National Academic Reference Standards

For

Pharmacy Education

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Abbreviations

ADR	Adverse Drug Reaction
DTC	Drug Therapeutic Committee
FDA	U.S. Food and Drug Administration
FIP	International Pharmacy Federation
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
GPMP	Good Pharmaceutical Manufacturing Practice
GSP	Good Storage Practice
I.V.	Intravenous
OTC	Over The Counter
R & D	Research and Development
TPN	Total Parenteral Nutrition
WHO	World Health Organization

Glossary

Academic standards: Specific standards decided by the institution and informed by external references and including minimum knowledge and skills to be gained by the graduate from the program and fulfilling the stated mission of the institution.[1]

Attributes: The set of characteristics expected of a graduate, which draw upon the acquired knowledge, understanding and skills for employment and/or further education and academic research at an appropriate level field.[1]

Benchmark statements: Benchmark statements set out expectations about standards of degrees in a range of subject areas. They describe what gives a discipline its coherence and identity, and define what can be expected of a graduate in terms of the abilities and skills needed to develop understanding or competence in the subject. Benchmark statements do not represent a national curriculum in a subject area rather they allow for flexibility and innovation in programme design, within an overall conceptual framework established by an academic subject community.[2]

Intended Learning outcomes (ILOs): The ILOs are the knowledge, understanding and skills which the institution intends for its program that are mission-related the use of external reference standards at appropriate level.[1]

Skills: The set of abilities to do tasks which will require the application of applied knowledge.[1]

Medication: A medication, as defined by the FDA, is any prescription medication; sample medication; herbal remedy; vitamin; nutriceutical; over-the-counter drug; vaccine; diagnostic and contrast agent used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medication; respiratory therapy treatment; parenteral nutrition; blood derivative; intravenous solution (plain, with electrolytes and/or drugs).[3] Other synonyms include drug, medicine, medicinal agent and pharmaceutical product.

Pharmaceutical Care: It is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.[4] It is considered as a philosophy of practice in which the patient is the primary beneficiary of the pharmacist's actions. Pharmaceutical care focuses on the attitudes, behaviors, commitments, concerns, ethics, functions, knowledge, responsibilities and skills of the pharmacist on the provision of drug therapy with the goal of achieving definite therapeutic outcomes toward patient health and quality of life.[5]

Pharmacovigilance: It is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines.[6] Generally speaking, pharmacovigilance is the science of collecting, monitoring researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, herbalism and traditional medicines with a view to:

- Identifying new information about hazards associated with medicines; and
- Preventing harm to patients.

Introduction

Pharmacists participate in the public health program within the national framework of pharmaceutical care in Egypt. Pharmacists are the main contributor to the development of local drug industry. Data from the national health account in Egypt indicate that about 35% of health expenditures are spent on drugs.[7] This fact, in addition to the significant role of pharmaceutical industry in Egypt in covering more than 90% of local drug consumption, demonstrates the importance of pharmacy profession in promoting health of the Egyptians and overall national economic development. Pharmacy profession is responsible for the achievement of the national drug policy objective of ensuring the safety, efficacy and quality of all medicines available in the Egyptian market.

Pharmacy profession is also responsible for ensuring equity, accessibility and affordability of essential drugs and vaccines to all Egyptian population. In addition, pharmacist's role in development of pharmacy education, science and technology research and continued professional development is essential to meet the global challenges and the new technological development in pharmaceutical sciences.

In Egypt, the national pharmaceutical system includes several organizations that need to cooperate and work together in harmony to achieve its national objectives. These organizations are:

- Academic and Research Institutions;
- National Regulatory Authorities, including the Central Pharmacy Administration and National Organization for Drug and biological Control and Research;
- Egyptian Pharmacists Syndicate;
- Egyptian Pharmaceutical Societies;

- Pharmaceutical drug companies, medical offices and distribution companies; and
- Community and hospital pharmacies, biomedical laboratories and other pharmaceutical service institutions.

