

# Continuing Pharmaceutical Education: Guide to Establishing Quality Assured and Accredited Programs



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# Continuing Pharmaceutical Education: Guide to Establishing Quality Assured and Accredited Programs

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### **About ACPE**

Accreditation Council for Pharmacy Education (ACPE) is the U.S. national agency for the accreditation of professional degree programs in pharmacy and providers of continuing pharmacy education. ACPE was established in 1932 for the accreditation of pre-service education. In 1975, ACPE's scope of activity was broadened to include accreditation of providers of continuing pharmacy education. In 2011, ACPE's International Services Program was established to strengthen ACPE's ability to assist international stakeholders who seek guidance related to quality assurance and advancement of pharmacy education. Since 2015, ACPE has collaborated with the American Society of Health-System Pharmacists to accredit education and training programs for pharmacy technicians.

### **About SIAPS**

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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### **Key Words**

accreditation, continuing education, continuing professional development, quality assurance, training

### **Systems for Improved Access to Pharmaceuticals and Services**

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## Preface

The lack of an adequately trained health care workforce creates a barrier to the delivery of quality health care services. Inadequate knowledge, limited skills, and inappropriate attitudes can all be obstacles to achievement of health outcomes. Advances in the treatment and diagnosis of diseases, new technologies, systems and process improvements, as well as changes in professional roles and responsibilities, require health care workers to engage in continuing professional development (CPD). In addition to changing roles and advancements in the management of patients, continuing education (CE) and training activities for pharmaceutical management in resource-limited countries are developed and delivered by a wide variety of organizations and donors. Often this education is designed to address these stakeholders' specific goals and objectives, which may or may not be directly linked to a larger health systems strengthening strategy.

CPD of individual pharmaceutical professionals (including pharmacists and pharmacy support personnel) through participation in quality CE and training activities is essential to the maintenance and advancement of health care worker competence. The CE/CPD process involves three main groups: (1) the individual pharmaceutical professional who engages in CE/CPD to maintain competence; (2) the provider or group that provides the CE/CPD activities to the pharmaceutical professionals; and (3) the CE/CPD accreditation body that oversees the CE/CPD quality assurance or accreditation process.

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Participation in lifelong learning is essential to ensuring the continued competence of pharmaceutical professionals. The quality of individual CE/CPD and training activities can be assured by using quality assurance criteria and standards to which individual activities may be compared. These criteria and standards for quality should address the “Pillars of Educational Quality” (*context, structure, process, outcomes, and impact*) and rest on the “Foundations” (*science, practice, and ethics*) of quality education.

Although this guidance document has been developed to focus on CE for pharmacy professionals, the principles and approach are applicable to CE for other categories of health care workers, including medical doctors, nurses, and allied health professionals. Accreditation and regulatory agencies are therefore encouraged to use this tool as a guide for benchmarking their CE/CPD systems to improve the quality and delivery of CE in low-resource settings.

The authors recognize that countries may be at different stages in the implementation of quality assurance for CE activities. Many may not yet have started such a program while others may have implemented some elements. In this regard, the guidance was developed with the intention that it be applied in a flexible and incremental manner, i.e., in its entirety or in components that would be compatible with the priorities of local national programs.

In general, the CE/CPD quality criteria and standards should incorporate the following aspects:

- Activity development based on identified professional practice gaps and the educational needs (e.g., knowledge, skills, performance) underlying those gaps
- Learning objectives that are specific and measurable
- Content and learning methods that are evidenced based and free of bias, commercialism, and conflicts of interest
- Presenters who are knowledgeable and experienced
- Instructional materials, including handouts and tools that can be used by the learners in the practice setting
- Active learning techniques that facilitate sustained learning
- Assessment of learning to ensure the learning objectives have been achieved
- Evaluation of the CE activity, including the learning environment, delivery of educational content, teaching and assessment methodologies used, satisfaction of learners, and achievement of intended outcomes

This guidance document (with associated tools) is designed to assure the quality of CPD and advance excellence in education for the pharmacy profession through the establishment of standards and criteria for the accreditation of CPD and CE programs for pharmacy professionals. This document will guide the establishment and benchmarking of accreditation programs for continuing pharmaceutical education and training in low- and middle-income countries. It is also a guide for governments and other stakeholders on how to establish and maintain quality and accredited programs for pharmaceutical training, CE, and CPD activities as a mechanism to ensure that knowledge and skills-based training offered to pharmacy staff meets a defined quality standard. Use of this guidance document will guide countries in the development of an accreditation process designed to ensure the quality of CE/CPD activities. The document is also intended to guide quality improvement initiatives in countries with existing CE/CPD accreditation procedures.

## Acknowledgments

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## Acronyms and Abbreviations

ACPE	Accreditation Council for Pharmacy Education
AIDS	acquired immunodeficiency syndrome
APC	Australian Pharmacy Council
CCCEP	Canadian Council on Continuing Education in Pharmacy
CE	continuing education
CPD	continuing professional development
CPE	continuing pharmacy education
DHA	Dubai Health Authority
EFMHACA	Ethiopian Food, Medicine, Health Care Administration and Control Authority
FIP	International Pharmaceutical Federation
HIV	human immunodeficiency virus
HPC Namibia	Health Professionals Councils of Namibia
MAT	Medical Association of Tanzania
MPDB Kenya	Medical Practitioners and Dentists Board of Kenya
MDC Ghana	Ghana Medical and Dental Council
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SMART	Specific, Measurable, Attainable, Relevant, Timed
SMC	Singapore Medical Council
WHO	World Health Organization

## Glossary

*Note: The definition and/or application of the terms listed here may vary from country to country. The text following each term is, therefore, intended primarily as a description of the general context in which the term has been used in this document by the authors and is not intended as a recommended definition for global adoption.*

**Accreditation:** the process whereby an association, agency, or accreditation body grants public recognition to an organization, site, or program that meets certain established qualifications or standards, as determined through initial and periodic evaluations.

**Active learning:** a process or methodology whereby learners are actively engaged in the learning process rather than “passively” absorbing lectures. Active learning involves reading, writing, discussion, and engagement in solving problems, analysis, synthesis, and evaluation.

**Activity:** an educational event that is based upon identified needs, has a purpose or objectives, and is evaluated to assure the needs are met. An activity is designed to support the continuing professional development (CPD) of pharmacists or pharmacy support personnel to maintain and enhance their competence. Each continuing education (CE) activity should promote problem-solving and critical thinking while being applicable to pharmaceutical practice. The CE activities should be designed according to the appropriate roles and responsibilities of the pharmacists and/or pharmacy support personnel.

**Accredited provider:** an institution, organization, or entity that has been recognized by the accreditation body, in accordance with its policy and procedures, as having demonstrated compliance with the standards, which are indicative of the provider’s capability to develop and deliver quality continuing education.

**Assessment:** a test or measure of knowledge, skills, performance, achievement, or learning for or in a specific area or process. The process of observing learning, such as describing, collecting, recording, scoring, and interpreting information about a pharmacist’s or support person’s learning. Assessments are used to determine achievement of objectives.

**CE/CPD logbook:** see **Portfolio**.

**Commercial bias:** a personal judgment in favor of a specific proprietary business interest of a commercial interest.

**Commercial interest:** any entity producing, marketing, reselling, or distributing health care goods or services consumed by, or used on, patients. Providers of clinical service directly to patients are not commercial interests.

**Commercial support:** financial or in-kind contributions given by a commercial interest that is used to pay all or part of the costs of a continuing pharmacy education (CPE) activity.

**Competence:** the ability to perform one’s duties accurately and confidently, make correct judgments, and interact appropriately with patients and with colleagues. Professional competence is characterized by good problem-solving and decision-making abilities, a strong knowledge base, and the ability to apply knowledge and experience to diverse patient-care situations.

**Competencies:** the knowledge, skills, behaviors, and attitudes that an individual accumulates, develops, and acquires through education, training, and work experience.

**Conflict of interest:** when an individual's interests are aligned with those of a commercial interest, the interests of the individual are in potential conflict with the interests of the public. Financial relationships can create actual conflicts of interest in CPE when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CPE about the products or services of that commercial interest.

**Continuing education (CE)/continuing pharmacy education (CPE):** a structured process of education designed or intended to support the continuing development of pharmacists and other members of the pharmacy workforce to maintain and enhance their professional competence.

**Continuing professional development (CPD):** the lifelong process of active participation in learning activities that assists in developing and maintaining continuing competence, enhancing professional practice, and supporting achievement of career goals. A self-directed, ongoing, systematic, and outcomes-focused approach to lifelong learning that is applied into practice.

**Criteria:** see **Standard**.

**Educational outcomes:** the intended quantifiable and measurable results (such as new knowledge or skills) that should be achieved on completion of a course or program of study.

**Evaluation:** the forming of a judgment based on the collection, analysis, and interpretation of data from process and outcome measures with a view to determining the quality of one or more activities and the achievement of desired outcomes.

**Evidence based:** the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. (Centre for Evidence-Based Medicine)

**Faculty:** a person who guides and delivers or writes the content of a CE activity. (Similar term: **Presenter**)

**Financial relationships:** financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options, or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received or expected. **Relevant financial relationships:** financial relationships in any amount that create a conflict of interest.

**Framework:** the visual representation of the interactions between the different required structures, people and processes so to assure specific desired outcomes.

**Guide/guidance document:** refers to this document that describes a framework and a set of tools to support stakeholders interested in establishing quality and/or accredited programs for CE/CPD.

**Learning style:** an individual's mode of gaining knowledge, especially a preferred or best method; an individual's unique approach to learning based on strengths, weaknesses, and preferences.

**License:** a credential issued by a government or regulatory body that indicates that the holder is in compliance with minimum mandatory requirements necessary to practice in a particular profession or occupation. (Similar term: **Registration**)

**Lifelong learning:** all learning that occurs during the career of a practitioner (including structured educational programs or activities, training, informal or unstructured learning, and work-based learning) that aims to improve knowledge, skills, and competencies.

**Mission:** the fundamental purpose, objective, or reason to exist (*raison d'être*) for an organization or institution that guides its planning and activities.

**Needs assessment:** identification of educational needs of pharmacists or pharmacy support personnel that serve as the basis for planning CE activities.

**Noncommercialism:** CE activities that provide an in-depth presentation with fair and full disclosure as well as objectivity and balance. Appropriate topics and learning activities shall be distinguished from those topics and learning activities that are promotional or appear to be intended for the purpose of endorsing either a specific commercial medicine or other commercial product (as contrasted with the generic product/medicine entity and its contents or the general therapeutic area that it addresses), or a specific commercial service (as contrasted with the general service area or the aspects or problems of professional practice that it addresses).

**Objectives:** statements that describe what the pharmacists or pharmacy support personnel can expect to know or do after completion of the CE activity. Objectives are preferably written in behavioral terminology and should suggest outcome measures for a program's success or effectiveness.

**Outcome:** something that is achieved or results from an activity or series of activities.

**Pharmaceutical professionals:** the term used in this document to include all members of the pharmacy workforce, including pharmacists and pharmacy support personnel.

**Pharmacy support personnel:** includes pharmacy technicians, pharmacy assistants, pharmacy aides, pharmaceutical technologists, medicine sellers, medicine shop attendants, druggists, dispensers, etc.

**Portfolio:** a document (paper based or electronic) in which a learner records his or her CPD-related activities, including reflection, planning, learning, evaluation, application in practice, and impact of learning. A tool designed to support and provide evidence of self-directed lifelong learning. (Similar terms: **CPD portfolio, learning portfolio, CE/CPD logbook**)

**Practice gap:** the difference between health care processes or outcomes observed in practice and those desirable or achievable on the basis of current professional knowledge; provides the basis for the development of activities or interventions to address the educational needs that underlie the gap. Practice gaps can exist in any area where the practitioner provides services to patients, the public, or the profession.

**Presenters:** see **Faculty**.

**Programmatic outcomes:** the broad range of deliverables (results or products) that an organized and cohesive group of activities (a program) produces.

**Providers:** the entity or organization charged with development and delivery of the CE/CPD activity.

**Quality assurance:** the systematic review of educational programs to ensure that acceptable standards of education, scholarship, and infrastructure are being maintained.

**Relevant financial relationships:** (see under **Financial relationships**)

**Standard(s):** the requirement(s) that must be met.

**Substantive change:** a major or substantial change in a provider or its educational program that might reasonably be expected to materially affect the quality of its educational activities.

**Training:** Training involves learning through specialized instruction, repetition and practice of a task or series of tasks until proficiency is achieved. Education, in contrast, involves a deeper understanding of a subject, based on explanation and reasoning, through systematic instruction and teaching.

# Introduction and Use of This Guide

## Why is there a need to build pharmaceutical workforce capacity and accredit programs for continuing education and training in low- and middle-income countries?

The delivery of quality pharmaceutical care depends on the existence of qualified and competent pharmaceutical professionals. (Note that *pharmaceutical professionals* include both pharmacists, and pharmacy support staff and personnel.) In addition, sufficient numbers of pharmacists and pharmacy support staff must exist in the pharmaceutical profession to address pharmaceutical needs in a country. The pharmaceutical profession in any given country is a complex mix of individuals and includes different cadres who are at varying stages of development and are working in a range of practice settings under changing national conditions and pressures. Maintenance of the pharmaceutical workforce at an adequate number and skill level is dependent on three main factors:<sup>1</sup>

- Improving recruitment of qualified workers
- Improving the performance of the existing workforce
- Improving retention

Performance by members of the pharmaceutical profession is directly linked to health care outcomes. The competence of the pharmaceutical workforce has an immediate impact on the quality of services and care provided and affects the overall public health of the nation. Delivery of subquality care can have a negative impact on patient safety and the health care outcomes of individuals and populations. Health care workers, including members of the pharmaceutical profession, must continually maintain their professional knowledge, skills, and abilities to meet evolving standards of professional competence and ongoing societal needs.

Participation in CE/CPD is essential for the maintenance and enhancement of competence to practice and ultimately to improve the quality of care and services delivered. Participation in CE and training activities has been demonstrated to enhance knowledge, skills, and performance of health care workers.<sup>2</sup> Participation in CE/CPD activities can motivate pharmaceutical professionals to be drivers for change. Participation in CPD activities has been demonstrated to contribute to improved interactions with other health care providers.<sup>3</sup> CE/CPD participants have reported improvements in knowledge, attitudes, and values that have contributed to improvements in the workplace, including improved patient care.

Yet not all health care workers actively participate in CE activities once they are in practice unless it is mandated by law. A cross-sectional study of 319 health care workers from public health facilities in Addis Ababa reported that only 25% of study participants actively engaged in optional CE.<sup>4</sup>

Retention and attrition of health care workers directly affect workforce strength. Attrition through migration of qualified personnel leads to the loss of qualified health care workers.<sup>5</sup> Migration includes both intracountry movement (from rural to urban, lower-income areas to more affluent areas) as well as intercountry movement (from less-developed to more-developed countries). Education and training opportunities are one of many factors that that can motivate worker migration.<sup>6</sup> Work environments that are more conducive to education and training can “pull” workers from other, less desirable environments.<sup>5</sup> Opportunity for advancement, which may require added qualifications, is another factor that can influence worker migration.

It is critical that countries develop and implement strategies designed to maintain a competent pharmaceutical and health care workforce. Measures to ensure continued competency of workers to enhance patient safety and the provision of quality health care are essential. Such measures may also aid in reducing migration of health care workers.

Low- and middle-income countries may not adequately address all aspects of CE and training, and systems to accredit or otherwise ensure quality of CE and training may be lacking or in need of improvement. Development or enhancement of systems designed to ensure the quality of CE and training activities is needed to ultimately improve the quality of services provided by the members of the pharmaceutical profession.

## The Framework for Establishing Quality in CE/CPD

The overall approach to CE/CPD involves a needs-based model (figure 1).<sup>7</sup> The needs may be local (e.g., hospital-based initiatives), regional, national, or international (e.g., global initiatives such as “An AIDSFree Generation”) and are tied to the services provided by the pharmaceutical professionals. As services provided by the pharmaceutical profession vary from country to country, so too will the educational needs. CE/CPD and training activities are targeted to fill the educational need or gap in an effort to ensure that pharmaceutical professionals are competent to provide services in accordance with their practice-setting expectations.

**Figure 1. Needs-based education model**



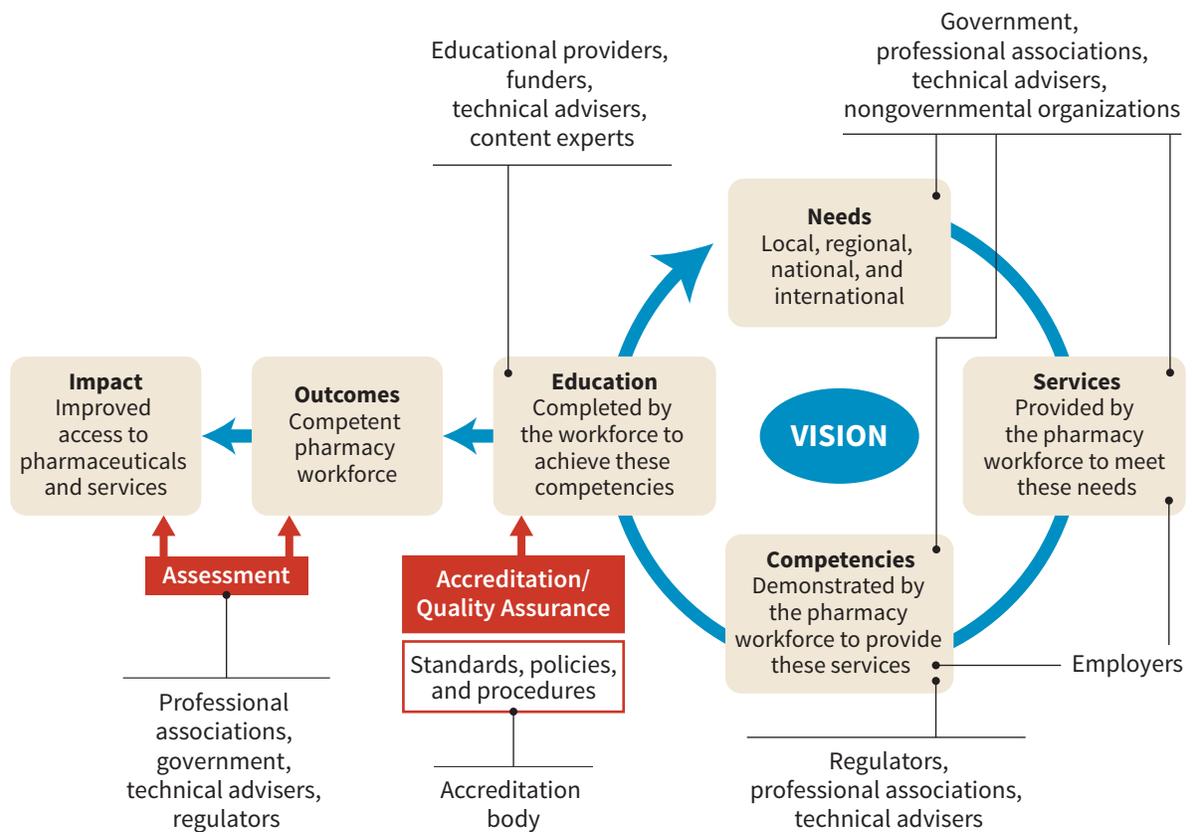
Source: International Pharmaceutical Federation (FIP), 2013 FIPed Global Education Report.<sup>7</sup> Used with permission.

The framework for establishing quality and accredited CE/CPD is summarized in figure 2. It builds upon the International Pharmaceutical Federation (FIP) needs-based education model (figure 1). In this model, the process starts with identification of the needs, which helps determine the services required to meet those needs. The expected services then help determine the competencies required to provide those services. The expected competencies in turn help formulate the appropriate curriculum, content and delivery methods for the CE/CPD of the health care workforce to achieve or maintain, and enhance those competencies.

The CE/CPD framework (described in figure 2) also identifies the key stakeholders that have a vested interest and contribution to make in the CE/CPD process. As depicted, many stakeholders have an interest in ensuring the continued and enhanced competence of pharmaceutical professionals, practicing both within a particular workplace setting and in the country at large. These stakeholders are further described in “Section III: Establishing the CE/CPD Accreditation Body.”

