**BANGLADESH PHARMACY MODEL INITIATIVE (BPMI)**

**INSPECTION AND MONITORING STRATEGY FOR PRIVATE RETAIL PHARMACEUTICAL SERVICES IN BANGLADESH**

**MANAGEMENT SCIENCES FOR HEALTH**

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Chapter One: Background

## 1.1: Introduction

The Ministry of Health and Family Welfare of Bangladesh through the Directorate General of Drug Administration (DGDA) with technical assistance from Management Sciences for Health (MSH) is implementing the Bangladesh Pharmacy Model Initiative (BPMI). The primary objective of the program is to design and implement a pharmacy model to improve access and appropriate use of quality medicines and pharmaceutical services in Bangladesh through accreditation and monitoring of private sector retail medicine outlets. The first phase of the assignment includes preliminary model development, planning for targeted district implementation and evaluation, and capacity building of national institutions that include DGDA and Pharmacy Council of Bangladesh (PCB) to implement the BPMI.

One of the major components of the BPMI is to support DGDA and PCB to strengthen regulatory oversight and operations of retail drug outlets in Bangladesh. The regulatory component includes sub components such as development of standards of operations of different drug outlets models and revision or development of regulations governing drug outlets operations. Developed standards will include requirements for premises, dispensing personnel, types of medicines to be stocked and dispensed, medicines storage conditions, and minimum record-keeping. Another sub component is the review and revision of the inspection and monitoring system of medicine outlets which will include levels of inspection and related human resources, inspection tools, and reporting.

## 1.2: Pharmaceutical Regulatory System in Bangladesh

Pharmaceutical regulatory services are governed by the Ministry of Health and Family Welfare through the Directorate General of Drug Administration (DGDA) and Pharmacy Council of Bangladesh (PCB).

The Department of Drug Administration was established in 1976 under MOHFW. Upgraded as the Directorate General Drug Administration (DGDA) on 17 January 2010. The responsibilities of the DGDA cover all medicines regulatory functions, such as registration, licensing, inspection, quality control, post-marketing surveillance and Pharmacovigilance (PV), pricing, import and export control, control of promotion and advertisement, and control of clinical trials. Its mission is to ensure the quality, safety, efficacy, and usefulness of all drugs and medicines that are produced, imported, and marketed in the country and also those exported overseas, and to make essential drugs available and affordable for the common people of Bangladesh. Products regulated by the DGDA include allopathic medicines; homeopathic, biochemical, Unani, Ayurvedic, and herbal products; vaccines and biologics; medical devices; and veterinary medicines. The scope of the DGDA does not include food or cosmetics, which are currently regulated by the Bangladesh Standards and Testing Institutions (BSTI) (*Assessment of the Regulatory Systems and Capacity of the DGDA in Bangladesh SIAPS 2012).*

All the activities of DGDA are governed & guided by:

\* The Drug Act 1940

\* The Drug Rules 1945 and their amendments

\* The Drug Rules 1946 and their amendments

\* The Drug (Control) Ordinance 1982 and its amendments

\* The Drug (Control) Ordinance Amendment Act 2006

\* National Drug Policy 2005

\* National Drug Policy 2016

The Pharmacy Council of Bangladesh (PCB) is an autonomous organization under the Ministry of Health and Family Welfare (MOHFW) of Bangladesh responsible for regulation of practice of pharmaceutical personnel in the country. Operations of PCB are governed by the Pharmacy Ordinance of 1976. The Pharmacy Council registers three categories of Pharmaceutical personnel namely A, B and C grade where by A grade are graduate pharmacists, B grade are diploma pharmacists and C grade are Pharmacy Technician who pass a Pharmacy Council examination. Grade A pharmacists are mainly found working in pharmaceutical manufacturing companies, B grade found mostly practicing in hospital (both public and private) pharmacies and C grade working in retail medicine outlets.