Pharmacy Education

A five years pharmacy education program, offering a bachelor degree of pharmaceutical sciences (B. Pharm. Sci.), should:

- Provide the appropriate mix of basic, pharmaceutical, medical, social, behavioral, management, health and environmental sciences as well as pharmacy practice to support the role of pharmacists in multidisciplinary health team;
- Enhance pharmaceutical care and problem solving approaches;
- Promote knowledge of pharmacoeconomics as well as communication, presentation and management skills;
- Encourage lifelong-learning and evidence-based practices; and
- Develop and implement an efficient system for quality assurance and accreditation.

The pharmacy programs must have:

- Mission and vision statements.
- Strategic goals and objectives.
- Intended learning outcomes.
- Curriculum content and Syllabus.
- Teaching and assessment methods.

Pharmacy program must be regularly evaluated and the content of the curriculum must be revised and assessed to conform to the NARS and ensure relevance to recent advances in pharmacy practice.

Pharmacy Career

Pharmacy Practice in Egypt

The majority of pharmacists in Egypt work in community pharmacies followed by hospitals as well as industrial, academic and research institutions. Pharmacists are also involved in other professional practices including forensic services, biomedical laboratories, cosmetic industry, veterinary medicines and military pharmacy services. Furthermore, a large number of Egyptian pharmacists work abroad, mainly in Arab countries.

Future Development of Pharmacy Profession

Pharmacy profession is one of the most dynamic professions that need to develop to face the continuous changes and challenges in the health sector. Pharmacy profession during the last four decades has moved from drug-oriented profession to patient- and community-oriented profession. Pharmacy practice has evolved from a compounder and a drug supplier services towards a pharmaceutical care provider.

Although the definition of pharmaceutical care focuses on drug therapy in the individual patient, its beneficiary has expanded to the public as a whole. The pharmacist is also recognized as a health care provider who can actively participate in illness prevention and health promotion along with other members of the health care team.[8]

The concept of the seven-star pharmacist, introduced by WHO and taken up by FIP in 2000 in its policy statement on Good Pharmacy Education Practice, sees the pharmacist as a caregiver, communicator, decision-maker, teacher, life-long learner, leader and manager. Role of pharmacist as a researcher has been recently added.

According to the Pharmacy Practice Activity Classification,[9] four main areas covering mainly community and hospital services are described as follows:

A. Ensuring appropriate therapy and outcomes

This area covers the development of appropriate pharmacotherapy plan and ensuring patient adherence to this plan.

B. Dispensing medications and devices

This area covers the professional procedure to dispense medication and medical devices.

C. Health promotion and disease prevention

This covers the role of pharmacist to promote and protect public health and prevent diseases and promote the rational use of drugs.

D. Health systems management

The area covers the effective management of drug supply system and good management of pharmaceutical facilities.

In addition to community and hospital pharmacy services, other areas where pharmacists can work are also recognized, including:

- Regulatory control and drug management;
- Industrial pharmacy;
- Academic institutes;
- Biomedical laboratory services;
- Forensic services;
- Radiologic and nuclear pharmacy services;
- Complementary and alternative medicines;
- Veterinary pharmacy;
- Cosmetics; and
- Medical devices and diagnostic kits.

The detailed activities of pharmacists in these areas are further elaborated as follows:

1. **Community Pharmacy**

The largest number of pharmacists in Egypt is working as community pharmacists. More and more community pharmacists are practicing some components of pharmaceutical care services.

The major areas covered by community pharmacists are:

- Pharmacy management and business administration;
- Dispensing of prescription medicines;
- Extemporaneous preparation;
- Responding to symptoms of minor ailments and dispensing over the counter (OTC) drugs;
- Public health activities to promote healthy lifestyles including healthy nutrition, combating drug abuse, stop smoking, and physical activities;
- Domiciliary services (providing home pharmaceutical services);
- Patient medicines record and information services; and
- Participating in drug utilization and post marketing surveillance studies.

2. **Hospital Pharmacy**

A) Clinical pharmacy services in hospitals

Clinical pharmacy services are practiced to different extent at various specialized departments and hospitals in collaboration with patients and other health care professionals based on evidence-based data. The main areas covered in clinical pharmacy practice in Egypt are:

- Patient counseling to decide on patient's drug needs;

- Develop and implement pharmacotherapy plan including preparation and dispensing of the required dose as well as total parenteral nutrition (TPN);
- Evaluate and manage drug interactions; and
- Monitor and evaluate therapeutic outcomes.