These stakeholders play various and complementary roles. Based on the specified vision of the health sector, governments, professional associations, technical advisers, nongovernmental organizations and employers determine the pharmaceutical needs and services to be accomplished by the different cadres of pharmaceutical staff. They also define the competencies needed to deliver services. The educational providers, technical advisers and content experts guide the design and delivery of the CE/CPD training programs, often with support from funders, including donors. The accreditation/quality assurance bodies have a role in setting standards, policies and procedures and in overseeing and monitoring adherence to such standards and procedures to ensure that the pharmaceutical personnel are well-trained and are competent to deliver quality services for good health outcomes. Stakeholders such as professional associations, government, technical advisers, and regulators should periodically assess the results, outcomes and impact of the CE/CPD activities. Besides helping to evaluate the degree of effectiveness, such assessments also help identify continuing gaps and needs, which can be valuable in feeding into further strengthening and refinement of the training programs, thus contributing to continuous quality improvement.

**Figure 2. CE/CPD overall framework including roles of different stakeholders**



The CE/CPD process then can be considered from three main levels, which are different but interrelated.

- The first level involves the individual pharmaceutical professional who, through the CPD process or evaluation by a third party (such as an employer), identifies individual educational gaps and needs that must be addressed to maintain or enhance competence and ultimately close practice gaps.
- The second level involves the provider of the CE/CPD and training activity, which must be of sufficient quality to adequately address the individual pharmaceutical professional's educational and training gaps and needs.
- The third level involves the oversight of the overall process through the development of a quality assurance or accreditation process.

Additionally, the regulatory body (or bodies) responsible for oversight of practice may require practitioners to participate in accredited CE/CPD activities for maintenance of licensure or registration.

## Who should use this framework?

The framework presented in this guide is intended as a tool, to be used in part or as a whole, to facilitate the development or quality improvement of CE/CPD accreditation procedures. The framework may be used in individual countries or at a regional level. For countries with limited resources, it is hoped the document will serve as a guide for current educational providers and other stakeholders who have an interest or role to play in the delivery of quality educational activities, as well as for the future development of accreditation procedures. The framework is intended to be a “living” document that will be tested and improved over time. As such, feedback on the application and utility of the framework and its contents, as well as suggestions for improvement, are welcome. Considerations for initiating use of the guide are included in Box 1.

### **Box 1. Use of This Framework**

The first step in using this framework is to analyze the current CE/CPD requirements and quality assurance or accreditation process within the country.

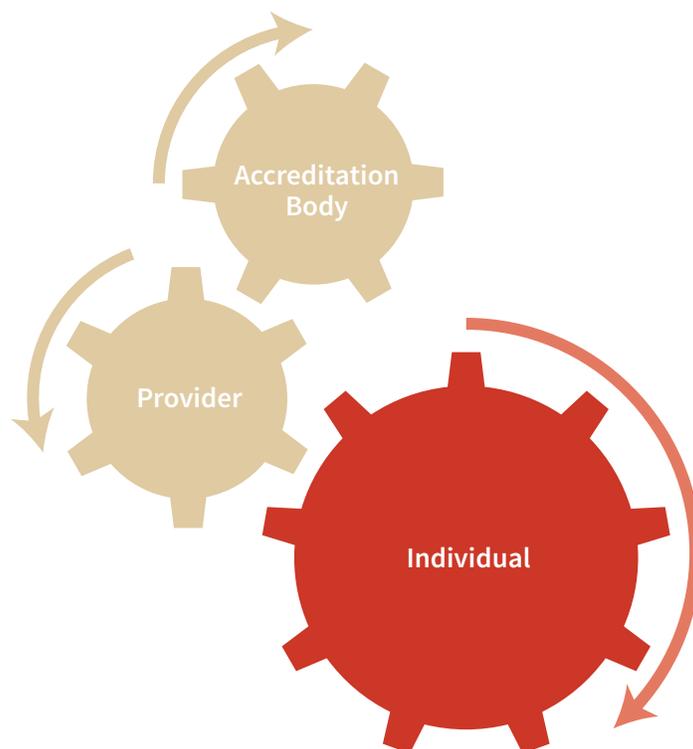
Countries needing to establish a CE/CPD system should begin with “Section I: Establishing a Quality Continuing Professional Development Process.” Section I outlines

- The difference between CE and CPD
- The CPD process
- Examples of a CPD logbook

Countries that have already established requirements for participation in CE/CPD activities but that lack an accreditation process designed to ensure the quality of such activities should focus on “Section II: Assuring the Quality of CE/CPD Training Activities.” Countries that have an existing accreditation process in place may also benefit from reviewing Section II to evaluate and improve the quality of their current accreditation procedures.

Countries seeking to establish an accreditation body to oversee the accreditation process should focus on “Section III: Establishing the Accreditation Body” for guidance.

## Section I: Establishing a Quality Continuing Professional Development Process



Significant gains have been achieved in biomedical knowledge over the last century. The impact these gains have had on the overall health of the population has been compromised by challenges regarding the translation of knowledge and skills from research to the patient-care setting.<sup>8</sup> Continued competence and development of new knowledge, attitudes, skills, and values on the part of health care workers require a commitment to lifelong learning and participation in quality CE/CPD and training.

The first level in the CE/CPD process focuses on the individual pharmaceutical professional. The continued competence of individuals is at the center of the CE/CPD process. Through participation in CE/CPD and training activities, the individual participates in a process of lifelong learning that is designed to maintain and enhance his or her competence as a pharmaceutical professional. This competence should contribute to increased access to and improved use of medicines locally and nationally. The first section of the framework addresses the process individual pharmaceutical professionals should focus on with regard to the lifelong learning and the CE/CPD and training process.

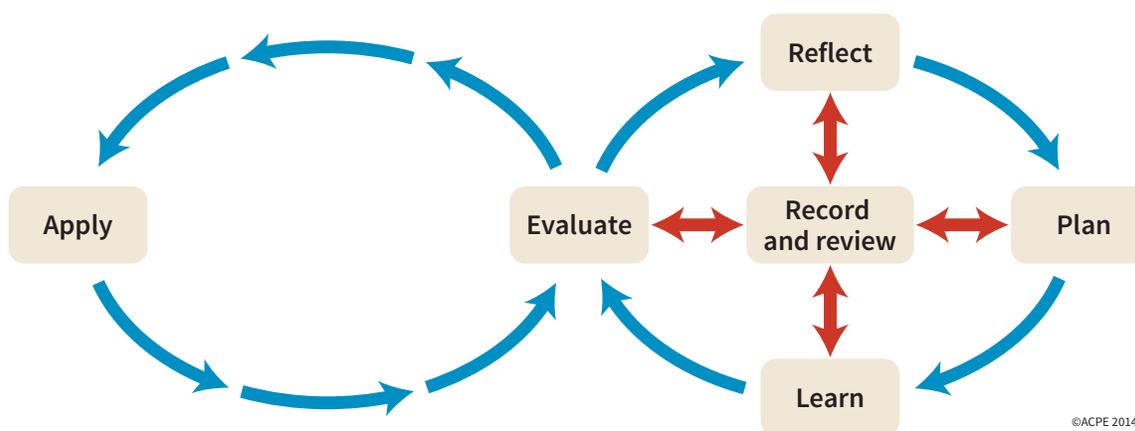
### What is continuing education?

*Continuing education* is a structured educational activity designed or intended to maintain and enhance the competence of pharmaceutical personnel and support the continuing development of the pharmaceutical profession. CE should promote problem solving and critical thinking and be applicable to the practice of pharmacy. CE is a component of lifelong learning. *Lifelong learning* is an ongoing process that involves participation in formal and informal learning activities designed to develop or maintain competence, enhance professional practice, and support achievement of patient health care outcomes and individual career goals.

## How does continuing education differ from continuing professional development?

*Continuing professional development* is a specific process that fosters self-directed lifelong learning by which an individual pharmaceutical professional maintains and enhances his or her competence to practice. CPD encompasses all activities, both formal and informal, that the learner undertakes to maintain, develop, and improve his or her professional skills, knowledge, and attitudes in relationship to the needs of patients, work setting or organization, and society. Accordingly, CE is an essential component of the CPD process. The CPD process requires that individuals assume responsibility for their learning through a process of reflection, planning, learning, evaluation, and application (figure 3).<sup>9</sup> CPD is a personal professional obligation that is essential for improving the quality of health care.

**Figure 3. Continuing professional development (CPD) cycle**



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### Reflection

- Reflection is the process of identifying individualized learning needs and opportunities for improvement.
- Reflection involves the individual pharmaceutical professional reflecting on
  - Himself or herself as a person
  - Himself or herself as a professional
  - His or her professional practice
  - His or her knowledge and skills
  - His or her learning style and preferences
- Reflection should take place in two distinct ways:
  - A scheduled “reflection on practice” whereby the pharmaceutical professional proactively considers
    - ◆ The roles and responsibilities associated with his or her job
    - ◆ The competencies needed to effectively carry them out
    - ◆ His or her personal learning style and preference

As a result the pharmaceutical professional identifies learning needs and opportunities. Examples of when this reflection on practice could occur include during an annual performance review or before a proposed career change.

- Unscheduled “reflection in practice” whereby day-to-day experiences and encounters reveal learning needs and opportunities
  - ◆ Peers and supervisors can provide valuable feedback to assist with reflection.
  - ◆ Example: a situation or event occurred in the workplace and a gap in knowledge, skills, performance, or behavior was identified.
- Learning needs should be for the individual pharmaceutical professional and tied to the scope of his or her practice and needs of the work setting or environment.
- An individual asks himself or herself, “What do I need to know? What do I need to be able to do?”
- Employers can provide input through inclusion of reflection in an employee’s performance appraisal and goal-setting process.
- Employers (or other third parties, such as consultants or advisers; see Figure 2) can also identify learning needs when planning the introduction of a new service or the improvement of an existing process, technology, or system.
- In their reflection, individuals might consider input from a number of sources, including review of employer initiatives, local and national health care goals, and identification of new medicines or practice guidelines.

### **Box 2. Reflection Examples: Practice Examples**

*Questions to ask yourself:*

- What common disease states or medical problems do patients present with?
- What questions or requests do you regularly receive from patients, physicians, or other health care workers?
- What technical or logistical challenges or problems are commonly encountered that could be overcome with new systems or processes?
- What percentage of your day do you spend on various job-related activities?
- What services do you currently provide at your workplace?
- What services do you want to provide at your workplace?
- What skills and knowledge do you need to meet the daily expectations at your workplace and to overcome any challenges or problems?
- What skills and knowledge do you need to improve practice and systems related to your work?

*End result of this stage:*

- Identify and list two or three potential learning needs or opportunities.

### **Box 3. Examples of Reflection**

A pharmacist was working in the pharmacy when a patient who is pregnant and HIV-positive presented a prescription. On reflection, the pharmacist realized that he needed to be better informed regarding the current guidelines, adverse reactions of medicines, and contraindications of antiretrovirals in pregnancy.

Another pharmacist was approached by a patient with a question about a new antibiotic medicine used in the management of urinary tract infections. On reflection, the pharmacist realized she could not adequately answer the patient’s question and needed additional knowledge to provide better care to the patient.

## Plan

- Planning is the process of developing a learning plan designed to address the needs or opportunities identified through reflection.
- The plan should be individualized with SMART (Specific, Measurable, Attainable, Relevant, Timed) learning objectives and timelines for completion. The individual's needs should be prioritized as far as short-, medium- and long-term needs.
- The individual's learning style should be taken into consideration.
- Employers can assist pharmacy personnel by providing resources, including time for individuals to participate in CPD-related activities.
- The individual asks, "How can I learn? Do I need to look for a course on a particular subject provided locally or internationally? Physically or online? Can I do some self-study or read a journal article? Where do I begin? How will I demonstrate learning? Can my employer assist me with achievement of my learning needs? Is the course appropriate to meet my learning need? Is the course accredited?"
- Employers can assist individuals by asking, "How can I as an employer assist my employees? What resources do they need that I can provide or facilitate? How can organizational development goals be aligned with personal and professional development goals of employees?"

### Box 4. Planning Examples

#### *Immediate:*

A patient asked a pharmacist about the common side effects of an antiepileptic medicine. The patient needed the information in a timely manner so the pharmacist had to respond to the patient's request immediately by searching available information sources.

#### *Long term:*

The head of a hospital pharmacy in Uganda was continuously looking for ways to improve the services delivered at the hospital. He routinely attended CE training sessions. While there, he identified the need for a more systematic and formalized course that would allow him to better educate his staff regarding medication management.

## Learn

- The learning plan should be implemented.
- The learning activities chosen should be focused on specific outcomes and tied to the individual's learning objectives and goals.
- A variety of activities should be used, including formal CE, informal learning activities, and work-based learning. When documented (recorded), these activities can collectively form an evidence portfolio.
- The employer may seek evidence of the employee's learning in relationship to the individual's plan. Alignment with the organization's development goals and plans should also be evident.

### Box 5. Learning Examples

#### *Immediate:*

The pharmacist reviewed the medicine in question and was able to educate the patient about the medicine's side effects.

#### *Long term:*

The head of pharmacy participated in a donor- or university-supported program and ensured that other members of his team were included in future training activities.

## Evaluate and Apply

- Evaluation should encompass assessment of what has been learned and whether the learning objectives were achieved.
- The individual asks, “What have I learned? Did the activity meet my learning objectives? How can I implement it in my practice? Do I need to learn more in this area? Do I have new learning objectives to address?”
- The individual applies the new knowledge or skill in the workplace and evaluates whether the identified gap has been corrected or service level improved. The individual asks, “Has the way I work changed? What impact has my learning had—on my patients, my organization, delivery of health care?”
- Employers may ask, “Has the performance of my employee(s) improved? If not, what else needs to be done to improve performance in this area? What impact do we expect to achieve in our organization and the services we provide?”
- Evaluation is linked to a new reflection stage, ensuring that the CPD process includes continuous refinement and is ongoing.

### Box 6. Evaluate and Apply Examples

#### *Immediate:*

After reviewing the medicine’s side effects the pharmacist was able to adequately answer the patient’s questions. The pharmacist will be prepared should another patient have a similar question.

#### *Long term:*

The head of pharmacy provided his pharmacy staff with tools he received in training. The staff adopted the tools to improve medication management. The tools allowed the pharmacy staff to identify areas of weakness and formulate plans to improve those areas.

CPD encompasses both traditional CE and training activities and unstructured self-directed learning activities. CE and other formal training activities must be of high quality to produce the desired outcomes. Use of a formalized accreditation process provides quality assurance oversight to CE and training activities.

In various countries, requirements for completion of CE/CPD activities are often tied to relicensure. Many countries require completion of a certain number of CE hours on an annual or biannual basis for pharmaceutical professionals to be eligible for relicensure. Alternatively, countries that use a CPD approach to relicensure may require pharmaceutical professionals to accrue a certain number of CPD “points,” complete periodic competency-based self-assessments, and maintain a personal learning portfolio or logbook.

### Box 7. CE/CPD Requirements

Health care professionals registered with the Health Professions Council of Namibia must complete 30 CE units annually, of which at least 5 CE units should be for ethics, human rights, and medical law. Individuals who do not successfully complete 30 CE units are considered noncompliant. The consequences of noncompliance include the following: registration in a category that requires supervision; required participation in a remedial CE and training activity; completion of an examination; suspension from practice for a period; or another recommended action.

## Putting it all together—the CPD portfolio or logbook

Pharmaceutical professionals may find it helpful to keep a written record of their CPD process and outcomes to track knowledge and skill development and provide evidence of competence in the targeted areas (see samples in forms 1 and 2).

### Form 1. Personal CPD Recording Sheets

<b>Reflect:</b> What do/did you need to learn? What are your professional strengths and opportunities for development?			
List work-related situations from the past learning cycle in which you felt confident or competent:			
What knowledge/skills contributed to the successes above?			
List work-related situations from the past learning cycle that you need to feel more comfortable or satisfied with:			
What knowledge/skills would you want to develop or improve to better manage similar situations in the future?			
What areas of improvement does your supervisor recommend from your performance improvement?			
What knowledge/skills, attitudes, or values do you need to work on or acquire for the coming learning cycle?			
<b>Plan:</b> Personal Learning Plan			
Goal SMART Learning Objective	Resources Planned Activities	Time Frame	Completed?
<b>Act:</b> Activity Completion Tracker			
Date completed:		Time engaged in learning:	
Learning objective(s) (What did you learn?):			

Learning resources (What did you use to achieve your objectives?):

**Evaluation and reflection**

What did you learn?

Were your learning needs fully met? Partially met? Not met?

What barriers to learning did you experience? How may they be overcome in the future?

What new learning needs were identified as a result of this experience?

**Outcomes**

Identify which outcomes apply to this activity:

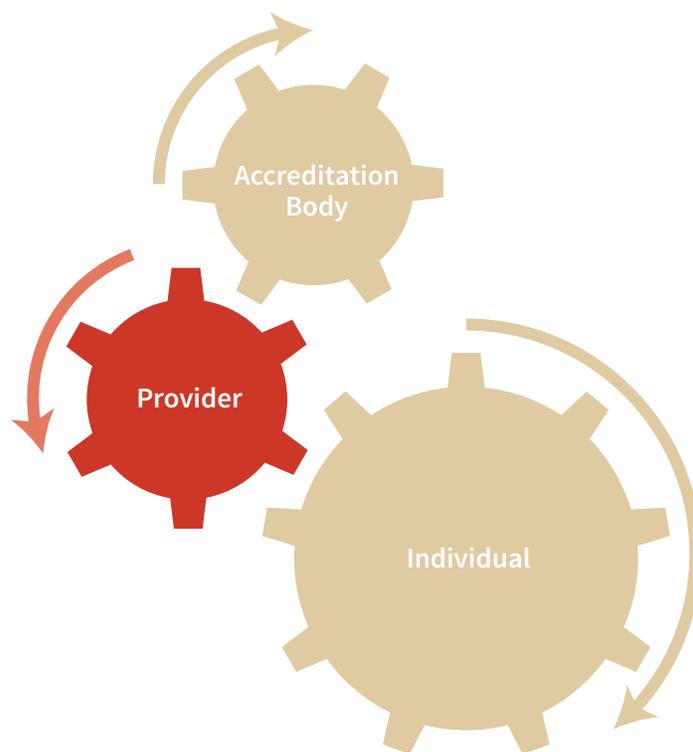
How will you change practice based on this learning? (Set specific goals.)

What additional information will you pursue? When and how will you pursue it?

Source: Adapted from *CPD Portfolio*, Accreditation Council for Pharmacy Education website, [https://www.acpe-accredit.org/pdf/CPD\\_Portfolio.pdf](https://www.acpe-accredit.org/pdf/CPD_Portfolio.pdf) (accessed June 30, 2014).



## Section II: Assuring the Quality of CE/CPD Training Activities



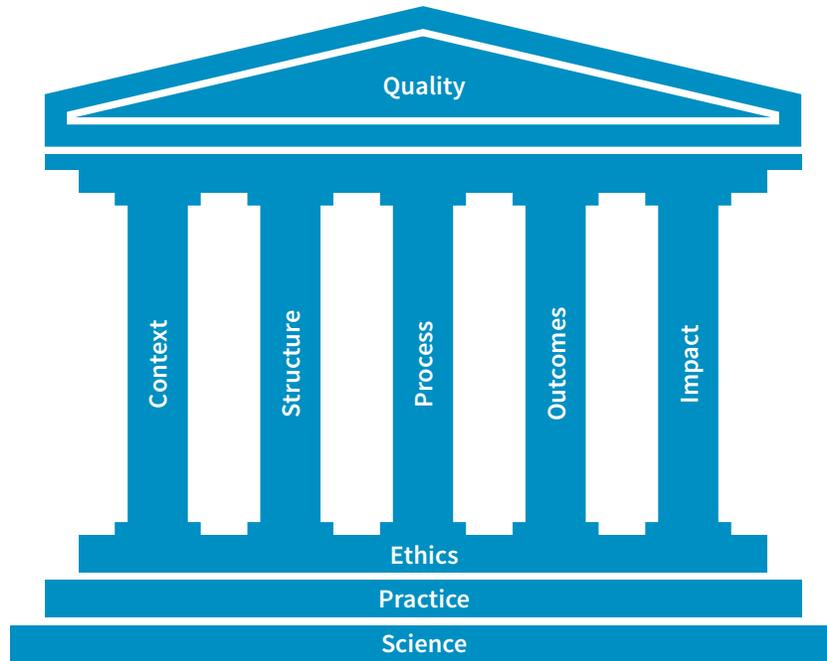
The provision of high-quality CE/CPD activities is essential to the CE/CPD process of individual pharmaceutical professionals. Activities that do not incorporate the criteria or standards for quality are less likely to address the educational gaps and needs of individual pharmaceutical professionals. Adherence to quality criteria or standards provides assurance to pharmaceutical professionals and other stakeholders, including regulators, that an activity has been reviewed for its educational quality and relevance to practice. Adherence can be ensured at the local level by individual CE/CPD providers (e.g., employer organizations who develop and provide CE/CPD activities for their own employees) or at the national level (e.g., national professional organization). In either case, the first step in ensuring the quality of individual CE/CPD and training activities is to define the elements that, when implemented in concert, lead to the production of high-quality CE/CPD and training activities.

