JOB DESCRIPTION AND SPECIFICATION

JOB TITLE:	Director, Pharmaceutical & Regulatory Affairs
JOB GRADE:	PMG/PHS 7
DEPARTMENT:	Pharmaceutical & Regulatory Affairs
REPORTS TO:	Director, Standards and Regulation
MANAGES:	Scientific Officer (2), Chief Drug Inspector, Chief Dangerous Drug Inspector, Dangerous Drug Inspector, (4) Drug Inspector, Registrar & Monitoring (Health Institutions)

This document is validated as an accurate and true description of the job as signified below

Employee	Date
Head of Department/Division	Date
Date received in Human Resource Division	Date created/revised

JOB PURPOSE

The Director has the responsibility to facilitate the administration of legislation, policies and guidelines in order to achieve the objectives of the ministry as regards to pharmaceuticals and other designated products.

KEY OUTPUTS

1. Reports
2. Systems/mechanisms for product registration reviewed and revised periodically.
3. Registered healthcare institutions.
4. Registered products.
5. Mechanisms/ to facilitate access to, availability of medicines and devices for life threatening conditions determined implemented and reviewed.
6. Active participation in processes to amend, existing and/or formulate new legislation undertaken.
7. Active involvement in projects, plans discussions, meetings to develop programmes for multisectoral approach to healthcare undertaken.

KEY RESPONSIBILITY AREAS

Management and Administration

1. Plans, organizes, directs, control and coordinates the work and activities of the P&RA Department.
2. Develops, establish and maintain systems for the department
3. Develops and maintains a system for monitoring and registering all healthcare institutions in both the public and private sectors.
4. Collaborates with the Regional Directorate in the design and implementation of post-basic training programmes for Pharmacist and Pharmacy Technicians.
5. Establishes and maintains an up-to-date database system and management information system for recording details of individuals, entities and institutions concerned.
6. Establishes and maintains registry of health care institutions including children's and Nursing Homes in private sector.

7. Liaises with statutory agencies, which take regulatory decisions relating to health care.

8. Interacts with other agencies such as the Children's Services Division and Public Health Departments, which have immediate responsibility for the operation of such institutions.

9. Monitors and inspects Health Care Institutions for purposes of registration.

10. Performs other related duties as assigned by the Director, Standards and Regulation.

11. Interacts and collaborates with other members of management team.

Technical/Professional

1. Develops and maintains a system for registration of pharmaceuticals, chemicals, cosmetics, foods and herbal products.

2. Develops guidelines and carries out inspections as required, under the relevant Acts.

3. Develops and implements a system for auditing the use of drugs, precursor chemicals and psychotropic substances.

4. Establishes and maintains a system for controlling and monitoring the importation of foods, drugs, herbal product, cosmetics, chemicals and related devices.

5. Reviews applications and grant permits for the manufacture and importation of pharmaceuticals, chemicals, herbal products, precursor substances and related devices for local consumption.

6. Assists in coordinating the accessing of life saving drugs from overseas or local sources in times of National Emergency.

7. Designs and coordinates a system of post-marketing surveillance pharmaceuticals, chemicals, etc, to verify safety, efficacy and quality.

8. Develops criteria for the registration and re-registration of health care institutions involved with drugs, pharmaceutical supplies, chemicals, cosmetics etc.

9. Participates in relevant international seminars and conferences.

10. Performs any other related duties as assigned by the Director, Standards and Regulations

PERFORMANCE STANDARDS

1. Statutory reports prepared and submitted as decided by the Ministry and the Division in the established timeframe

2. Professional research prepared and submitted in a timely fashion

3. Active participation in activities related to delivery of quality healthcare

4. Criteria for registration and re-registration of health care facilities developed and communicated to stakeholders

5. System for post-marketing surveillance pharmaceuticals, chemicals, etc, to verify safety, efficacy and quality adhered to/maintained.

6. System for controlling and monitoring the importation of foods, drugs, herbal product, cosmetics, chemicals and related devices maintained in accordance with established procedures

7. Permits processed within established time frame

8. Mechanisms in place to minimize the Incidence of illegal substances being imported

9. Guidelines and relevant legislation adhered to

REQUIRED COMPETENCES

Core Competencies	Levels
Problem solving and decision making skills	3
Written Communication Skills	3
Oral Communication skills	3
Compliance	3
Interpersonal skills	3
Planning and organizing skills	3
Initiative	3
Analytical thinking	3
Managing external relations	3
People Management	3
Integrity	3
Leadership	3

Functional/Technical	Levels
Knowledge of Public Service Regulations	3
Knowledge of Legislation governing the health sector	3
Technical skills-pharmacy	

MINIMUM REQUIRED QUALIFICATION AND EXPERIENCE

- B.Sc. in Pharmacy
- MSc. In Health Related Science/Public Administration/Management Studies

Plus

- Eight (8) years experience in the public sector health care system, of which four (4) years should be in Regulatory Affairs
- Registration with the Pharmacy Council of Jamaica

SPECIAL CONDITIONS ASSOCIATED WITH THE JOB

- Numerous critical deadlines
- Exposure to highly confidential and sensitive information
- Expected to display a high degree of integrity
- Irregular and long working hours

AUTHORITY

- To recommend withdrawal of pharmaceuticals from the market
- To inspect premises, seize supplies and initiate legal action in respect of breaches to laws/regulations
- To grant permits for the manufacture and importation of pharmaceuticals, Chemicals, herbal products and precursor substances and specific products etc. for local consumption.