Five-Year Strategic Plan of DGDA (2022-2026)

Directorate General of Drug Administration
Mohakhali, Dhaka-1212.

Health Service Division
Ministry of Health and Family Welfare
Government of the People's Republic of Bangladesh

This is a five-year Strategic Plan for the Directorate General of Drug Administration in Bangladesh that provides the strategic direction for regulatory system strengthening to ensure improved access to quality, safe and effective medical products for all.

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MESSAGE FROM THE DIRECTOR GENERAL

I am very much delighted to say that DGDA has finalized the five-year strategic plan 2022- 2026.

DGDA is the organization entrusted with the quality, safety, and efficacy of pharmaceutical products through the enforcement of relevant legislation. It supervises and implements all prevailing pharmaceutical regulations in the country and regulates all activities related to procurement, import and export of raw and packing materials, production, and distribution of finished medicines. Furthermore, DGDA regulates pricing, sale and export of active pharmaceuticals ingredients and finished medicines. DGDA authority includes Allopathic, Ayurvedic, Unani, Herbal, Homeopathic, medical devices and Vaccines and Biologics.

A committee was formed to guide the overall development process of the five-year Strategic Plan (SP). Several workshops were conducted with participation of the committee, DGDA officials, representatives from WHO, United States Agency for International Development (USAID)'s Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program, United States Pharmacopeial Convention (USP)'s Promoting the Quality of Medicines Plus Program (PQM+), Better Health in Bangladesh (BHB) for the development of the document. In collaboration with the Coalition of Interested Partners (CIP), DGDA with technical assistance of USAID MTaPS program worked with other development partners to identify priority areas for inclusion by reviewing the current strategic plan's implementation status for 2017-2021 and identifying DGDA's new priority areas, considering the current country, regional and global context for access to medicines for public health. A draft of the SP was then prepared and shared with DGDA officials and CIP partners for discussion and agreement. After addressing feedback, finally, a five-year Strategic Plan 2022-2026 has been finalized.

On behalf of all DGDA officers, I would like to thank to the concerned DGDA officials for their concerted efforts in developing the five-year SP 2022–2026. DGDA acknowledges the overall technical assistance and support provided by the USAID MTaPS Program for facilitating the strategic planning workshops and leading the development of the five-year strategic plan with DGDA. Special thanks are to WHO, PQM+ Program, and other development partners for their collaboration and technical inputs at various stages of the development process of this strategic document. Sincere appreciations are extended to the DGDA SP monitoring and evaluation committee for providing all the necessary guidance and input to develop the five-year SP 2022–2026, and in doing so, demonstrating practical commitment for the implementation of the strategies.

The seven Key Results Area (KRA) of the SP are mentioned in the introduction part of this document. The purpose of the document is to serve as a roadmap to strengthen regulatory systems and build the capacity of DGDA to implement regulatory functions efficiently and effectively, and at the same time to cover the regulatory functions and activities captured in the 4th Health, Nutrition, and Population Sector Program (HNPSP).

Major General Mohammad Yousuf
Director General
Directorate General of Drug Administration (DGDA)

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TECHNICAL CONTRIBUTORS

DGDA extends special gratitude and thanks to the following individuals for their enormous efforts and supports throughout the process of this Strategic plan upgradation:

1. **Major General Mohammad Yousuf,** Director General, DGDA
2. **Mohammad Mozammel Hossain,** Director (cc), DGDA
3. **Md. Eyahya,** Director (cc), DGDA
4. **Hossain Mohammad Imran,** Assistant Director, DGDA
5. **Md. Razibul Habib,** Assistant Director, DGDA
6. **Shaikat Kumar Kar,** Assistant Director, DGDA
7. **Shaila Nowshad,** Assistant Director, DGDA
8. **Md. Abul Kalam Azad,** Senior Technical Advisor, USAID MTaPS Program

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ABBREVIATIONS AND ACRONYMS

ADR	Adverse Drug Reaction
API	Active Pharmaceutical Ingredient
BAPI	Bangladesh Association of Pharmaceutical Industry
DGDA	Directorate General of Drug Administration
GOB	Government of Bangladesh
GBT	Global Benchmarking Tool
GMP	Good Manufacturing Practices
GOB	Government of Bangladesh
GRP	Good Regulatory Practices
HNPSP	Health, Nutrition, and Population Sector Programme
IRIMS	Integrated Regulatory Information Management System
IT	Information Technology
KRA	Key Result Area
LDC	Least-Developed Country
LIMS	Laboratory Information Management System
M&E	Monitoring and Evaluation
MOHFW	Ministry of Health and Family Welfare
NCL	National Control Laboratory
NDP	National Drug Policy
NRA	National Regulatory Authority
OMCL	Official Medicines Control Laboratory
OP	Operational Plan
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PMS	Post-Marketing Surveillance
PQ	Prequalification
PSC	Public Service Commission
PV	Pharmacovigilance
QMS	Quality Management System
RIMS	Regulatory Information Management System
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	Standard Operating Procedure
SP	Strategic Plan
SWOT	Strengths, Weaknesses, Opportunities, and Threats
TRIPS	Trade-Related Aspects of Intellectual Property Rights
USAID	US Agency for International Development
USP-PQM+	US Pharmacopeia-Promoting the Quality of Medicines Plus
WHO	World Health Organization
WHO-UMC	World Health Organization Uppsala Monitoring Centre

STRATEGIC PLAN MONITORING AND EVALUATION COMMITTE

A six-member strategic plan monitoring and evaluation (M&E) committee has been formed with defined terms of reference to oversee the strategy, any modification needs, development requirement of a new strategy, and for creating budget provision in the Directorate General of Drug Administration's (DGDA) Operational Plan (OP) for further strategic plan development. The committee will develop an action plan to implement, monitor, and evaluate the strategic plan. The committee can co-opt expert members if necessary.

See Annex-A for the strategic plan M&E committee.

Committee terms of reference

Sl.	Provisions under terms of reference
1	Monitoring and evaluation of five-year strategic plan and action plan of DGDA
2	Gap analysis and recommendation to different functions to take necessary actions
3	The committee can co-opt expert members if necessary

INTRODUCTION

Bangladesh has made considerable progress in recent decades in strengthening the pharmaceutical sector and, as a result, improving the health of the population. The DGDA of Bangladesh is actively involved in the development of the pharmaceutical sector and, by extension, the health sector in the country.

The pharmaceutical sector has contributed significantly to improvements in the public health of the people of Bangladesh by ensuring equitable access to quality assured, safe, efficacious medicines and supplies at affordable costs. Recently, the pharmaceutical sector has emphasised the rational use of medicines throughout Country.

At present, there are 285 allopathic, 203 Ayurvedic, 283 Unani, 34 herbal and 71 homeopathic drug manufacturing companies in the country. The DGDA monitors and regulates all the activities of these 776 companies.

The head of the DGDA, designated as the Director General, is empowered by the government to act as the licensing authority to issue licenses to manufacture, store, sell, import, and export drugs and medical products. At present, there are 55 district offices of the directorate in the country. All the officers of the directorate function as drug inspectors pursuant to the drug laws and assist the licensing authority in properly discharging their responsibilities. In addition, several committees, such as the Drug Control Committee (DCC), Standing Committee for import of pharmaceuticals (procurement and import of raw materials and finished drugs), Pricing Committee, and a few others, are comprised of experts that are there to advise the licensing authority and to make recommendations on matters related to medical products.