B) Hospital pharmacy services

The areas covered by hospital pharmacy services may include:

- Drug selection and management of hospital formulary by drug therapeutic committee (DTC);
- Efficient drug procurement;
- Management of drug distribution system in hospitals;
- Promotion of rational use of drugs;
- Management of antibiotic resistance and infection control;
- Management of drug and poison information centre;
- Safe disposal of hazardous matters including expired drugs;
- Radiopharmaceutical services;
- Investigational drug studies and clinical trials; and
- Adverse drug reaction (ADR) reporting system.

3. Regulatory control and drug management

Pharmacists working in the various departments of national medicine regulatory authorities may be involved in one or more of the following areas:

- Formulation of national medicine policy as integral component of national health policy;
- Medicine registration department;
- Quality control and quality assurance of medicines and biological products;
- Enforcement of laws and regulations including good pharmaceutical manufacturing practice (GPMP), good

laboratory practice (GLP), good clinical practice (GCP), good storage practice (GSP) and good distribution practice (GDP) inspections;

- Licensing of pharmaceutical facilities;
- Management of public drug supply system;
- Professional development of human resources; and
- Cooperation with national, regional and international bodies.

4. Industrial pharmacy

It is important to emphasize the importance of pharmacists working in various areas related to pharmaceutical industry. These include:

- Formulation and manufacturing of medicines within the overall quality assurance (QA) system;
- Quality control (QC) activities and studies;
- Drug research and development (R & D);
- Planning and conducting clinical trails and post marketing surveillance;
- Involvement in patent applications and drug registration;
- Managing and promoting the sales and marketing of medicines according to professional and ethical criteria; and
- Involvement in industrial management and drug economics.

5. Academic Institutions

In academic institutions, pharmacists are engaged in teaching, research, and pharmacy practice development. Undergraduate, postgraduate and continuing education require that the educators should be aware of global pharmacy profession development and the national needs. Academic institutions should be also involved in environment development and community services.

6. **Biomedical Laboratory Services**

The scientific background and skills of pharmacists in microbiological, pharmaceutical, toxicological and biochemical analysis strongly support pharmacists working in the area of biomedical laboratory services.

7. **Forensic Services**

Pharmacists in Egypt have long tradition in working in this field. Their knowledge of toxic substances including natural products and forensic chemistry strongly support pharmacists working in forensic services.

8. **Radiologic and Nuclear Pharmacy Services**

Radiopharmaceuticals are increasingly used for both diagnostic and treatment purposes. Successful preparation and administration of radiopharmaceuticals require pharmacist's experience in formulation, preparation, storage, dispensing and disposal of radiopharmaceuticals.

9. **Complementary and Alternative Medicine**

The extensive knowledge of pharmacist in pharmacognosy and phytochemistry as well as other pharmaceutical sciences provide the necessary knowledge and skills to work in the areas of cultivation, preparation, formulation, manufacturing, and rational use of herbal medicine.

10. **Veterinary Pharmacy**

Handling and processing of veterinary medicines without professional pharmacy supervision can cause serious health hazards. Pharmacists should, therefore, be involved in proper production, processing, and dispensing of veterinary medicines.

11. **Cosmetics**

Public health hazards due to non-professional production and processing of cosmetics are widely recognized. Pharmacists' knowledge

and expertise are essential to ensure the safety and quality of cosmetic preparations.

12.Medical Devices and Diagnostic Kits

Proper selection, maintenance and rational use of medical devices and diagnostic kits contribute to the most cost-effective health care services. In many settings, pharmacists are involved in selection, procurement and management of medical devices.

It is important, however, to consider involvement of pharmacists in various areas of pharmacy practice to orient and design pharmacy education.