## 1.3: Retail Pharmaceutical Services

Retail medicine outlets are licensed by DGDA through application made under form No. 7 of the Drug Rules of 1945. Applications are made to DGDA by applicants who wish to operate the business of pharmaceuticals. Applications are accompanied by a number of documents such as application letter along with Form 7, copy of trade license, copy of pharmacist registration certificate and copy of National ID card. License of retail medicine outlet is issued with respect to availability of a registered pharmaceutical personnel under the three PCB professional categories however majority of them are C grade. Approved applications are issued with license upon payment of prescribed licensing fee which is Tk. 3000 for City Corporation and Pourasava area and Tk. 1500 for other areas. Renewal of license is required in every two years upon payment of Tk. 1800 for City Corporation and Pourasava area and Tk. 700 for other areas. Presently there is no categorization of retail medicine outlets in Bangladesh. All outlets sell all types of medicines except those under schedule C irrespective of the educational background of the dispenser. There are so far about 121,465 licensed medicine outlets in Bangladesh according to DGDA indicate that the number of drug outlets operating without license is almost equivalent to those registered as estimated by BPMI survey done in 2016. DGDA has stopped issuing new licenses in order to address the challenges facing the licensing and operations of the existing outlets. Inspection of retail outlets is conducted by DGDA superintendents either from central level or those located at district level. The Drug Rules require that medicine outlets are inspected at least twice every year.

Chapter Two: Situation of Inspection of Retail Pharmaceutical Services in Bangladesh

The situational analysis previously carried out by various stakeholders identified key issues with the current retail pharmaceutical service system status in Bangladesh. This section will elaborate on the various areas of strength,weakness, opportunities, and challenges of the system.

## 2.1: Existing Strengths and Opportunities on Regulatory Systems to Support Inspection and Monitoring of Retail Pharmaceutical Services

2.1.1: Existence of legal mandate to support inspection of retail medicine outlets

The DGDA is responsible for licensing of retail medicine outlets in the country. Licensing of retail medicine outlets is by the Drug Act 1940 and Drug (Control) Ordinance 1982. Currently DGDA has staff dedicated to inspection of retail pharmaceutical outlets and other premises. The authority has about 84 technical personnel, 60 of those are drug superintendent (DS) of which about 55 are at district level (Source: DGDA website, 12 September 2017). The Drug Rules 1945 provides guidelines for establishment and operation of retail pharmaceutical outlets.

The Pharmacy Ordinance 1976 provides guidance for registration of three categories of pharmacy personnel to provide services in retail medicine outlets. Licensing Registration of a retail medicine outlet requires presence of either A, B or C grade pharmacist PCB is the regulatory body responsible for personnel registration.

2.1.2: Existence of inspection SOPs and checklists to support inspection activities

Standard Operating Procedure (SOP) for inspection of retail and wholesale medicine outlets has recently been developed with support from USAID/SIAPS program in Bangladesh. The SOP indicates the qualification and power of inspectors, duties of inspectors, inspection process of retail and wholesale medicine outlets, random sampling and drug seizure, sample collection and procedure for quality control. Other areas described include report writing, follow up and regulatory management.

The SOP may also serve as a tool for training of new inspectors at central and local level who will assume the responsibility of inspection of the newly accredited medicine outlets under BPMI project. Additional material will need to be developed to supplement the SOP based on the new categorization of retail pharmaceutical services and associated standards. A guideline for operationalization of the developed standards, an inspection guide and inspectors training manuals may need to be developed to supplement the SOP.

Existing SOP for inspection of retail and wholesale medicine outlet needs to be aligned with the newly developed inspection and monitoring strategy, and guide under BPMI.

Other existing tools includes

* Application form (Form 7) for establishment of retail medicine outlets
* Drugs seizure form
* Sample collection form
* Inspection checklist for premise intending to operate the pharmaceutical business has not been made available. Application forms, preliminary inspection, routine and final inspection checklists will therefore need to be developed to focus on the agreed categorization and associated standards of retail pharmaceutical services.

2.1.3: Collaboration with District Health System

District drug licensing committee chaired by Civil Surgeon and drug superintendent as the member secretary exists in some districts. The committee is responsible for issuing and cancellation of licenses on behalf of DGDA. Establishment of the committee is guided by Ministry (MOHFW) order. However, the committees seem to be not regularly meeting or minimally functioning. The newly developed inspection and monitoring strategy, and guide under BPMI recommend to change the name of existing District Drug Licensing Committee into District Drug Committee.

2.1.4: Support from Ministry of Health and Family Welfare (MOHFW (, Directorate General of Drug Administration (DGDA) and Pharmacy Council of Bangladesh (PCB)

The MOHFW DGDA and PCB are in full support to review the operations of retail medicine outlets in Bangladesh for the purpose of improving quality of services provided. A National Steering Committee (NSC) and Technical Management Committee (TMC) have been formed to discuss progress on implementation of Bangladesh Pharmacy Model initiative (BPMI) aiming at improving services provided by retail medicine outlets in the country. PCB has recently employed 3 lecturers cum inspectors who will be focusing on supervising activities related to pharmacy professional services both in public and private sector including retail pharmaceutical services.