The five-year strategic plan (SP) 2022-2026 focuses on the following key result areas (KRAs):

1) Good governance and regulatory framework
2) Financing and sustainability
3) Human resources
4) Strengthening drug testing laboratories; establishing an Animal Breeding facility; and establishing a testing laboratory for medical devices, assistive health technologies, and traditional medicines
5) Intregrate information management systems, knowledge sharing and management, and business processes
6) Effective regulatory processes
7) Customer, client, and stakeholder engagement and management.

The SP outlines critical issues, strategies, objectives, broad activities, and timelines that provides an indicative budget to achieve the DGDA's overall goals and aspirations.

This comprehensive plan contains a budget and an M&E plan to facilitate its operationalisation, which includes a logical framework and action plan.

During development of this strategic plan, development partners (USAID MTaPS, US Pharmacopeia-Promoting the Quality of Medicines Plus [USP-PQM+], and Better Health in Bangladesh) including the World Health Organization (WHO) were involved in the process of developing the SP 2022-2026.

BACKGROUND

In 1974, the Directorate of Drug Administration was established under the Ministry of Health and Family Welfare (MOHFW) of the government of Bangladesh (GOB). The introduction of the Drugs (Control) Ordinance, 1982 resulted in rapid development and growth of the pharmaceutical industry and a substantial increase in the production of allopathic and traditional medicines. The NDP was updated in 2005 to further increase the export potential of the country and to strengthen the regulatory authority in order to become a more fully functional and effective institution. In 2010, the Directorate of Drug Administration was upgraded to Directorate General of Drug Administration to strengthen and increase its capacity, consequently enabling it to further develop the pharmaceutical and health sectors in Bangladesh. In 2016, another version of the NDP was formulated and approved and a gazette notification was issued for implementation. One of the key components of the NDP 2016 is to strengthen DGDA into a fully functional national regulatory authority (NRA).

In 2012, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program assessed the regulatory systems and capacity of the DGDA. The WHO and USP-PQM Program also conducted a few gap analyses of the regulatory systems in Bangladesh in 2016. The main observations and findings from these assessments indicated that the country's national regulatory system needed strengthening in several functional areas as well as cross-cutting operational areas.

In March 2016, WHO met with other technical agencies and partners—SIAPS, the International Vaccine Institute, Bill and Melinda Gates Foundation, USP-PQM, USAID, and the World Bank—to develop a road map and strategy to coordinate efforts to strengthen Bangladeshi regulatory systems, with the GOB as the key party and DGDA as the lead agency. It was agreed that Bangladesh was an ideal candidate to pilot a more coordinated approach to regulatory system strengthening. In addition, several Bangladeshi manufacturers, including vaccine manufacturers, expressed interest in applying for WHO prequalification (PQ). Such expressions of interest have been supported by Bangladesh authorities and welcomed by all partners. At the end of the meeting, a defined strategy and draft road map were developed for targeted functional areas. An agreed-upon framework and mechanisms for coordination among stakeholders, confirmed participation, roles and responsibilities, and contributions of partner institutions including steps for 2016 were established. One of the key activities agreed upon was the development of a five-year strategic plan (SP) for the DGDA to achieve full functionality.

As a government priority, the DGDA showed interest to achieve maturity level 3 per WHO's Global Benchmarking Tool (GBT) and engaged development partners to assist them. Formal interim benchmarking at DGDA started in September 2018. The USAID-funded MTaPS Program (successor of SIAPS) started working with DGDA in 2018. The DGDA's focus was a vaccine and biologics regulatory system using the WHO GBT to measure the maturity of the system.

The development partners including MTaPS assisted DGDA to update the institutional development plan of DGDA and other affiliated institutions to address existing and/or potential gaps as well as prioritise recommendations for implementation to raise the overall maturity of the regulatory system up to level 3. Then a self-benchmarking exercise was executed in 2020.

For a formal desk assessment, WHO visited DGDA in July 2021 to assess the level of implementation of the institutional development plan, and DGDA then developed a Corrective and

Preventive Action Plan (CAPA) with the support of development partners, which was endorsed by WHO. In 2022, DGDA formed a strategic plan monitoring and evaluation (M&E) committee to oversee the implementation and address the challenges of the strategic plan and any new priorities to include in the upcoming plan.

VISION

The DGDA will strive to ensure quality, efficacious and safe medical products for all.

MISSION

- Safeguard the health of humans and animals by ensuring that medicines and medical devices meet applicable standards of safety, quality, and efficacy
- Ensure the safety and security of the supply chain for medical products
- Ensure accessibility, including availability and affordability, and rational use of essential medicines
- Foster a regulatory environment that supports research and innovation, thereby ensuring movement toward global standards for quality production

VALUES

Values are critical to guiding behaviours. The DGDA has defined and streamlined their values to ensure a common understanding. The following are the values of the DGDA and their supporting services for the common good:

- **Professionalism:** Commit to upholding professionalism with objectivity, persistence, and integrity
- **Responsiveness:** Anticipate, if possible, and provide quick response to address issues
- **Integrity:** Be consistent and stand firm in upholding noble ethics and beliefs
- **Respect for People:** Prioritise mutual trust, communication, and transparency
- **Credibility:** Be recognised by the public as a trustworthy institution
- **Innovation:** Be aware of current developments in science and technology and update regulations and procedures as needed

SITUATIONAL ANALYSIS AND SWOT ANALYSIS

Current Situation

A review of DGDA's successes and challenges was conducted in the task force committee meeting held on December 18, 2016, and again in the monitoring and evaluation (M&E) committee's meeting of strategic plan development in regard to the KRAs of the SP (Table 1). Internal and external assessment of DGDA using WHO GBT tool up to 2021 also contributed to this analysis.

Table 1: Successes and challenges with respect to the KRAs

KRA	Successes	Challenges
1. Regulatory frameworks	The NDP was updated and approved in 2016; DGDA was upgraded to the level of directorate within the MOHFW, and a revised organogram was approved. Regulatory framework is under development	Lack of autonomy makes the DGDA susceptible to government bureaucracy, e.g., in finance and human resources and flexibility in responding to the changing regulatory environment
2. Financing and sustainability	The GOB is committed to and is increasing support to the DGDA including new offices; there is a history of successful support from other technical assistance partners in strengthening the regulatory system	DGDA does not retain the collected revenue to augment the financial support from the treasury; government bureaucracy removes flexibility to respond to changing needs
3. Human resources	To increase the number of DGDA staff, a new organogram has been approved by MOHFW	Lengthy recruitment process by the GOB's Public Service Commission (PSC), high vacancy rate, lack of qualified and skilled manpower, limited career growth
4. Strengthening drug testing laboratories, establishing an animal breeding facility, and establishing a testing laboratory for traditional medicines	National Control Laboratory (NCL) achieved WHO PQ for chemical and microbiology laboratory. The same is in process for vaccine laboratory	Inadequate human resources, training, and physical infrastructure; very limited availability of laboratory equipment, instruments, and reference materials; limited financial resources for testing activities
5. Information systems, knowledge management, and business processes	Integrated regulatory information management system (IRIMS) to be launched in 2022; knowledge management and business process are to be placed under process of initiation	Lack of central server system implementation, inadequate human resources to effectively manage the work, lack of regular information technology (IT) support

