



Ministry of Health & Population  
Egypt

# Pharmaceutical Sector Reform Program HSRP

## Pharmaceutical Training Program in collaboration with Europe Aid

Identification Number: EuroAid/121454/D/SV/EG

### Program Specifications

### Program 5: Drug Registration, Pricing, & Licensing



KONINKLIJK INSTITUUT  
VOOR DE TROPEN  
ROYAL TROPICAL INSTITUTE



## Program 5: Drug Registration, Pricing, & Licensing

### 1. General Objectives

To inform trainees about different procedures, steps, methods, and documents needed for licensing new pharmaceuticals, factories, pharmacies, laboratories, and academic bureaus.

The program aims at identifying legal and institutional framework applicable to drug registration, pricing, and licensing.

### 2. Intended Learning Outcomes (ILOs) of the program

#### 2.1. Knowledge/Understanding

**By the end of this program the trainee should be able to demonstrate understanding of:**

2.1.1. Regulatory legal framework.

2.1.2. Good Regulatory Practices.

2.1.3. Rationale behind pharmaceutical registration, pricing, and licensing as well as techniques followed.

2.1.4. Applications of Total Quality Management in drug registration, pricing, & licensing<sup>1</sup>

2.1.5. Interpretation of stipulations of the World Trade Organization (WTO) and Trade-Related Aspects of Intellectual Property Rights (TRIPS) on the level of national practice

2.1.6. How to preserve and protect public health through his/her jobs

#### 2.2. Intellectual Skills

**By the end of this program the trainee should be able to:**

2.2.1. Analyze available practical and procedural data from companies and professionals.

2.2.2. Correlate the national and international measures introducing new products and/or licenses.

#### 2.3. Professional and Practical Skills

**By the end of this program the trainee should be able to:**

2.3.1. Operate in compliance with the laws and regulations

2.3.2. Compile definite documentation needed and others to be revised for each procedure of registration and licensing

2.3.3. Monitor and evaluate conventional practice for improvement and quality reasons actions.

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<sup>1</sup> Total Quality Management will be covered in details in Program 1

## 2.4. Transferable Skills

**By the end of this program the trainee should be able to:**

- 2.4.1. Handle practical problems and contemporary procedural requirements.
- 2.4.2. Get consistent with advancements.
- 2.4.3. Search and obtain information needed to enrich technical performance.
- 2.4.4. Report and present professional outcomes.

## 3. Program Contents

### Topics

- 3.1. Restructuring Strategies of the Pharmaceutical Sector as Part of the Health Sector Reform.
  - 3.1.1. Functional Restructuring and its Rationale
- 3.2. Regulatory Matrix, Concept and Rationale
  - 3.2.1. Overview
  - 3.2.2. Matrix
  - 3.2.3. Legal Framework, Legislations' Impacts; and Fundamental Local Virtues
  - 3.2.4. Remuneration Guidelines for Medical Technologies
  - 3.2.5. World Trade Organization (WTO) and Trade-Related Aspects of Intellectual Property Rights (TRIPS) Provisions on Pharmaceuticals
  - 3.2.6. Unification and Harmonization
- 3.3. Good Regulatory Practices
  - 3.3.1. Code of Conduct
    - 3.3.1.1. Functional Statements for Regulatory Bodies
    - 3.3.1.2. Regulatory procedures manual:
      - 3.3.1.2.1. Registration Procedures of Pharmaceuticals & Marketing Authorization
      - 3.3.1.2.2. Compliance Management and Operations
      - 3.3.1.2.3. Compliance Policy, Sharing Information and Quality Assurance
      - 3.3.1.2.4. Labeling, Recalls, and Training
      - 3.3.1.2.5. Regulatory Measures
      - 3.3.1.2.6. Work Documentation

- 3.3.1.2.7. Committees
  - 3.3.1.2.8. Computerization
  - 3.3.1.2.9. Monitoring & evaluation of prices internationally and across-country
- 3.4. Pricing System, Methods, and Components of Medicines pricing
- 3.4.1. Socioeconomics
  - 3.4.2. Drug Economics
  - 3.4.3. Pharmaco-Economics
  - 3.4.4. Pricing
- 3.5. Licensing of Pharmaceutical Facilities
- 3.5.1. Legal Aspects
  - 3.5.2. Technical Aspects
- 3.6. Application of Total Quality Management in Drug Registration, Pricing, & Licensing<sup>2</sup>
- 3.7. Practical problems and contemporary procedural requirements:
- 3.7.1. Registration constraints and problems
  - 3.7.2. Compliance with the laws, legislations, stipulations and ethics;
  - 3.7.3. Preserving and protecting the public and their health;
  - 3.7.4. Compliance with international standards.

## 4. Training and Learning Methods

- 4.1. Lecturing
- 4.2. Workshops
- 4.3. Case studies
- 4.4. Role playing
- 4.5. Problem solving sessions

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<sup>2</sup> Total Quality Management will be covered in details in Program 1

## **5. Assessment**

- 5.1. Class and group participation (25%)
- 5.2. Presentation and open discussion exercises (30 %)
- 5.3. On time delivered homework (20 %)
- 5.4. Pre vs. post tests (25 %)

## **6. Target Groups**

- 6.1. Staff working in registration, licensing and pricing departments

## **7. Number of Participants**

Twenty-Five Participants

## **8. Duration:**

6 days (36 hours)

## **9. References:**

- 9.1. WHO medicines bookshelf version 4.0 – 2004;
- 9.2. Regulatory procedures and medicines registration FDA; 2006
- 9.3. Organization analysis and training needs assessment of pharmaceutical sector in Egypt; MOHP-CDTP May, 2004.
- 9.4. Egyptian pharmacy related articles, records and publication; 2000-2006.