2.1.5: Readiness of other stakeholders to support inspection system

Discussions conducted between MSH and stakeholders including Bangladesh Chemist and Druggist Samity (BCDS), Bangladesh Association of Pharmaceutical Industries (BAPI), Consumer Association of Bangladesh (CAB), Directorate of National Consumer Rights Protection (DNCRP), Academicians, Bangladesh Pharmacy Graduate Association (BPGA), BRAC and other NGOs indicated the need to review the retail pharmaceutical sector services. They all indicated their dissatisfaction with the operations of many licensed and unlicensed medicine outlets and lack of registered and trained pharmacist in retail sector. Operation of licensed outlets without trained persons, poor dispensing skills, poor premise status and overall storage conditions in retail medicine outlets were mentioned as the major operational challenges. They all supported the new initiative to improve the retail pharmaceutical services.

2.1.6: Contribution of medicine outlets to improve access to medicines and pharmaceutical services at community level.

The large network of licensed and unlicensed medicine outlets increases availability of medicines closer to where people live and hence complement the shortage in public health facilities as well as fills the gap to some extent of the inaccessibility of public health facilities Improving services provided by retail drug outlets will ultimately improve the availability of quality medicines and pharmaceutical services that people receive at community level.

## **2.2: Challenges Facing Regulatory System to Support Inspection and Monitoring of Retail Pharmaceutical Services.**

2.2.1: Existing gaps in the current legal framework to support inspections of retail medicine outlets

The Drug Act 1940, Drug ordinance 1982 did not categorise the operations of private retail pharmaceutical services based on their level of services, human resource qualifications and premise standards requirements . Small rural or even in large cities medicine outlets receive the same licensing status with large pharmacies. No classification of premise requirements as well as type of professionals to operate the business exists. Furthermore type of services to be provided by medicine outlets is also neither identified nor classified. For effective inspection system, standards of operation and premises must first be set so that inspectors uniformly know what type of compliance they have to be monitored. In the absence of established standards inspections are in effective and adherence cannot be comprehensively monitored even though the current law requires that each drug shop must be visited at least twice every year. The Pharmacy ordinance 1976 also did not clearly describe to address issues of inspection of retail pharmacies at least to ensure that professional services in each drug outlet are appropriately provided and by the right personnel registered by the PCB. Collaboration between the two pharmaceutical regulatory bodies on inspection activities would increase the synergy and hence increase adherence to legal requirements and set standards.

2.2.2: Inadequate human resource at DGDA and PCB to manage inspections activities

Currently, DGDA has only one district superintendent in some districts (55/64) to oversee all DGDA activities including inspection of retail medicine outlets. At central level, the number of superintendents and inspectors is also very low to manage all DGDA activities as well as carry out retail inspections. DGDA has about 118 allocated positions for technical staff but currently there are only 86 of them. Lack of resources hinders filling of the allocated positions. Looking at the large population of Bangladesh and the number of retail drug outlets, even when the allocated positions are filled it is not certain that the number will be sufficient enough to meet the inspection requirements.

Currently PCB does not have technical staff to carry out any inspection activities in retail medicine outlets to ensure that professional staff is available in each licensed drug outlets.

Collaboration between DGDA and district health teams seems to be insufficient enough to support DGDA activities at district level in the absence of DGDA superintendents.

2.2.3: Large number of drug outlets in the country compared to number of registered pharmaceutical personnel

Currently there are about 121,465 (DGDA and presentation in NSC meeting) licensed drug outlets operating in the country. There is also a substantial number of drug outlets operating without drug license. PCB has registered about 82000 C grade pharmacist, 11506 B grade pharmacists and 11836 A grade pharmacists (Source: PCB), where most of the A grade pharmacists work in pharmaceutical industries and/or abroad, and most of the B grade pharmacists work in hospital pharmacies (both govt. and private). This clearly shows that there are many licensed medicine outlets operating without registered pharmacists posing a concern on the quality of service provided by these outlets.

2.2.4: Financial resources to support inspection activities

District superintendents do not have sufficient resources to cater for transport and other logistic related needs in order to reach all rural locations Financial limitations also hinder the staff ability to carry out inspections even once a year let alone the twice per year as per requirement. The reality is that very few medicine outlets are inspected per year while some are never inspected.