KRA	Successes	Challenges
6. Effective regulatory processes	Established the Adverse Drug Reaction Monitoring Cell and National Pharmacovigilance (PV) Centre at DGDA; Bangladesh became a full member of the WHO's Uppsala Monitoring Centre (WHO-UMC); some companies have been inspected by stringent NRAs and are exporting outside Bangladesh; local pharmaceutical companies are meeting 98% of the country's pharmaceutical needs; DGDA is going through WHO GBT assessment for vaccines towards maturity level 3	Limited support from different agencies and hospitals, insufficient numbers of skilled and trained people, training for the industry in medical and regulatory affairs and direct involvement of the Bangladesh Association of Pharmaceutical Industries in different committees, lack of or partial compliance with WHO Good Manufacturing Practices (GMP) standards, irregular trade, unlicensed dealers
7. Customer, client, and stakeholder engagement	Pilot coalition of interested partners in Bangladesh helping to ensure coordination of partner support to DGDA	System development for interaction is inadequate for appropriate planning and action

SWOT Analysis

An analysis to evaluate the strengths, weaknesses, opportunities, and threats (SWOT) that impact the DGDA's effective implementation of its mandate was undertaken by the task force committee along with the SP development and M&E committee members; this is detailed below in Table 2 along with the key issues identified from the analysis.

Table 2: DGDA SWOT Analysis

Strengths	Weaknesses
• Commitment from the DGDA leadership and top management for improvement • Flexible to adopt changes • Strong support from different partners and stakeholders • Support from the local pharmaceutical industry • NCL has the potential capability to test medicines and vaccines with the opening of the vaccine wing • National PV Centre established and is part of the WHO–UMC • New organogram approved by the MoHFW	• Inadequate number of technical personnel to cover the regulatory requirements and workload • Limited number of personnel with appropriate skills and experience in regulatory activities • Lengthy recruitment process that is beyond DGDA's control • Lack of autonomy in hiring own staff • Lack of sustainable leadership • Inadequate financial resources and lack of autonomy to use the revenue collected from fees to augment government support • Inability to recover all costs • Very old Drug Act 1940 enacted, waiting for approval of the New Drug Act 2022 in the parliament • Inadequate information management system and IT infrastructure

Opportunities	Threats
• Testing capacity to build for vaccines and biologics per WHO PQ standards • Availability of funding and technical support from different external partners • Coalition of interested partners presents an opportunity for unified development approach and coordinated support for DGDA • Established pharmaceutical manufacturing base capable of meeting local needs (98%) and exporting globally (around 150 countries) • Some manufacturing facilities have achieved a “degree of excellence” and obtained international recognition, for example, US Food and Drug Administration, UK Medicines and Healthcare products Regulatory Agency, etc. • Stable economy with strong economic growth (average gross domestic product growth rate of 6.5% over past decade) • Increase in IT penetration and government support for a digital Bangladesh	• Frequent changes in top management could lead to changes in priorities and focus • Change in government may change the policy direction • Involvement of the industry in decision-making • Existence of potential conflict of interests • Reliance on external partner support for key regulatory functions with no sustainability plan in place threatens the continuation of key regulatory activities beyond the funding phase • Inequal implementation of DGDA and government service rules • Political instability and lack of required willingness • General lack of skilled workers in the country • Lack of strong regional harmonisation and cooperation in medicine regulation

STRATEGIC GOALS AND OBJECTIVES

The strategic plan is aimed at strengthening medicine regulatory systems in Bangladesh by addressing the weaknesses and threats guided by the following strategic goals:

1) Ensure an appropriate legal and organizational framework in line with WHO and global standards
2) Mobilise adequate financial resources
3) Ensure recruitment of competent human resources in sufficient numbers to carry out essential regulatory services
4) Ensure operation of a well-equipped and functional quality control laboratory that meets global standards
5) Ensure effective automation of integrated information management systems that support regulatory functions and monitor organizational performance
6) Increase implementation and effectiveness of the processes for key regulatory functions according to recognised Good Regulatory Practices (GRP)
7) Improve organizational management with transparency and accountability to all key stakeholders

The strategic goals informed the KRAs for this SP and are aligned with the HNP SP. They are as follows:

1) Good governance and regulatory framework
2) Financing and sustainability
3) Human resources
4) Strengthened drug testing laboratories, establishment of an animal breeding facility, and establishment of a new drug testing laboratory for traditional medicines
5) Integrated information management systems, knowledge sharing and management, and business processes
6) Effective regulatory processes
   6–1 Scientific evaluation and regulatory decision making
   6–2 Strengthened post-marketing surveillance (PMS) and enhanced DGDA capacity
   6–3 Strengthened national PV system and promotion of rational use of drugs
   6–4 Support local pharmaceutical industries and retail pharmacy
7) Customer, client, and stakeholder engagement and management

The following strategic objectives shall allow the DGDA to achieve the vision, purpose, strategic goals, and expected results of this SP:

1) Update the regulations and organizational framework in line with WHO and global recommendations for NRAs
2) Improve regulatory compliance to relevant levels of the WHO GBT in all identified regulatory functions applicable to DGDA to become a fully functional NRA
3) Mobilise adequate resources to support the SP and DGDA activities
4) Reduce the job vacancy rate to less than 20% by 2025
5) Reduce the competency gap to less than 20% by December 31, 2025
6) Achieve WHO Maturity Level 3 for the NCL by December 31, 2023

7) Establish a functional vaccine laboratory
8) Increase automation of key business processes to above 80% by June 2025
9) Ensure compliance with set timelines for key processes of regulatory functions
10) Attain and maintain WHO Maturity Level 3 certification for the organisation
11) Ensure compliance with global standards and transparency in approval of clinical trials, medical products, and health technologies
12) Ensure compliance with global standards and transparency in PMS activities for medical products and health technologies
13) Ensure compliance with global standards and transparency in PV activities for medical products and health technologies
14) Ensure compliance with global standards and security of the supply chain system in manufacturing, storage, distribution, and use of medical products and health technologies
15) Comply 100% with government requirements for state entities and GRP
16) Ensure customer satisfaction above 80%

CONCEPTUAL FRAMEWORK

Figure 1 shows the conceptual framework for medical product regulation. This framework links the inputs, regulatory activities, outputs, outcomes, and the goal or impact of medical product regulation in terms of public health. The input factors include human and financial resources, legislative framework, infrastructure, and equipment as well as political will or support. This conceptual framework also provides a clear distinction between activities that an NRA has to perform on its own and those that can be relied on from other agencies through collaborative mechanisms. Thus, the inputs, activities, and outputs are specific to the country situation, whereas the outcomes and goals are expected to be similar between countries, as the mission for NRAs is usually the same: To promote and protect public health by ensuring access to safe, effective, and good quality medicines and health technologies. The strategy addresses mainly the input factors and activities in response to DGDA's weaknesses and threats, which need to be implemented to achieve the desired outcomes and goals.

