



Eurasian Centre for Accreditation and Quality Assurance in Higher Education and Health Care

**STANDARDS FOR PROGRAMME
ACCREDITATION PHARMACY,
PHARMACEUTICAL TECHNOLOGY AND
INDUSTRY**



ALMATY 2017

**EURASIAN CENTRE FOR ACCREDITATION AND QUALITY
ASSURANCE IN HIGHER EDUCATION AND HEALTH CARE**

**STANDARDS FOR PROGRAMME ACCREDITATION
PHARMACY
PHARMACEUTICAL TECHNOLOGY AND INDUSTRY**

ALMATY 2017

1. **DEVELOPED** by Non-profit Entity "Eurasian Centre for Accreditation and Quality Assurance in Higher Education and Health care".
2. **APPROVED AND INTRODUCED** by the Order #5 February 7, 2017 of the Director General, Eurasian Centre for Accreditation and Quality Assurance in Higher Education and Health care.
3. In this standard, the Provisions of the Law of the Republic of Kazakhstan "On Education» July 27, 2007, #319-III (with Amendments from April 9, 2016) has been introduced.

The Standards for programme accreditation based on the World Federation for Medical Education Global Standards for Quality Improvement in Basic Medical Education (Revision 2015) with specification according to institutional needs and national Health Care System priorities.

All rights reserved by the Eurasian Centre for Accreditation and Quality Assurance in Higher Education and Healthcare (ECAQA) and it is not be fully or partially reproduced, copied and distributed without permission.

CONTENTS

1.	APPLICATION AND USE OF STANDARDS	5
2.	REFERENCE TO REGULATIONS AND LAW	5
3.	TERMS AND DEFINITIONS	5
4.	ABBREVIATION	11
5.	GENERAL PROVISION	11
6.	PURPOSE OF INTRODUCTION OF STANDARDS FOR PROGRAMME ACCREDITATION	12
7.	PRINCIPLES OF QUALITY ASSURANCE AND PROGRAMME ACCREDITATION	13
8.	GENERAL STEPS AND MAIN ELEMENTS IN ACCREDITATION PROCESS	13
9.	DECISION ON ACCREDITATION	14
10.	FELLOW UP ACTIVITIES	15
11.	DEVELOPMENT AND REVISION OF THE ACCREDITATION STANDARDS	15
12.	STANDARDS FOR PROGRAMME ACCREDITATION OF PHARMACEUTICAL EDUCATION	15
	STANDARD 1: MISSION AND OUTCOMES	15
	Mission	
	Institutional Autonomy and Academic Freedom	
	Educational Outcomes	
	Participation in Formulation of Mission and Outcomes	
	STANDARD 2: EDUCATIONAL PROGRAMMES	17
	Framework of the Programme	
	Scientific Method	
	Basic Biomedical Sciences	
	Behavioural and Social Sciences, Medical Ethics and Jurisprudence	
	Pharmaceutical Sciences and Skills	
	Programme Structure, Composition and Duration	
	Programme Management	
	Linkage with Medical Practice and the Health Sector	
	STANDARD 3: ASSESSMENT OF STUDENTS	19
	Assessment Methods	
	Relation between Assessment and Learning	

STANDARD 4: STUDENTS	20
Admission Policy and Selection	
Student Intake	
Student Counselling and Support	
Student Representation	
STANDARD 5: ACADEMIC STAFF/FACULTY	21
Recruitment and Selection Policy	
Staff Activity and Staff Development	
STANDARD 6: EDUCATIONAL RESOURCES	22
Physical Facilities	
Clinical Training Resources	
Information Technology	
Research and Scholarship	
Educational Expertise	
Educational Exchanges	
STANDARD 7: PROGRAMME EVALUATION	24
Mechanisms for Programme Monitoring and Evaluation	
Teacher and Student Feedback	
Performance of Students and Graduates	
Involvement of Stakeholders	
STANDARD 8: GOVERNANCE AND ADMINISTRATION	25
Governance	
Academic Leadership	
Educational Budget and Resource Allocation	
Administration and Management	
Interaction with Health Sector	
STANDARD 9: CONTINUOUS RENEWAL	26
REFERENCES	28

STANDARDS FOR PUBLIC HEALTH PROGRAMME ACCREDITATION

GENERAL PROVISION

1. Application and Use of Standards

1.1 The Standards define the general provisions and requirements of Standards for educational programme accreditation at the HEIs for Health Professions Education

1.2 The Standards is a tool for quality assurance and improvement Pharmaceutical education .

1.3 The Standards should be used for programme accreditation and carrying out external evaluation of educational programme.

1.3 The Standards should be used for the educational programme self-evaluation and its improvement, support the development quality assurance and of the quality culture.

2. Reference to Regulations and Law

The Standard references to the following Laws and Regulations:

2.1 The Law of the Republic of Kazakhstan "On Education» July 27, 2007, #319-III (with Amendments from April 9, 2016)

2.2 State Programme Education Development in the Republic of Kazakhstan 2016-2019. The President of the Republic of Kazakhstan Decree #205, March 7, 2016.

2.3 The State Programme for Healthcare System Development 2016-2020. The President of the Republic of Kazakhstan Decree#176, January 15, 2016.

2.4 The Republic of Kazakhstan State Compulsory Education Standard. RK SCES 3.07 - 476-2006; Higher Professional Education. Bachelor Degree Programme. Pharmacy. Pharmaceutical Technology and Industry - approved by the Kazakhstan Ministry of Health. Date of Introduction: September 1, 2007.