2.2.5: Inadequate inspection tools/materials to support inspection process

Recently, DGDA developed SOPs for use during inspection however inspection guidelines, inspectors training manuals and standardized inspection forms/checklists have not been developed to capacitate inspectors at different levels to be able to carry out effective inspections. Inspection checklists for medicine outlets intending to operate the pharmaceutical business have not been made available. Standardized forms for preliminary, final and routine inspection will need to be developed to focus on the agreed categorization of premises and respective standards of retail pharmaceutical services. Similar tools do not exist at Pharmacy Council of Bangladesh to oversee the quality of services provided by pharmaceutical professionals.

Chapter Three: Strategies for Improving Inspection System

Strengthening the inspection system for drug outlets will require several strategies. Implementation of these strategies will also require a full commitment from the actors as well as systematic engagement of stakeholders at different levels. The following strategies have been identified for implementation to improve inspection of retail medicine outlets including pharmaceutical services.

1. Categorization of private retail pharmaceutical services to optimize regulatory operations
2. Development of standards and regulations for establishment and operations of retail pharmaceutical services.
3. Strengthening the capacity of DGDA to conduct inspections of retail pharmaceutical services
	1. Development of inspection manual/guideline for inspection of retail pharmaceutical services
	2. Development of inspection checklists and reporting forms for preliminary, final and routine inspection.
	3. Reviewing the number and type of inspectors at central and local level
4. Strengthening collaboration between DGDA HQ and local levels (District and Upazila) to expand inspection of retail medicine outlets and pharmaceutical services
	1. Establishment of District Committee
	2. Establishment of Upazila inspection team
5. Capacity building of inspectors at all levels
6. Review of fees, collection and disbursement mechanisms to improve inspection activities
7. Strengthening the use of DGDA database and introduce digital technology to support inspection, monitoring, reporting, communication and revenue collection

## 3.1: Categorization of Retail Pharmaceutical Services to Optimize Regulatory Operations

In order to develop the standards of operations of retail medicine outlets, the standards for premises and pharmaceutical services was needed for categorization of retail services was seen as the first step of implementation. BPMI has proposed two categories of retail outlets in Bangladesh:

* Level I retail medicine outlets which will be called Model Pharmacy
* Level II retail medicine outlets which will be called Model Medicines Shop

The categories are mainly based on premise requirements, type of products and services to be provided and level of professional qualification needed to oversee each category.

## 3.2: Development of Standards and Regulations for Establishment and Operation of Retail Medicine Outlets

For effective management of inspections of retail outlets, standards for establishment and operation need to be in place so that development of inspection materials can be done based on the available standards. Standards have been developed by BPMI for each category and they focus on;

* Premise standards- Premise size and required facilities
* Personnel standards- Staff qualifications, staff appearance and dressing
* Signage, security, access to premise, temperature control
* Professional services
* Products to be sold
* Equipment and furniture – Water supply, refrigeration, medicines cabinets and shelves
* Documentation and record keeping

Developed standards will then be implemented to improve retail services. Upon finalization and evaluation of the 1st phase of implementation, revision of standards and associated inspection tools will be done and finalized for wider use.

In order to the standards to be enforced, regulations need to be defined and therefore the role of inspectors will be to enforce adherence to set standards in accordance with the established regulations. Legal actions will be taken against those who commit offenses and violate the regulations.

## 3.3: Strengthening the Capacity of DGDA to Effectively Manage Inspection Activities of Retail Medicine Outlets.

For DGDA to effectively manage inspection of retail medicine outlets and pharmaceutical services, several sub strategies need to be put in place and define their operationalization.

3.3.1. Development of Inspection Guide for Inspection of Retail Medicine Outlets and Pharmaceutical Services

Inspectors at different levels who will be conducting inspection in retail outlets should be trained for inspecting retail medicine outlets based on established standards. An inspection guide for inspectors needs to be developed that will highlight the following components.