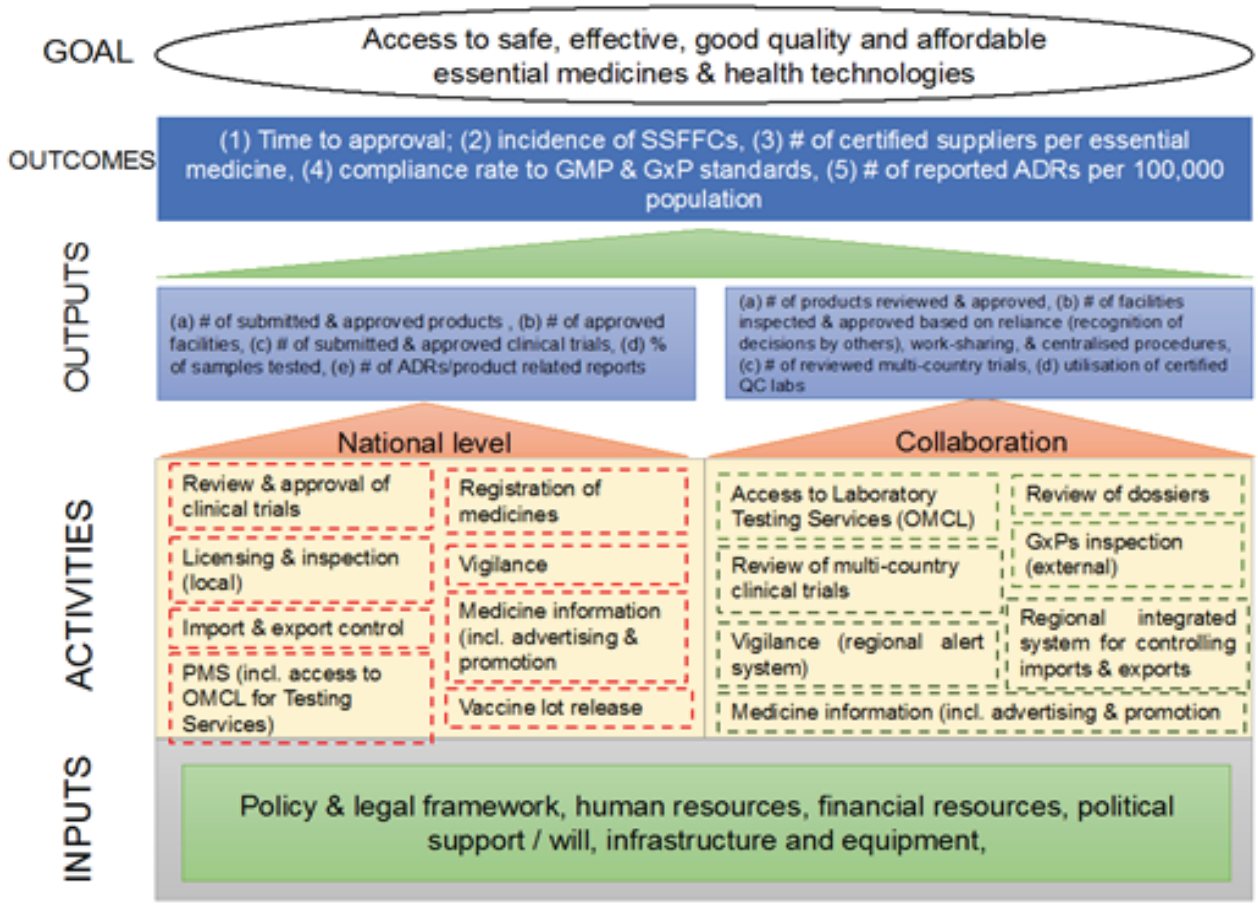

Figure 1: Conceptual framework for medical product regulation

Source: L. Gwaza and G.N. Mahlangu. Business Plan for the African Medicines Agency, 2016

Figure 2 illustrates the interplay between the input factors, with the institutional and legislative framework forming the foundation on which other input factors (financing, human resources, and infrastructure) rely. The strength of the regulatory and business processes are the key pillars, which ensure that the strategic outcomes are achieved. The key strategic outcomes for this strategy are summarised at the top in Figure 2. Achieving these will ensure that the key regulatory outcomes and goal (as shown in Figure 1) are achieved. The M&E plan includes a log frame for the DGDA, which incorporates the conceptual framework for medicine regulation and this SP.

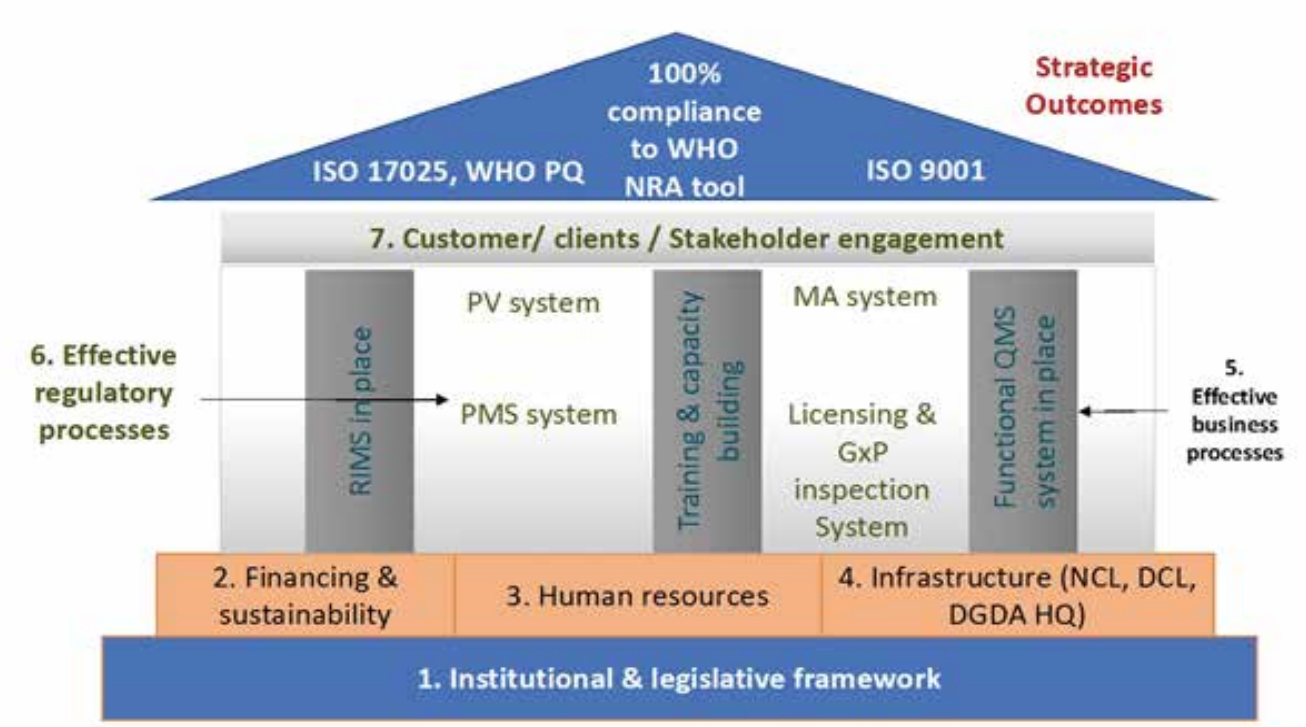

Figure 2: Interplay of the KRAs and the regulatory system, quality management system, regulatory information management system, district quality control laboratory, market authorisation, and Good Practices guidelines

STRATEGIC DIRECTIONS

The strategic directions for this plan are guided by the existing gap analysis reports and the strategic planning workshops. In this respect, the proposed objectives, outcomes, strategies, outputs, and targets have been analysed in accordance with the seven KRAs. This SP takes note of the existing situation and trends, proposes objectives and strategies that would help address the existing weaknesses and threats, and ensures adequate strengthening of the medical products regulatory system in Bangladesh. Taking note of the rising threat of antimicrobial resistance, the SP emphasises the key role of DGDA in addressing this threat, in line with the national action plan on antimicrobial resistance.

