technical Requirements for Registration of Medicinal Products for Medical Use (ICH). Experts are members of the E11 Pediatric extrapolation and E9 Statistical Principles for Clinical Trials working groups and also participate in ICH meetings. Within the framework of quality standardization (GF RK), the Enterprise is a full member of the US Pharmacopoeia Convention, an official observer in the European Pharmacopoeia Commission. A Memorandum was signed with the British Pharmacopoeia, as well as with the Chinese Pharmacopoeia Commission. The representative of the Enterprise, who is in the teaching staff, is the Deputy Chairperson of the FC EAEU.https://drive.google.com/drive/folders/1NN4PERyjUbtdAaPBuhvTn_r-nIB-a-7-).

REC teachers regularly undergo advanced training, in August 2021 they completed the course "Innovative technologies in education" in the amount of 120 hours. It is planned to train REC teachers under the USAID programme "Education for Adults", "Personnel Training and Didactic Design".
Strengths of the organization: 1) RSE on REM "NCEM and MD" KKK and BTU MoH RK successfully cooperates with private, state and international organizations striving to improve the qualifications of their employees; 2) Decent pay for teachers and staff; 3) Active feedback from listeners through filling out "reviews and suggestions" on the website, passing a questionnaire and commenting on social networks;

Conclusions of the EEC on the criteria. Out of 5 standards conform: completely - 5, significantly - 0, partially - 0, do not correspond - 0.

Standard 9: correspondence is established.

Recommendations for improvement identified during the external visit: not defined.

6. Recommendations for improvement institutional action RSE on REM "National Center for Expertise of Medicines and Medical Devices" of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan:

1. Introduce learning platforms for distance learning (2.2.2).
2. Introduce an electronic journal to mark attendance and assess the educational achievements of students (3.3.2).
3. Revise the scales for assessing the competencies of students (indicating the assessment criteria and points corresponding to the marks) (3.3.1.1-3.3.1.4).
4. Improve the base of test items for testing students with the validity of test items (3.3.2).
5. Develop and implement a "Code of Honor for the Listener" (4.4.1.6)
6. Develop a mechanism for determining the basic knowledge of the student to establish the level of training of a specialist in accordance with the sectoral qualifications framework of the RK (SQF) (4.4.1.7)
7. Expand cooperation with universities of the Republic of Kazakhstan near and far abroad (5.5.1)
8. Inclusion of the journal "Pharmacy of Kazakhstan" in the list of journals included in the CCES (6.6.6).

7. Recommendation to the ECAQA Accreditation Council

Members of the EEC established compliance with the Standards of institutional accreditation of medical organizations of additional and non-formal education (Continuing Professional Development) and came to a unanimous opinion to recommend to the Accreditation Council of ECAQA to accredit the RSE on REM "National Center for Expertise of Medicines and Medical Devices" of the Medical and Pharmaceutical Control Committee of the Ministry of Health of the Republic of Kazakhstan as an organization providing additional and non-formal education at period of 5 years.

7. Recommendation to the ECAQA Accreditation Council

The members of the EEC established compliance with the Standards of institutional accreditation of medical organizations of additional and non-formal education (continuing professional development) and came to a unanimous opinion to recommend to the ECAQA Accreditation Council to accredit RSE on REM "National Center for Examination of Medicines and Medical Devices" OF CM and FC of the Ministry of Health of the Republic of Kazakhstan as an organization providing additional and non-formal education for a period of 5 (five) years.

Chairperson of the EEC
Dzhakova Gulzhanat Yertayevna

Foreign expert
Urmambetova Zhumakan Samyybekovna

National Academic Expert
Ustinova Gulbaram Omargazievna

Expert-representative of employers
Yeralieva Bibihan Abdelievna

Expert representative student
Isaeva Nesibeli Kizatkyzy

Observer from ECAQA
Umarova Makpal Aldibekova

Attachment 1.

Quality profile and criteria for external institutional assessment (synthesis)
Organizations of additional and non-formal education (Continuing Professional Development)

Standard	Criteria for evaluation	Number of standards	Grade			
			Totally coincides	Significantly matches	Partially compliant	Does not match
1.	MISSION AND OUTCOMES	10	10			
2.	EDUCATIONAL PROGRAMME	13	12	1		
3.	ASSESSMENT AND DOCUMENTATION	11	9	2		
4.	THE HEALTHCARE PROFESSIONALS	13	11	2		
5.	CPD PROVISION	11	10	1		
6.	EDUCATIONAL AND CPD ACTIVITIES	15	14	1		
7.	EVALUATION OF CPD ACTIVITIES	10	10			
8	ORGANISATION	8	8			
9	CONTINUOUS RENEWAL	5	5			
	Total:	96	89	7		
			96			