



TERMS OF REFERENCE

Organizational Development Consultancy for The Restructuring of the Standards & Regulation Division – 6 month period

INTRODUCTION

The Ministry of Health and Wellness (MOHW) is responsible for ensuring that health services are adequate and that they are delivered effectively and efficiently in accordance with prescribed standards and regulations. The MOHW Vision for Health 2030 - Ten-year Strategic Plan¹ signals the need for comprehensive, equitable and quality health services and a renewed thrust for promoting and realizing the right to the enjoyment of the highest attainable standard of health. The achievement of the Ministry's strategic goal 2 – 'safeguarding access to equitable, comprehensive and quality healthcare,' requires a greater emphasis on

- client-centric healthcare;
- the existence of the legislative landscape that can pre-empt and respond to the potential and emerging changes in the business environment;
- the human machinery and systems to apply risk-based principles to monitor products, processes and practices related to the delivery of healthcare; and
- the development of quality assurance programs to assess and support the delivery of health services.

In the context of the National Development Plan: Vision 2030 and the Public Sector Transformation and Modernization Programme, it is clear that while the MOHW executes its mandate it should ensure that trade and commerce are facilitated and that the systems it employs are resilient to external shocks and robust enough to safeguard the populace.

The Standards and Regulation Division (SRD), the regulatory arm of the MOHW, Jamaica was established in March 1999 under the health reform process of the then-named Ministry of Health & Environment. The advent of this division occurred during a period in which:

- the suite of products and health services being regulated was minimal;
- the demand for monitoring and evaluation as a means of ensuring compliance and fitness for consumption was significantly less;
- consumers were not as au fait with regulatory requirements and international standards and so did not demand much of the service providers;
- the ministry was centralized;
- telecommerce and telemedicine were unheard of, and
- the exponential growth of the Micro, Small and Medium-Sized Enterprises (MSMEs) and the roles and functions of the division were not as expansive.

The landscape being regulated has changed dramatically, and the structure to execute these functions has not since been reformed. The functions of the Division undoubtedly are central to ensuring the achievements of the Sustainable Development Goal 3 and the strategic Goal 2 for the MOHW but cannot be effected if the machinery to execute these functions has been outgrown by the industry the Division was established to serve.

¹Ministry of Health Strategic Business Plan for 2019 – 2030

BACKGROUND

The role and functions of the division are regulatory and administrative and are executed through three (3) branches; Standards Research and Development; Investigation and Enforcement and Pharmaceutical and Regulatory Affairs. The Division exists to provide quality assurance services for the management of the health sector.

This is achieved through the development of standards and technical regulations, maintaining an effective complaint management system, regulating the importation and distribution of designated products, regulating the operations of designated private health care facilities and contributing to policy formulation on health issues. The following laws and regulations primarily govern the functions of the Division:

- Food and Drugs Act, 1964 and Regulations, 1975
- Precursor Chemicals Act, 2005 and Regulations, 2014
- Nursing Homes Registration Act, 1934 and Regulations, 1934
- Dangerous Drug Act, 1948 and Regulations, 1948

Mandate

To contribute to the achievements of the Ministry's Corporate Goals and objectives by leading the process of quality improvement through standard-setting and monitoring of the health sectors.

Purpose

To establish and monitor healthcare standards in collaboration with stakeholders; regulate health institutions and facilities, and designated products and encourage the responsiveness of the health industry to the right of clients.

Our Specific Responsibilities

- Maintain an effective regulatory framework supported by sound legislation for the regulation of pharmaceuticals, medical devices, cosmetics, foods, precursor chemicals, industrial chemicals and other designated products.
- Develop and maintain relevant standards, technical regulations and guidelines for the provision of health care in public and private institutions.

- Identify and contribute to the development of a legislative framework for appropriate management of the health system
- Monitor systems and programmes in health to determine compliance with standards and technical regulations established by the MOHW.
- Identify areas for quality improvement and guide the development of quality improvement programmes in the health management system.
- Grant permits and approvals to companies to make, distribute and market medicines after a review of their safety, quality and effectiveness.
- Assess and evaluate narcotics, psychotropics, herbal products and other drugs, cosmetics, foods, chemicals and medical devices for safe use by the public;
- Regulate manufacturing, wholesale and distribution companies, other health product facilities and designated private health care facilities.
- Monitor and enforce standards, guidelines and regulations (as a shared responsibility with other state agencies in some areas).
- Maintain an effective and efficient complaint management system through the network of Regional Health Authorities, their public hospitals, health centres.
- Monitor research involving human subjects to ensure they are ethically sound and do not impinge upon the rights of humans.
- Contribute to policy formulation on health issues
- Maintain critical linkages with local, regional and international bodies

Rationale for Consultancy

The Government of JAMAICA (GOJ) has embarked on a programme of rationalisation and transformation of key areas of the public sector which are critical to enhancing competitiveness and growth. In doing so, the GOJ aims to create an enabling environment for the private sector and also fulfil the task of protecting the wellbeing and health of the populace. To that end, the GOJ, through the Ministry of Finance & the Public Service, entered into an agreement with the World Bank to finance initiatives under the Strategic Public Sector Transformation Project² (SPSTP).