KRA 1: Good Governance and Regulatory Framework

Overview

Medical products regulation is governed by the following legislation:

- The Drug Act, 1940, Regulatory Overview for Drugs in Bangladesh
- The Drug Rules, 1945, under the Drug Act, 1940 (as amended up to August 15, 2013
- The Bengal Drugs Rules, 1946 (as amended by the Government of East Bengal up to December 1952)
- Drugs (Control) Ordinance, 1982: Ordinance No. VIII of 198
- National Drug Policy 2016

The Drug Act 2022 is undergoing revision and updates. DGDA, as a directorate general under the MoHFW, is subject to government rules and procedures with respect to human resources, such as recruitment, compensation, organisational structure, capacity building of staff, and financial management, which requires the DGDA to submit collected revenue to the Treasury. A mature and coherent legislative backbone that provides greater independence and transparency for the DGDA is needed.

Goal

Ensure an appropriate legal and institutional framework in line with WHO global standards.

Objectives

1) Update the regulations and institutional framework in line with WHO recommendations for NRAs
2) Improve regulatory compliance to relevant levels of the WHO GBT in all identified regulatory functions applicable to DGDA for fully functional NRA
3) Achieve regulatory compliance with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) guidelines for accession to the forum
4) Necessary measures to overcome challenges after TRIPS flexibility regarding access to medical products, upon graduation from Least-developed Country (LDC) to Developing Country according to the TRIPS (trade-related aspects of intellectual property rights) agreement

The foundation for medical products regulation is constituted by an appropriate regulatory framework in the coordination of required legal and regulatory provisions, supported by an appropriate institutional and operational governance system. Medical products regulatory activities have been consolidated under DGDA; however, the legislation is undergoing revision to

be in line with international norms and WHO recommendations. The updated legislation should be approved within this strategic plan period. The institutional framework requires alignment with the key regulatory functions. It is envisaged that the revised organogram along with the required staffing levels for Bangladesh will be approved within this strategic planning period. Further, DGDA will be strengthened so that it will be able to comply with relevant levels of competencies based on the WHO GBT by the end of the planning period.

To achieve these objectives, the following assumptions have been made: There is the political will to implement the necessary changes and to support the DGDA, and adequate financial and human resources and commitment from the GOB will be provided to implement the required changes for DGDA to reach the necessary level of competence. In addition to WHO regulatory compliance for NRAs, DGDA intends to initiate procedures for accession to PIC/S and become a member of the forum. Obtaining final membership is subject to certification of DGDA's GMP inspection and licensing system, quality management system (QMS), legislative requirements, inspector training, etc. As the priority is the WHO regulatory assessment, the PIC/S assessment may be completed after successful completion of the WHO NRA assessment.

Activities

Some key activities will be implemented to achieve the goal and set objectives (Table 3).

Table 3. Activities related to KRA 1

Activities	Sub-activities
Support for approval and implementation of legislation, the Drug Act, and Rules	• Advocate to policy makers and stakeholders on the proposed Drug Act, Rules, and regulations • Implementation support from stakeholders • Dissemination and circulation of the Drug Act, Rules and regulations
Implement assessments of DGDA using the WHO GBT	• Monitor compliance of DGDA through self-assessments on biennial basis as well as an external assessment of DGDA using the WHO GBT • Gain competency in line with WHO GBT
Initiate preparedness for accession to PIC/S with support from stakeholders and partners	• Externally review the proposed DGDA organisational structure to ensure fit for purpose for PIC/S • Monitor the DGDA through self-assessments in compliance with PIC/S regulatory requirements
Overcome challenges regarding access to health care products upon graduation from LDC to Developing Country according to the TRIPS agreement	• Develop an action plan to promote access to medical products upon graduation from LDC to a Developing Country • Implement the action plan to mitigate challenges in collaboration with governments' parallel stakeholders/ counterparts and ensure public and private partnerships address multisectoral engagement • Monitor and evaluate the progress of implementation and outcome • Promote research and development in the country for new drug development and molecular reverse engineering • Implement a patent protection system for new medical products

Activities	Sub-activities
Promote regulatory convergence toward achieving Sustainable Development Goal 3.8 (access to safe, effective, quality, and affordable essential medicines and vaccines for all)	• Update the essential medical products list to ensure affordability and availability for public health protection • Collaborate with Central Medical Stores Depot to ensure a better supply of quality-assured, safe, and effective medical products for all • Implement regulatory inspection-related software to promote GMP compliance of manufacturers to ensure traceability and accountability of inspectors • Promote competency for GMP compliance
Establish DGDA offices including testing labs in five district and divisional offices	• Establish 20 DGDA offices (6 divisional offices excluding Dhaka and Chattogram, and Gazipur, Narayanganj, Cumilla, Noakhali, Faridpur, Gopalganj, Pabna, Cox's Bazar, Bogura, Jessore, Dinajpur, Jhenaidah, and others based on priority) • Establish training centre (Dhaka/Chattogram) • Establish 5 new port offices (Dhaka airport, Benapole, Mongla, Chattogram airport, Chattogram seaport) • Establish port minilab with Raman and IR Spectrometer • Upgrade and standardise Chattogram Laboratories • Establish functional laboratories in Barisal and Rajshahi • Prepare budget and plan funding from GOB, Asian Development Bank, and other donor organisations
Establish Legal Panel wing	• Recruit law officer • Recruit expert panel lawyer • Mobilise financial assistance for legal support

Indicators of Success/Critical Milestones

1) Final approval of Drug Act 2022, implementation and dissemination of Drug Act, Rules, and guidelines by 2023
2) Formulation of Drug rules after approval of Drug Act 2022 by 2024
3) Compliance with necessary levels of competencies based on the WHO GBT by 2023
4) Establishment of DGDA's 20 new offices by 2026
5) National Pharmacovigilance Centre establishment by 2026
6) Establishment of port offices by 2026
7) Action plan to promote access to medical products upon graduation of the country from LDC to a developing country by 2023
8) Promotion of research and development in the country for new drug development and molecular reverse engineering by 2026
9) Comprehensive training plan, Training of Trainers (ToT), and training for competency development to promote local production of active pharmaceutical ingredient (API) by 2026
10) Update the Essential Medicine List (EML) to ensure affordability and availability for public health protection by 2024
11) In collaboration with the Central Medical Stores Depot, conduct an assessment for need-based medical products supply in ensuring the quality, safety, and efficacy of medical products by 2025

KRA 2: Sustainable Financing

Overview

Although there is strong support from the government and interest from funding partners, the DGDA does not receive sufficient funds from the government to fulfil its mandate and lacks financial autonomy to retain the revenue collected from their services. Furthermore, the current fee structure is not based on an accurate accounting of the cost of services provided. Considering the size of the population (more than 165 million people) and the size of the pharmaceutical industry including traditional medicines (more than 880 manufacturing facilities), financial resources for the DGDA are inadequate to meet current demands. Charging appropriate fees with restructuring options may provide resources to recruit and retain competent staff in sufficient numbers to speed up regulatory approvals.