* Procedures for establishment and operations of retail medicine outlets i.e. Model Medicine Shop and Model Pharmacy
* Standards of operation of retail medicine outlets i.e. Model Medicine Shop and Model Pharmacy pharmaceutical outlets
* Different tools used for inspection of retail drug outlets; preliminary and final and routine premise inspection checklists to be developed.
* Categories of inspectors and their associated legal mandates
* Code of ethics for inspectors
* Conducting an inspection ( preparations for inspection, what to inspect, how to inspect and reporting for an inspection)
* Identifying financial and human resources for inspection and monitoring

3.3.2: Development of inspection checklists and reporting forms

SOP for inspection of retail outlets have recently been developed at DGDA to support inspections but they only focused in summary of procedure on how to conduct inspection. Inspection tools and reporting forms will be developed to guide the inspection process and ensure that inspectors know exactly what to inspect step by step and what to report at the end of the inspection. Tools to be developed include:-

* Preliminary, final and routine inspection checklists Reporting form for all the inspections

3.3.3: Review the number and type of inspectors at central and local level

The current number of inspectors/ superintendents at DGDA is by far outweighed by the number of retail medicine outlets operating in the country. DGDA has stopped issuing new licenses for the purpose of carrying out inventory of existing medicine outlets as well as ensuring that they all operate in conformity with standards and rules. There are also a substantial number of unlicensed existing medicine outlets which are not recognized by DGDA but are in operation. For DGDA to be able to effectively manage operations of retail medicine outlets including licensing and inspections, the number and type of personnel needs to be reviewed and possibly increased. DGDA needs to revisit the current number of superintendents with direct responsibility of overseeing operations of retail medicine outlets for the purpose of determining adequacy, working environment, resources needed and responsibilities. In order to do this, a rapid assessment may be carried out to review the following:

* What is the optimal number of superintendents needed at central and district level to support inspections not only for retail medicine outlets but also for other pharmaceutical delivery points under DGDA mandate.
* What other health officials at different levels (Union, Upazila and district) and BCDS can be coopted to work closely with DGDA superintendents to support inspection and monitoring of retail medicine outlets and other related DGDA activities.
* What are the optimal resources needed to conduct inspections at district level and thereafter to the whole country ( working space or office, inspection materials/tools, allowances for inspectors, means of transport and communication)
* What resources can be made available by district health office and what needs to be provided by DGDA
* How adequate is the revenue collected by DGDA from retail drug outlets as licensing and renewal fees to support inspection activities and if there are any possibilities of making adjustments on the fees.
* How the financial resources needed for inspection will be tapped need to be addressed through discussion with MOHFW and Ministry of Finance e.g. retention and use of certain percentage of fees collected by DGDA.

## 3.4: Strengthening Collaboration between DGDA and District Health System to Improve Inspections

Additional collaborative and support systems to leverage efforts and resources in order to effectively reach all retail medicine outlets in the country are necessary. District health system becomes an obvious collaborative mechanism at the district level. Upazila health complex administration is another potential sub level to be explored. The existing system is that the district health authority supports DGDA to conduct initial inspections for new premises and also support the district superintendent wherever available to carry out inspections. District Drug Licensing Committees exist but minimally functions in some districts. The committee is formed by six members and is chaired by the Civil Surgeon while DGDA superintendent acts as member secretary to the committee. The Primary function of the committee is to issue licenses for newly established outlets as well as revocation of licenses for outlets found carrying out malpractices. DGDA do not have human resources posted at Upazila and Union level.

It is recommended that the existing district committee needs to be strengthened and given legal empowerment and more responsibilities to support the inspection system. The rationale for strengthening the collaboration is threefold;

* District health system is closer to the medicine outlets within the district than central and therefore it is efficient for the district to have a legal mandate to extend its arms to the medicine outlets at local level public sector.
* Resources to be utilized when monitoring the ,medicine outlets at district level are more effective than when it is done from central level,
* The collaboration improves local ownership and sustainability of the whole health system improvement process.

Previous assessments have also shown weaknesses facing the district involvement in monitoring of the drug outlets. They need to be addressed because they might still pose a threat to the new initiative that needs effective inspection system to be sustainable. One of the weaknesses observed include shortage of DGDA human resource at district level is one of the challenges that might affect the collaboration. Some of the districts may not have the necessary required personnel anticipated to form the suggested district committee.

As the system becomes implementable, sensitization seminars will be carried out to many stakeholders particularly medicine outlets owners and local government to ensure that they are well informed of the changes. Declaration of conflict of interest is an important requirement for any appointed inspector before he/she assumes the new responsibility.

Proposed strategy for improvement of district health system collaboration with DGDA may follow the following approach.