²Public Sector Modernization & Transformation Programme

The Division has undertaken some steps in recent times to align its operations with the pillars of the SPSTP; the digitization of the permitting and product registration processes, and the implementation of ISO 9001:2015 Quality Management System (QMS). Though these efforts were geared towards optimizing the operations within the SRD, the focus of the projects amplified the silo operations of the Division and thus countering the very intent of the projects.

The ISO 9001:2015 Gap Audit Report of the SRD (2020) cited operational silos, the inadequacy of the structure to support the portfolio of the Division and the complexity and high risk of the processes which function on a manual system as issues that contributed to sub-optimised performance. Likewise, the CARICOM Drug Registration and Regulation Assessment Report (2009) identified the inadequate structure of the SRD as one of the many factors which impact drug regulation within the country and recommended the need to explore the retention of fees to support the operations of the Division.

There has also been a protracted debate on the need to review the structure of the Division to ensure separation of its regulatory role from that of standard-setting. This issue remains unresolved and should be addressed to ensure the balancing of its enforcement responsibilities, the need to facilitate trade and enable growth and efficiency of the private health sector and a greater focus on steering the development of standards and quality practices for the public health sector.

This consultancy is expected to contribute to defining the role of the division to regulate and establish quality systems for the health sector. The consultancy should also examine the role of the SRD as a division of the MOHW against its role as an agency of the MOHW to ensure the best fit for purpose.

OBJECTIVES

The overall objective of the consultancy is to provide the Ministry of Health and Wellness with the required technical advice and support for restructuring the Standards and Regulation Division (SRD) according to the revised business processes as outlined in the strategic review report of the Division prepared by same. The consultant will be required to:

- 1) Provide guidelines to closely align functionalities/ responsibilities of the SRD with the overarching central government principles and best practices for standard development, healthcare regulation, client relation management, quality assurance initiatives, legal support, communication activities and performance management within the Division
- 2) Propose a suitable model in line with Public Sector Transformation and Modernization and Trade Facilitation, outsourcing where necessary, as evidenced by logical and practicable recommendations.
- 3) Redesign and revise the existing structure of the SRD by redefining the job descriptions and specifications, hierarchical relationships, key performance measures, remunerations and accountability mechanisms.

SCOPE OF WORK

The Consultant Firm will be expected to:

- 1) Review strategic, policy and legislative documents and engage in consultations with key stakeholders to identify the core functions and organizational strategies of the Division. Special focus should be on answering the questions: Are we meeting the MOHW mandate? Would the legislative and policy mandates be best met as an agency? Can true regulatory functions be exercised under current positioning?
- 2) Evaluate the existing structure for adequacy of systems and staffing to deliver on core functions and key performance indicators.
- 3) Identify other functions critical to fulfil mandate, not presently being carried out

- 4) Conduct capacity assessment of the branches and suggest if and how same may be optimally utilized in relation to requirements of ISO 9001:2015 Quality Management System, Performance Management Evaluation System (PMES), Human Resource Management, Medium Term Results Based Budgeting (MTRBB). Also, review the management team's ability to effect these and outline an achievable process with implementation steps for succession planning.
- 5) Clearly outline skill sets present and those necessary for advancement of the processes.
- 6) Propose suitable options for automation of the processes within the Division
- 7) Assess the processes, individually and collectively, and provide insight into the best use of resources for streamlining/ realignment to meet objectives
- 8) Compare the operations with similar regulatory entities/ agencies within the government of Jamaica that may be further along/ have completed the reform process in an effort to unearth best practices/ expected challenges/ delays
- 9) Contrast the operations with similar international regulatory authorities outlining the deficiencies and recommend short, medium and long term goals to close the gaps.
- 10) Define a new organizational structure for SRD with requisite charts, outline of posts with accompanying job descriptions relative to PMAS format.
- 11) Develop policy manual(s) to operationalize the division and standard operating procedures regarding internal functioning.
- 12) Provide guidance to SRD on how to plan and execute the required change management strategies.

LOCATION AND SUPPORT

To support the firm in executing its tasks, the Standards & Regulation Division, Ministry of Health & Wellness will provide the consultant with access to information and to managerial/technical personnel as needed to enable the Consultant to undertake the assignment as outlined in this TOR. The Consultant will therefore be expected to make adequate provision in the Financial Proposal for all the necessary requirement to complete the assignment.