3. Terms and Definitions

The Terms and Definitions are used to clarify, amplify expressions in the Standards and refer to the Law of the Republic of Kazakhstan «On Education» July 27, 2007, #319-III (with Amendments from April 9, 2016) and the World Federation for Medical Education Global Standards for Quality Improvement in Basic Medical Education (Revision 2015):

Accrediting agencies – legal entities that develop set of Standards (Guidelines) and accredit of the HEIs that as the institutions meet predefined quality Standards (Guidelines);

Accreditation of Higher Education Institutions – recognition procedure used in higher education by accreditation agency that confirms the Education, Research and Service compliance with and meet predefined standards (guidelines) in order to provide the evidence about their quality and improvement of the internal quality assurance mechanisms;

Institutional accreditation – external evaluation by the accrediting agency and its formal and independent decision indicating that a higher education institution meets certain predefined standards and current status as the HEI;

International accreditation – external evaluation of the higher education institutions (institutional accreditation) or educational programmes (specialized accreditation) that meet predefined standards (guidelines) and its should be carried out by the national or foreign accrediting agency recognized and listed on Register #1 of the Kazakhstan Ministry of Education and Science;

National accreditation – external evaluation of the higher education institutions (institutional accreditation) or educational programmes (specialized accreditation) that meet predefined standards (guidelines) and its should be carried out by the national accrediting agency recognized and listed on Register #1 of the Kazakhstan Ministry of Education and Science;

Educational programme accreditation – recognition procedure used in higher education by accreditation agency that confirms the educational programmes compliance with and meet predefined standards (guidelines) in order to provide the evidence about their quality and improvement of the internal quality assurance mechanisms;

Standards (Guidelines) for accreditation – external evaluation of the quality assurance of educational programmes that offered by the higher education institution

According to the WFME Global Standards for Quality Improvement of Basic Medical Education (Revision 2015) following definitions related to Standards:

Mission provides the overarching frame to which all other aspects of the educational institution and its programme have to be related.

Mission statement would include general and specific issues relevant to institutional, national, regional and global policy and needs. Mission in this document includes the institutions' vision.

Postgraduate education would include preregistration education (leading to right to independent practice), vocational/professional education, specialist/subspecialist education and other formalised education programmes for defined expert functions.

Life-long learning is the professional responsibility to keep up to date in knowledge and skills through appraisal, audit, reflection or recognised continuing professional development (CPD) activities. CPD includes all activities that the pharmacist undertake, formally and informally, to maintain, update, develop and enhance their knowledge, skills and attitudes in response to the needs of their patients.

Encompassing the health needs of the community would imply interaction with the local community, especially the health and health related sectors, and adjustment of the curriculum to demonstrate attention to and knowledge about health problems of the community.

Institutional autonomy would include appropriate independence from government and other counterparts (regional and local authorities, religious

communities, private cooperations, the professions, unions and other interest groups) to be able to make decisions about key areas such as design of curriculum (cf. 2.1 and 2.6), assessments (cf. 3.1), students admission (cf. 4.1 and 4.2), staff recruitment/selection (cf. 5.1) and employment conditions (cf.5.2), research (cf. 6.4) and resource allocation (cf. 8.3).

Academic freedom would include appropriate freedom of expression, freedom of inquiry and publication for staff and students.

Appropriate student conduct would presuppose a written code of conduct.

Principal stakeholders would include the dean, the faculty board/council, the curriculum committee, representatives of staff and students, the university leadership and administration, relevant governmental authorities and regulatory bodies.

Other stakeholders would include representatives of other health professions, patients, the community and public (e.g. users of the health care delivery systems, including patient organisations). Other stakeholders would also include other representatives of academic and administrative staff, education and health care authorities, professional organisations, medical scientific societies and postgraduate medical educators.

Educational outcomes or learning outcomes/competencies refer to statements of knowledge, skills and attitude that students demonstrate at the end of a period of learning. Outcomes might be either intended or acquired. Educational/learning objectives are often described in terms of intended outcomes

The pharmaceutical sciences would ó depending on local needs, interests and traditions ó include clinical chemistry, extemporaneous compounding, medicinal chemistry, pharmaceutical calculations, pharmaceuticals/biopharmaceuticals, pharmacogenomics/genetics, pharmacokinetics, pharmacology and toxicology.

The basic biomedical sciences would - depending on local needs, interests and traditions - include anatomy, biochemistry, biophysics, cell biology, genetics, immunology, microbiology (including bacteriology, parasitology and virology), molecular biology, pathology, and physiology.

Behavioural and social sciences would - depending on local needs, interests and traditions - include biostatistics, community medicine, epidemiology, global health, hygiene, medical anthropology, medical psychology, medical sociology, public health and social medicine, ethics, history of pharmacy, pharmacoconomics, pharmacy law and regulatory affairs, management, professional communication, professional development/social and behavioral aspects of practice and research design.

Medical ethics deals with moral issues in medical practice such as values, rights and responsibilities related to physician behavior and decision making.

Medical jurisprudence deals with the laws and other regulations of the health care delivery system, of the profession and medical practice, including the regulations of production and use of pharmaceuticals and medical technologies (devices, instruments, etc.).

The behavioural and social sciences, medical ethics and medical jurisprudence would provide the knowledge, concepts, methods, skills and attitudes necessary for

understanding socio-economic, demographic and cultural determinants of causes, distribution and consequences of health problems as well as knowledge about the national health care system and patients' rights. This would enable analysis of health needs of the community and society, effective communication, clinical decision making and ethical practices.

Professional skills would include patient management skills, team-work/team leadership skills and inter-professional training.

Instructional/ learning methods would encompass lectures, small-group teaching, problem-based or case-based learning, peer assisted learning, practicals, laboratory exercises, bed-side teaching, clinical demonstrations, clinical skills laboratory training, field exercises in the community and web-based instruction.

Principles of equality mean equal treatment of staff and students irrespective of gender, ethnicity, religion, sexual orientation, socio-economic status, and taking into account physical capabilities.

Elements of original or advanced research would include obligatory or elective analytic and experimental studies, thereby fostering the ability to participate in the scientific development of medicine as professionals and colleagues.

The authority of the curriculum committee would include authority over specific departmental and subject interests, and the control of the curriculum within existing rules and regulations as defined by the governance structure of the institution and governmental authorities. The curriculum committee would allocate the granted resources for planning and implementing methods of teaching and learning, assessment of students and course evaluation

Assessment utility is a term combining validity, reliability, educational impact, acceptability and efficiency of the assessment methods and formats.

Assessment principles, methods and practices refer to assessment of student achievement and would include assessment in all domains: knowledge, skills and attitudes.

Adjustment of number and nature of examinations would include consideration of avoiding negative effects on learning. This would also imply avoiding the need for students to learn and recall excessive amounts of information and curriculum overload.