### What are the elements of high-quality continuing pharmacy education activities?

The criteria or standards for CPE describe the key principles and elements that should be included in the accreditation process (figure 4). The criteria provide a basis for CE/CPD and training activities that addresses the *context, structure, process, outcomes, and impact* of the CE/CPD activity and are based on a well-accepted strategy for assessing quality. The criteria, taken together, provide the basis within which CE/CPD and training activities can be designed, implemented, and evaluated and can serve as a tool to facilitate the assessment of quality for CE/CPD and training in countries where formal systems are lacking or in the quality improvement of existing systems. Such criteria may be implemented at the local,

regional, or national level. Locally, individual hospitals or employers can evaluate potential CE/CPD and training activities against the quality criteria to assess their quality prior to pharmaceutical professionals' participation. Similarly, regional organizations or CE providers can use the criteria to determine quality.

**Figure 4. Pillars and foundations of educational quality<sup>10</sup>**



## Context

Ideally, the CE/CPD and training activities should address the educational needs of the pharmaceutical professionals within the target audience in relation to local, regional, or national health care needs. Many environmental factors need to be accounted for when considering the context for an educational activity; they include political, social, regulatory, professional, and technical issues. Learning needs should relate to “gaps” in knowledge, skills, attitudes, values, behaviors, performance, or practice that have been observed or documented. Gaps indicate a difference between where pharmaceutical professionals are currently in their knowledge, skill, or practice and where they need to be to achieve the desired health care outcomes. Many sources can be used to identify pharmaceutical professionals’ needs, including national health care initiatives, health institutions’ health care goals, and the like.<sup>11</sup>

Pharmaceutical professionals should choose activities that address their individual learning needs or goals. Activities chosen should be appropriate to the individual’s current level of knowledge and experience. As noted previously, pharmaceutical professionals must identify their own learning needs through a process of reflection, possibly with assistance from relevant third parties (such as employers), and develop a plan that involves choosing activities that can assist in addressing such needs.

### Box 8. Needs Assessment Example

A new program has the following objectives:

- Strengthening pharmaceutical sector governance
- Building individual, organizational, and institutional capacity for pharmaceutical supply management and services
- Addressing the information for decision-making challenges in the pharmaceutical sector
- Strengthening financing strategies and mechanisms to improve access to medicines
- Improving pharmaceutical services to achieve desired health outcomes

For the delivery of pharmaceutical services in the following areas:

- Malaria and other communicable diseases
- Tuberculosis
- Human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS)
- Maternal, newborn, and child health
- Family planning and reproductive health

How can a district hospital manager define the gaps in delivery of pharmaceutical services and the capacity staff needs to achieve the program objectives?

For CE/CPD providers, a systematic and structured process of learning needs assessment should be used to identify the need for the activity and provide the basis for the development of learning objectives and content. Providers should determine the gap between what pharmaceutical professionals do know or can do and what they should or want to know or be able to do. Resources that may be used to determine the educational needs include the following:

- Local or national government development or adoption of health care goals or guidelines
  - World Health Organization (WHO) Millennium Development Goals
    - ◆ Reduce child mortality
    - ◆ Improve maternal health
    - ◆ Combat HIV/AIDS, malaria, and other diseases
  - WHO revised guidelines for HIV treatment
  - FIP Education Initiatives, Pharmacy Education Taskforce: Global Competency Framework (version 1)<sup>12</sup>
- Input from committees or advisory groups (e.g., hospital safety committee)
- Epidemiologic data
- Quality assurance and audit data
- Incident and event reports
- Infection control or other disease statistics
- Professional society or national requirements
- New pharmaceutical agents or treatments
- New medication related technology or techniques
- Input from experts regarding advances in medical knowledge
- Input from technical and logistics experts
- Acquisition of new facilities or equipment
- Legislative, regulatory, or organizational changes
- Needs assessment surveys completed by pharmaceutical professionals (see form 3 for an example of a needs assessment survey)

**Form 3. Sample Needs Assessment Survey Questions for Planning CE Activities**

**What is your position?**

- Pharmacist
- Pharmacy technician/pharmacy assistant/pharmaceutical technologist
- Medicine shop attendant
- Druggist
- Dispenser

**Indicate your present and needed level of knowledge/skill regarding the following disease states.**

<b>1</b>	<b>2</b>	<b>3</b>
No knowledge, skill, or experience	Working knowledge, skill, experience	Mastery knowledge, skill, experience

<b>Topic</b>	<b>Present level</b>			<b>Needed level</b>		
Malaria	1	2	3	1	2	3
Other communicable diseases	1	2	3	1	2	3
Tuberculosis	1	2	3	1	2	3
HIV and AIDS	1	2	3	1	2	3
Family planning and reproductive health	1	2	3	1	2	3
Noncommunicable disease	1	2	3	1	2	3

**What specific area should the CE activity address? What specific area is needed to ensure continued competence to practice?**

- Advise population on health promotion/disease prevention
- Pathophysiology/pharmacology
- Treatment/monitoring strategies
- Outcomes documentation
- Education/counseling

**Please rank the following in priority order of need to address:**

- \_\_\_\_\_ Rational use of medicine
- \_\_\_\_\_ Antimicrobial resistance
- \_\_\_\_\_ Pharmaceutical care
- \_\_\_\_\_ Pharmacovigilance
- \_\_\_\_\_ Supply chain management
- \_\_\_\_\_ Pharmaceutical information systems

Are additional needs not included in this list? List/explain.

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Source: Adapted from Accreditation Council for Pharmacy Education, Needs Assessment Survey Questions for Planning CE Activities. unpublished internal document (June 2014).

The context should address the question: “What is the knowledge, skill, attitude, practices, or value-based need for the CE activity?” The educational need then drives the development of the particular CE/CPD activity. Without first adequately considering the *context*, the desired *outcomes* and *impact*—as discussed further in the text—may not be achieved.

## Structure

Data obtained from the needs assessment process should be used to structure the learning activity to optimize achievement of the desired outcomes. Ideally, CE activities should close the gap between the pharmaceutical professionals’ current knowledge or skills and what is desired. Identification of the needed knowledge or skills provides a focus for developing the learning objectives, content, and teaching and learning strategies.

Learning objectives should be developed based upon what the participant should be able to do following the CE/CPD or training activity. Learning objectives must be appropriate to the competencies and scope of practice of the target audience (pharmacists and pharmacy support staff). In aggregate (when all educational and training activities are taken into account), objectives should address all competency areas (knowledge, skills, attitudes, practices, and values).

Objectives are essential to the development of a quality CE/CPD activity because they (1) relate to the educational need identified; (2) guide the development of educational content; (3) influence the selection of active learning techniques; (4) provide the framework for learning assessment; and (5) outline the potential outcomes and impact of the activity.

In addition, educational activities should use SMART learning objectives, thereby ensuring that outcomes are specific and measurable. In this regard learning objectives should be

<b>Specific:</b>	Precise about the desired achievement
<b>Measurable:</b>	Quantifiable, so progress and achievement can be monitored
<b>Achievable:</b>	Realistic in their expectations
<b>Relevant:</b>	Aligned with workplace activities/services and organizational goals
<b>Timed:</b>	Have a specified time frame for achievement

Learning objectives should

- Include verbs that describe actions that can be observed or measured (see table 1)
- Use only one verb for each objective
- Describe the outcome from the learner’s perspective
- Be used to determine the appropriate teaching methods

### Box 9. Development of Learning Objectives

#### *Context or need:*

- National epidemiologic data have demonstrated that malaria is being undertreated.
- Management of patients with malaria needs to be improved.

#### *The activity has a statement of specific learning objectives:*

- Provide refresher training on malaria management to health care workers.
- Counsel patients regarding medications used in the treatment of malaria.
- Identify common adverse drug reactions of antimalarial medications.
- Identify common drug interactions of antimalarial medications.

**Table 1. Examples of Verbs That May Be Used**

Acquisition of knowledge	Enhancement of thinking skills	Development of psychomotor skills	Changes in attitudes, values, and feelings
chart	analyze	adjust	adopt
define	catalogue	assemble	advocate
describe	classify	check	challenge
distinguish	compare	conduct	choose
explain	compute	construct	defend
identify	contrast	demonstrate	dispute
inform	differentiate	detect	express
label	evaluate	draw	judge
list	formulate	manipulate	justify
outline	investigate	perform	persuade
prepare	modify	produce	question
rank	organize	sort	select
specify	plan		
state	research		

Source: Selected verbs from Caffarella RS. *Planning Programs for Adult Learners*. San Francisco: Jossey Bass; 1994.

Presenters should be qualified in terms of both experience and teaching ability and be able to adapt their teaching style based on the learning styles of participants. To prepare for the CE activity, presenters should refer to the checklist (see Form 4). Teaching methodologies should take into account and address the needs of diverse learners, including the following:

- Different learning styles and preferences
- Generational issues, cultural distinctions, and implications
- Different practice backgrounds
- Different educational qualifications
- Differing levels of prior work experience

Presenters should be free of conflict of interest. A *conflict of interest* exists when an individual has an opportunity to affect CE/CPD content about products or services of a commercial interest with which he or she has a financial relationship. *Commercial interests* are considered to be any entity producing, marketing, reselling, or distributing health care goods or services consumed by, or used on, patients.

CE/CPD providers should ensure that all individuals involved in planning the CE/CPD activity, including presenters and members of any planning committees, if applicable, complete and sign a conflict of interest disclosure form (see Form 5 for a sample). The presenters must make a full disclosure of any relevant connection, affiliation, or interest. Anyone who refuses to complete and sign a conflict of interest disclosure form should be disqualified from any involvement in the CE/CPD activity.

If a potential for conflict of interest exists, it must be managed. In this regard, CE/CPD providers should have an established mechanism to identify and resolve all relevant financial relationships that create conflicts of interest prior to the educational activity. Mechanisms that may be used to resolve conflicts of interest are listed in Table 2.

#### Form 4. Sample Presenter Guidance Checklist

**CE/CPD providers should provide presenters with guidance regarding their expectations for the activity or course. Ideally, presenters should receive written guidance materials that outline any expectations for the activity or course and provide guidance regarding how to achieve the expectations.**

Activity title: \_\_\_\_\_

Presenter name: \_\_\_\_\_

Completed by: \_\_\_\_\_

- A description of the target audience including its expected composition (pharmacists only or pharmacists and pharmacy assistants/technicians)
- A description of the educational needs/gap that serves as the basis for the CE/CPD activity
- Learning objectives
  - Expectation that learning objectives will be SMART objectives
  - Expectation that learning objectives will be based on the educational need/practice gap and will describe the intended competency improvement
- Expectation that teaching methodology will include active learning
- Expectations regarding instructional materials
- The provider's policy on equitable and fair balance/conflict of interest and policies and procedures regarding disclosure forms
- Expectation for inclusion of learning assessment in the offering and expectations with regard to use of learning assessment and provision of feedback to participants
- Means by which activity/course and presenter will be evaluated
- Specific areas addressed on participants' evaluation form

*Source:* Adapted from Faculty Guidance Checklist, Information for CE Providers, Accreditation Council for Pharmacy Education website, <https://www.acpe-accredit.org/ceproviders/resources.asp> (accessed June 30, 2014).

**Table 2. Mechanisms to Resolve Conflicts of Interest**

Type of resolution	Examples
Evaluate the role of the presenter	<ul style="list-style-type: none"> <li>▪ Choose another speaker</li> <li>▪ Limit the content to a report without recommendations</li> <li>▪ Change the content so it does not relate to the conflict</li> </ul>
Use an external validation process	<ul style="list-style-type: none"> <li>▪ Have the content reviewed by another qualified individual</li> <li>▪ Require presenter to reference the best available resources</li> </ul>

If providers receive financial support from a commercial interest, the provider should ensure that all decisions regarding the disposition and disbursement of funding are made by the provider. The commercial interest should not be able to condition provision of funds on stipulations regarding content or presentation of activity.

Written agreements documenting the terms of support should be developed and signed by both the provider and the commercial interest. Commercial interests should not be allowed to advertise or exhibit materials during the CE/CPD activity. Advertising and promotional materials should not be displayed or distributed in the educational space (including access points and areas close to the room or area in which the activity is delivered) immediately before, during, or after an activity. The content and format of CE/CPD and training activities should promote improvement in quality health care and should not promote a specific proprietary business interest. Presentations must provide a balanced view of therapeutic options and should include generic names of any pharmaceutical agents. Providers should routinely monitor CE/CPD activities for perceptions of bias on behalf of the participants. These recommendations do not preclude pharmaceutical companies or other commercial interests from organizing events to promote their products or services, but such events should be treated as promotional and not educational events.

Sources of commercial support and relevant financial relationships for all faculty and individuals with the potential to control content of a CE/CPD activity should be disclosed to participants before the beginning of the activity. Disclosing to participants the relevant financial relationships that were present and resolved assists participants in assessing the potential for bias in information that is presented. Such disclosure contributes to the transparency and accountability of the system.

Content must be balanced, objective, evidence based, referenced, and unbiased, especially free from commercial interest and promotional activity. Additional materials and resources should be provided to participants (or cited) to enhance comprehension and application of the material in practice. The setting, environment, and facilities must be conducive to learning and enhance the learning experience.

**Form 5. Sample Conflict-of-Interest Disclosure Form**

The XXXX Agency offers this document as a template for providers to use for obtaining relevant financial relationship information. With modification it could be used for teachers, authors, and members of planning committees. It offers the provider the opportunity to be explicit about the expectations of CE/CPD activities.

Dear <insert name of Presenter/Author/Teacher>:

**Re: Relevant Financial Relationships with Commercial Interests**

We are pleased that you are willing and able to participate in our CE/CPD activity scheduled for <Insert date> at the <insert location> in <insert city>.

<Insert Accredited Provider Name> is accredited by the XXX Agency. As such, we have made the choice to meet the Agency’s expectations for our practice of continuing pharmacy education. Our accreditation is important to us. We look forward to working together to provide CE/CPD at the highest standard.

The activity we have asked you to participate in is based on <insert identified need>. We have planned the activity so that <insert expected result>. The purpose or objective of your contribution is <insert purpose or objective> and we expect the content will relate to <insert summary of content>.

<Insert Accredited Provider Name> has implemented a process where everyone who is in a position to control the content of an education activity has disclosed to us all relevant financial relationships with any commercial interest (see below for definitions). In addition, should it be determined that a conflict of interest exists as a result of a financial relationship you may have, this will need to be resolved prior to the activity. In order to do this, please provide us with the following information by <insert date>. This information is necessary in order for us to be able to move to the next steps in planning this CE/CPD activity. If you refuse to disclose relevant financial relationships, you will be disqualified from being a part of the planning and implementation of this CE/CPD activity.

**First**, list the names of proprietary entities producing health care goods or services, consumed by, or used on, patients, with the exemption of non-profit or government organizations and non-health care related companies with which you or your spouse/partner have, or have had, a relevant financial relationship within the past 12 months. For this purpose we consider the relevant financial relationships of your spouse or partner that you are aware of to be yours.

**Second**, describe what you or your spouse/partner received (e.g., salary, honorarium, etc.). <Insert Accredited Provider Name> does NOT want to know how much you received.

**Third**, describe your role.

Commercial Interest	Nature of Relevant Financial Relationship (Include all those that apply)	
	What I received	My role
<i>Example: Company 'X'</i>	<i>Honorarium</i>	<i>Speaker</i>
<input type="checkbox"/> <b>I do not have any relevant financial relationships with any commercial interests</b>		
Signature		Date

**What was received:** Salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit.

**My Role(s):** Employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities.

Again, thank you for agreeing to work with us in this CE/CPD activity. We look forward to this activity making an important contribution to the continuing professional development of our learners and to your professional practice.

Sincerely,

<Insert Name>

<Insert Job Title>

## **GLOSSARY OF TERMS**

### **Commercial Interest**

The XXXX Agency defines a “commercial interest” as any entity producing, marketing, reselling, or distributing health care goods or services consumed by, or used on, patients. Providers of clinical services directly to patients are not “commercial interests.”

### **Financial Relationships**

Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received or expected. The XXXX Agency considers relationships of the person involved in the CE/CPD activity to include financial relationships of a spouse or partner.

### **Relevant Financial Relationships**

The XXXX Agency focuses on financial relationships with commercial interests in the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CE/CPD activity. The XXXX Agency has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship. The XXXX Agency defines “relevant financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

### **Conflict of Interest**

Circumstances create a conflict of interest when an individual has an opportunity to affect CPE content about products or services of a commercial interest with which he or she has a financial relationship.

Source: Adapted from ACPE Disclosure Form Relevant Financial Interests (Template), Information for CE Providers Checklists and Samples, Standard 5, Accreditation Council for Pharmacy Education website, <https://www.acpe-accredit.org/ceproviders/resources.asp> (accessed June 30, 2014).

## Process

The activity format for CE/CPD activities should be chosen to assist with achievement of the learning objectives. CE/CPD activities can be classified as live or enduring activities. Live formats can include activities where the learner and presenter interact in person (e.g., conferences, seminars) as well as online activities that allow real-time interactions between the learner and the presenter. Enduring activities include printed, recorded, or computer-presented content that can be used over time (e.g., journal publications, web-based CE/CPD that does not allow real-time interaction). Journal and computer-based CE/CPD activities typically require learners to read an article and complete a learning assessment.

Active engagement of the participant is critical to the learning outcomes achieved in CE/CPD and training activities.<sup>13,14</sup> Active engagement encourages learners to actively participate in the activity by using the knowledge gained during the activity. Active engagement requires learners to talk, listen, and reflect on the information presented. CE/CPD and training activities should use learning strategies that are based on adult learning principles, account for the learning styles of participants, and where appropriate, engage pharmacists and pharmacy support staff.

Active-learning strategies should provide feedback to participants during the CE/CPD activity regarding the adequacy of their learning, such as taking polls to test information being covered and discussing why answers given were wrong during the assessment of learning. Although such methodologies pose a greater challenge for the individual presenter and provider organization, they are accepted as best practice for effective teaching and learning.

Examples of active-learning strategies include but are not limited to the following:

- Ask what learners would like to be addressed at the beginning of the activity and use that information to guide the activity.
- Incorporate a brief pause to allow participants to review and reflect on information presented.
- Ask a question and request a show of hands from learners regarding possible answers.
- Ask a question and then request learners to share their answer with the person next to them.
- Start the activity with a review of the learning objectives and end with a summary of each of the objectives.

Table 3 provides additional examples of active-learning strategies matched to the learning objectives of the CE/CPD activity. Use of such learning strategies is intended to facilitate participants' achievement of the learning objectives.