Goal

Ensure financial sustainability by mobilising adequate resources to fulfil DGDA's mandate.

Objective

Mobilise adequate resources from multiple sources to support the SP and DGDA activities.

This objective seeks to ensure that adequate financial resources are available to enable the DGDA to implement the SP (including any identified capital expenditure required) and to maintain ongoing operations and an acceptable level of performance of regulatory functions.

The following assumptions are made: that the government can provide some of the needed financial resources for the DGDA and continued interest and support from partners will complement the government's financial commitments.

Activities

Some key activities will be implemented to achieve the goal and set objectives (Table 4).

Table 4. Activities related to KRA 2

Activities	Sub-activities
Mobilise resources from the government and partners	• Develop an annual budget to achieve the goals and meet performance standards, monitor and report on budget execution, advocate to policy makers for increased financial support from the government budget, and identify and develop proposals for submission to development partners
Ensure sustainable financing	• Perform a costing and modelling for DGDA services and revise the fee structure and fees in line with the costing and modelling results • Develop a transparent and accountable financial management mechanism

Indicators of Success/Critical Milestones

1) Estimation of DGDA's annual funding requirements for performing different activities by 2023
2) Cost analysis of DGDA services by 2023
3) Revision of existing fees structure by 2025
4) Financing mechanism supporting use of revised fees for DGDA's sustainable operations by 2026

KRA 3: Human Resources

Overview

There are inadequate numbers of qualified and skilled personnel within DGDA to cover the regulatory workload. To put this in context, the total number of DGDA staff is 720 as per the new organogram, of which 419 are technical staff and 301 are administrative/supporting staff. In addition, 65 more personnel are allocated from the development budget, of which 36 are technical and 29 support posts. In the context of allopathic medicines, they are expected to cover more than 880 manufacturers and more than 200,000 retail pharmacies and control over 40,000 registered medicines. This excludes other types of products that are under the authority of the DGDA. Further, the job vacancy rate is relatively high—more than 40% of positions are vacant. Even though initiatives have been taken to recruit the right number of people for DGDA activities, the recruitment process is long (one to two years) and outside the control of the DGDA. The government approval process involves five ministries or departments, including DGDA, MOHFW, Ministry of Public Administration, Ministry of Finance, and the PSC.
Notwithstanding the scarcity of people within the country with the required qualifications, training, skills, and experience; the specialised nature of medicine regulation; and competition from the growing pharmaceutical industry, salary compensation is based on the general government policy, which is three to five times less than the private sector. Thus, DGDA fails to attract and retain the needed people with the required skill set.

Goal

Ensure recruitment of competent human resources in adequate numbers to perform essential regulatory activities.

Objectives

1) Reduce the vacancy rate to less than 20% by December 31, 2025
2) Reduce the competency gap to less than 20% by December 31, 2025

The goal of these objectives is to ensure that the approved posts are filled with skilled and competent personnel and appropriately assigned to each function of the DGDA. Further, human resource capacity building will focus on ensuring that DGDA has skilled assessors, inspectors, and analysts. The assumptions include the availability of the people with the required skills in Bangladesh, financial resources to support the human resource requirements, and competency-based training programmes for in-service personnel.

Activities

Some key activities will be implemented to achieve the goal and set objectives, as described in Table 5.

Table 5. Activities related to KRA 3

Activities	Sub-activities
Recruit human resources	• Monitor passage of proposed organogram with 1,968 employees • Fill up vacant positions in existing organogram • Establish a human resource planning division that will be responsible for staff development, budgeting, programme planning, etc. • Advocate to policy makers to accelerate the recruitment process for class 1 and 2 officers • Sensitise and implement integrated human resources information system • Coordinate with MOHFW, PSC, and Ministry of Finance to ensure the recruitment of qualified positions based on job descriptions • Establish IT wing with qualified personnel • Deploy human resources in DGDA headquarters, divisional offices, and tertiary-level hospitals for adverse drug/vaccine/medical device reaction monitoring activities using funding and assistance from revenue/OP/deputation/development partners
Build human resource capacity	• Conduct a competency audit of existing staff • Set up a training centre for human resource capacity building (functional organogram, allocate budget) • Develop and implement human resources training policy (based on short-, medium- and long-term training needs) • Develop and implement an annual training plan • Develop/adapt and implement a competency framework for regulatory staff • Build capacity of human resources considering ISO (International Organization for Standardization), WHO PQ, and PIC/S standards • Build capacity in DGDA in relation to API industry • Develop expertise for DGDA to overcome TRIPS-related challenges after LDC graduation

Indicators of Success/Critical Milestones

1) Approval of DGDA's proposed organogram (1,968 persons) by 2023
2) Vacancy rate less than 20% by 2025
3) Competency framework in place by 2023
4) Competency gap less than 20% by 2025
5) Training facilities with adequate human resources established by 2025
6) Number of DGDA staff (class 1 and 2) who received training on Good Practices (35% by 2023, 50% by 2024, 75% by 2025, and 100% by 2026)
7) Deployment of human resources in DGDA headquarters, divisional offices, and tertiary- level hospitals for adverse drug reaction monitoring activities using funding and assistance from revenue/OP/deputation/development partners by 2024.

8) Establishment of fully functional IT wing with qualified personnel by 2024
9) Preparedness for pre-accession to PIC/S and assessment on attaining maturity level 3 through inspection from the competent external expert completed by 2026
10) Capacity built in DGDA in relation to API industry by 2024
11) Expertise developed for DGDA to overcome TRIPS-related challenges after graduation from LDC by 2023

KRA 4: Strengthening Drug Testing Laboratories, Establishing an Animal Breeding Facility, and Establishing a Testing Laboratory for Medical Devices and Traditional Medicines

Overview

To ensure the quality of drugs and vaccines, the government needs to evaluate the quality standard of each drug and vaccine available in the market on a routine basis. The modernization of the DGDA's NCL has been completed. At present, a few local companies are producing vaccines, but to export vaccines to other countries including UN organization, NCL needs to achieve WHO Maturity Level 3 in terms of vaccines. A dedicated and modern Animal Testing Facility is urgently required so that vaccines can be tested at NCL. Therefore, establishment of an Animal Testing Facility has been proposed in the 4th HNPSP.

N.B: For detailed Strategic Plan of NCL, refer to the document "Five-Year Strategic Plan of NCL, DGDA".

KRA 5: Information Systems, Knowledge Management, and Business Processes

Overview

There was no central information management system. They had a desktop-based, registered drug database which was maintained efficiently. DGDA had a web site that was semi- automated. Lack of an integrated RIMS impacts the efficiency and effectiveness of the regulatory and business processes of the DGDA. Moreover, efficiency and effectiveness of the regulatory and business processes is hampered by the lack of full implementation of a QMS for the DGDA.