Encouragement of integrated learning would include consideration of using integrated assessment, while ensuring reasonable tests of knowledge of individual disciplines or subject areas.

The statement on process of selection of students would include both rationale and methods of selection such as secondary school results, other relevant academic or educational experiences, entrance examinations and interviews, including evaluation of motivation to become doctors. Selection would also take into account the need for variations related to diversity of medical practice.

Policy and practice for admission of disabled students will have to be in accordance with national law and regulations.

Periodically review the admission policy would be based on relevant societal and professional data, to comply with the health needs of the community and society,

and would include consideration of intake according to gender, ethnicity and other social requirements (socio-cultural and linguistic characteristics of the population), including the potential need of a special recruitment, admission and induction policy for underprivileged students and minorities.

Academic counselling would include questions related to choice of electives, residence preparation and career guidance. Organisation of the counselling would include appointing academic mentors for individual students or small groups of students.

Addressing social, financial and personal needs would mean professional support in relation to social and personal problems and events, health problems and financial matters, and would include access to health clinics, immunization programmes and health/disability insurance as well as financial aid services in forms of bursaries, scholarships and loans.

Student representation would include student self governance and representation on the curriculum committee, other educational committees, scientific and other relevant bodies as well as social activities and local health care projects (cf. B 2.7.2).

Physical facilities would include lecture halls, class, group and tutorial rooms, teaching and research laboratories, clinical skills laboratories, offices, libraries, information technology facilities and student amenities such as adequate study space, lounges, transportation facilities, catering, student housing, on-call accommodation, personal storage lockers, sports and recreational facilities.

A safe learning environment would include provision of necessary information and protection from harmful substances, specimens and organisms, laboratory safety regulations and safety equipment.

Training facilities would include hospitals (adequate mix of primary, secondary and tertiary), sufficient patient wards and diagnostic departments, laboratories, ambulatory services (including primary care), clinics, primary health care settings, health care centres and other community health care settings as well as skills laboratories, allowing clinical training to be organised using an appropriate mix of settings and rotations throughout all main disciplines.

Evaluate would include evaluation of appropriateness and quality for medical training programmes in terms of settings, equipment and number and categories of patients, as well as health practices, supervision and administration.

Effective and ethical use of information and communication technology would include use of computers, cell/mobile telephones, internal and external networks and other means as well as coordination with library services. The policy would include common access to all educational items through a learning management system. Information and communication technology would be useful for preparing students for evidence-based medicine and life-long learning through continuing professional development (CPD).

Medical research and scholarship encompasses scientific research in basic biomedical, clinical, behavioural and social sciences. Medical scholarship means the academic attainment of advanced medical knowledge and inquiry. The medical research basis of the curriculum would be ensured by research activities within the

medical school itself or its affiliated institutions and/or by the scholarship and scientific competencies of the teaching staff. Influences on current teaching would facilitate learning of scientific methods and evidence-based medicine.

To *facilitate student activities* would include consideration of providing technical and financial support to student organisations.

Educational expertise would deal with processes, practice and problems of medical education and would include medical doctors with research experience in medical education, educational psychologists and sociologists. It can be provided by an education development unit or a team of interested and experienced teachers at the institution or be acquired from another national or international institution.

A *policy for transfer of educational credits* would imply consideration of limits to the proportion of the study programme which can be transferred from other institutions. Transfer of educational credits would be facilitated by establishing agreements on mutual recognition of educational elements and through active programme coordination between medical schools. It would also be facilitated by use of a transparent system of credit units and by flexible interpretation of course requirements.

Programme monitoring would imply the routine collection of data about key aspects of the curriculum for the purpose of ensuring that the educational process is on track and for identifying any areas in need of intervention. The collection of data is often part of the administrative procedures in connection with admission of students, assessment and graduation.

Programme evaluation is the process of systematic gathering of information to judge the effectiveness and adequacy of the institution and its programme. It would imply the use of reliable and valid methods of data collection and analysis for the purpose of demonstrating the qualities of the educational programme or core aspects of the programme in relation to the mission and the curriculum, including the intended educational outcomes. Involvement of external reviewers from other institutions and experts in medical education would further broaden the base of experience for quality improvement of medical education at the institution.

Governance means the act and/or the structure of governing the medical school. Governance is primarily concerned with policy making, the processes of establishing general institutional and programme policies and also with control of the implementation of the policies. The institutional and programme policies would normally encompass decisions on the mission of the medical school, the curriculum, admission policy, staff recruitment and selection policy and decisions on interaction and linkage with medical practice and the health sector as well as other external relations.

Academic leadership refers to the positions and persons within the governance and management structures being responsible for decisions on academic matters in teaching, research and service and would include dean, deputy dean, vice deans, provost, heads of departments, course leaders, directors of research institutes and centres as well as chairs of standing committees (e.g. for student selection, curriculum planning and student counselling).

Management means the act and/or the structure concerned primarily with the implementation of the institutional and programme policies including the economic and organisational implications i.e. the actual allocation and use of resources within the medical school. Implementation of the institutional and programme policies would involve carrying into effect the policies and plans regarding mission, the curriculum, admission, staff recruitment and external relations.

4. Abbreviation

The following abbreviations are used in the Standards:

AC	Accreditation Council
CPD	Continuing Professional Development
EB	Expert Board
ECAQA	the Eurasian Centre for Accreditation and Quality Assurance in Higher Education and Healthcare
EEC	External Expert Commission
ESG	Standards for accreditation the Higher Education Institutions for Health Professions Education based on the Standards and Guidelines for Quality Assurance in the European Higher Education Area
HEIs	Higher Education Institutions
MoH	Ministry of Health of the Republic of Kazakhstan
RK	
MoEDSc	Ministry of Education and Science of the Republic of Kazakhstan
WFME	World Federation for Medical Education
WHO	World Health Organization

5. General Provision

5.1 Programme accreditation on Pharmacy and Pharmaceutical Technology and Industry carried out according to the following Standards:

1. MISSIONS AND OUTCOMES;
2. EDUCATIONAL PROGRAMME;
3. ASSESSMENT OF STUDENTS;
4. STUDENTS;
5. ACADEMIC STAFF/FACULTY;
6. EDUCATIONAL REOURCES;
7. PROGRAMME EVALUATION;
8. GOVERNANCE AND ADMINISTRATION;
9. CONTINUOUS RENEWAL.