**Table 3. Examples of Active-Learning Strategies**

<b>Bloom's taxonomy</b>	<b>Suggested active-learning techniques</b>
<i>Knowledge-type verbs</i> Define List Record Repeat	Lecture Visuals Examples Illustrations Analogies
<i>Comprehension-type verbs</i> Describe Discuss Explain Identify Recognize Translate	Test/assessment Matching questions/answers Questions Discussion Report
<i>Application-type verbs</i> Apply Demonstrate Illustrate Interpret Use	Role play Simulations Practice exercises Demonstrations Projects
<i>Analysis-type verbs</i> Analyze Calculate Compare/Contrast Debate Diagram Differentiate Distinguish	Case studies Problems Discussion Pro/con grids Application exercises
<i>Synthesis-type verbs</i> Arrange Construct Create Compose Design Formulate Organize Plan Prepare Propose	Problems Case studies Plan development Simulations Projects
<i>Evaluation-type verbs</i> Assess Choose Evaluate Judge Select	Case studies Problem exercises Projects Critiques Simulations

Source: Information for CE Providers Checklists and Samples, Standard 4, Suggested Acceptable Verbs, Accreditation Council for Pharmacy Education website, <https://www.acpe-accredit.org/ceproviders/resources.asp> (accessed June 30, 2014).

CE/CPD and training activities should provide the opportunity for participants to evaluate whether the activity met the following objectives (see sample in form 6):

- The CE/CPD or training activity met their individual educational needs.
- The content was aligned with the learning objectives.
- Each stated learning objective was achieved.
- The participant's competency was improved.
- The quality of the presentations (e.g., presentation skills of presenters) was adequate.
- The educational materials provided were useful.
- Learning methods used were effective in achieving the learning outcomes.
- The learner will use what was learned to make changes at his or her workplace.
- The learning assessment activities were appropriate.
- Participants perceived any bias or commercialism.

Data from such assessments and evaluations should be provided to the individual instructor and used for quality improvement of future activities and the overall educational enterprise (see form 7).

#### Form 6. Sample Questions for CE/CPD Evaluation Form

*Sample questions:*

(1 = Strongly disagree to 5 = Strongly agree)

- |   |   |   |   |   |   |
|---|---|---|---|---|---|
| ▪ Participation in this CE/CPD activity will enable me to       |   |   |   |   |   |
| • < insert Objective 1 >  | 1 | 2 | 3 | 4 | 5 |
| • < insert Objective 2 >  | 1 | 2 | 3 | 4 | 5 |
| • < insert Objective 3 >  | 1 | 2 | 3 | 4 | 5 |
| ▪ The content was relevant to my practice/workplace.            | 1 | 2 | 3 | 4 | 5 |
| ▪ The activity presented was free from bias.                    | 1 | 2 | 3 | 4 | 5 |
| ▪ The content was fair and well balanced.                       | 1 | 2 | 3 | 4 | 5 |
| ▪ The presenter was clear and to the point.                     | 1 | 2 | 3 | 4 | 5 |
| ▪ The presenter kept my attention.                              | 1 | 2 | 3 | 4 | 5 |
| ▪ The presenter demonstrated mastery of the subject.            | 1 | 2 | 3 | 4 | 5 |
| ▪ The instructional materials were of appropriate length.       | 1 | 2 | 3 | 4 | 5 |
| ▪ The instructional materials complemented the presentation.    | 1 | 2 | 3 | 4 | 5 |
| ▪ The instructional materials were well organized.              | 1 | 2 | 3 | 4 | 5 |
| ▪ The instructional materials will serve as a useful reference. | 1 | 2 | 3 | 4 | 5 |
| ▪ Active learning activities were appropriate to the content.   | 1 | 2 | 3 | 4 | 5 |
| ▪ Active learning activities helped me achieve the objectives.  | 1 | 2 | 3 | 4 | 5 |

*How can future CE/CPD activities be improved?*

- What did you like best about the CPE activity?
- What did you like least about this activity?
- Suggest one change to improve future CPE activities.
- What will you tell others about this activity?
- I would rate my level of involvement as \_\_\_\_\_ because: \_\_\_\_\_.

Source: Adapted from Information for CE Providers Checklists and Samples, Standard 11, Sample Activity Evaluation Form Questions, Accreditation Council for Pharmacy Education website, <https://www.acpe-accredit.org/ceproviders/resources.asp> (accessed June 30, 2014).

## Form 7. Guidance for Interpreting Feedback from Activity Evaluation

### 1. Did the activity accomplish what was planned?

- Was there consensus among the participants that the activity achieved the learning outcomes?  
*Consensus among participants provides stronger evidence for the utility of the data collected. Large variations among participants indicate their perceptions may differ. Significant outliers should be viewed cautiously.*
- Did the activity meet or exceed expectations?  
*Activities that did not meet expectations should be carefully analyzed to identify issues contributing to participants' findings.*
- Were there other outcomes beyond those which were planned?  
*Unexpected outcomes, both favorable and unfavorable, should be reviewed and evaluated to identify the reason for the findings.*
- What needs to be improved?  
*The areas that scored the worst should be carefully analyzed to determine ways they might be improved.*
- Are case studies applicable in both public and private settings?  
*Findings should be carefully analyzed to determine if any significant differences exist between represented practice settings. Did pharmaceutical professionals in one practice setting rate the question differently from those in another practice setting? Such differences may indicate the need to add additional information pertaining to pharmaceutical professionals in one practice setting or another.*

### 2. If the activity did not accomplish what was planned, where did the activity fail and why?

- Did the evaluation provide specific enough detail to indicate where the activity failed?  
*If sufficient detail was not obtained, the evaluation form should be revised accordingly. Subsequent analysis should be conducted on the revised evaluation form.*
- Can the problem be linked to the activity design and development or to activity delivery?  
*Issues should be carefully analyzed to determine the source of any problems.*
- At what stage(s) of the planning and delivery process did the activity fail?
- What caused the activity to fail?

### 3. How should the activity be revised if it is offered again?

- Are decisions about adjustments to the activity based on assumptions or facts?  
*Evaluation data should be used as the basis for making adjustments.*
- Were the activity deficiencies a one-time happening or do they represent a basic flaw within the activity?  
*Analysis should be conducted to determine the root cause of the problem. Did something unforeseen occur at the activity that may contribute to poor findings of the evaluation data? Or does the activity have a flaw that should be addressed before the activity is offered again?*
- What is likely to occur if certain adjustments are made?  
*The expected outcomes of adjustments should be considered and evaluated in future activities.*

### 4. What was learned from one activity evaluation that can be used in strengthening other activities?

- Did the evaluation reveal a problem or trend that might be occurring in other activities, perhaps a problem that has not been identified by other activity evaluations?  
*The evaluation results should be reviewed to determine if changes should be made in other and future activities.*
- Can the findings from successful activities be applied to other activities?  
*Activities that are well received should be carefully analyzed to determine the factors that led to their success. These factors should be incorporated into future programs to verify their benefits.*

Source: Adapted from Information for CE Providers Checklists and Samples, Standard 11, Guidance for Interpreting Feedback from Activity Evaluation, Accreditation Council for Pharmacy Education website, <https://www.acpe-accredit.org/ceproviders/resources.asp> (accessed June 30, 2014).

Commitment-to-change statements can be used to affect and measure practice change.<sup>15</sup> A commitment-to-change statement is, in essence, a written contract in which a pharmaceutical professional commits to making a change in future behavior or practice. The statements do not need to be signed. Participants view such statements as a promise to be kept.<sup>16</sup> The effectiveness of the commitment-to-change model can be found in three questions asked of participants:

- “Based on your participation in the continuing education activity, will you make a change in your practice?”
- “Did you make the intended change?”
- “What prevented you from making the change?”<sup>17</sup>

Participants who commit to making changes are more likely to implement a change in their practice than participants who do not commit.<sup>18</sup>

## Outcomes

Ideally, CE/CPD and training activities must contribute to the continuing development of pharmaceutical professionals to ensure their continued fitness for practice. Learning outcomes should be assessed in an effort to ensure such fitness for practice. Activities should be evaluated in relation to the educational needs assessment and knowledge or skills gap identified. The focus should be on determining if the gap was addressed.

Demonstration of learning (rather than simply participation) should be used for purposes of awarding CE/CPD credit in countries that use credit-based systems. Learning outcomes should be aligned with the knowledge and skills gaps and daily practice needs of the pharmaceutical professionals as well as goals and objectives of the professional and technical organizations. In the “pillars of quality” model, *outcomes* are considered to be immediate or short-term and directly associated with or related to the educational intervention; and relatively easily observed or measured (see Table 4). At the lowest levels, outcomes include participation and satisfaction (level 1 and level 2 in the Expanded CME Framework).<sup>19</sup> These outcomes are assessed through the CE/CPD course evaluation form. At the next higher levels, outcomes relate to learning, competence development, behavior changes, and performance improvement (outcomes levels 3, 4, and 5).

**Table 4. Levels of Outcomes**

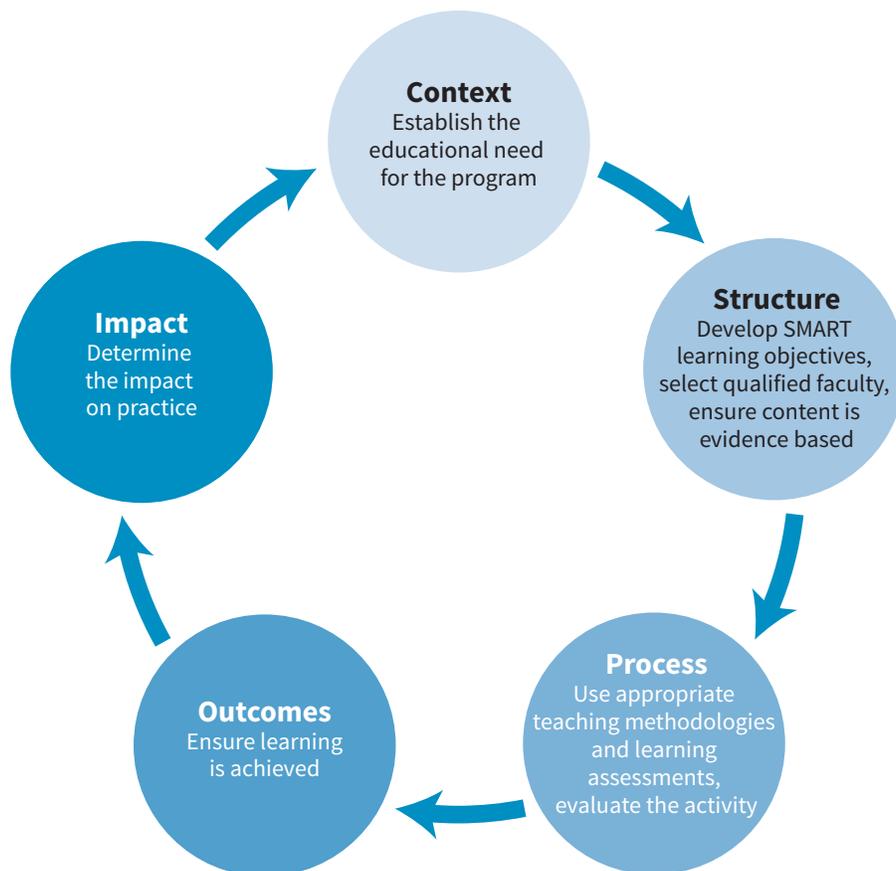
Level	Outcome	Assessment method
1	Participation	Course evaluation form
2	Satisfaction	
3	Learning	Learning assessment tools
4	Performance	Commitment-to-change forms; direct observation by trained assessors
5	Patient health	Patient outcomes
6	Population health	Population outcomes

## Impact

In the “pillars of quality” model, *impact* is considered to be local, national, and social changes and advances at higher level. Impact is more challenging to measure and, in general, factors other than CE/CPD activities have a role. Assessment of the impact of CE/CPD activities, although more challenging, should be undertaken whenever possible. Ideally, participation in CE/CPD activities should lead to practice and behavior changes that have a positive impact for the pharmacist’s organization, patients, populations, and national health–related issues. Impact is often indicated by increased motivation on the part of the pharmaceutical professional. Such motivation can lead to a greater sense of responsibility and commitment to change. As a result, pharmacist and pharmacy support staff competencies and job responsibilities can be developed or enhanced, and new projects, services, or activities can be developed in the pharmaceutical professional’s workplace.

CE/CPD activities do not fully achieve their desired objectives unless accompanied by changes in the behavior and competence of pharmaceutical professionals. True success is not in the CE/CPD or training activity itself, but in the application of what is learned within the CE/CPD or training activity and the associated benefit to health care.<sup>20</sup> This approach views CE/CPD and training as a process that leads to a measurable increase in knowledge and skills and observable improvement in attitudes, values, and behaviors that contribute to changes in competence and practice.

**Figure 5. “Pillars of quality” cycle demonstrates the relationship between the five pillars (context, structure, process, outcomes, and impact) in the CE activity development process**



## What are the foundations of quality education?

In addition to addressing the five pillars (context, structure, process, outcomes, and impact), quality education should be based on three foundations: *science* (knowledge, such as evidence or facts), *practice* (skills and experience), and *ethics* (attitudes and values). The choices that pharmaceutical professionals make throughout practice require the application of knowledge that is based on prior experience and personal values; these choices are also aligned with their professional and technical roles and responsibilities.<sup>21</sup> The effectiveness of such decisions is a measure of an individual's competence. Based on his or her knowledge, experience, attitudes, and values, a competent pharmaceutical professional has to make the *best* decisions and to establish an appropriate relationship with patients and colleagues, including other health care professionals.<sup>22</sup> Educational activities should address all competency areas, namely knowledge, skills, attitudes, and values.

Historically, CE/CPD and training activities have typically focused on acquiring new knowledge.<sup>23</sup> The rationale for focusing on obtaining new knowledge includes the following factors: (1) knowledge-based activities are typically easier to deliver; (2) qualified and willing presenters are often plentiful; (3) funding from the pharmaceutical industry has historically been available to support such activities (in accordance with the codes of conduct in place for regulation of the industry in the country); and (4) the method of delivery (didactic, lecture based) suits the most commonly preferred learning style of participants and can be used in the delivery of activities with a large audience.<sup>24,25</sup>

### Science

CE/CPD and training activities should be developed from a scientific foundation. A scientific or data-driven, evidence-based foundation validates the activity and increases its authenticity. Educational activities should use and appropriately cite evidence from the medical, pharmacy, scientific, and technical literature. Content of educational activities should not include any inaccurate interpretations of scientific data leading to recommendations that cannot be supported by evidence or unapproved uses. Presenters should be adequately educated, unbiased, and qualified and experienced in their field. Content lacking an evidence base (e.g., opinions or anecdotes) should not be provided in materials or included verbally during the presentation; this includes content presented at round tables and panel discussions led by experts.

Conflicts of interest can arise when educational activities are used as marketing tools by members of the pharmaceutical industry or by wholesalers. It cannot be assumed that an educational activity is of poor quality based solely on the fact that it is organized or supported by a pharmaceutical company. Many pharmaceutical companies recognize pharmaceutical professionals as partners in patient care and support their education and professional development. In some countries, however, it has been necessary to introduce standards or criteria for commercial support of CE activities (e.g., Accreditation Council for Continuing Medical Education Standards for Commercial Support).<sup>26</sup> A code of conduct for the pharmaceutical industry's interactions with health care professionals has also been adopted (Pharmaceutical Research and Manufacturers of America Code).<sup>27</sup> Highlights of this code include the following:

- Financial support for CE/CPD and training activities is intended to support the full spectrum of treatment options and not promote a specific pharmaceutical agent.
- Financial support should be given to the CE/CPD provider who in turn should determine how the funding will be used.

- The CE/CPD provider should have control over the development of the learning objectives and the selection of content, presenter, educational methods, materials, and location of the activity.
- Financial support should not be offered to cover the costs of travel, lodging, or other personal expenses of the learners.

**Box 10. Sample Accreditation Application Process for a CPE Activity**

As previously explained, the criteria or standards (e.g., pillars and foundations of educational quality) describe the core elements for accreditation and can serve as a tool to facilitate the establishment of accreditation standards in low-resource countries. These criteria may be used by individual providers (i.e., employers, hospitals, pharmacies, etc.) in the absence of a national CE/CPD accreditation system. Aspects of these elements are often found in the criteria used by many accreditation bodies around the world, including the following:

Step 1: Identify the Need	The activity is based on an identified performance gap or educational need.
Step 2: Develop Objectives	Clear, measurable learning objectives have been developed based on the educational need identified in step 1.
Step 3: Identify Presenters	Presenters are qualified by background, experience, and training to deliver the CE/CPD and training activity. The presenters identified do not have conflicts of interest.
Step 4: Develop Content	The content of the activity is fair, unbiased, and related to current standards of care. The content is based on relevant literature, practice-based professional evidence, or both.
Step 5: Develop Teaching	The method of delivery used is appropriate to and will assist learners in achieving the learning objectives.
Step 6: Instructional Materials	Develop written materials that will be given to learners that will enhance their achievement of the learning objectives.
Step 7: Learning Assessment	Determine the method that will be used to assess if learners achieved the learning objective. Achievement of the learning objectives can be viewed as addressing the educational gap.
Step 8: Evaluation	Develop an evaluation tool that will give learners the opportunity to assess the activity. Intent to maintain or change behavior pertaining to the learning objectives can also be assessed.
Step 9: Outcome/Impact	The outcomes and desired impact of the CE/CPD activity, as well as measures and evaluation strategies, have been identified.

## Practice

Another important foundation of quality includes the practical aspect of CE/CPD and training activities. CE/CPD and training activities should include clear and relevant links to the practical applications of the material. Wherever possible, CE/CPD and training activities should use practicing pharmaceutical professionals as presenters because activities are more likely to be rated highly when the presenter is viewed as experienced in the content area. To facilitate application of the content, CE/CPD and training activities should be interactive and include practical examples that promote problem solving and critical thinking (e.g., case studies). CE/CPD and training activities should incorporate up-to-date changes to pharmacy practice.

## Ethics

CE/CPD and training activities that incorporate the ethical aspect of practice will encourage pharmaceutical professionals to reexamine their motives, values, and attitudes. Such introspection on the part of pharmaceutical professionals is crucial to bring about change and improvement in health care. Principles of professional ethics and autonomy should be used to promote optimal patient care. CE/CPD activities should incorporate ethical issues where appropriate. Educational processes that shape behavior are considered to be of highest value because they tend to increase motivation and professionalism and to advance the reputation of the pharmacy profession in the health system.<sup>28-31</sup> CE/CPD and training activities, through the incorporation of ethical issues, should strive to build the self-image of pharmaceutical professionals, foster a commitment to change, and enhance the professional autonomy and personal development of pharmacists and pharmacy support personnel.<sup>32-34</sup>

Providers can use the Sample Activity Evaluation Form (Form 8) to gather information about potential CE/CPD and training activities that are being considered for accreditation. This form should be given to presenters or other entities that are developing activities for which they are seeking approval or accreditation. The form may be used by the agency to identify areas of the proposed CE/CPD activity that have been adequately developed and those that still need improvement. The agency can provide feedback to presenters or entities proposing the CE/CPD activity on how to improve the activity to ensure that all CE/CPD standards are met. A revised form should be submitted to demonstrate full compliance with the standards. Where needed, additional guidance or education regarding the standards can be provided to presenters or entities responsible for the activity to ensure compliance with the standards.

More detailed criteria and standards for individual accreditation bodies around the world are located in Annex A: Criteria and Standards of Accreditation Bodies.

Annex B: Sample of Self-Assessment or Checklist for CE/CPD Quality provides a list of 50 questions that can be used in the development or assessment of quality CE activities. These questions may be used in a number of different scenarios. Individual presenters may use these questions as a guide to the development of quality CE/CPD activities. Alternatively, in the absence of a formalized accreditation system, individual providers, learners, employers, or other entities involved in the delivery of CE/CPD activities may use these questions as a means to assess quality of the individual CE/CPD activity.