Attributes of Pharmacy Graduates

Pharmacy graduates work in a multi-disciplinary profession and must acquire the necessary attributes in various pharmacy aspects for pursuing their career. They should demonstrate comprehensive knowledge, clear understanding and outstanding skills as follows:

1. Handle chemicals and pharmaceutical products effectively and safely with respect to relevant laws and legislations.
2. Capable of formulating, preparing pharmaceutical products from different sources and participating in management systems for dispensing, storage and distribution of medications.
3. Perform various qualitative and quantitative analytical techniques and fulfill criteria of GLP and GPMP to assure the quality of raw materials, pharmaceutical products and procedures.
4. Provide information and education services to community and patients about rational use of medications and medical devices.
5. Recognize principles of pathophysiology of diseases and participate with other health care professionals in improving health care services using evidence-based data.
6. Plan, design and conduct research using appropriate methodologies and participate in R&D activities.
7. Develop presentation, promotion, marketing, business administration, numeric and computation skills.
8. Demonstrate capability of communication skills, time management, critical thinking, problem solving, decision making and team working in pharmacy practice.
9. Perform responsibilities in pharmacy practice in compliance with legal, ethical and professional rules.
10. Able to be a life-long learner for continuous improvement of professional knowledge and skills.

National Academic Reference Standards for Pharmacy Education

I. Knowledge and Understanding

The pharmacy graduate must demonstrate comprehensive knowledge and clear understanding of the core information associated with the profession as follows:

1. Principles of basic, pharmaceutical, medical, social, behavioral, management, health and environmental sciences as well as pharmacy practice.
2. Physico-chemical properties of various substances of natural and synthetic origin used in preparation of medicines including inactive and active ingredients as well as biotechnology and radio-labeled products.
3. Principles of pharmacokinetics and biopharmaceutics with applications in therapeutic drug monitoring, dose modification and bioequivalence studies using biotechnology techniques.
4. Properties of different pharmaceutical dosage forms including novel drug delivery systems.
5. Principles of various instruments and techniques including sampling, manufacturing, packaging, labeling, storing and distribution processes in pharmaceutical industry
6. Principles of different analytical techniques using GLP guidelines and validation procedures.
7. Principles of hospital pharmacy including I.V. admixtures, TPN and drug distribution system.
8. Principles of drug design, development and synthesis.

9. Principles of isolation, synthesis, purification, identification, standardization methods of different pharmaceuticals including natural substances
10. Principles of public health issues including sources and control of microbial contamination as well as sterilization methods and microbiological quality control of pharmaceutical products.
11. Principles of body function in health and disease states as well as basis of genomic and different biochemical pathways regarding their correlation with different diseases.
12. Pharmacological properties of drugs including mechanism of action, clinical uses, dosage, contra-indications, adverse drug reactions and interactions.
13. The etiology, epidemiology, laboratory diagnosis and clinical features of different diseases and pharmacotherapeutic approaches.
14. Basis of complementary and alternative medicine including phytotherapy.
15. Toxic profile of drugs and other xenobiotics including sources, identification, symptoms, management control and first aid measures.
16. Methods of statistical analysis and pharmaceutical calculations.
17. Management principles including financial and human resources, system development and planning.
18. Principles of drug promotion, sales and marketing, business administration, accounting and basis of pharmacoeconomics in pharmacy practice.
19. The regulatory affairs, pharmacy laws and ethics of health care and pharmacy profession.

II. Skills

II.A. Intellectual skills

1. Apply basic pharmaceutical knowledge in the formulation of safe and effective medicines as well as in the development of new drug delivery systems.
2. Use the knowledge of biotechnology principles in the development of new biopharmaceutical products.
3. Apply the principles of bio-informatics and computer aided tools in drug design.
4. Recognize and control any possible physical and/or chemical incompatibilities that may occur during drug dispensing.
5. Design, develop and evaluate qualitative and quantitative analytical and biological methods for quality control of pharmaceutical preparations.
6. Develop and establish good storage and drug distribution systems.
7. Select the appropriate methods of extraction, isolation, purification, identification, standardization and formulation of natural products.
8. Select and assess appropriate methods of infection control to prevent infections and promote public health.
9. Implement the pharmacological basis of therapeutics in the proper selection and use of drugs in various disease conditions.
10. Calculate and adjust dosage and dose regimen of medications.
11. Monitor and manage drug interactions and adverse drug reactions.
12. Utilize the principles of pharmacoeconomic to promote cost/effective pharmacotherapy.
13. Analyze and interpret scientific research results.
14. Analyze and evaluate evidence-based information needed in pharmacy practice.