5.2 Standards for programme accreditation developed and based on the WFME Global Standards for Quality Improvement in Basic Medical Education (Revision 2015) with national specifications of the healthcare system and health professions education.

5.3. Standards are specified for each sub-area using two levels of attainment:

- **Basic Standards** are expressed by a **õmustõ**, this means that the standard in principle must be met by every school and fulfillment demonstrated during evaluation of the school.
- **Standards for Quality Development** are expressed by a **õshouldõ**, this means that the standard is in accordance with international consensus about best practice for medical institutions and basic medical education. Fulfillment of - or initiatives to fulfill ó some or all of such standards should be documented by HEIs.

5.4 Standards based on the WFME Global Standards for Quality Improvement of Basic Medical Education (Revision 2015), comprising altogether 106 basic standards, 90 quality development standards and 127 annotations, are presented in the section#3.

5.5 The decision on accreditation is awarded by ECAQA's Accreditation Council according to the External Evaluation Report of the EEC containing recommendations regarding the decision on accreditation and including the evidence about the higher education institution meets certain predefined Standards.

5.6 The ECAQA's Accreditation Council includes all main groups of stakeholders and based on recommendations of the WHO/WFME Guidelines for Accreditation of Basic Medical Education. The Members of the Accreditation Council are represented by the Directors of Departments of the MoED. Sci. RK and MoH RK, Members of Kazakhstan Parliament, Senior Academic Staff of the HEIs for Health Professions Education, National Research Centres, Societies of the Employers, International and National Professional Association, Students.

6. Purpose of introduction of Standards for Programme accreditation

6. The main purposes for implementation of the programme accreditation are following:

6.1.1 to implement internal quality assurance within institution and develop the national external quality assurance system that harmonized with principles of good international practice for quality assurance in higher education;

6.1.2 to support and encourage the development of a quality culture that is embraced by students, academic staff/faculty, institutional leadership and management.

6.1.3 to evaluate the HEI and its professional educational programmes in Medicine, Dentistry, Pharmacy, Public Health and Nursing to ensure that a higher education institution meets certain predefined standards.

6.1.4 to promote the quality improvement of health professions education to meet the needs of the changing environment and achieve competitiveness of the national system of higher professional education;

6.1.5 to publish and provide reliable information for society and authorities concerned in higher education and healthcare regarding the HEIs external evaluation outcomes and submit the summary report and formal decision on accreditation.

7. Principles of Quality Assurance and Accreditation

7.1 Quality assurance and accreditation system based on the following principles:

7.1.1 *Voluntariness/Freedom* ó the accreditation is voluntary process and accrediting agency recognizes the freedom and autonomy of the HEIs and their programmes.

7.1.2 *Responsibility* ó the accreditation process clear defines the responsibility of both accrediting agency and higher education institution; accrediting agency has strong relationship with main stakeholders: the Public, HEIs, Students, the Professions, Professional Organizations, Government; provides the Standards and Guidelines, appropriate resources of innovation and training reviewers/experts.

7.1.3 *Transparency* ó internal and external evaluation are carried out fairly and transparently providing access to relevant information regarding the accreditation process and procedures, accreditation standards, guidelines for self-study, guidelines for external evaluation that are available for all stakeholders.

7.1.4 *Independence* - external evaluation, decision making process based on the published standards and procedures taking into consideration the outcomes both the institutional self-study and external review, the reliable information and data, accrediting agency is independent of the third parties (MoH, MoEDSci., HEIø Leadership and Public).

7.1.5 *Confidentiality* ó institutional self-study reportø information and other information provided by HEIs and data gained in external review are confidential.

7.1.6 *Efficiency* ó external evaluation focus on content and outcomes that allowed improving internal quality assurance mechanisms, support the development of a quality culture and ensure the link between internal and external quality assurance.

7.1.7 *Public information*- the decisions on accreditation must be announced and made public, publication of the reports providing the basis for the decisions, or a summary of the reports, should also be considered and posted on the accrediting agencyø web-site.

8. General steps and main elements in accreditation process

8.1 Accreditation process includes the following main elements:

8.1.1 Submission of the application and the summary and education database of the higher education institution to the accrediting agency;

8.1.2 Signing the Agreement between higher educational institution and accrediting agency that included terms of payment and conditions for performance, training of staff/faculty on conducting the institutional self-study;

8.1.3 Planning and conducting the Educational Programme self-evaluation; submitting Educational Programme Self-evaluation Report (in Kazakh, Russian and English) to the accrediting agency;

8.1.4 Consideration the Educational Programme Self-evaluation Report by the Members of EECø accrediting agency before the site-visit;

8.1.5 The external expert commission carries out the external evaluation and develops the draft of the Report and conclusions that is presented to the administrative and academic staff.

8.1.6 Submission of the final External Evaluation Report with recommendations for improvement to the accrediting agency and the Accreditation Council;

8.1.7 Decision on accreditation consideration of the final Report and recommendations of the external expert commission by Accreditation Council

8.1.8 Publication of a summary of the External Evaluation Report and decision on accreditation and post them on accrediting agency's web-site.

9. Decision on accreditation

9.1 Decisions on accreditation based on the fulfillment or lack of fulfillment of the Standards.

Categories of accreditation decisions:

- 1) Full accreditation- the duration of full accreditation is 5 years;
- 2) Conditional accreditation- will be reviewed after 1 year to check fulfillment of the conditions;
- 3) Denial or withdrawal of accreditation.

9.2 Full accreditation for the maximum period must be conferred if all Standards are fulfilled.

9.3 Conditional accreditation, meaning that accreditation is conferred for the entire period stated but with conditions, to be reviewed after 1 year to check fulfillment of the conditions. Conditional accreditation can be used in cases where a few Standards are only partly fulfilled or in cases where more Standards are not fulfilled. The seriousness of the problem is to be reflected in the specification of conditions.

9.4 Denial or withdrawal of accreditation must be the decision, if many Standards are not fulfilled, signifying severe deficiency in the quality of the programme that cannot be remedied within a few years.