3.4. a: Central level agreement between relevant directorates (DGDA, DGHS and DGFP) under the MOHFW

An agreement/memorandum of understanding, government order or any other appropriate mechanism that may be applicable can be drawn between relevant directorates under the MOHFW. Under the MoU, the following will be clearly defined;

* Structure and composition of the district/DGDA collaboration mechanism at district level
* Proposed roles of DGDA and district health team under this collaboration
* Functions of the committee including meetings and reports
* Resource mobilization and utilization
* Support to be provided by MOHFW/DGDA to the district

3.4.b: Structure and composition of the committee

Under the collaboration, a committee (District Drug Committee-Proposed) will be formed. Composition of the committee will be defined, leadership (Chairman, Secretary) will be identified and other members will also be defined. Under this committee, a team of inspectors will be appointed by their positions to carry out all inspections activities on behalf of the committee. It is proposed that the following positions could be considered;

1. Civil Surgeon – Chair
2. Deputy Director of Family Planning – Co-chair
3. Upazilla Health and Family Planning Officer (Sadar) - Member
4. Health Officer from Municipality/City Corporation- Member
5. Assistant Director, department of Narcotics Control - Member
6. Senior Health Education Officer - Member
7. Representative from BCDS -Member
8. Drug Superintendent - Member secretary

The proposed inspectors under this committee are;

* Superintendent of Drugs, DGDA
* Medical Officer CS
* Senior Health Education Officer of CS Office
* Health Officer of Municipality/city corporation

3.4.c: Proposed roles of DGDA and district health team under this collaboration

Under the MOU/letter of collaboration/Government Order (GO), the proposed roles of both district health team and DGDA under the collaboration will include but not limited to the following;

* Ensure that committee members are appointed and provided with the necessary operation information/materials as stipulated in the MoU.
* Ensure that the committee have financial resources as well as working space/office to execute its defined functions as for example: meeting will be conducted in conference room of Civil Surgeon office and committee members will work in their individual own office room.
* Ensure that the committee conducts its functions as defined and in the MoU/GO

Proposed roles of DGDA under the collaboration will include;

* Support training of inspectors, provision of necessary working tools and materials including furnishing of the operating office/space
* During donor funded project period, the project may bear the cost and/or DGDA to financially support the operations of the district committee through its central budget allocated for DGDA district office.
* DGDA district authority to perform secretarial role for the district health committee scheduled meetings and for scheduled inspection activities.

3.4.d: Proposed functions of the committee

1. To conduct regular scheduled meetings to discuss new applications and operations of existing drug outlets.
2. Prepare and submit inspection reports and recommendations to DGDA for information and action as needed.
3. Take necessary action within the mandate of the district committee as shall be granted by DGDA.
4. Conduct formal enquiry on published news and complains
5. Take help from law enforcing agencies as and when required
6. Perform other duties as may be directed by DGDA and other higher authorities

3.4.e: Resource mobilization and utilization

DGDA will assume the responsibility of mobilizing resources to ensure that the committee performs its functions. Financial resources required for district level activities would be budgeted by central DGDA through annual planning. DGDA may also provide additional resources as may be required to accomplish additional activities which require additional resources beyond the routine activities.

3.4.f: **Establishment of Upazila and City Corporation Drug Committee**

It is recommended to establish a committee at Upazila and City Corporations to oversee operations of retail drug outlet. The name of the committees are proposed to be **Upazila Drug Committee** and **City Corporation Drug Committee**. Membership and responsibilities of the committee are described below;

**2.6: Membership Composition of City Corporation Drug Committee**

1. Chief Health Officer – Chair
2. Medical Officer from CS Office – Member
3. Health Officer, City Corporation - Member
4. Livestock Officer, City Corporation – Member
5. Representative of BCDS - Member
6. Superintendent of Drugs – Member Secretary

**2.7: Membership Composition of Upazila Drug Committee**

* Upazila Health and Family Planning Officer (UHFPO) – Chair
* Upazila Family Planning Officer (UFPO) – Co-chair
* Government Officer selected by Upazila Parishad – Member
* Upazila Livestock Officer - Member
* Health Inspector/Sanitary Inspector – Member
* Representative of BCDS - Member
* Pharmacy personnel from Upazila Health Complex – Member Secretary

**2.8: Responsibilities of the Upazila/City Corporation Drug Committee**

* Receive new applications and conduct preliminary inspections for accreditation/drug license
* Compile and submit inspection reports and recommendations for new applications to the district committee
* Conduct routine inspection of existing drug outlets
* Hold routine meetings to discuss inspection findings, prepare and submit reports with recommendations to the district drug committee
* Take help from law enforcing agencies as and when required
* Perform other duties as may be directed by DGDA and other higher authorities

Establishment of Upazila Drug Committee also aims at improving collaboration between district and DGDA to support inspection activities at district level.