Goal

Ensure effective automation and information management systems that support regulatory activities.

Objective

Increase automation of key business processes above 50% by June 2026.

Activities

Some key activities will be implemented to achieve the set objectives and goal (Table 6).

Table 6. Activities related to KRA 5

Activities	Sub-activities
Conduct a system requirement analysis for a DGDA data centre	• Procure the necessary computer hardware and software (data centre) • Establish the data centre with appropriate security in national data centre/cloud • Prepare a written SOP for management of the data centre

Activities	Sub-activities
Validate the process maps and system requirements for integrated regulatory management	• Review the current process and find the gaps • Prepare new system requirements and mapping in line with WHO guidelines
Implement an adequately customised and integrated version of an e-registration tool to support all regulatory functions required by the WHO GBT	• Organise periodic training for industry and regulatory personnel for proper implementation of e-registration tool • Review the process after implementation to find the gaps, considering the WHO GBT
Implement an electronic adverse drug reaction (ADR) and clinical registry system; implement integrated Regulatory Information Management System (IRIMS), its testing and deployment	• Organise training of the relevant person for proper implementation of ADR, clinical registry system and IRIMS • Periodically review the progress of implementation and generate a report

Indicators of Success/Critical Milestones

1) Installation of functional LIMS by 2023
2) Introduction of e-registration tool by 2023
3) Scale up of e-registration tool by 2024
4) Installation of IRIMS by 2025
5) Full use of IRIMS and LIMS by 2026
6) Use of data from both IRIMS and LIMS for decision-making by 2026
7) Established interoperability capabilities between IRIMS and LIMS by 2026

KRA 6: Effective Regulatory Processes

Overview

The DGDA is generally moving in the right direction in improving regulatory functions including consolidation, for example, bringing the NCL under the DGDA and developing the appropriate tools for key regulatory functions. However, the availability of essential regulatory tools, such as guidelines, processes, and technical expertise, which are necessary for the DGDA to perform its mandate effectively and efficiently, are limited in several areas.

Further, performance of the key regulatory functions does not fully comply with WHO recommendations for NRAs or GRP. For instance, the submission of applications (dossiers) for registration of medicines and the review and decision-making process do not fully comply with WHO recommendations. For example, direct involvement of the pharmaceutical industry in the DGDA committees that approve applications for registration of medicines may signify regulatory conflict of interest. In addition, there are unlicensed dealers in the market and irregular trade in medicines. Implementation of QMS with proper training will help DGDA work towards an effective regulatory process.

The quality manual has been updated in 2021 for review and implementation to attain GRP principles and governance.

Regulations and inspection for retail drug outlets and wholesalers are lacking. This includes the following regulatory processes:

6–1 Scientific evaluation and regulatory decision-making

6–2 Strengthening PMS and enhancing the capacity of DGDA (local training on GMP, QMS, accreditation, quality assurance, quality control, vaccine technology, biologics, and DGDA officer training on GMP for API manufacturing and PV)

6–3 Strengthening the national PV system and promoting rational use of drugs

6–4 Support for local pharmaceutical industries and retail pharmacies

Goal

Increase implementation and effectiveness of the processes for key regulatory functions.

Objectives

1) Ensure compliance with set timelines for key processes of regulatory functions
2) Promote a risk-based bioequivalence study approach for the products registered and marketed and to be marketed in Bangladesh
3) Promote regulation of contract research organisations in Bangladesh for the establishment of clinical trial studies in Bangladesh
4) Attain and maintain WHO Maturity Level 3 certification for the organisation
3) Ensure compliance with global standards and transparency in the approval of clinical trials and registration of medical products and health technologies
4) Ensure compliance with global standards and transparency in PMS activities for medical products and health technologies
5) Ensure compliance with global standards and transparency in PV activities for medical products and health technologies
6) Ensure compliance with global standards and security of the supply chain system for manufacturing, storage, distribution, and use of medical products and health technologies
7) Ensure compliance with DGDA regulations and inspection standards for retail outlets and wholesalers
8) Ensure that the decision-making process follows the proper implementation of a QMS

Activities

Some key activities will be implemented to achieve the set objectives and goals described in Table 7.

Table 7. Activities related to KRA 6

Activities	Sub-activities
Promote clinical trial and bioequivalence studies in the country	• Strengthen clinical trial oversight activities • Implement a risk-based bioequivalence study for the medical products registered and marketed/ to be marketed in Bangladesh • Promote establishment of the contract research organisations in Bangladesh for the clinical trial studies of a new molecule or reverse-engineered molecule for health care.

Activities	Sub-activities
Regularise cross-functional gap assessment, workflow analysis, and improvement of key regulatory processes	• Process optimisation based on the revised organisational structure • Optimise timeframe for manufacturing license renewal on the basis of the revised organisational structure • Continue workflow management systems • Continue awareness training of the continual improvement work processes • Define and monitor timelines for key processes
Expedite QMS implementation plan and progress monitoring to achieve GBT maturity level 3 in terms of vaccine	• Implement QMS roadmap aligned with the WHO QMS manual • Align mission and vision of quality management between DGDA and testing laboratories • Measure QMS implementation progress through key performance indicator
Expedite strengthening audit system for the continual improvement towards GBT maturity level 3 in terms of vaccine	• Plan for internal and external audit • Train and select a pool of auditors (for internal and external) • Prepare audit report and follow up for corrective and preventive action plan implementation and track process improvement
Conduct regular management review meeting more inclusively	• Prepare plan for management review meeting • Allocate budget for the said event • Prepare minutes and follow up for implementation
Develop digital archiving system	• Prepare a process map of a digital archival system • Prepare user requirement specifications for the archival tool • Allocate budget and purchase the system • Build the in-house capacity to operate the system and troubleshooting
Ensure guidelines, SOPs are in place and implemented in line with WHO standards	• Prepare to complete the list of documentation to fulfil the requirements of DGDA • Timely review and update guidelines, SOPs to meet WHO requirements • Follow up on proper implementation of documents.

Indicators of Success/Critical Milestones

1) Attain certification of WHO Maturity Level 3 for vaccine by 2023
2) Implement comprehensive system for annual product quality sampling and testing program with full support of the Testing Labs by 2023
3) Increase the number of inspections of warehouses and retail pharmacy shops every year
4) Increase the number of health care facilities from which ADR reports are collected
5) Increase the number of pharmaceutical manufacturers from which ADR reports are collected (100 by 2024 and 150 by 2026)
6) Increase the number of ADR reports collected (900 by 2024 and 1,200 by 2026)
7) Strengthen implementation of Good Practices (GXP) guidelines by 2026 in line with global standard to ensure sustainability.
8) Ensure Implementation of QMS roadmap to increase and sustain compliance by 2023
9) Conduct an assessment to identify potential risks and products for the bioequivalence study requirement by 2026

KRA 7: Customers and Stakeholders

Overview

Appropriate systems for customer and stakeholder engagement are the key to achieve WHO maturity level 3. Coordinated partner engagement, a systematic approach and framework for stakeholder engagement in all the regulatory processes is required. As per WHO, to become a fully functional NRA, involvement of the industry in decision-making process is not acceptable. Transparency in regulatory decision-making is also a key issue that needs to be addressed in line with GRP principles and good governance.