**Form 8. Sample Activity Evaluation Form**

Provider name:	
Title of activity:	
Target audience:	
Date of activity:	
<p><b>Step 1: Briefly describe the educational need/practice gap that provides the basis for the CE/CPD activity:</b></p>	
<p><input type="checkbox"/> <b>Meets the Requirements</b></p> <ul style="list-style-type: none"> <li>▪ The educational need/gap has been clearly described.</li> <li>▪ The process used to identify the educational need/practice gap included multiple sources of data (e.g., national guidelines, survey findings, practice requirements, etc.).</li> </ul>	<p><input type="checkbox"/> <b>Needs Improvement</b></p> <ul style="list-style-type: none"> <li>▪ An educational need/gap was not identified as the basis for the CE/CPD activity.</li> <li>▪ Data were not provided in support of the educational/practice gap.</li> </ul>
<p><b>Step 2: List the learning objectives for the activity (Note: Link the learning objectives to the educational need):</b></p>	
<p><input type="checkbox"/> <b>Meets the Requirements</b></p> <ul style="list-style-type: none"> <li>▪ The learning objectives are SMART.</li> <li>▪ The learning objectives are linked to the educational need that forms the basis of the activity.</li> <li>▪ The educational objectives are appropriate to the practice of pharmaceutical professionals.</li> </ul>	<p><input type="checkbox"/> <b>Needs Improvement</b></p> <ul style="list-style-type: none"> <li>▪ The learning objectives are not SMART.</li> <li>▪ The learning objectives are not linked to the educational need.</li> <li>▪ The learning objectives are not appropriate to the practice of pharmaceutical professionals.</li> </ul>

<p><b>Step 3: Briefly describe the presenters for the activity and state their qualifications in support of the activity. Include a curriculum vitae for presenters if available.</b></p>	
<p><input type="checkbox"/> <b>Meets the Requirements</b></p> <ul style="list-style-type: none"> <li>▪ The presenters are qualified by education and experience to deliver the CE/CPD and training activity.</li> <li>▪ For new presenters, a process is in place to adequately guide the presenter regarding the expectations for the activity.</li> </ul>	<p><input type="checkbox"/> <b>Needs Improvement</b></p> <ul style="list-style-type: none"> <li>▪ The presenters are not qualified by education and experience to deliver the CE/CPD and training activity.</li> <li>▪ For new presenters, a process is not in place to adequately guide presenters regarding the expectations for activities.</li> </ul>
<p><b>Step 4: Briefly describe the process that will be used to ensure the activity is evidence based, referenced, and free from commercial interest and promotional activity:</b></p>	
<p><input type="checkbox"/> <b>Meets the Requirements</b></p> <ul style="list-style-type: none"> <li>▪ Expectations that the activity be evidence based, referenced, and free from commercial interest have been communicated to presenters as evidenced by written guidance provided to presenters.</li> </ul>	<p><input type="checkbox"/> <b>Needs Improvement</b></p> <ul style="list-style-type: none"> <li>▪ Evidence that presenters have been adequately educated regarding expectations that the activity be evidence based, referenced, and free from commercial interest and promotional activity has not been provided.</li> </ul>
<p><b>Step 5: Briefly describe the teaching and learning methods that will be used during the activity (e.g., lecture, discussion, case studies) to ensure achievement of the learning objectives:</b></p>	
<p><input type="checkbox"/> <b>Meets the Requirements</b></p> <ul style="list-style-type: none"> <li>▪ Based on materials submitted, it is expected that the activity will utilize teaching and learning methods that will assist participants to achieve the learning objectives.</li> <li>▪ The teaching and learning activities match the learning objectives for the activity.</li> </ul>	<p><input type="checkbox"/> <b>Needs Improvement</b></p> <ul style="list-style-type: none"> <li>▪ Based on materials submitted, it does not appear that the activity will effectively utilize teaching and learning methods to ensure achievement of the learning objectives.</li> <li>▪ The teaching and learning activities that will be utilized do not match the learning objectives for the activity.</li> </ul>

**Step 6: Briefly describe the teaching and learning materials that will be provided to the learners (attach a copy of these materials if available):**

**Meets the Requirements**

- Presenters have been apprised of expectations that participants will be provided with written materials that may be used subsequent to the activity.

**Needs Improvement**

- There are no plans to provide learning materials to learners.

**Step 7: Briefly describe the methods that will be used to assess whether the learners have achieved the learning objectives:**

**Meets the Requirements**

- The activity will use a method to assess whether learners have achieved the learning objectives.

**Needs Improvement**

- The activity will not use a method to assess whether learners have achieved the learning objectives.

**Step 8: Briefly describe the methods that will be used to evaluate the activity:**

**Meets the Requirements**

- Participants will receive an evaluation form through which they may evaluate the activity.

**Needs Improvement**

- A process is not used that allows learners to evaluate the activity.

**Step 9: Briefly describe the activity’s intended outcomes and any methods that will be used to determine the impact of the activity:**

**Meets the Requirements**

- The intended outcomes and methods to determine the impact have been identified.

**Needs Improvement**

- The intended outcomes and methods to determine the impact have not been identified.

*This section to be completed by the Accreditation Agency:*

Provide feedback to the presenter/entity proposing the CE/CPD activity regarding items above in need of improvement and justifying the basis for the overall accreditation assessment:

**Overall Assessment:**

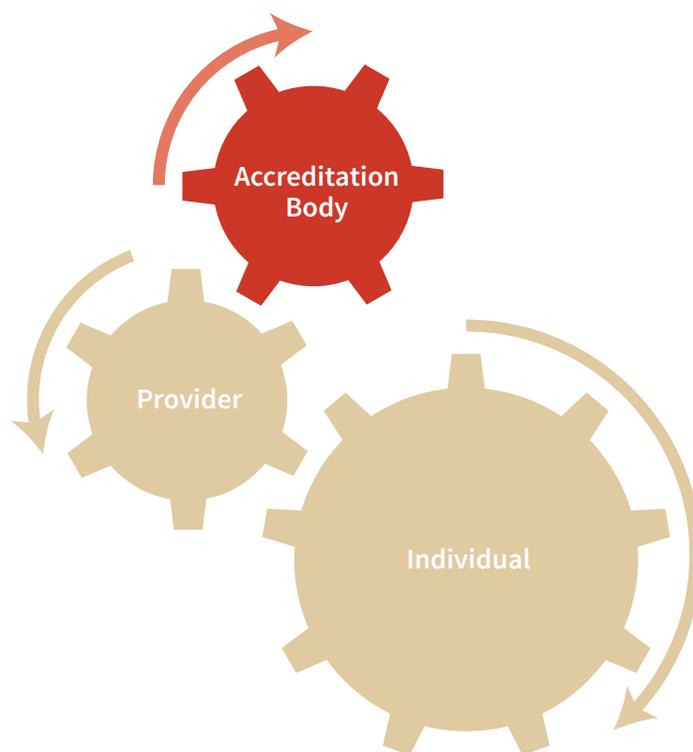
Accreditation of activity approved

**Overall Assessment:**

Accreditation of activity denied

*Source:* Adapted from the Accreditation Council for Pharmacy Education, Individual CPE Activity Evaluation Form, unpublished internal document (June 2014).

## Section III: Establishing the CE/CPD Accreditation Body



This section of the framework provides the key elements to consider regarding the development of a CE/CPD accreditation body. Recognizing the global diversity, the framework identifies the elements that should be considered during development of the CE/CPD accreditation process but does not attempt to prescribe how the elements should be developed. In addition, not all elements will apply to all countries.

Development of an accreditation process or other quality assurance system ensures that the CE/CPD and training activities and the providers offering the activities have met predetermined criteria established to ensure the quality of the educational offerings. Participation in CE/CPD activities that have been accredited or follow another formal developmental process that includes needs assessment, development of learning objectives, use of learning methods based on the learning objectives, evaluation of the activity, and freedom from conflicts of interest is associated with improvements in practice as compared to participation in nonaccredited activities.<sup>35</sup> Use of an accreditation process or other quality assurance system for CE/CPD and training activities assures members of the pharmaceutical profession and other stakeholders, including the public, that the CE/CPD activities offered are based on quality standards.

Although each country ideally would create its own system of quality assurance that reflects national practice and education initiatives, thereby meeting the specific needs of the country, this has not been the case and may not be quickly feasible for many resource-limited countries. Development of a common framework is based on the principle that the core elements of quality assurance of CE/CPD and training activities or providers do not differ significantly, if at all, from country to country. Countries seeking to establish or improve their system of quality assurance will benefit from this guide in strengthening their national CE/CPD and training quality assurance systems.

This framework is intended as a tool, to be used in whole or in part, to assist in the development or improvement of CE/CPD accreditation systems in countries either lacking or seeking to improve such systems. The framework may be applied at a regional level in cases where similarities or prior collaborations exist among countries. The framework may also be used as a plan for the future, should resources or other constraints limit the timely implementation of some of the principles outlined.

The framework is an evolving structure that will advance over time in accordance with global changes to CE/CPD and training. Feedback regarding the application and utility of the framework, as well as comments and suggestions for improvement, is welcome and encouraged.

## How should a country proceed if sufficient resources (both financial and human) exist to support the development of a continuing professional development accreditation body or other review group?

For countries with sufficient resources, the development of an accreditation body or other review group with responsibilities for oversight of the CE/CPD process should be considered. This may involve development of an independent agency or creation of an accreditation body within an existing entity (e.g., professional organization or governmental group). The objective of an accreditation body for CE/CPD is not to ensure that all CE/CPD providers or activities are identical. Rather the objective of the accreditation system is to ensure that core elements are addressed so that desired learning outcomes and impact are achieved (see “Section II: Assuring the Quality of CE/CPD Training Activities”).

## What are the different models for accreditation bodies?

Although accreditation can be perceived as a simple oversight process, a comprehensive accreditation system should incorporate many elements and promote a culture of quality improvement. One of the key foundations of any accreditation system is the *criteria* or *standards* by which quality is defined. All accreditation systems should be based on well-defined criteria or standards that clearly state their purpose and expectation. Such criteria or standards should be

- Developed through a collaborative and transparent process involving all key stakeholders (see discussion on stakeholders)
- Endorsed by the profession
- Based on evidence
- Validated through reliable measures and outcomes
- Disclosed to the public
- Reviewed and revised periodically to ensure contemporary applicability

National criteria for CE/CPD and training accreditation should ensure that core educational outcomes (as defined by the profession) are achieved while allowing innovation in the CE/CPD and training enterprise. Mission-related differences should be allowed to exist between different CE/CPD and training activity providers.

Ideally, a statutory agency or other defined body (e.g., government agency, independent agency, or professional association) should regulate accreditation of the CE/CPD and training system. Governments are often the entity responsible for the accreditation of CE/CPD and training for health care professionals through either a department or ministry (such as health or education) or a specific government agency established for the purpose of quality assurance. Alternatively, responsibility for accreditation of the CE/CPD and training system can be assigned to a private entity, such as a self-governing national pharmacy organization. In some countries, more independent and autonomous bodies have been

established. Such accreditation bodies typically maintain a large degree of independence and autonomy in their operating and decision-making processes. The use of an independent agency represents a growing trend. In some instances, countries may collaborate on a regional basis to provide CE quality assurance, using a common set of criteria or standards, policies, and procedures.

**Box 11. Examples of Different Accreditation Bodies**

In Kenya, a separate board, the Pharmacy and Poisons Board of Kenya, was established and constituted under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya.

The Medical Association of Tanzania is a professional organization that has implemented a CPD award system for its members.

Although many different systems for accreditation exist, each with advantages and disadvantages, this document does not address the differences of each system, because the principles included are believed to apply to any accreditation or other quality assurance system.

The approach to accreditation of CE/CPD and training activities can differ depending on whether the accreditation process is aimed at the level of the individual CE/CPD and training activity or the level of the provider of the CE/CPD and training activity. In the former, each individual CE activity is evaluated to ensure that the predetermined criteria or standards for quality are met. In the latter, the provider organization must meet standards for provider organizations and then subsequently assure the quality of the CE/CPD and training activities. In both scenarios, the individual CE/CPD and training activities are expected to meet the general criteria for quality as described in “Section II: Assuring the Quality of CE/CPD Training Activities.”

Accreditation of each individual CE/CPD and training activity is more time-consuming and may be difficult for countries in which numerous activities are offered. Review of the individual activities, however, does have advantages in that each individual activity is reviewed for content, delivery, and assessment. Accrediting the provider is less time-consuming when many CE/CPD and training activities are being conducted. Once the CE/CPD provider has demonstrated its ability to repeatedly organize quality CE/CPD and training activities based on such review, the accreditation body can approve it as a provider of quality CE/CPD. The accreditation body still must review the status of the provider on a regular basis, including reviewing a representative sampling of individual educational activities.

Each country must identify which approach is appropriate for its particular circumstances. Countries with numerous CE/CPD and training activities offered by only a few providers may find the process of assuring quality of the provider organization to be more efficient. Countries with many CE/CPD and training activity providers that offer few CE/CPD activities may find that either process is cost-effective. Occasionally, countries may accredit both individual activities and CE/CPD providers; the Canadian Council on Continuing Education in Pharmacy is one such example.

If a country or region does not have a formal accreditation system, then national guidelines or criteria can be developed and implemented on a voluntary basis. Alternatively, providers of CE/CPD and training activities should be encouraged to establish their own quality criteria that they adhere to and that allow for self-assessment and quality improvement as described in “Section II: Assuring the Quality of CE/CPD Training Activities.”

## What are the steps to consider in the development of an accreditation body?

A number of steps should be included when considering developing an accreditation body. These steps include: (1) conducting an environmental analysis; (2) engaging stakeholders; (3) identifying the national vision and mission for CE/CPD, including the mandate for the accreditation body; and (4) developing the accreditation body.

### *Step 1: Conduct an environmental analysis*

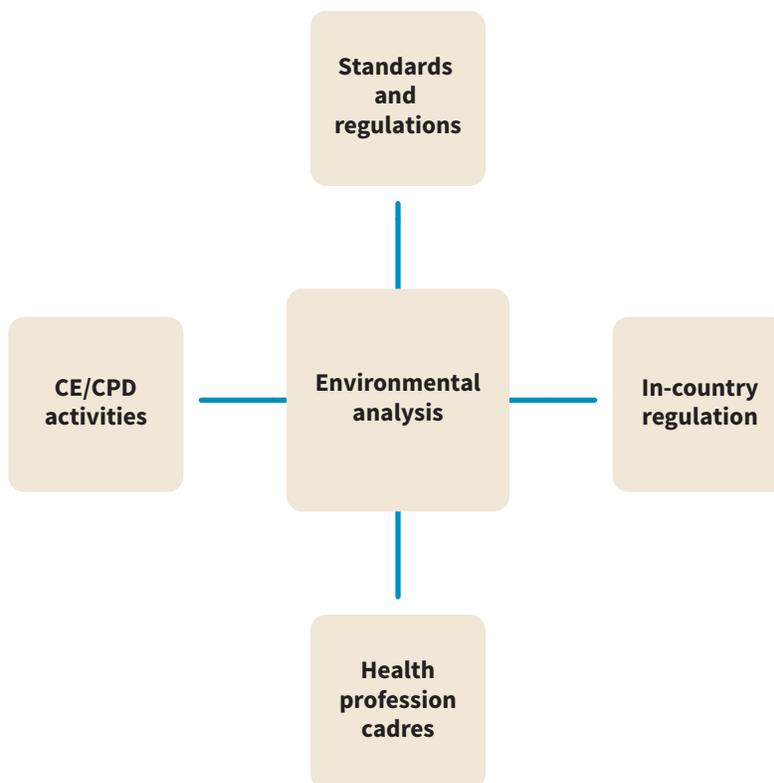
Individual countries will be at different stages with regard to development of a quality assurance system for CE/CPD and training activities. Regardless of the stage of development and whether an accreditation body is already in place, each country should begin by identifying an organization or entity to be in charge of the accreditation development or review process. For countries with existing accreditation bodies, these entities will likely lead the review process. For a country that does not have an existing accreditation body, an entity must assume the lead. Such an entity may be appointed by the government or a professional organization. Regardless, a leadership group within the pharmacy profession must lead the charge for development of an accreditation body.

Development or improvement of an accreditation system occurs within the context of existing systems and regulations. Environmental analysis involves mapping the existing environment to establish a baseline from which new interventions are considered or existing ones are adapted. Although the main focus of the environmental analysis is on the quality assurance system, it will identify connections between the regulation of the pharmacy workforce and providers of CE activities.

The initial step then is to conduct an environmental analysis of the professional regulation of pharmacy practice and CE/CPD education within the country (see Figure 6). Some elements to consider include the following:

- What professional organizations or governmental agencies are already involved in regulation of the practice?
- What are the different cadres of pharmaceutical professionals practicing within the country?
- What legislation already exists regarding CE/CPD requirements for pharmaceutical professionals?
  - If legislation mandating participation of pharmaceutical professionals in CE/CPD does not exist, what steps would be needed to enact legislative changes?
  - Are such legislative changes feasible?
  - What organizations or entities need to be involved in the process to change the legislation?
- Does a quality assurance agency for CE/CPD already exist?
  - Does it have established standards and regulations to ensure quality?
  - What aspects should be modified in an effort to improve the quality assurance process?
- What organizations are involved in the provision of CE activities offered in the country?
  - What are their purposes for offering CE/CPD activities?
  - What are their levels of activity (active, passive, dormant)?

**Figure 6. Environmental analysis**



### **Step 2: Identify and engage stakeholders**

Information collected during the environmental analysis will assist in identifying many of the main groups of stakeholders vital to creating an accreditation body for CE/CPD. Ideally, all stakeholders relevant to the CE/CPD process should be identified for input into the process. A commitment to quality improvement means a commitment to change and therefore requires commitment from all stakeholders. *Stakeholders* are people or organizations with a direct or indirect interest in the process and outcomes of the exercise or project, whether positive or negative. A stakeholder should be thought of as any individual or group that can affect or is affected by, the actions, decisions, policies, practices, or goals of the project. Because every country differs, not every stakeholder group will be relevant for each country. Each country is encouraged initially to conduct an environmental analysis to identify stakeholders and their perspectives.

Examples of such stakeholders include regulators, policy makers, practitioners, and CE providers. Table 5 lists descriptions of these and additional stakeholders. As depicted in Figure 2 in the introduction to this document, stakeholders will have interests in varying areas of the CE/CPD process.

**Table 5. Possible Stakeholders**

Possible stakeholder group	Comments
Government agencies	Entity responsible for regulation of pharmacy practice (e.g., ministry of health or education)
Accreditation agencies	Entity responsible for regulation of entry-level education and CE/CPD and training
Preservice education programs	Entities involved in the education of entry-level practitioners and support personnel
Funders of continuing education and training	Any entity providing financial support for CE/CPD and training (e.g., grant sources; employers)
Nonprofit agencies	Any entity that may have an interest in the development of quality health care delivery systems and benefits from competent pharmaceutical personnel delivering services
Continuing education providers	Organizations currently involved in the delivery of CE/CPD activities
General public	End users of pharmacy services (e.g., patients)
Students and prospective students	Future practitioners
Employers	Public or private groups that employ practicing pharmacists or support personnel
Professional and technical associations	Organizations of practicing pharmacists and pharmacy support staff
Individual practitioners	Pharmacists and pharmacy support personnel
Donors	Entities that provide funding for the development of a quality assurance agency

Regulators and policy makers such as the government and, where applicable, other specific authorities responsible for the regulation of education and skills development as well as the practice of pharmacy have the responsibility of ensuring the competence of the pharmacy workforce. This role requires that the government assure the public that pharmacists and pharmacy support personnel are competent to deliver the range of services permitted by the country’s practice acts and regulations. These stakeholders then will have interests in all areas of the CE/CPD process.

Government agencies, such as the ministry of health or other statutory authorities (e.g., the Pharmacy and Poisons Board in Kenya, established under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya, regulates the practice of pharmacy in that country) are key stakeholders and need to be included in the development of the national CE/CPD process. A regulatory tie-in is one essential component to ensuring the participation of the pharmacy workforce in CE/CPD and training activities designed to maintain and enhance competence. Involvement of such entities should occur at the beginning of the development process.

Invariably, as major (or exclusive) contributors to the financing of higher education, governments have another reason to desire continued competence of practitioners. In most countries, governments—either directly or indirectly through a statutory body—have traditionally taken on the responsibility for quality

assurance of higher education, including professional degree programs such as pharmacy, but this responsibility has not been extended to the quality assurance of CE/CPD activities in many countries.

Agencies responsible for the regulation of CE and training activities, if applicable, should also be engaged. Alternatively, input can be sought through liaisons with agencies located in other countries in the region. Such agencies may be a valuable source of information regarding the procedures for establishing a regulatory agency or improving the oversight process. Lessons learned from these agencies may be helpful in avoiding barriers to success.