9.5 If the decision on accreditation will be denial or withdrawal of accreditation the higher education institution will be excluded or not listed at the National Register #3 (accredited HEIs) of the Ministry of Education and Science of the Republic of Kazakhstan.

9.6 Accrediting agency issues the Certificate for awarding the full accreditation for 5 years.

9.7 According to the Kazakhstan Ministry of Education and Sciences (MoEd.Sci.) Order of #629/Article4./ p.16-17, from November 1, 2016 the accrediting agency's decision on accreditation of HEI and its educational programmes should be posted on the MoEd.Sci.'s web-site.

In addition to that the summary of external evaluation report of HEIs and programmes should be submitted to the MoEd.Sci. in order to be listed on the National Register #2,3 of the Ministry of Education and Science of the Republic of Kazakhstan.

9.8 Accrediting agency has published procedure for appeals related to its external evaluation and decision making process and the following action by accrediting agency affecting accreditation are the subject to appeal: Denial or Withdrawal of accreditation.

9.9. Higher education institution should submit the application for re-accreditation after 5 years to confirm its accredited status.

10. Fellow up activities

10.1 Accredited HEIs are monitored by the accrediting agency throughout the duration of the accreditation term.

10.2 The HEIs should submit the brief progress report annually to shed light on how the institution has addressed the recommendations for improvement that made by the External Evaluation Commission.

10.3 The HEIs must inform accrediting agency of any substantive changes in scope of activities of the institution, including the educational programmes changes.

10.4 The accrediting agency will consider complaints about the quality of accredited HEIs and the accrediting agency will conduct initial evaluation and it would be arranged the site-visit.

11. Development and revision of the accreditation standards

11.1 Amendments for accreditation standard are addressed for its further improvement.

11.2 Amendments to accreditation standard are proposed by the accrediting agency.

11.3 In case of amendments initiation to the standard by main stakeholders, they address their suggestions and remarks to the accreditation agency.

11.4 Accrediting agency consider all suggestions and remarks related to accreditation standards for their validity and appropriateness.

11.5 Revised Standards adopted by the accrediting agency, approved by the Experts Board and signed by Director General will be issued as a new version of Standards and published on its web-site.

12. STANDARDS FOR PROGRAMME ACCREDITATION PHARMACY AND PHARMACEUTICAL TECHNOLOGY AND INDUSTRY

Standard 1. MISSION AND OUTCOMES

1.1 Mission

1.1.1 The higher education institution **must** state its educational programme's mission and make it known to its constituency and the health sector it serves.

The mission statement and value are compatible with the vision and mission of the higher education institution. The statements address the institution's commitment to

professional education, research and scholarship, professional and community service, pharmacy practice, and continuing professional development.

1.1.2 The higher education institution **must** in its educational programme's mission outline the aims and the educational strategy resulting in a pharmacist

- competent at a basic level;
- with an appropriate foundation for future career in any branch of pharmacy;
- capable of undertaking the roles of pharmacist as defined by the health sector;
- prepared and ready for postgraduate medical education;
- committed to life-long learning.

1.1.8 The higher education institution **must** consider that the mission encompasses the health needs of the community, the needs of the health care delivery system and other aspects of social accountability.

1.1.9 The higher education institution should ensure that the mission encompasses pharmaceutical research attainment and aspects of global health.

1.2 Institutional Autonomy and Academic Freedom

1.2.1 The higher education institution **must** have institutional autonomy to formulate and implement policies for which its faculty/academic staff and administration are responsible, especially regarding design of the curriculum and use of the allocated resources necessary for implementation of the curriculum.

1.2.2 The higher education institution **should** ensure academic freedom for its staff and students in addressing the actual curriculum and in exploring the use of new research results to illustrate specific subjects without expanding the curriculum.

1.3 Educational Outcomes

1.3.1 The higher education institution **must** define the intended educational outcomes that students should exhibit upon graduation in relation to:

- their achievements at a basic level regarding knowledge, skills, and attitudes;
- appropriate foundation for future career in any branch of medicine;
- their future roles in the health sector;
- their subsequent postgraduate training;
- their commitment to and skills in life-long learning;
- the health needs of the community, the needs of the health care delivery system and other aspects of social accountability.

1.3.2 The higher education institution **must** ensure appropriate student conduct with respect to fellow students, faculty members, other health care personnel, patients and their relatives.

1.3.3 The higher education institution **must** make the intended educational outcomes publicly known.

1.3.4 The higher education institution **should**

- specify and co-ordinate the linkage of acquired outcomes by graduation with acquired outcomes in postgraduate training;
- specify intended outcomes of student engagement in medical research;

- draw attention to global health related intended outcomes.

1.4 Participation in Formulation of Mission and Outcomes

1.4.1 The higher education institution **must** ensure that its principal stakeholders participate in formulating the mission and intended educational outcomes.

1.4.2 The higher education institution **should** ensure that the formulation of its mission and intended educational outcomes is based also on input from other stakeholders.

Standard 2. EDUCATIONAL PROGRAMMES

2.1 Framework of the Programme

2.1.1 The higher education institution **must**

- define the overall curriculum;
- use a curriculum and instructional/learning methods that stimulate, prepare and support students to take responsibility for their learning process;
- ensure that the curriculum is delivered in accordance with principles of equality.

2.1.2 The higher education institution **should** ensure that the curriculum prepares the students for life-long learning.

2.1.3 The higher education institution ensures that learning and teaching **should** be student-centred with students encouraged and supported in taking responsibility for self-directed learning in order to encourage a culture of life-long learning

2.1.4 The higher education institution **should** ensure that the educational programme has a clearly formulated set of learning outcomes, conducive to the development of competences in pharmacy and which are responsive to changing environment, health needs and demands of populations.

2.1.5 The higher education institution **should** ensure that the educational program imparts to the graduate the knowledge, skills, abilities, behaviors, and attitudes necessary to provide patient-centered care, manage medication use systems, promote health and wellness, and describe the influence of population-based care on patient-centered care.