Goal

Ensure transparency of the regulatory process to key stakeholders and customers for their engagement and compliance to improve decision-making and to avoid any conflict of interest.

Objectives

1) Ensure customer satisfaction
2) Compliance with government requirements for state entities and GRP
3) Ensure engagement of key stakeholders

Activities

Some key activities will be implemented to achieve the set objectives and goals including those detailed in Table 9.

Table 8. Activities related to KRA 7

Activities	Sub-activities
Ensure internal control checks by the Internal Audit Unit	• Establish a team to conduct internal control checks • Conduct regular internal audits in line with the guideline • Periodically visit the divisional and district offices for compliance monitoring
Ensure customer satisfaction in district, divisional, and national level once a year	• Introduce customer satisfaction SOP at subnational level and provide training • Conduct the survey both at national and subnational level once a year • Provide feedback to the customer through better services
Develop protocol based on risk identification, assessment, and mitigation	• Adopt procedure to develop protocol for any identified risk • Assess the risk and create a mitigation strategy • Communicate the risk and mitigation strategy to the stakeholders

Indicators of Success/Critical Milestones

1) Number of consultative meetings with key stakeholders: Twice a year.
2) Conduct customer satisfaction surveys in district, divisional, and national level once a year
3) Conduct quality risk management: 10 risks identified and resolved by 2026

RESOURCE REQUIREMENTS

To efficiently achieve the defined goals, certain non-financial resources are required. Listed below in Table 9 are the requirements that were identified.

Table 9. Resource requirements to achieve goals

Human resources	Material and equipment
• Gradually increased human resources including IT personnel, training centre, and legal panel from the current 720 to 1,968 by 2026	• Necessary logistics including vehicles for performing district-level field activities for market surveillance and control. • Lab equipment for new lab • Raman infrared spectrophotometer for 5 port offices with logistics • Lab equipment repair and maintenance
Space requirements	**IT requirements**
• Establishment of 20 new office (6 divisional offices, Gazipur, Pabna, Narayanganj, Faridpur, Cumilla, Noakhali, Cox's Bazar, Gopalganj, and others based on priority) • Establishment of training centre (Dhaka/ Gazipur/Savar/Purbachal) • Establishment of 5 new port offices (Dhaka airport, Benapole, Mongla, Chattogram airport, Chattogram seaport) • Establishment of functional laboratories in Barisal, Rajshahi • Initiative to establish divisional laboratories in Khulna, Sylhet, Mymensing, Rangpur • Establishment of animal breeding facilities for vaccine & biologics testing • National Pharmacovigilance (PV) centre in Dhaka	• Data centre with data backup (national data centre/cloud) • Disaster management and data security • Software and hardware for IRIMS • Software and hardware for QMS tool • Software and hardware for national PV centre

MONITORING AND EVALUATION

The five-year SP of DGDA is a dynamic document. Many of the goals have a five-year time frame for achieving a fully functional NRA and meeting other requirements. The SP can be periodically reviewed and adjusted considering the progress of work against the set target.

A results-based M&E framework shall be used to monitor progress and measure performance. This focuses on the results obtained rather than just the inputs used or the activities conducted, hence it covers an array of processes from inputs to impact. This will play a key role in ensuring that the project implementation is in line with the set project goals and objectives. It will generate information and provide lessons during implementation that will be essential for improving strategy and ensuring that the project has an impact on the health of the people of Bangladesh. A report should be generated and shared among the partners and stakeholders that details progress.

The M&E plan includes the log-frame and action plans that are provided as annexes and show how this SP will be measured. The M&E framework and the milestones will also enable the project management team to collect relevant information for improving action and documenting lessons learned.

ANNEX

ANNEX-A: STRATEGIC PLAN MONITORING AND EVALUATION COMMITTEE

Government of the People's Republic of Bangladesh
Directorate General of Drug Administration
Ministry of Health and Family Welfare
Mohakhali, Dhaka-1212

Memo: DGDA/Roadmap-6/2016/ ১২৭ Date: 22/02/2022

Office Order

A committee has been formed with the following members to monitor and evaluate strategic plan and action plan of Directorate General of Drug Administration.

01.	Mr. Mohammad Mozammel Hossain, Director (cc) and Head of QMS, DGDA	President
02.	Mr. Mohammad Nayeem Golder, Deputy Director (cc), DGDA	Member
03.	Dr. Sarwat Jahan Pia, Assistant Director (Laboratory), DTL	Member
04.	Mr. Tanvir Ahmed, Assistant Director, DGDA	Member
05.	Mr. Shaikat Kumar Kar, Assistant Director, DGDA	Member
06.	Mr. Md. Razibul Habib, Assistant Director, DGDA	Member-Secretary

Terms of References

1. Monitoring and evaluation of five-year Strategic Plan and action plan of DGDA.
2. Gap analysis and recommendation to different functions to take necessary actions.
3. The committee can co-opt expert members if necessary.

Major General Md Mahbubur Rahman
Director General 22 FEB 2022
Directorate General of Drug Administration
Mohakhali, Dhaka-1212
Phone: 022222-80803
E-mail: dgda.gov@gmail.com

Distribution (not in order of seniority)

01. Mr. Mohammad Mozammel Hossain, Director (cc) and Head of QMS, DGDA
02. Mr. Mohammad Nayeem, Golder, Deputy Director (cc), DGDA
03. Dr. Sarwat Jahan Pia, Assistant Director (Laboratory), DTL
04. Mr. Tanvir Ahmed, Assistant Director, DGDA
05. Mr. Shaikat Kumar Kar, Assistant Director, DGDA
06. Mr. Md. Razibul Habib, Assistant Director, DGDA

ANNEX-B: FRAMEWORK FOR MONITORING, EVALUATION AND ACTION PLAN OF STRATEGIC PLAN

MINISTRY OF HEALTH AND FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
BANGLADESH

FRAMEWORK FOR

MONITORING AND EVALUATION PLAN

FOR THE STRATEGIC PLAN 2022-2026

Version 01,

July 2022

Logical Framework for DGDA SP 2022-2026

	Description	Indicator	Target	Means of verification	Assumptions
Overall goal for DGDA					
Long Term Outcomes					
	Intermediate outcomes/strategic outcomes based on the DGDA strategy				
Intermediate Outcomes	strategic Goal 1: Ensure appropriate legal and institutional framework in line with WHO global standards				
	Description	**Indicator**	**Target**	**Means of verification**	**Assumptions**

DGDA Action Plan for the Year:_ _ _ _ _ _

Ref: Five-Year Strategic Plan of DGDA (2022-2026)

KRA 1	**Regulatory Framework** .					
Goal 1:	Ensure that the DGDA has appropriate legal and institutional framework in line with WHO and PIC/S global standards					
Objective(s)	Activities	Timelines	Outputs/Milestones	Resources	Who?	Budget Est.

Disclaimer

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Directorate General of Drug Administration

Aushad Bhavan, Mohakhali, Dhaka-1212.
Telephone: +022222-80803
Email: dgda.gov@gmail.com
Web: www.dgda.gov.bd

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