Entities involved in the preservice education of pharmacists (colleges and schools of pharmacy) or pharmacy support personnel (technical or vocational programs, if available) should be engaged in development of the quality assurance process for the CE/CPD activity. Such entities can provide valuable insight as to the level of current graduates' preparedness for practice and therefore have input into the changing CE/CPD needs of the workforce. In many cases, these educational institutions may already be providing CE/CPD activities.

The profession as a whole, as it seeks to advance and better serve society and its members, relies heavily on the quality assurance system to ensure the competence, professionalism, and leadership of practitioners. Input from professional organizations, if functioning within the country, can be used as a means to obtain input from the profession as a whole.

Individual practitioners will need to participate in the CE/CPD process and therefore are key stakeholders in the quality assurance process. Whereas practitioners on the front lines of health care play a pivotal role in the ability to affect health care outcomes, their involvement in the accreditation process is essential. Involvement of practitioners should include all cadres of the pharmacy workforce and incorporate personnel working in both rural and urban environments.

Finally, the public, as the ultimate "consumers" of the wide range of services provided directly or indirectly by the pharmacy workforce, derives the greatest benefit from a system that assures the quality of CE/CPD. Consequently, it is increasingly becoming standard practice that members of the public are involved in the quality assurance process for CE/CPD activities.

Employers provide another essential group to include in the development of the model for the quality assurance of CE/CPD and training activities. Employers need reassurance that employee participation in CE/CPD and training activities will enhance their competency to practice. In this regard, employer knowledge and support of the quality assurance process is an essential factor. Employers who do not see value in the quality assurance process may be less likely to support employee participation in CE/CPD and training activities.

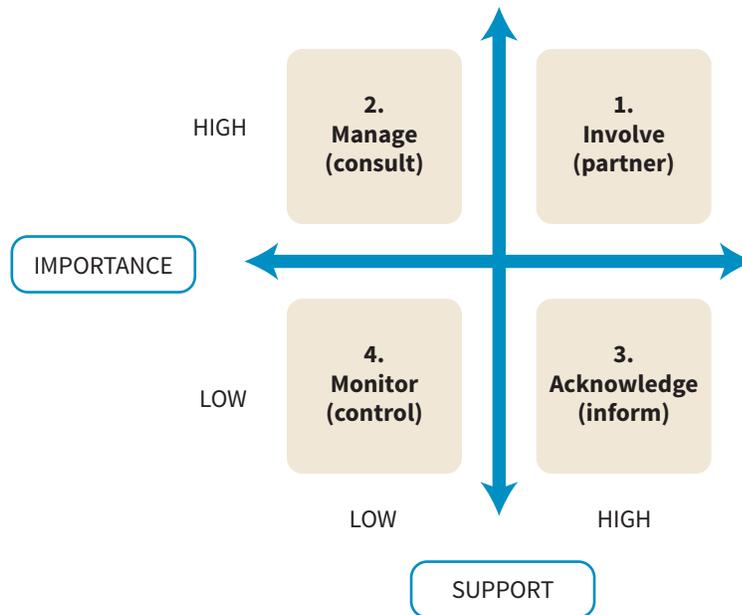
Once identified, a plan to engage stakeholders in the process must be developed. For each stage of the development of the accreditation body, each country needs to determine which stakeholders to engage, as well as the best method of engaging them. The nature and role of the stakeholders must be considered before obtaining input, because they will differ in a number of key characteristics, such as the following:

- Motives
- Needs
- Interests
- Expertise
- Resources

In addition, the plan for stakeholder engagement should take into consideration the resources available to support the development process. It is recognized that low- and middle-resource countries may be limited in their abilities to extensively engage stakeholders in face-to-face meetings (e.g., national forums). In these instances, individual countries are encouraged to seek creative means to engage stakeholders such that input from a variety of sources can be obtained into the accreditation body development process.

Not all stakeholders are equal for the purposes under discussion. *Key stakeholders* are those that can significantly influence or that are important to the success of the accreditation process. When developing an accreditation body, each country must identify the critical stakeholders whose endorsement must be achieved for the final quality assurance system to be a success. For example, a mandatory relicensure requirement may be essential to ensuring pharmaceutical professionals participate in CE/CPD activities. In countries currently lacking relicensure requirements, the entity responsible for oversight of the practice of pharmacy would need to be engaged. Thus, each country must prioritize efforts to ensure that energy is directed at obtaining input from the most appropriate stakeholders for that country. An initial step in this regard is to determine the degree to which each stakeholder has influence over the relevant issues and its level of interest and commitment; completion of a strategy–influence matrix (figure 7) can be instrumental in this regard.<sup>36</sup>

**Figure 7. Strategy–influence matrix**



Stakeholder importance refers to the power that stakeholders have over the quality assurance process whereas support refers to the interest the stakeholder has for participating in the quality assurance process. Stakeholders can exert influence and can either facilitate or block development and implementation of the quality assurance process. In other words, what control does the stakeholder have over the decision-making process? How instrumental will the stakeholder be to implementation of the quality assurance process? Can the stakeholder negatively influence the development and implementation of the quality assurance process? Not all stakeholders will have positive attitudes toward the process of developing a quality assurance system. Some stakeholder groups will seek to maintain the status quo and resist change: they will actively participate only as a means to ensure that they voice their opinion. The importance of each stakeholder group varies.

The first step to using the matrix is to identify and list the stakeholders in the quality assurance process as outlined in table 5. Stakeholder interests in relation to the development or improvement of the quality assurance process then need to be identified. Finally, the relative power and ability of each stakeholder group to support the system needs to be determined. The following questions may be helpful in determining stakeholder influence or power:

- Does the stakeholder have any legal control over the process? (e.g., government agencies or policy makers)
- Does the stakeholder have control over any strategic resources for the process? (e.g., CE providers, employers)
- Does the stakeholder possess any knowledge or skills that will be instrumental to the quality assurance process? (e.g., CE providers, employers)
- Can the stakeholder be used to assist with other stakeholder groups that may resist the development of a quality assurance process?

The importance and support should then be charted in the matrix, along the lines of figure 7, in an effort to determine the level at which stakeholders should be encouraged to participate in the development process.

- **Category 1** stakeholders are both highly important and supportive. This category of stakeholders will have a positive impact on the process of developing the quality assurance system. It is essential to involve and partner with these stakeholders. Good working relationships should be constructed to ensure effective support.
- **Category 2** stakeholders are those that are highly important but have little ability to support the process. These stakeholders should definitely be consulted because they can likely provide good insight into the process. Such stakeholders may need to be managed and might require special incentives to encourage participation.
- **Category 3** stakeholders are highly supportive but of low importance. These stakeholders should be acknowledged and kept informed as development of the quality assurance system proceeds.
- **Category 4** stakeholders are of low importance and cannot support the process. These stakeholders should be kept informed through general methods. Stakeholders should be monitored in an effort to increase their support for the quality assurance process.

One key method for ensuring stakeholder involvement is formation of a board or steering group that is representative of the different stakeholder groups. The steering group is involved in all stages of the development process, including implementation of the quality assurance process and review of its progress. The board or steering group should be the main focus for accountability and the main decision-making body that communicates to other stakeholders. Clear terms of operation for the steering group need to be established.

An effective stakeholder engagement strategy should establish the objectives of stakeholder engagement throughout the process and indicate how the involvement of stakeholders is achieved at each stage of the preparation and dissemination process. It should indicate how the process of development of the quality assurance system will be undertaken such that transparency is ensured. As part of ensuring transparency in the process, the strategy should be made publicly available. The strategy should include the vision for stakeholder engagement and the purpose, methods, and responsibility for ensuring involvement. The process used to develop the accreditation body should be inclusive, transparent, appropriate, clear, and comprehensive.

Once stakeholders have been identified and their importance and ability to support the process determined, the development process can proceed by identifying the different stages of development (see Table 6). Each country should proactively determine the following:

- What are the different stages for the process? Based on the environmental analysis, is the development of a quality assurance process starting at the beginning (e.g., a quality assurance mechanism does not already exist in the country) or is a process in place that can be improved (e.g., a process for assuring the quality of CE/CPD activities is in place but not functioning adequately)?
- At each stage, what is the purpose of stakeholder involvement? What input is being sought? Answers to such questions will help determine which stakeholders should be involved.
- What are the methods for ensuring stakeholder involvement at each stage? How will stakeholder input be obtained?
- What party is responsible for ensuring stakeholder involvement?

The stakeholder engagement process should be used throughout the accreditation body development process because stakeholder engagement is essential to the development of an effective accreditation process. Strategic partnerships between stakeholders such as governmental bodies (e.g., the ministry of health or education), educational institutions (colleges and schools of pharmacy, vocational or other training programs), professional bodies, regional and international organizations, CE providers, and employers, among others, have been shown to be valuable in enabling progress in pharmacy workforce planning and development, regulation, and reform in education and practice.<sup>37</sup>

In one study conducted in Jimma Township, Ethiopia, 153 (71.8%) health care workers surveyed indicated that lack of support from their current employer was the reason for not participating in CE.<sup>4</sup> Logistic regression analysis done to identify the effect of independent variables on CE showed that health care professionals lacking management support were 2.4 times more likely not to participate in advanced education than those with support from management. Without adequate support from stakeholders, the CE/CPD system adopted by a country will not realize its vision regardless of the quality of the system developed.

**Table 6. Stakeholder Engagement throughout the Accreditation Body Development Process**

Stage of process	Purpose of stakeholder involvement	Relevant stakeholders to be involved	Methods for achieving involvement	Entity responsible for involvement
<p><b>Step 1:</b> Conduct environmental analysis</p>	<p>Identify the need for the development of a CE/CPD accreditation body</p>	<p>Representatives of all stakeholders involved in the pharmaceutical profession: regulators (e.g., ministry of health); quality assurance agency (if applicable); CE providers; professional organizations; practitioners; educators; employers</p>	<p>Establish steering group; conduct national forum; begin dialogue within the pharmacy profession</p>	<p>Leadership group within the pharmaceutical profession willing to lead the process to establish a CE/CPD accreditation body</p>
<p><b>Step 2:</b> Identify and engage stakeholders</p>	<p>Ensure stakeholder input is obtained throughout the process to develop an accreditation body</p>	<p>All stakeholders involved in the pharmaceutical profession</p>	<p>Identify feasible processes that will reach and engage a broad array of stakeholders (e.g., letters, advertisements, websites, social media, e-mail blasts, focus groups, national forums)</p>	<p>Steering group or other entity charged with development of a CE/CPD accreditation body within the country</p>
<p><b>Step 3:</b> Collect data that will be used to develop or revise the CE/CPD accreditation process</p>	<p>Collect input from stakeholders regarding the CE/CPD accreditation process</p>	<p>All stakeholders involved in the pharmaceutical profession</p>	<p>Use a process that will be user-friendly and feasible, and ensure accuracy of feedback (e.g., surveys, public forums, conference calls, etc.)</p>	<p>Steering group or other entity charged with development of a CE/CPD accreditation body within the country, subgroup of steering group, government agency, professional organization, etc.</p>
<p><b>Step 4:</b> Analyze data collected</p>	<p>Review collected data in an effort to validate the information and provide greater depth</p>	<p>Steering group or other entity charged with responsibility for development of the CE/CPD accreditation process plus stakeholders able to offer informed reviews</p>	<p>Focus groups, subcommittees of steering group</p>	<p>Steering group or other entity charged with development of a CE/CPD accreditation body within the country, etc.</p>

Stage of process	Purpose of stakeholder involvement	Relevant stakeholders to be involved	Methods for achieving involvement	Entity responsible for involvement
<b>Step 5:</b> Draft initial quality assurance plan for development of a CE/CPD accreditation process	Provide input on draft plan during the development process	Stakeholders from whom agreement on the draft plan will be sought prior to its release to the public (e.g., regulators, CE providers)	Focus groups, subcommittees of steering group	Steering group or other entity charged with development of a CE/CPD accreditation body within the country, etc.
<b>Step 6:</b> Distribute draft plan to all stakeholders involved in the pharmaceutical profession	Assist with dissemination of draft plan	All stakeholders including general public; different groups may be informed in different ways	Disseminate a copy of the draft plan to stakeholders—make copies available on website or mail copies to relevant providers (professional organizations, regulatory entities, employers, etc.)	Steering group or other entity charged with development of a CE/CPD accreditation body within the country, etc.
<b>Step 7:</b> Collect data related to draft plan	Collect stakeholder feedback on the draft plan	All stakeholders including general public; different groups may be informed in different ways	Utilize a process that will be user-friendly and feasible, and ensure accuracy of feedback (surveys, public forums, conference calls)	Steering group or other entity charged with development of a CE/CPD accreditation body within the country, etc.
<b>Step 8:</b> Analyze data	Review collected data regarding the draft plan	Steering group plus stakeholders able to offer informed reviews	Focus groups, subcommittees of steering group	Steering group or other entity charged with development of a CE/CPD accreditation body within the country, etc.

### Step 3: Identify the national vision for CE/CPD

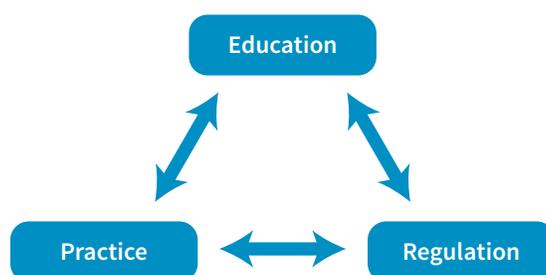
National health care needs and priorities and the scope of pharmacy practice vary globally. Overall, the role and contributions of pharmaceutical professionals have changed in recent history, and pharmacists now assume greater responsibility for the safe and effective use of medications.<sup>7</sup>

Countries are at many different stages in the evolution of pharmacy practice, and many factors—including culture, history, and politics—can affect the rate of change in practice. Infrastructure to support the change in scope of practice has included changes to the education of pharmacists and regulation of pharmacy practice. Greater emphasis has been placed on accountability with more attention being given to the continued competence of pharmacists and, therefore, the quality of CE/CPD and training activities offered.

Because the responsibilities of pharmacists vary, so too does the job description for pharmacy support staff. In many low-resource countries, pharmacy support staff members have responsibilities for a variety of job tasks.

The health care system depends on a comprehensive interaction between education, regulation, and professional practice. This dynamic interaction is shown in Figure 8.

**Figure 8. Interaction between education, regulation, and practice**



Given the benefits that can be achieved by expanding pharmaceutical professionals' roles and responsibilities, many countries are reviewing the education and training requirements of the different cadres of pharmacy staff. As practice evolves, education will need to be changed to meet the shifting needs of practitioners. Changes in the education process should address both preservice education and postservice CE/CPD and training to ensure that current practitioners are capable of meeting evolving practice responsibilities, consistent with any changes in the regulation of pharmacy practice.

Consistent with this process, quality assurance agencies should review requirements for CE/CPD and training. It is essential that the review of such requirements include all stakeholders so that a profession-wide consensus and vision can be successfully developed. Moreover, the discussions should take into account the required resources needed to achieve change and should fully examine the implications of any proposed changes. A clear and achievable national vision for CE/CPD and training should be developed collaboratively and involve the appropriate stakeholders.

## Step 4: Develop the accreditation body

This step involves development of the actual accreditation body, including the structure, governance, and policies and procedures. Annex C: Checklist of Key Components to Consider in the Development of an Accreditation Body provides a complete outline of these elements.

### **Mission and Vision**

*The accreditation body or other quality assurance program body should have a mission and vision that clearly articulate its scope of operations.*

The first step in the development of an accreditation system is to determine the structure and purpose of the entity (e.g., agency/commission/committee, hereafter referred to as the accreditation body) charged with assuring the quality of CE/CPD providers or activities. In this regard, determining the accreditation body's mission and scope of operations is essential. Methods that will be used to communicate the mission to stakeholders should be identified. An evaluation plan that will be used to determine if the mission has been achieved should be developed. The evaluation plan should clearly identify the assessment tools that will be used and the individuals responsible for the assessment process.

#### **Box 12. Mission Checklist**

- Identify the accreditation body's mission.
- Determine the method that will be used to communicate the mission to stakeholders.
- Determine the method that will be used to evaluate achievement of the accreditation body's mission.
- Identify who is responsible for tracking achievement of the mission.
- Identify the assessment tools that will be used to track achievement of the mission.
- Identify the timeline that will be used to track achievement of the mission.

#### **Box 13. Mission Examples**

The mission of the South African Pharmacy Council is to ensure the provision of quality pharmaceutical services in South Africa by developing, enhancing, and upholding universally acceptable standards.

The mission of the Canadian Council on Continuing Education in Pharmacy is advancing pharmacy practice through quality continuing pharmacy education.

The Uganda Continuing Professional Development Accreditation Agency aims at assisting all health professionals to keep up with developments in their specialties and in fields (such as leadership and management, team building, etc.) that affect their practices. The competencies that practitioners would gain from accredited CPD opportunities should improve their performance and ultimately raise the quality of the health care they provide to the patients and communities they serve.

## **Legal Status or Other Oversight Requirement**

*A regulatory mandate or other oversight requirement should govern the operations of the accreditation body or other quality body.*

If applicable, the legal or statutory status of the accreditation body should be identified, including the laws governing its scope of practice. Other oversight bodies should also have a clear description of what their scope of authority is and who has provided it (e.g., professional organization). Accountable parties should be identified, along with entities that recognize the body. The body's relationship with government, professional organizations, and other stakeholders should be described. Any requirements or criteria that the accreditation body must meet should be clearly delineated when it is established. Methods that will be used to ensure autonomy must be carefully identified, and steps must be taken to ensure that the body is not affected by undue influences and is free from conflicts of interest.

### **Box 14. Legal or Statutory Status (if Applicable)**

- Identify the accreditation body's legal/regulatory authority.
- Identify the laws that govern the accreditation body.

### **Recognition, authority, and accountability**

- Identify any entities that recognize the body.
- Identify the mandate that gives the body authority.
- Identify the parties to whom the body is accountable.
- Identify the requirements and criteria that the body must meet.

### **Degree of autonomy in decision making**

- Identify the methods that will be used to ensure that the body has autonomy in its decision making.
- Identify the methods that will be used to ensure that the body is free from any undue political or other influences.
- Identify the methods that will be used to ensure that the body is free from conflicts of interest.

### **Influence of market forces**

- Determine the accreditation body's ability to influence or be influenced by market forces (including human resources and employment issues, commercial or competitive interests, etc.).

## Box 15. Accreditation Examples

### *Legislative systems*

CPD activities in Ethiopia were fragmented. No systems were in place to standardize, regulate, or accredit CPD, and participation in CPD activities was not historically linked to licensure. The Ethiopian Food, Medicine, Health Care Administration and Control Authority (EFMHACA), the legally mandated agency to license and relicense federally regulated health professionals, believed that CPD should be systematically organized, tied to a relicensing system, and occur in concert with other developments in the health care system to improve the quality of health services. The EFMHACA firmly believed that a CPD system was needed to help maintain and enhance professional competence and to ensure quality health services in Ethiopia. Therefore, to set up a CPD system in the country whereby CPD is standardized, accredited, and tied to relicensure, the EFMHACA prepared a guideline with the technical support of the Human Resource Development Directorate of the Federal Ministry of Health, development partners, professional associations, and training institutes. This guideline was followed by an implementation plan that outlined a phased approach in undertaking the activities for establishing the CPD system.

All medical and dental practitioners in Ghana are required by law to be registered with the Medical and Dental Council and to be in good standing to practice. The council implemented a system that requires completion of 30 hours of credit to maintain registration. Consistent with this system, CE/CPD could only be completed through CPD providers who had the capacity to organize programs and had received prior certification from the council. CPD providers during the pilot phase of the program were limited to the following: the Medical and Dental Council, Colleges of Health Sciences, the Ghana Medical Association, the Ghana Dental Association, and their affiliate associations and groupings and postgraduate colleges of physicians and surgeons.

### *Nonlegislative systems*

The Accreditation Council on Pharmacy Education (United States) is an autonomous and independent agency whose board of directors is derived through the American Association of Colleges of Pharmacy, the American Pharmacists Association, the National Association of Boards of Pharmacy (three appointments each), and the American Council on Education (one appointment).