2.1.6 The qualification resulting from a programme **should** be clearly specified and communicated, and refer to the correct level of the national qualifications framework for higher education and, consequently, to the Framework for Qualifications of the European Higher Education Area. (ESG 1.2)

2.1.7 The higher education institution's programmes **should** provide students with both academic knowledge and skills including those that are transferable, which may influence their personal development and may be applied in their future careers. (ESG G 1.2)

2.1.8 The higher education institution's programmes **should** be

- designed with overall programme objectives that are in line with the institutional strategy and have explicit intended learning outcomes;
- designed by involving students and other stakeholders in the work;
- benefit from external expertise and reference points;

- designed so that they enable smooth student progression;
- defined the expected student workload, e.g. in ECTS;
- included well-structured placement opportunities where appropriate; and it is a subject to a formal institutional approval process. (ESG G 1.2)

2.2 Scientific Method

2.2.1 The higher education institution **must** throughout the curriculum teach

- the principles of scientific method, including analytical and critical thinking;
- medical research methods;
- evidence-based medicine.

2.2.3 The higher education institution **should** in the curriculum include elements of original or advanced research.

2.3 Basic Biomedical Sciences

2.3.1 The higher education institution **must** in the curriculum identify and incorporate the contributions of the basic biomedical sciences concepts and methods fundamental to acquiring and applying health sciences.

2.3.2 The higher education institution **should** in the curriculum adjust and modify the contributions of the biomedical sciences to the

- scientific, technological and clinical developments;
- current and anticipated needs of the society and the health care system.

2.4 Behavioural and Social Sciences, Medical Ethics and Jurisprudence

2.4.1 The higher education institution **must** in the curriculum identify and incorporate the contributions of the: behavioural sciences, social sciences, medical ethics, medical jurisprudence, changing demographic and cultural contexts.

2.4.2 The higher education institution **should** in the curriculum adjust and modify the contributions of the behavioural and social sciences as well as medical ethics and medical jurisprudence to

- scientific, technological and clinical developments;
- current and anticipated needs of the society and the health care system;
- changing demographics and cultural contexts.

2.5 Pharmaceutical Sciences and Skills

2.5.1 The higher education institution **must** in the curriculum identify and incorporate the contributions of the pharmaceutical sciences to ensure that students

- acquire sufficient knowledge and professional skills to assume appropriate responsibility after graduation;
- spend a reasonable part of the programme in planned contact with patients in relevant clinical settings;
- experience health promotion and preventive medicine;
- specify the amount of time spent in training in major pharmaceutical and clinical disciplines.

2.5.2 The higher education institution **must** organise training with appropriate attention to patient safety.

2.5.3 The higher education institution **should** in the curriculum adjust and modify the contributions of the pharmaceutical sciences to the

- scientific, technological and clinical developments;
- current and anticipated needs of the society and the health care system.

2.5.4 The higher education institution **should** ensure that every student has patient contact gradually including participation in pharmaceutical care.

2.5.5 The higher education institution **should** structure the different components of clinical skills training according to the stage of the study programme.

2.6 Programme Structure, Composition And Duration

2.6.1 The higher education institution **must** describe the content, extent and sequencing of courses and other curricular elements to ensure appropriate coordination between different subjects.

2.6.2 The higher education institution **should** in the curriculum ensure horizontal integration of associated sciences, disciplines and subjects and allow optional (elective) content and define the balance between the core and optional content as part of the educational programme.

2.7 Programme Management

2.7.1 The higher education institution **must** have a curriculum committee, which under the governance of the academic leadership (the dean) has the responsibility and authority for planning and implementing the curriculum to secure its intended educational outcomes and in its curriculum committee ensure representation of staff and students.

2.7.2 The higher education institution **should** through its curriculum committee plan and implement innovations in the curriculum and in its curriculum committee include representatives of other stakeholders.

2.7.3 The higher education institution **should** have processes for the design and approval of their programmes. (ESG 1.2)

2.8 Linkage with medical practice and the health sector

2.8.1 The higher education institution **must** ensure operational linkage between the educational programme and the subsequent stages of education or practice after graduation.

2.8.2 The higher education institution **should** ensure that the curriculum committee

- seeks input from the environment in which graduates will be expected to work, and modifies the programme accordingly;
- considers programme modification in response to opinions in the community and society.

Standard 3. ASSESSMENT OF STUDENTS

3.1 Assessment methods

3.1.1 The higher education institution **must**

- define, state and publish the principles, methods and practices used for assessment of its students, including the criteria for setting pass marks, grade boundaries and number of allowed retakes;
- ensure that assessments cover knowledge, skills and attitudes;
- use a wide range of assessment methods and formats according to their assessment utility;
- ensure that methods and results of assessments avoid conflicts of interest;
- ensure that assessments are open to scrutiny by external expertise;
- use a system of appeal of assessment results.

3.1.2 The higher education institution **should** evaluate and document the reliability and validity of assessment methods, incorporate new assessment methods where appropriate and encourage the use of external examiners.

3.2 Relation between Assessment and Learning

3.2.1 The higher education institution **must** use assessment principles, methods and practices that

- are clearly compatible with intended educational outcomes and instructional methods;
- ensure that the intended educational outcomes are met by the students;
- promote student learning;
- provide an appropriate balance of formative and summative assessment to
- guide both learning and decisions about academic progress.

3.2.2 The higher education institution **should**

- adjust the number and nature of examinations of curricular elements to encourage both acquisition of the knowledge base and integrated learning;
- ensure timely, specific, constructive and fair feedback to students on basis of assessment results.

Standard 4. STUDENTS

4.1 Admission policy and selection

4.1.1 The higher education institution **must** formulate and implement an admission policy based on principles of objectivity, including a clear statement on the process of selection of students.

4.1.2 The higher education institution **must** have a policy and implement a practice for admission of disabled students.

4.1.3 The higher education institution **must** have a policy and implement a practice for transfer of students from other national or international programmes and institutions.

4.1.4 The higher education institution **should** state the relationship between selection and the mission of the school, the educational programme and desired qualities of graduates.

4.1.5 The higher education institution **should** periodically review the admission policy and use a system for appeal of admission decisions.

4.2 Student intake

4.2.1 The higher education institution **must** define the size of student intake and relate it to its capacity at all stages of the programme.