DELIVERABLES AND REMUNERATION

The Consultant is expected to provide clear, concise and comprehensive reports that specifically outline activities undertaken. As compensation for the services provided, the consultant/firm shall be paid per deliverable. Payments will be made on satisfactory completion of tasks as seen in the schedule below. No variation to the contract will be accommodated.

| Item | Deliverable | Desired Contents | % Payment |
|------|--|--|-----------|
| A | <i>Inception Report Work Plan</i> | <p>Detailed Project Work Plan</p> <p>The Work Plan document must detail the following:</p> <ul style="list-style-type: none"> - An overview of the methodology that will be used to provide the key outputs of the consultancy. - The process model which shows the execution of the methodology - timelines and deliverables. - The requisite support necessary from the contracting entity in order to execute on the Scope of Work. | 10% |
| B | <i>Situational Analysis Report (As Is)</i> | <ul style="list-style-type: none"> ● Define existing Business Processes ● Gap Analysis and recommendations for improvement <ul style="list-style-type: none"> ○ The Situational Analysis will document the Division as it is currently, to describe and identify as follows: <ul style="list-style-type: none"> ▪ A map of the structure in effect (identification of what functions are presently being carried out and those not being performed) and compare the variances and changes as per the Establishment Act. ▪ Tasks and responsibilities for each post. ▪ Analysis of the relevance, effectiveness and efficiency of SRD roles and functions. ▪ Analysis of SRD's organogram and whether it conforms to the tasks assigned, and whether it is effective. | 10% |

| Item | Deliverable | Desired Contents | % Payment |
|------|---|--|-----------|
| | | <ul style="list-style-type: none"> ▪ Draw a comprehensive assessment of the skills of the teams in place. ▪ Assess the current transfer, promotion, and selection procedure and propose possible improvements. ▪ A SWOT and PESTLE analysis to determine external influences and trends and any strengths, weaknesses, opportunities, and threats that SRD will need to address to enable optimum performance. ▪ Analyse the decision making procedures. ▪ A comparison to the institutional arrangement of similar divisions in the wider government Ministries and internationally. <ul style="list-style-type: none"> ● Finally, provide the main rationale for the changes required for the efficient functioning of the Division. | |
| C | <i>Strategic Review Report (To Be)</i> | <p>The Strategic Review Report for SRD will detail the Mission/Vision, objectives, major functions and responsibilities, Work Programme, etc. The Plan will also:</p> <ol style="list-style-type: none"> 1. Identify business processes for the Division. 2. Identify key performance indicators of the division; 3. Indicate the skills, competencies/capabilities/qualifications required by staff to implement and sustain the regulation of all products named in the legislations administered and to perform | 20% |

| Item | Deliverable | Desired Contents | % Payment |
|------|---|--|-----------|
| | | <p>its regulatory, standards development and investigation roles;</p> <ol style="list-style-type: none"> 4. Indicate the level of staffing and post levels required to implement and sustain the above-stated roles; 5. Prepare output-based JDs for posts identified. 6. Identify appropriate technological solution for automation of processes. <p>Determine how the division should be organized – optimum organizational structure and processes automated with the following in mind:</p> <ul style="list-style-type: none"> - reporting relationship, succession planning, communications, support processes such as legal, ICT, public relations, management finance and accounting, Corporate Services, and also collaboration with external partners such as other Ministries, Departments and Agencies (Jamaica Customs Agency, Ministry of Agriculture, Pharmacy Council, Government Chemist, Hazardous Substances Regulatory Authority) and the industry. | |
| D | <i>Organizational Restructuring Proposal</i> | <p>The Organisational Restructuring Proposal is based on the agreements from the division’s Strategic Review (TO BE) Report and will outline at minimum:</p> <ul style="list-style-type: none"> ● Proposals for changes in job functions if required and introduction of new job functions ● Job Descriptions of each job function described in the new organisational chart taking into consideration the Government of Jamaica performance management appraisal system. ● Propose roles and functions and reporting relationships ● Propose new Organizational chart ● Propose current best fit for tasks | 50% |

| Item | Deliverable | Desired Contents | % Payment |
|------|---------------------|--|-----------|
| | | <ul style="list-style-type: none"> Propose new skill sets required for new roles Restructuring/ reorganization plan Estimated cost of restructuring | |
| | | <p>Monthly Progress Reports should detail the following:</p> <ul style="list-style-type: none"> Activities executed The progress made during the period (i.e. planned vs. actual targets, etc.) The proposed activities for the ensuing month Risks, challenges, gaps, and recommendations for addressing them | |
| E | Final Report | The final report will contain the summation of all efforts made by the consultant and will include information on the lessons learned and the mitigation measures that should be included in the preceding assignments. | 10% |

CHARACTERISTICS OF THE CONSULTANCY

Commencement Date & Period of Execution: The Consultant/Firm must be prepared to complete the assignment within a six (6) months period from the signing of the contract; submitting the final Strategic Review Report no later than the last day of the period; the finalized Schemes of Management to be submitted within the next three months where applicable.