II.B. Professional and Practical Skills

1. Use properly the pharmaceutical/medical terms, abbreviations and symbols in pharmacy practice.
2. Handle and dispose chemicals and pharmaceutical preparations including radio-pharmaceuticals safely and effectively.
3. Operate different pharmaceutical equipments and instruments and use emerging technologies.
4. Implement GLP, GPMP, GSP and GCP guidelines in pharmacy practice.
5. Compound, dispense, label, store and distribute medicines effectively and safely.
6. Manage drug supply and distribution systems.
7. Extract, isolate, purify, identify, standardize and formulate natural products and assure their rational use.
8. Assess toxicity profiles of different xenobiotics as well as detect and analyze poisons in biological specimens.
9. Maintain public awareness on social health hazards of natural and synthetic drug abuse and misuse.
10. Monitor and control microbial contamination in pharmaceutical industrial firms, hospitals, laboratories …etc.
11. Carry out laboratory tests for identification of infectious and non infectious diseases.
12. Select medicines based on understanding of etiology and pathophysiology of diseases.
13. Advise patients and other health care professionals about safe and proper use of medicines.
14. Develop, with other health care professionals, patient-centered and population-based care plans to optimize therapeutic outcomes.

15. Conduct research studies and utilize the results in different pharmaceutical fields.

II.C. Transferable Skills

1. Communicate clearly with patients and other health care professionals by verbal and written means.
2. Retrieve and evaluate information from different sources to improve professional competence.
3. Work effectively in a team.
4. Use numeracy, calculation and statistical methods as well as information technology tools in pharmacy practice.
5. Practice independent learning needed for continuous professional development.
6. Adopt ethical, legal and safety guidelines in pharmacy practice.
7. Develop problem-solving approach in various pharmaceutical areas.
8. Evaluate and criticize published literature.
9. Employ proper documentation and filing systems in different pharmaceutical fields.
10. Develop financial, sales and market management skills.
11. Demonstrate creativity and time management abilities
12. Implement writing and presentation skills.
13. Demonstrate critical thinking and decision making abilities.
14. Take responsibility for adaptation to changing needs in pharmacy practice.

Appendix

Pharmacy Undergraduate Program Core Curriculum

SCIENCES	SUBJECTS
BASIC 10-15%	**Physical, organic and analytical chemistry; biology; biophysics; computer sciences; mathematics.**
PHARMACEUTICAL 35-40%	**Pharmacy orientation; medical terminology; physical pharmacy; pharmaceutics; industrial pharmacy; pharmaceutical technology; biopharmaceutics; pharmacokinetics; pharmaceutical chemistry; drug design; pharmacognosy; chemistry of natural products; pharmaceutical microbiology; molecular biology and pharmaceutical biotechnology; quality assurance and quality control.**
MEDICAL 15-25%	**Anatomy; histology; physiology, pathology; biochemistry; parasitology, pharmacology; therapeutics; medical microbiology; immunology; virology.**
PHARMACY PRACTICE 10-15 %	**Pharmaceutical care and professional pharmacy (clinical, hospital, community ... etc); complementary and alternative medicines; drug and poison information; pharmacy laws and regulations.**
HEALTH AND ENVIRONMENTAL 5-10 %	**Public health; health policies; biostatistics; healthy lifestyle; toxicology and forensic medicine; first aid and emergency medicine.**
BEHAVIORAL AND SOCIAL 2-4%	**Psychology; communication; social and administrative pharmacy; pharmacy ethics.**
PHARMACY MANAGEMENT 2-4%	**Sales, marketing and drug promotion; pharmaceutical business administration; drug and pharmaco-economics.**
ELECTIVES 3-5%	**Professional and non-professional sciences.**

Summer training (not less than 300 hours) should be included in B. Pharm. Sci. Program.

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