4.2.2 The higher education institution **should** periodically review the size and nature of student intake in consultation with other stakeholders and regulate it to meet the health needs of the community and society.

4.3 Student Counselling and Support

4.3.1 The higher education institution **must** have a system for academic counselling of its student population.

4.3.2 The higher education institution **must** offer a programme of student support, addressing social, financial and personal needs.

4.3.3 The higher education institution **must** allocate resources for student support and ensure confidentiality in relation to counselling and support.

4.3.4 The higher education institution **should** provide academic counselling that is based on monitoring of student progress and includes career guidance and planning.

4.3.5 The higher education institution **should** provide to students the documentation explaining the qualification gained, including achieved learning outcomes and the context, level, content and status of the studies that were pursued and successfully completed. (ESG G 1.4)

4.4 Student Representation

4.4.1 The higher education institution **must** formulate and implement a policy on student representation and appropriate participation:

- in mission statement;
- design of the programme;
- management of the programme;
- evaluation of the programme and other matters relevant to students.

4.4.2 The higher education institution **should** encourage and facilitate student activities and student organisations.

Standard 5. ACADEMIC STAFF/FACULTY

5.1 Recruitment and Selection Policy

5.1.1 The higher education institution **must** formulate and implement a staff recruitment and selection policy which

- outline the type, responsibilities and balance of the academic staff/faculty of the basic biomedical sciences, the behavioural and social sciences and the clinical sciences required to deliver the curriculum adequately, including the balance between medical and non-medical academic staff, the balance between full-time and part-time academic staff, and the balance between academic and non-academic staff;

- address criteria for scientific, educational and clinical merit, including the balance between teaching, research and service functions;
- specify and monitor the responsibilities of its academic staff/faculty of the basic biomedical sciences, the behavioural and social sciences and the clinical sciences.

5.1.2 The higher education institution **should** in its policy for staff recruitment and selection take into account criteria such as relationship to its mission, including significant local issues and economic considerations.

5.2 Staff activity and staff development

5.2.1 The higher education institution **must** formulate and implement a staff activity and development policy which

- allow a balance of capacity between teaching, research and service functions;
- ensure recognition of meritorious academic activities, with appropriate emphasis on teaching, research and service qualifications;
- ensure that clinical service functions and research are used in teaching and learning;
- ensure sufficient knowledge by individual staff members of the total curriculum;
- include teacher training, development, support and appraisal.

5.2.2 The higher education institution **should** take into account teacher-student ratios relevant to the various curricular components.

5.2.3 The higher education institution **should** design and implement a staff promotion policy.

Standard 6. EDUCATIONAL RESOURCES

6.1 Physical Facilities

6.1.1 The higher education institution **must** have sufficient physical facilities for staff and students to ensure that the curriculum can be delivered adequately.

6.1.2 The higher education institution **must** ensure a learning environment, which is safe for staff, students, patients and their relatives.

6.1.3 The higher education institution **should** improve the learning environment by regularly updating and modifying or extending the physical facilities to match developments in educational practices.

6.2 Clinical training resources

6.2.1 The higher education institution **must** ensure necessary resources for giving the students adequate clinical experience, including sufficient number and categories of patients, clinical training facilities and supervision of their clinical practice.

6.2.2 The higher education institution **should** evaluate, adapt and improve the facilities for clinical training to meet the needs of the population it serves.

6.3 Information Technology

6.3.1 The higher education institution **must** formulate and implement a policy which addresses effective and ethical use and evaluation of appropriate information and communication technology.

6.3.2 The higher education institution **must** ensure access to web-based or other electronic media.

6.3.3 The higher education institution **should enable** teachers and students to use existing and exploit appropriate new information and communication technology for

- independent learning;
- accessing information;
- managing patients;
- working in health care delivery systems;
- optimise student access to relevant patient data and health care information systems.

6.4 Research and Scholarship

6.4.1 The higher education institution **must** use research and scholarship as a basis for the educational curriculum.

6.4.2 The higher education institution **must** formulate and implement a policy that fosters the relationship between research and education.

6.4.3 The higher education institution **must** describe the research facilities and priorities at the institution.

6.4.4 The higher education institution **should** ensure that interaction between research and education

- influences current teaching;
- encourages and prepares students to engage in research and development.

6.5 Educational Expertise

6.5.1 The higher education institution **must** have access to educational expertise where required.

6.5.2 The higher education institution **must** formulate and implement a policy on the use of educational expertise in curriculum development and development of teaching and assessment methods.

6.5.3 The higher education institution **should** demonstrate evidence of the use of in-house or external educational expertise in staff development.

6.5.4 The higher education institution **should** pay attention to current expertise in educational evaluation and in research in the discipline of medical education.

6.5.5 The higher education institution **should** allow staff to pursue educational research interest.

6.6 Educational Exchanges

6.6.1 The higher education institution **must** formulate and implement a policy for

- national and international collaboration with other educational institutions, including staff and student mobility;
- transfer of educational credits.

6.6.2 The higher education institution **should** facilitate regional and international exchange of staff and students by providing appropriate resources.

6.6.3 The higher education institution **should** ensure that exchange is purposefully organised, taking into account the needs of staff and students, and respecting ethical principles.

Standard 7. PROGRAMME EVALUATION

7.1 Mechanisms for programme monitoring and evaluation

7.1.1 The higher education institution **must** have a programme of routine curriculum monitoring of processes and outcomes.

7.1.2 The higher education institution **must** establish and apply a mechanism for programme evaluation that

- addresses the curriculum and its main components;
- addresses student progress;
- identifies and addresses concerns.

7.1.3 The higher education institution **must** ensure that relevant results of evaluation influence the curriculum.

7.1.4 The higher education institution **should** periodically evaluate the programme by comprehensively addressing

- the context of the educational process;
- the specific components of the curriculum;
- the long-term acquired outcomes;
- its social accountability.

7.1.5 The higher education institution **should** ensure that they collect, analyse and use relevant information for the effective management of the programme and other activities. (ESG S1.7)

7.2 Teacher and Student Feedback

7.2.1 The higher education institution **must** systematically seek, analyse and respond to teacher and student feedback.