Location: Ministry of Health and Wellness, New Kingston, Jamaica

Type of Consultancy: Firm

Type of contract: Lump sum.

MINIMUM QUALIFICATIONS & EXPERIENCE

The selected consultant/firm will have technical competence and 5 years' experience in Organization Development, business process reengineering, and quality improvement. In addition, the consulting firm/team is expected to have the following key expertise:

The Team Leader:

A least a Master's Degree in Business Administration, Development Studies or Public Administration, Organizational Development/ Human Resource Management, Psychology or other related behavioural science degree.

At least 5 years' experience in Organizational Development and or (Industry) Administration or Human Resources in Government Organization, for an intermediate to large size organization i.e. over 400 employees.

A minimum of two (2) similar assignments in business process analysis/ reengineering

Two (2) years Senior Management experience, plus three (3) years recent experience in group process, team development.

Successful completion of a similar activity within the last 5 years.

Good working knowledge of public health would be an asset.

Certificate/Diploma in Management Analysis would be an asset.

Required Specific Knowledge & CompetenceTechnical

Sound knowledge of Organizational Development Theories, philosophies and methods; organizational analysis; change management models and theories.

Ability to design and develop OD tools and methods for complex organizational strengthening.

Sound knowledge of Government Administration systems and operations management.

Knowledge of the Ministry's core business strategies to inform business process reviews.

Knowledge of drug regulatory affairs and the legislation administered by SRD.

Knowledge of international best practices in drug regulation.

Professional

Research skills, ability to design and conduct surveys and interviews

Ability to work with multidisciplinary teams and cultivate strategic alliances with local and international organizations.

Excellent leadership and negotiating.

Proficiency in Microsoft Word, Excel, PowerPoint.

Ability to prepare clear and concise written and oral reports.

REPORTING RELATIONSHIP AND SIGN OFF

The consultant/firm will report to the Director, Standards & Regulation Division. The Director will be supported by a technical working group (TWG) with the requisite skills that will be established to provide technical advice and oversee the project. Deliverables will be determined to be satisfactory when accepted by the TWG and the Permanent Secretary.

The consultant/firm should request problem-solving meetings as soon as there is any indication of factors that could result in changes in the scope, schedule or costs so the risks associated can be adequately managed. No variations are to be made to the agreed time or cost without the prior approval.

EVALUATION

The consultant/firm will be evaluated based on the following criteria:

| AREA | SCORE |
|---|-----------|
| Qualification and Experience | 60 |
| Team Lead | 40 |
| At least a Masters in Development Studies, Business Management, Business Administration or other relevant discipline including public health related disciplines. | 12 |
| At least 5 years' experience working in Organizational Development (OD) and/or (Industry) Administration or Human Resources | 12 |
| Certification Certificate/Diploma in Management Analysis | 3 |
| At least 2 successful OD or change management project in an intermediate to large size organization i.e. over 400 employees | 6 |
| 2 years of Senior Management experience, plus 3 years of recent experience in group process, team development. | 3 |
| Demonstrated experience designing and developing OD tools and methods. | 2 |
| Good working knowledge of the public health sector. | 2 |
| Technical | 15 |

| | |
|---|-----------|
| Understanding of Organizational Development (OD). theories, philosophies and methods; organizational analysis and change skills | 4 |
| Ability to design and develop OD tools and methods for complex organizational strengthening | 4 |
| Knowledge of drug regulatory affairs and the legislation administered by SRD. | 4 |
| Knowledge of Government Administration systems and operations management. | 1 |
| Knowledge of international best practices in drug regulation. | 1 |
| Possesses organizational analysis and change skills | 1 |
| Professional | 5 |
| Research skills, ability to design and conduct surveys and interviews; | 1 |
| Ability to prepare clear and concise written and oral reports; | 1 |
| Ability to work with multidisciplinary teams and cultivate strategic alliances with local and international organizations; | 1 |
| Proficiency in Microsoft Word, Excel and PowerPoint. | 1 |
| Excellent leadership and negotiation skills | 1 |
| Work Plan (Schedule, Technical approach and methodology) | 40 |
| Application of OD theories, philosophies and methods | 5 |
| Outlines the means by which OD tools and methods will be designed and developed for this assignment | 5 |
| Distinguishes the approach to training and development-needs analysis | 10 |
| Utilizes contextually appropriate use of knowledge about Government administrative systems human resources and operations management; | 5 |
| Delineates how employees will be involved and clarifies how knowledge of PMAS will be employed in the assignment | 5 |

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|---|------------|
| Sufficient time allocated to conducting analysis and preparing the functions and structures of the SRD (including job descriptions) | 10 |
| Total | 100 |