## Governance

*The organizational structure of the accreditation body or other quality assurance program body should be appropriate to discharge the obligations mandated by the legislation or other authority.*

Governance of the accreditation body or other quality assurance program must be determined. The accreditation body will typically include a staff that runs the day-to-day operations of the accreditation process and a decision-making entity (e.g., board of directors). The composition of the decision-making entity or board of the body should be established, and consideration should be given to incorporating representatives from a broad array of stakeholders (e.g., CE/CPD providers, regulators, employers, members of the public). Once the composition has been determined, the process that will be used to select or appoint individual members of the decision-making body and the role and selection process for officers, if used, should be determined. The identification process and terms that the officers and members of the decision-making body will serve in their various capacities should also be established. In general, it is considered good practice to have overlapping terms for some members of the decision-making body to ensure consistency.

**Box 16. Composition**

- Determine the composition of the decision-making entity.
- Identify methods that will be used to ensure the inclusion of key stakeholder perspectives in the decision-making process.

**Officers**

- Identify the process that will be used to elect or appoint officers (if applicable).

**Public input**

- Identify the methods that will be used to obtain public input.
- Determine how public input will be used in the accreditation process.

**Criteria for appointment or selection of members**

- Determine the process that will be used to select or appoint members of the governing body.
- Determine the process that will be used to establish or implement criteria that will be used to select members.

**Term of office of members**

- Determine the terms of office for members of the decision-making body.
- Identify the process that will be used to communicate terms of office to stakeholders.

**Box 17. Governance Example**

The Uganda Continuing Professional Development Accreditation Agency was established by all the health professional councils (Uganda Medical and Dental Professional Council, Nurses and Midwives Council, Pharmacy Council, and Allied Health Professions Council) with representation of other key stakeholders, namely the Ministry of Health and CPD providers. The board of directors initially was constituted by representatives of the health professional councils. In future, other selected stakeholders will be invited to participate. The board will be the policy-making organ of the agency and oversee its operations.

However the system is structured, the possibilities for conflict of interest should be minimized or removed. Members of the decision-making body are typically trusted, knowledgeable, and respected members of the profession and community. In their role on the decision-making body, these individuals have a responsibility to the profession and the general public. Members of the accreditation body's decision-making body (e.g., board, commission, etc.) have a fiduciary obligation to act in the best interest of the accreditation body. Each accreditation body should develop and implement a conflict-of-interest policy that requires signed statements from all members of the decision-making body and is reviewed periodically. Consistent with this policy, representatives of the accreditation body's decision-making group and its employees should periodically identify any CE/CPD providers for which a conflict of interest exists. Examples of potential conflicts of interest include but are not limited to the following:

- The representative or an immediate family member (defined as a spouse, life partner, child, parent, or sibling) has been connected with the CE/CPD provider (i.e., employee, contracted agent, etc.) within the past five years.
- The representative or an immediate family member has interviewed for employment with the CE/CPD provider in the past two years.

- The representative has some affiliation or relationship with a program or activity that may be considered to be in competition for financial or other resources with the CE/CPD provider because of similar locations or scope of work.
- The representative is engaged in substantial cooperative or contractual agreements with the CE/CPD provider.
- The representative or an immediate family member has a financial, political, professional, or other interest that may conflict with the interest of the accreditation body.
- The representative believes that a conflict of interest may exist because of other circumstances, such as participation in accreditation or review of the program for other agencies or close personal relationships with individuals at the program.
- The CE/CPD provider has reason to believe, and can document to the satisfaction of the accrediting body, that the participation of the representative could be unfairly prejudicial.

Conflict-of-interest policies should require that any representatives of the accreditation body (defined as its decision-making body and staff) should recuse themselves from participation in discussions or the decision-making process for CE/CPD providers for which a conflict of interest is possible.

#### **Box 18. Examples Involving Conflict of Interest**

Membership of the Canadian Council on Continuing Education in Pharmacy represents a mix of educators, practitioners, and regulators:

- Alberta College of Pharmacists
- Association of Faculties of Pharmacy of Canada
- Canadian Society of Hospital Pharmacists
- Canadian Pharmacists Association
- Canadian Association of Pharmacy Technicians
- College of Pharmacists of British Columbia
- L'Ordre des Pharmaciens de Quebec
- Manitoba Pharmaceutical Association
- New Brunswick Pharmaceutical Society
- Newfoundland and Labrador Pharmacy Board
- Nova Scotia College of Pharmacists
- Ontario College of Pharmacists
- Prince Edward Island Pharmacy Board
- Saskatchewan College of Pharmacists

Members of the board of directors (the decision-making body) serve in a representative capacity and, though expected to express the general policies and positions of their appointing group, shall act in accordance with personal best judgment and initiative after hearing and participating in debate on issues within the lawful authority of the board. While directors ensure that the views and perspectives of member organizations are brought to the discussions of the board, they must act in the best interests of the accrediting body and the profession.

The Accreditation Council on Pharmacy Education's conflict-of-interest policy requires all involved with the accreditation process (e.g., Accreditation Council on Pharmacy Education board members, field reviewers, commission members, professional staff, consultants, and other representatives) to sign a conflict-of-interest statement. Individuals for whom a conflict is identified must refrain from participation in the decision-making process for those providers with which a conflict has been identified.

Finally, the funding sources to support the accreditation body must be identified. Funding sources can include government or other grants and fees for accreditation and other services. In low-resource countries, however, reliance on government funding may not be realistic, and fees for services may be needed. Regardless of the source, funding should be provided free from conflicts of interest as previously described. The fee structure for services should be established so that the ongoing needs of the accreditation body are addressed without being too punitive to the individual providers. The accreditation body should develop and determine its own budget, without review by or consultation with any other entity or organization.

**Box 19. Funding and Fees for Services**

- Determine how the accreditation body will be funded.
- Identify the fee structure for the accreditation body's services.
- Identify the process that will be used to communicate fees to stakeholders and constituents.

**Box 20. Fee Structure Examples**

The Australian Pharmacy Council charges organizations seeking accreditation an initial application fee. Accredited organizations must also pay the council an annual fee and an additional fee at each accreditation review (the frequency of the accreditation review is determined by the accreditation term).

Although costs of the Uganda CPD Accreditation Agency are subsidized by funding from government and the health professional councils, those seeking accreditation for their proposed CPD activities (and other elements related to CPD described previously) will be expected to pay an accreditation fee to be determined by the agency in consultation with the stakeholders. Health professionals seeking relicensure will also be expected to pay an annual relicensure fee to be determined by each health professional council in consultation with stakeholders.

The Medical and Dental Council of Ghana requires that providers apply for accreditation annually. A fee is a required component of the process.

## **Operations**

*The organizational operations should be appropriate to discharge the obligations mandated by the legislation or other governing body.*

The procedures that will be used by the decision-making body should be established and communicated to stakeholders. Communication can involve posting on the accreditation body's website, if available. Procedures should be established to ensure consistency in the decision-making process. Examples of such procedures include allowing for overlap in the terms of members of the decision-making bodies and using standardized evaluation instruments and forms or rubrics throughout the evaluation process.

The decision-making body will need to be convened to implement the accreditation process. In this regard, timing, location, and frequency of meetings of the decision-making body need to be determined.

**Box 21. Board/Committee/Council Operations**

- Determine the methods that will be used to establish and communicate the key elements of the quality assurance process.
- Identify the mechanisms that will be implemented to ensure that the process will be consistently applied.

**Meetings of the decision-making body**

- Identify the frequency with which meetings will be held.
- Identify where meetings will be held.
- Identify the process that will be used to conduct meetings.

**Box 22. Ensuring Consistency**

The process used by the Australia Pharmacy Council includes review of CPD provider applications by an independent international reviewer.

The Accreditation Council for Pharmacy Education in the United States uses a Continuing Pharmacy Education Commission that conducts a comprehensive review of the provider's CE organization and provides a recommendation to the board of directors, the decision-making body. Both the commission and the board use rolling terms for members so that overlap of the groups' membership is achieved and continuity in the decision-making body can be enhanced. In addition, the Accreditation Council for Pharmacy Education uses standardized evaluation instruments, forms, and rubrics throughout the accreditation process.

**Criteria or Standards**

*Predetermined criteria or standards should be established as the basis of the process of the accrediting agency or other quality assurance body.*

The accreditation process involves review of the CE/CPD provider activity against a predetermined set of criteria or standards. In this regard, the criteria or standards need to be established and widely disseminated. Further discussion regarding suggestions for essential components of the criteria or standards for individual CE/CPD activities can be found in "Section II: Assuring the Quality of CE/CPD Training Activities."

**Box 23. Criteria on Which Decisions Are Based**

- Determine how the criteria will be developed.
- Determine the method that will be used to assure that the criteria are consistently applied.
- Determine the process that will be used to review the criteria.
- Determine the frequency with which the criteria will be reviewed.

## ***Accreditation Process for Continuing Education Providers: Evaluation, Recognition, and Approval***

*The accreditation system or other quality assurance process should be efficient, fair, transparent, credible, and accountable.*

If the accreditation process evaluates CE/CPD providers, an initial evaluation should be conducted with regularly scheduled follow-up evaluations. The follow-up evaluations are to ensure ongoing compliance with existing or revised criteria or standards, especially because of the sometimes dynamic nature of professional education and environmental changes. In this regard, the requirements for eligibility and the components of the initial application for evaluation, recognition, or approval need to be established. Important factors to consider include whether the provider needs to have offered CE/CPD and training activities in the past, the duration the provider needs to have been operating, and the need for a qualified individual charged with administration of the provider's CE/CPD enterprise.

The frequency with which the accreditation body will review CE/CPD providers and the process that will be used to periodically reevaluate CE/CPD providers need to be established. The initial period of accreditation may be shorter to allow greater oversight of the provider during this initial time period. Accreditation cycles vary globally: some countries require providers to reapply annually, and others accredit providers for a longer term (e.g., three to six years between required applications).

Increasingly, accreditation systems are incorporating a greater element of self-assessment into the accreditation process. In this regard, CE/CPD providers undertake a comprehensive exercise and make their own assessment of their compliance (or noncompliance) with the established criteria or standards. Such a process encourages the CE/CPD and training activity provider to self-identify areas in which it feels the need for improvement and to proactively develop and implement strategies to address any identified deficiencies. This approach is intended to encourage CE/CPD providers to assume responsibility for their own ongoing accreditation and quality improvement.

The evaluation process should ideally incorporate a "peer review" component. The peer review process should involve individuals with appropriate qualifications, expertise, and experience (e.g., other CE/CPD providers) and incorporate other individuals who bring different perspectives and experience (e.g., practitioners or regulators). If those participating in the evaluation process are respected members of the CE/CPD community, the system is more likely to be viewed as credible and will therefore achieve a greater level of acceptance. The accreditation body should provide standardized orientation and training to all those involved in the accreditation process.

### **Box 24. Requirements for Initial Eligibility**

- Determine the requirements that CE/CPD providers must meet to apply for initial accreditation.
- Determine the different stages of accreditation and the requirements for progressing through the different stages.
- Determine the duration of the standard accreditation cycle.
- Determine any requirements for maintenance of accreditation, including reporting, annual monitoring data, and audits.
- Determine the process that will be used to train individuals involved in the accreditation process
- Determine consequences (including, for example, suspension, probation, withdrawal of accreditation) of noncompliance.
- Determine the method that will be used to communicate the consequences.

### **Box 25. Accreditation Process Examples**

The process of applying to become an accredited CPD provider in Australia begins with the submission of an Application to Become an Accrediting Organisation of Continuing Professional Development for Pharmacists and the application fee. The Accreditation Committee initially assesses the application. In certain cases, additional documentation may be requested from the provider. A secondary assessment of the application is completed by an independent, internationally based reviewer with commensurate expertise in pharmacy and CPD accreditation. The independent reviewer either verifies the findings of the Accreditation Committee or requests additional documentation. The Accreditation Committee then develops a recommendation that is submitted to the Australian Pharmacy Council. The council considers the recommendation and notifies the provider of the decision. If the application is unsuccessful, the provider is given the opportunity to rectify problems identified; to respond to the council, the Accreditation Committee, or the independent reviewer's concerns; or both. After the provider meets the requirements for accreditation, it is listed on the Council website as an accredited CPD provider. At least two audits of the provider will be performed during the three-year accreditation period. The auditors nominated by the Australian Pharmacy Council report to the Accreditation Committee on their findings. The initial audit is typically a one-day site visit that is scheduled within six months from the date accreditation status is achieved. Providers are notified of the audit a minimum of two weeks beforehand and advised of the material (evidence) that may be required. A second desktop audit to review evidence of quality improvement is arranged in consultation with accrediting bodies, however, a period of 18 months from the date of receiving accreditation to accredit CPD should be regarded as an indicative time. At the discretion of the Accreditation Committee, another site audit may be required if concerns arise from the paper audit. In addition to the site audit and the desk audit, accredited providers are continuously monitored by the council over the period of accreditation. The council also conducts an independent review of not less than one CPD activity per provider per year.

To be accredited by the Canadian Council on Continuing Education in Pharmacy, providers must submit an application. The application is reviewed by an Accredited Provider Review Panel composed of members of the board of directors. If successful, the organization may be accredited for an initial period of five years, with a probationary review conducted at the end of the second year. Subsequent renewals are for a period of five years.

The consequence of noncompliance with the criteria or standards needs to be determined. Possible consequences can include requiring additional reporting, placing the provider on probation, or withdrawing the provider's accredited status. The method that will be used to communicate the consequence to providers should also be identified. Although a letter to the individual provider may provide sufficient communication regarding the accreditation body's findings of noncompliance, follow-up real-time interactions may be beneficial to provide greater depth regarding the accreditation body's concerns. Written communication to the key stakeholders should occur when the accreditation body has put the provider on probation or withdrawn the accreditation status of the provider. With withdrawals, the accreditation body should communicate the effective date. Informing the general public usually can be accomplished through the accreditation body's website.

## Public Disclosure

*The decisions of the accreditation agency or other quality assurance body must be made public to increase transparency and credibility of the system.*

The accreditation body will need to make its criteria/standards, policies, and procedures available to the providers, stakeholders, and the public. Posting such information on its website, if available, provides one means to accomplish this task. In addition, the decision-making body will need to communicate information regarding its decisions/actions related to provider accreditation. As noted above, this is especially relevant for providers on probation or whose accredited status has been withdrawn. In general, the accreditation body should provide the public with a list of accredited providers in an effort to assist interested practitioners seeking quality CE/CPD activities.

### **Box 26. Determine the Method That Will Be Used to Communicate the Actions of the Decision-Making Body**

- Determine the nature and type of information that will be publicly disclosed (such as decisions, proceedings from meetings, and communications with the accreditation body).
- Identify the method that will be used to communicate such information and who will receive the information.

## Policies and Procedures

*The accreditation agency or other quality assurance body should operate in a consistent manner with established policies and procedures.*

Central to the accreditation process is the application of rigorous policies and procedures that ensure the evaluation decision-making processes are consistent and impartial. Such policies and procedures should be developed through a transparent process (allowing stakeholder input as previously described) and made publicly available.

Confidentiality should be ensured, and a policy in this regard is essential. Policies about how conflicts of interest will be identified and resolved are essential to minimize bias in the accreditation body's evaluation and decision-making processes. Individuals involved in the review process should receive adequate training to ensure consistency. The process used to select and train individuals involved in evaluation needs to be developed as part of the accreditation body's policies and procedures.

Policies should outline the types of substantive change that would require providers to notify the accreditation body as well as the timing and the process that should be used to communicate such changes. The accreditation body's policies and procedures should provide an appeals process for providers receiving an adverse accreditation decision (such as denial or withdrawal of accreditation). Similarly, the accreditation body's policies and procedures should include the process by which any complaints received by the accreditation body (e.g., with respect to an accredited provider) will be addressed.

The duration that the accreditation body will maintain its records on each provider should be determined along with the location where the records will be maintained. Finally, the process that will be used to safeguard the rights of pharmacists, pharmacy support staff, and other participants of CE/CPD activities should be identified.

**Box 27. Confidentiality**

- Determine the method that will be used to ensure confidentiality.

**Conflict of Interest**

- Determine the process that will be used to identify and resolve conflicts of interest.

**Evaluators**

- Determine the process that will be used to select and train external reviewers.

**Substantive Change**

- Identify what constitutes substantive change for providers.

**Appeals**

- Identify the process that will be used for appeals.

**Complaints**

- Identify the process that will be used to address complaints about a provider or an educational activity.

**Record Keeping**

- Determine the duration for which records will be maintained. Determine where and how records will be kept.

**Revision/Updating of Standards**

- Determine how often the standards or criteria will be revised or reviewed.
- Identify the process that will be used to review or revise the standards.
- Determine how stakeholder input will be incorporated.

**Safeguards for Pharmacist and Pharmacy Support Personnel**

- Identify how the rights of stakeholders will be addressed.

### *Step 5: Monitor the implementation of the accreditation body*

Once developed and implemented, the CE/CPD accreditation process should be closely monitored to ensure it is meeting its intended outcomes. Feedback from stakeholders should be obtained through the process outlined in step 2 above. Modifications to the CE/CPD accreditation standards, policies, or procedures should be implemented as needed.

#### *Alternatives to the Development of an Accreditation Body*

Countries lacking sufficient resources to develop a national accrediting body from the ground up may consider adapting the accreditation system used by another country. Accreditation bodies are in place for many health care disciplines across the globe, and such systems may be adapted to meet the local needs of another country. Some examples regarding such agencies are provided in table 7. The WHO has developed Regional Guidelines for Continuing Medical Education/ Continuing Professional Development Activities that may be consulted.<sup>38</sup>

**Table 7. Selected Global Examples of CE/CPD Regulation**

Country	Discipline	CPE/CPD accreditation body	Comments
Australia <sup>39</sup>	Pharmacy	Australian Pharmacy Council	Has an established process for becoming an accredited organization; application available on website; requirements of CPD activities stated
Canada <sup>40</sup>	Pharmacy	Canadian Council on Continuing Education in Pharmacy	Standards and accreditation process available on the website
Dubai <sup>41</sup>	Physicians, nurses, allied health professionals	Dubai Health Authority	<i>CPD Accreditation Policies and Procedures</i> available on the website
Ethiopia <sup>42</sup>	All health professionals licensed by Ethiopian Food, Medicine and Healthcare Administration and Control Authority	Ethiopian Food, Medicine and Healthcare Administration and Control Authority	Standards for CPD for health professionals and CPD activity accreditation process have been developed; accreditation of CPD providers described; roles and responsibilities of stakeholders of CPD accreditation included
Ghana <sup>43</sup>	Dentistry Medicine	Medical and Dental Council	Guidelines for providers and accreditation requirements have been developed, including scope of CPD, accreditation requirements, and an application form
Kenya <sup>44</sup>	Dentistry Medicine	Medical Practitioners and Dentists Board Kenya	Application for Accreditation as CPD Provider available online; CPD guidelines available, including guidelines for CPD activities, providers, and practitioners
Kenya <sup>45</sup>	Nursing	Nursing Council of Kenya	Minimum standards for CPD activities provided; accreditation process described; application for accreditation as a CPD provider available; CPD framework for nurses in Kenya available
Namibia <sup>46</sup>	Allied health, dentistry, medicine, nursing, pharmacy, psychology, social work	Health Professions Councils of Namibia	Application for accreditation as a provider available

Country	Discipline	CPE/CPD accreditation body	Comments
Singapore <sup>47</sup>	Medicine	Singapore Medical Council	Standards for Continuing Medical Education providers available
South Africa <sup>48</sup>	Medicine	Health Professions Council of South Africa	CPD guidelines and criteria for accreditors available; noncompliance with CPD described; application for recognition as a provider available; accreditation fees listed
South Africa <sup>49</sup>	Pharmacy	South African Pharmacy Council	Description of CPD cycle provided
Sudan <sup>50</sup>	Health professionals	Federal Ministry of Health	Guidelines for the provision of CPD available
Tanzania <sup>51</sup>	Medicine Dentistry	Medical Association of Tanzania	Statement of obligations for CPD-approved providers available
Uganda <sup>52</sup>	Dentistry Medicine Nursing Pharmacy	Uganda Continuing Professional Development Accreditation Agency	Preliminary accreditation standards and policies and procedures available
United States <sup>53</sup>	Medicine	Accreditation Council for Continuing Medical Education	Standards, accreditation process, and policies and procedures for CE
United States <sup>54</sup>	Pharmacy	Accreditation Council for Pharmacy Education	Accreditation process and policies and procedures for CE
Zimbabwe <sup>55</sup>	Pharmacists	Pharmacists Council of Zimbabwe	Application for accreditation as a CPD provider available

## Conclusion

Participation in lifelong learning is essential to ensure the continued competence of pharmaceutical professionals. In this regard, pharmaceutical professionals should engage in a process of CPD that includes participation in high-quality and accredited CE/CPD and training activities. The quality of CE/CPD and training activities can be ensured by development of and adherence to quality criteria or standards that are based on the “pillars of quality” model. Ideally, a national plan for the development and implementation of a method to assure the quality of CE/CPD activities should be developed. Use of this framework, if properly applied, can guide countries in the development of an accreditation process designed to ensure the quality of CE/CPD activities. Alternatively, this framework may be used to guide the quality improvement initiatives of countries with existing CE/CPD accreditation procedures.