7.2.2 The higher education institution **should** use feedback results for programme development.

7.3 Performance of Students and Graduates

7.3.1 The higher education institution **must** analyse performance of cohorts of students and graduates in relation to mission and intended educational outcomes, curriculum and provision of resources.

7.3.2 The higher education institution **should** analyse performance of cohorts of students and graduates in relation to student background and conditions, entrance qualifications.

7.3.3 The higher education institution **should** use the analysis of student performance to provide feedback to the committees responsible for student selection, curriculum planning and student counselling.

7.4 Involvement of Stakeholders

7.4.1 The higher education institution **must** in its programme monitoring and evaluation activities involve its principal stakeholders.

7.4.2 The higher education institution **should** for other stakeholders

- allow access to results of course and programme evaluation;
- seek their feedback on the performance of graduates;
- seek their feedback on the curriculum.

Standard 8. GOVERNANCE AND ADMINISTRATION

8.1 Governance

8.1.1 The higher education institution **must** define its governance structures and functions including their relationships within the university.

8.1.2 The higher education institution **should** in its governance structures set out the committee structure, and reflect representation from principal stakeholders and other stakeholders.

8.1.3 The higher education institution **should** ensure transparency of the work of governance and its decisions.

8.2 Academic Leadership

8.2.1 The higher education institution **must** describe the responsibilities of its academic leadership for definition and management of the medical educational programme.

8.2.2 The higher education institution **should** periodically evaluate its academic leadership in relation to achievement of its mission and intended educational outcomes.

8.3 Educational budget and resource allocation

8.3.1 The higher education institution **must** have a clear line of responsibility and authority for resourcing the curriculum, including a dedicated educational budget.

8.3.2 The higher education institution **must** allocate the resources necessary for the implementation of the curriculum and distribute the educational resources in relation to educational needs.

8.3.3 The higher education institution **should** have autonomy to direct resources, including teaching staff remuneration, in an appropriate manner in order to achieve its intended educational outcomes.

8.3.4 The higher education institution **should** in distribution of resources take into account the developments in medical sciences and the health needs of the society.

8.4 Administration and Management

8.4.1 The higher education institution **must** have an administrative and professional staff that is appropriate to support implementation of its educational programme and related activities and ensure good management and resource deployment.

8.4.2 The higher education institution **should** formulate and implement an internal programme for quality assurance of the management including regular review.

8.5 Interaction with Health Sector

8.5.1 The higher education institution **must** have constructive interaction with the health and health related sectors of society and government.

8.5.2 The higher education institution **should** formalise its collaboration, including engagement of staff and students, with partners in the health sector.

9. CONTINUOUS RENEWAL

9.1 The higher education institution **must** as a dynamic and socially accountable institution

- initiate procedures for regularly reviewing and updating the process, structure, content, outcomes/competencies, assessment and learning environment of the programme;
- rectify documented deficiencies;
- allocate resources for continuous renewal.

9.2 The higher education institution **should** base the process of renewal on prospective studies and analyses and on results of local evaluation and the medical education literature.

9.3 The higher education institution **should** ensure that the process of renewal and restructuring leads to the revision of its policies and practices in accordance with past experience, present activities and future perspectives.

9.4 The higher education institution **should** address the following issues in its process of renewal:

- adaptation of mission statement to the scientific, socio-economic and cultural development of the society.
- modification of the intended educational outcomes of the graduating students in accordance with documented needs of the environment they will enter.
- adaptation of the curriculum model and instructional methods to ensure that these are appropriate and relevant.
- adjustment of curricular elements and their relationships in keeping with developments in behavioural and social sciences, changes in the demographic profile and health/disease pattern of the population, and socioeconomic and cultural conditions. The adjustment would ensure that new relevant knowledge, concepts and methods are included and outdated ones discarded.
- development of assessment principles, and the methods and the number of examinations according to changes in intended educational outcomes and instructional methods.
- adaptation of student recruitment policy, selection methods and student intake to changing expectations and circumstances, human resource needs, changes in the premedical education system and the requirements of the educational programme.
- adaptation of academic staff recruitment and development policy according to changing needs.

- updating of educational resources according to changing needs, i.e. the student intake, size and profile of academic staff, and the educational programme.
- refinement of the process of programme monitoring and evaluation.
- development of the organisational structure and of governance and management to cope with changing circumstances and needs and, over time, accommodating the interests of the different groups of stakeholders.

REFERENCES

1. International standards in medical education: assessment and accreditation of medical schools'--educational programmes. A WFME position paper. The Executive Council, The World Federation for Medical Education. *Med Educ.* 1998 Sep; 32(5):549-58.
2. International recognition of basic medical education programmes. Karle H, Executive Council, World Federation for Medical Education. *Med Educ.* 2008 Jan; 42(1):12-17.
3. Basic Medical Education. WFME Global Standards for Quality Improvement. World Federation of Medical Education (WFME); New edition 2012, revised 2015 (<http://wfme.org/standards/bme/78-new-version-2012-quality-improvement-in-basic-medical-education-english/file>, accessed 19 December 2016).
4. WFME Global Standards for Quality Improvement in Medical Education. European Specifications. The World Federation for Medical Education (WFME) and The Association of Medical Schools in Europe (AMSE); 2007 (<http://wfme.org/standards/european-specifications/21-europeanspecifications-english/file>, accessed 19 December 2016).
5. WHO-WFME Guidelines for Accreditation of basic medical education. Geneva/Copenhagen: WFME, 2005 (<http://wfme.org/accreditation/whowfme-policy/28-2-who-wfme-guidelines-for-accreditation-of-basic-medical-education-english/file>, accessed 20 November 2016).
6. Promotion of Accreditation of Basic Medical Education. A Programme within the Framework of the WHO/WFME Strategic Partnership to Improve Medical Education. WFME Office: The Panum Institute, Faculty of Health Sciences University of Copenhagen; November 2005 (<http://wfme.org/accreditation/whowfme-policy/30-1-promotion-of-accreditation-of-basic-medical-education-who-wfme-strategic-partnership/file>, accessed 20 November 2016).
7. Lindgren S, Karle H. Social accountability of medical education: Aspects on global accreditation. *Med Teach.* 2011; 33:667-72.