## Annex A. Criteria and Standards of Accreditation Bodies

The criteria and standards listed below are excerpts from the following quality assurance agencies, in many cases addressing similar issues:

- Australian Pharmacy Council (APC)<sup>38</sup>
- Canadian Council on Continuing Education in Pharmacy (CCCEP)<sup>39</sup>
- Dubai Health Authority (DHA)<sup>40</sup>
- Ethiopian Food, Medicine and Healthcare Administration and Control Authority (EFMHACA)<sup>41</sup>
- Ghana Medical and Dental Council (MDC Ghana)<sup>42</sup>
- Medical Practitioners and Dentists Board of Kenya (MPDB Kenya)<sup>43</sup>
- Health Professionals Councils of Namibia (HPC Namibia)<sup>45</sup>
- Singapore Medical Council (SMC)<sup>46</sup>
- Medical Association of Tanzania (MAT)<sup>50</sup>
- Accreditation Council for Pharmacy Education (ACPE)<sup>53</sup>

### Needs Assessment

- The course is based on perceived and objective CPD needs or results of assessment of training needs (EFMHACA).
- Ideally, the need should already have been demonstrated or should be clearly perceived, for instance, because the CPD activity covers significant recent advances relevant to the practice of the intended participants (HPC Namibia).
- The provider must develop activities based on a multifaceted process where educational needs are prospectively identified (ACPE).

### Learning Objectives

- The activity must have specific learning objectives—actionable statements that define what the individual should be able to do at the completion of the activity (APC).
  - Objectives must be linked to competency standards.
  - Objectives must be actionable statements.
  - Objectives must be specific and measurable.
  - Objectives must be published to facilitate choosing the activities.
- The learning objectives are “SMART” (Specific, Measurable, Attainable, Relevant, and Timed) and focused on outcomes (CCCEP).
- The learning objectives are appropriate and relevant to the learning and practice needs of the targeted participants (CCCEP).
- The learning objectives must be specifically defined, and appropriate for the target audience (MDC Ghana).
- Objectives must be appropriate to a specified group or groups of health professionals (HPC Namibia).
- The objectives of the program are clearly defined and made known to participants (SMC).
- The provider must develop objectives for each activity that defines what the pharmacists and pharmacy support staff should be able to do at the completion of each activity (ACPE).

## Commercial Bias and Conflicts of Interest

- The activity must be developed free of commercial bias (APC).
- Conflicts of interest must be disclosed (APC).
- Involvement of an entity with a commercial interest related to the subject area must be disclosed, and the entity must not unduly influence the content of the activity (APC).
- All parties involved in development, including expert reviewers, must disclose conflicts of interest whether actual or perceived (APC).
- Active ingredient and brand names must be used to achieve a balanced presentation (APC).
- The activity provides an accurate, fair, balanced, and thorough presentation of the best available evidence pertaining to the subject matter (CCCEP).
- The provider is responsible to clearly and accurately disclose all sponsors' names along with their influence on the content of the activity, format of the meeting, and choice of speakers (DHA).
- The selection of educational topics, speakers, and course materials must be based upon the educational needs of healthcare professionals, and must not be influenced by commercial sponsors (DHA).
- All presenters, speakers, and instructors participating in activities submitted for accreditation should have no potential conflicts of interest or support that might cause a bias in their presentation (DHA).
- The provider shall declare absence of commercial interest by presenting the signed agreement between the sponsoring organization and the provider (EFMHACA).
- The course must have nonpromotional commercial sponsorship (EFMHACA).
- Certified Continuing Medical Education (CME) activities are free of commercial bias (MAT).
- The proposed activity should be ethically acceptable, of educational value, should provide a balanced view, and must not be unduly promotional (HPC Namibia).
- The program must not promote any specific medicinal products or any practices of a commercial nature (SMC).
- The provider must plan all activities independent of commercial interest. The educational content must be presented with full disclosure and equitable balance (ACPE).
- Appropriate topics and learning activities must be distinguished from topics and learning activities that are promotional or appear to be intended for the purpose of endorsing either a specific commercial medicine, device, or other commercial product, or a specific commercial service (ACPE).

## Faculty

- There must be significant pharmacist and/or subject matter expert involvement in the development of the activity. Faculty charged with developing the activity must be able to demonstrate they are suitably qualified and/or experienced (APC).
- The activity is developed and delivered, either in person or through technology, by competent developers and facilitators enabling a successful, quality learning experience (CCCEP).
- Faculty must possess the relevant level of academic and professional qualifications and/or relevant teaching and working experience (DHA).

- Faculty should have an appropriate experience and expertise relevant to the activity objectives (DHA).
- The faculty for each program must be competent in the subject matter and experienced and/or trained in the methods of the program delivery (EFMHACA).
- Faculty will be required to show proven qualification and expertise (MDC Ghana).
- Evidence must be provided that the presenters and/or facilitators have the expertise to deliver the learning objectives using the methods chosen (MPDB Kenya).
- Faculty should all be accepted as experts in their fields and good communicators (HPC Namibia).
- The author or presenter is a recognized and reputable figure within the pharmacy profession or a profession relevant to the subject matter (SMC).
- The provider must communicate and collaborate with CE activity faculty regarding the identified educational needs, intended audience, objectives, active participation, and learning assessments for each activity (ACPE).

## Evidence Based

- The content must be based on critical evaluation of relevant literature and/or practice-based professional evidence (APC).
- Limitations on information must be disclosed (APC).
- The program does not promote a particular product, service, perspective, or organization (CCCEP).
- All groups and individuals involved in program sponsorship, development, review, delivery, and evaluation disclose all funding, payments, influences, and relationships that may impair their objectivity or give rise to perception of bias (CCCEP).
- The activity must be based on evidence that is accepted within the discipline of health sciences (EFMHACA).
- All information used in programs should be evidence-based, and ethical issues should be spelled out for practitioners (MDC Ghana).

## Learning Methods

- The method of delivery must promote effective adult learning (APC).
- Activities delivered face to face must allow time for interaction and questions or otherwise allow active involvement of participants and the opportunity to address problems relevant to practice (APC).
- Activities that are not conducted face to face (e.g., journal articles, online modules) must be designed using the principles of adult learning and include active learning components (APC).
- The instructional design is appropriate and relevant to the learning and practice needs of the targeted participants (CCCEP).
- The educational methods selected permit the realization of the learning objectives (EFMHACA).
- The teaching methods used must result in the achievement of the stated learning objectives (MDC Ghana).

- The program should cover the subject matter in the depth and breadth appropriate to the intended participants and should allow ample time for discussion (HPC Namibia).
- The provider must assure that all CE activities include active participation and involvement of the pharmacist and pharmacy support staff (ACPE).

## Instructional Materials

- Instructional materials must enhance the understanding of the content (APC).
- Instructional materials must include references and be dated (APC).
- The provider must offer educational materials for each activity that will enhance participants' understanding of the content and foster applications to professional practice (EFMHACA).
- All of the instructional materials offered must be of satisfactory technical quality, current in content, and designed to enhance the participants' understanding of the topic (EFMHACA).
- The provider must offer educational materials for each activity that will enhance participants' understanding of the content and foster applications to pharmacy practice (ACPE).

## Learning Assessment

- Learning assessment should be capable of demonstrating the improvement in knowledge and/or skills (APC).
- Learning assessment must be designed to evaluate achievement of the learning objectives (APC).
- The provider in collaboration with faculty must include learning assessments in each activity to allow pharmacists and technicians to assess their achievement of the learned content. Completion of a learning assessment is required for CPE credit (ACPE).

## Evaluation

- Participants must be given the opportunity to evaluate the quality of the activity (APC).
- Participants have the opportunity to assess and to receive feedback on their achievement of the learning objectives (CCCEP).
- Arrangements to evaluate the course with regard to content, process, and outcome must be included (EFMHACA).
- All practitioners participating in any event will be required to fill in an evaluation form (MDC Ghana).
- The providers should be obtaining feedback on the program by providing participants with a means by which they can easily record their rating of the relevance, quality and effectiveness of the activity (HPC Namibia)
- Feedback and evaluation of the program by the participants are conducted (SMC).
- Large conferences include a brief satisfaction survey of participants at the conclusion. Results are reviewed by the Planning Committee for the next conference (MAT).
- Providers must develop and conduct evaluations of each activity (ACPE).

**Summary of Countries' Quality Criteria and Standards**

Country	Needs	Learning objectives	Faculty	Free of bias	Evidence based	Learning methods	Instructional materials	Learning assessment	Evaluation
Australia		*	*	*	*	*	*	*	*
Canada		*	*	*	*	*			*
Dubai			*	*					
Ethiopia	*		*	*	*	*	*		*
Ghana		*	*		*	*			*
Namibia	*	*	*	*		*			*
Singapore		*	*	*					*
Tanzania				*					*
United States	*	*	*	*	*	*	*	*	*

## Annex B. Sample Self-Assessment or Checklist for CE/CPD Quality

These questions—based on the “Pillars and Foundations of Educational Quality”<sup>10</sup>—may be used in a number of different scenarios. Individual presenters may utilize the questions as a guide to the development of quality CE/CPD activities. In lieu of a formalized accreditation system, individual providers, employers, participants, or other entities involved in the delivery of CE/CPD activities may use these questions as a means to assess the quality of the individual CE/CPD activity.

1	SCIENCE	The lecturers and trainers are adequately educated, qualified, unbiased, and recognized as the experts in the scientific community.	YES - NO
2	SCIENCE	The content and teaching methods are current, evidence based, and source referenced.	YES - NO
3	SCIENCE	The content is recognized as relevant in the academic community and sourced from scientific databases.	YES - NO
4	PRACTICE	The education addresses an educational need and/or a knowledge or practice gap.	YES - NO
5	PRACTICE	Presenters are experienced in the topic area of the lecture or workshop.	YES - NO
6	PRACTICE	The educational activity provides practical examples and the opportunity to participate and exchange experiences.	YES - NO
7	PRACTICE	New challenges and tasks in pharmacy practice are well addressed and updated with current information and guidelines.	YES - NO
8	PRACTICE	The educational activity is useful and applicable to learners’ daily work and practice.	YES - NO
9	ETHICS	The participants are provided the opportunity not only to receive new knowledge and skills, but also to reexamine their motives, values, and attitudes.	YES - NO
10	ETHICS	Open-ended ethical issues are well addressed in the educational content.	YES - NO
11	ETHICS	Education provides answers to ethical dilemmas, allowing participants to develop decision-making skills in the process of pharmaceutical care.	YES - NO
12	ETHICS	Behavior-shaping processes in education increase motivation and professionalism in the pharmacy profession.	YES - NO
13	ETHICS	Education is building the self-image of pharmacists and fosters pharmacists’ commitment to change.	YES - NO
14	ETHICS	Education is enhancing professional autonomy and personal development based on ethical aspects of the pharmacy profession.	YES - NO
15	ETHICS	Principles of professional ethics and autonomy are guiding pharmacists in the responsible use of medicines.	YES - NO
16	ETHICS	Pharmacists are reminded of an Oath of a Pharmacist and/or Code of Ethics for the pharmacy profession.	YES - NO

17	CONTEXT	Education is based on the evidence of real educational needs, such as from competency evaluation or other “gap” analysis.	YES - NO
18	CONTEXT	The real changes in science and practice are considered in the education program.	YES - NO
19	CONTEXT	The content is well aligned with official (legal) scope of practice.	YES - NO
20	CONTEXT	There are opportunities for projects and activities suitable for competency development.	YES - NO
21	CONTEXT	Education provides national and international perspectives on the selected topics.	YES - NO
22	STRUCTURE	Pharmacists are recognized as partners in the patient treatment.	YES - NO
23	STRUCTURE	There are no conflicts of interest, or conflicts of interest are appropriately managed.	YES - NO
24	STRUCTURE	Learning objectives are appropriate to the competencies and scope of practice of the learners.	YES - NO
25	STRUCTURE	Educational content and teaching style address generational issues.	YES - NO
26	STRUCTURE	Teaching and learning methodologies account for and cater to diverse learners, including different learning styles and preferences.	YES - NO
27	STRUCTURE	Teaching and learning methodologies account for different practice backgrounds.	YES - NO
28	STRUCTURE	Teaching and learning methodologies account for educational qualifications.	YES - NO
29	STRUCTURE	Teaching and learning methodologies account for different levels of work experience.	YES - NO
30	STRUCTURE	Materials and resources are provided to the learners (or cited) to enhance understanding and application of the educational material in practice.	YES - NO
31	STRUCTURE	Educational activities address all competency areas (knowledge, skills, attitudes, values).	YES - NO
32	PROCESS	The educational activity ensures interactive involvement of the learners.	YES - NO
33	PROCESS	Content is balanced, objective, and unbiased, especially free from commercial interest and promotional activity.	YES - NO
34	PROCESS	The educational activity uses active learning strategies and exercises and promotes problem solving and critical thinking.	YES - NO
35	PROCESS	Learners actively participate in the identification of learning needs.	YES - NO
36	PROCESS	Each stated learning objective is achieved.	YES - NO
37	PROCESS	Time is well managed.	YES - NO
38	PROCESS	Presenters make full disclosure of any relevant connection, affiliation, or interest.	YES - NO

39	PROCESS	Evaluation of the activity is provided and completed by participants.	YES - NO
40	PROCESS	Elements of the evaluation form address: applicability of the activity to meeting learners' educational needs, achievement of each stated objective, quality of all presenters, usefulness of educational material, effectiveness of teaching and learning methods (including active learning), appropriateness of learning assessment activities, perceptions of bias or commercialism.	YES - NO
41	OUTCOMES	Outcomes are specific and measurable.	YES - NO
42	OUTCOMES	Learning outcomes are assessed.	YES - NO
43	OUTCOMES	CE credits are awarded on demonstration of learning, not just on participation.	YES - NO
44	OUTCOMES	Learners are developing new skills and accepting new knowledge to improve patient and population health.	YES - NO
45	IMPACT	Impact of educational activities is assessed.	YES - NO
46	IMPACT	Learning leads to practice and behavior changes, which have an impact on patients, populations, and the learner's organization.	YES - NO
47	IMPACT	Impact is visible through increased motivation that leads to a greater sense of responsibility and commitment to change.	YES - NO
48	IMPACT	New projects, services, or activities are visible in pharmacy practice and competency development as a result of the education.	YES - NO
49	IMPACT	Impact is achieved in leadership and advocacy in the development of the profession and agents of change.	YES - NO
50	IMPACT	Innovations and changes that address or solve national and/or international health care needs and priorities are encouraged.	YES - NO

# Annex C. Checklist of Key Components to Consider in the Development of an Accreditation Body

## 1. Mission, terms of reference, and scope of operations

### 1.1 Mission and vision

- Identify the accreditation body's mission.
- Determine the method that will be used to communicate the mission to stakeholders.
- Determine the method that will be used to evaluate achievement of the accreditation body's mission.
- Identify who is responsible for tracking achievement of the mission.
- Identify the assessment tools that will be used to track achievement of the mission.
- Identify the timeline that will be used to track achievement of the mission.

### 1.2 Legal/statutory status

- Identify the accreditation body's legal/regulatory authority.
- Identify the laws that govern the accreditation body.

### 1.3 Recognition, authority, and accountability

- Identify any entities that recognize the accreditation body.
- Identify the mandate that gives the accreditation body authority.
- Identify the parties to whom the accreditation body is accountable.
- Identify the requirements and criteria that the accreditation body must meet.

### 1.4 Degree of autonomy in decision making

- Identify the methods that will be used to ensure that the accreditation body has autonomy in its decision making.
- Identify the methods that will be used to ensure that the accreditation body is free from any undue political or other influences.
- Identify the methods that will be used to ensure that the accreditation body is free from conflicts of interest.

### 1.5 Influence of market forces

- Determine the accreditation body's ability to influence or be influenced by market forces (including human resources/employment issues, commercial or competitive interests, etc.).

### 1.6 Relationships with government, professional/technical organizations, and other stakeholders

- Determine if any relevant formal or informal relationships exist.

## 2. Governance and decision making

### 2.1 Composition

- Determine the composition of the decision-making body.
- Identify methods that will be used to assure the inclusion of all key stakeholder perspectives in the decision-making process.

## 2.2 Officers

- Identify the process that will be used to elect or appoint officers (if applicable).

## 2.3 Public input

- Identify the methods that will be used to obtain public input.
- Determine how public input will be used in the quality assurance process.

## 2.4 Criteria for appointment or selection of members

- Determine the process that will be used to select or appoint members of the governing body.
- Determine the process that will be used to establish or implement criteria that will be used to select members.

## 2.5 Term of office of members

- Determine the terms of office for members of the decision-making body.
- Identify the process that will be used to communicate terms of office to stakeholders.

## 3. Funding and fees for services

- Determine how the accreditation body will be funded.
- Identify the fee structure for the accreditation body's services.
- Identify the process that will be used to communicate fees to stakeholders and constituents.

## 4. Operations

### 4.1 Board/committee/council operations

- Determine the methods that will be used to establish and communicate the key elements of the quality assurance process.
- Identify the mechanisms that will be implemented to ensure that the process will be consistently applied.

### 4.2 Meetings of the decision-making body

- Identify the frequency with which meetings will be held.
- Identify where meetings will be held.
- Identify the process that will be used to conduct meetings.

### 4.3 Criteria on which decisions are based

- Determine how the criteria will be developed.
- Determine the method that will be used to ensure that the criteria are consistently applied.
- Determine the process that will be used to review the criteria.
- Determine the frequency with which the criteria will be reviewed.

## 5. Evaluation and accreditation

### 5.1 Requirements for initial eligibility

- Determine the requirements that CE providers must meet to apply for initial accreditation.

### 5.2 Stages of the accreditation process including requirements for progression through stages

- Determine the different stages of accreditation and the requirements for progressing through the different stages.

### 5.3 Standard accreditation cycle

- Determine the duration of the standard accreditation cycle.

- 5.4 Additional requirements for maintenance of accreditation, including reporting, annual monitoring data, audits
- Determine any requirements for maintenance of accreditation including reporting, annual monitoring data, and audits.
- 5.5 Consequences of noncompliance with the criteria/standards.
- Determine the method that will be used to communicate the consequences.

## 6. Public disclosure

- 6.1 Determine the method that will be used to communicate the actions of the decision-making body.
- Determine the nature and type of information that will be publicly disclosed (such as decisions, proceedings from meetings, and communications with the accreditation body).
  - Identify the method that will be used to communicate such information and who will receive the information.

## 7. Policies and procedures

- 7.1 Confidentiality
- Determine the method that will be used to ensure confidentiality.
- 7.2 Conflict of interest
- Determine the process that will be used to identify and resolve conflicts of interest.
- 7.3 Evaluators
- Determine the process that will be used to select and train external reviewers.
- 7.4 Substantive change
- Identify what constitutes substantive change for providers.
- 7.5 Appeals
- Identify the process that will be used for appeals.
- 7.6 Complaints
- Identify the process that will be used to address complaints about a provider or an educational activity.
- 7.7 Record keeping
- Determine the duration that records will be maintained.
  - Determine where and how records will be kept.
- 7.8 Revision/updating of standards
- Determine how often the standards/criteria will be revised/reviewed.
  - Identify the process that will be used to review/revise the standards.
  - Determine how stakeholder input will be incorporated.
- 7.9 Safeguards for pharmacist and pharmacy support personnel
- Identify how the rights of stakeholders will be addressed.

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