At City Corporation, a team of inspectors that can be appointed may include the following;

* Superintendent of Drugs
* Health Officer, City Corporation
* Medical Officer from CS Office
* Senior Health Education Officer of CS Office
* Monitoring & Quality Assurance Officer
* EPI supervisor of City Corporation
* Representative of BCDS – Member

At Upazila level, a team of inspectors that can be appointed may include the following;

* Sanitary Inspector (SI)
* Health Inspector (HI)
* Family Planning Inspector (FPI)
* Assistant Health Inspector (AHI)
* Pharmacy personnel from Upazila Health Complex

Inspectors at Upazila/City Corporation level will conduct inspections as described in the inspection guide. Inspectors will report their inspection activities to the district level. Resources for conducting inspections which includes inspection tools and inspection identity cards will be provided by DGDA through district committee. Upazila level financial resources would be managed by UHFPO and or UFPO, and district level financial resources would be managed by DGDA (Superintendent of Drugs).

3.4.g: Collaboration with BCDS to conduct inspection of retail medicine outlets

As part of improving self-compliance through collaboration among DGDA, district health team and medicine outlets owners, BCDS leadership at district level will be sensitized to conduct self-inspection and monitoring to its members. BCDS inspection and monitoring may focus on the following;

1. Ensure that only members of BCDS do operate the business of retail drug outlets.
2. All registered medicine outlets becomes member of BCDS
3. Outlets which opens and operates without DGDA license and BCDS membership warned and reported to district drug committee and DGDA for action
4. Ensure that BCDS members have paid their annual membership and bi-annual license fees of DGDA
5. Premise standards maintained
6. Only trained personnel operates the business
7. Other components as may be determined by the Samity.

While planning for inspection, BCDS members can invite one of the district or Upazila inspectors to be part of inspection team. BCDS will develop its own inspection tool but can be supported by the district and DGDA inspectors and may also incorporate some of the components from DGDA inspection tools

## 3.5: Capacity building of inspectors at all levels

As part of capacity building for DGDA to effectively manage inspections of retail drug outlets, training of inspectors at different levels is an important undertaking. During scale up of BPMI project, inspectors should be trained on newly established system of retail drug outlets which comprise of standards of operation, regulations, and inspection tools. The following sub components will be implemented;

3.5.1: Type of Inspectors to be trained

Inspectors to be trained will include

* Central level DGDA inspectors and superintendents of drugs
* District level DGDA superintendents of drugs
* District level newly appointed/nominated inspectors
* Upazila level newly appointed/nominated inspectors

Once approved by the competent authority, the new categories of inspectors will be assigned in every district and upazila through proper channel.

3.5.2: Management of inspectors

The new group of inspectors will be engaged based on GO/MOU/Letter of Collaboration. District level inspectors would be managed by District Drug Committee while Upazila level inspectors would be managed by Upazila Drug Committee. DGDA will issue Identity cards for all level of inspectors to be used for identification during inspections.

3.5.3: Training materials for Inspectors

Training materials will be developed by the project based on available inspectors training manual/guideline. The training will also be accompanied by orientation on various medicine outlets operation tools such as drug/medicine dispensing registers, expired drugs forms and others.

3.5.4: Duration of training

DGDA Superintendents of Drugs will receive a two day training session. One day will be used for theoretical training and the second day will be used for practical demonstration in the field A two day session will be conducted for newly appointed inspectors at district and upazila level. Training will cover both the theory part and practical session where inspectors will be exposed to nearby drug shops for orientation on inspection of new premises applying for operation of medicine outlet business and will also be oriented on routine inspection for operating outlets.

3.5.5: Roles of Inspectors

* Inspect medicine outlets and other premises as directed by **DGDA** or **District Drug Committee**
* Issue written directives on areas that require correction
* Order temporary closure of premises where necessary
* Take samples of medicines or photos in the respective premises
* Receive complaints or recommendations from the client
* Impose fines or penalties on committed offences as established by DGDA
* Prepare and submit inspection reports(Automated)
* Adduce evidence before the court or any other office as may be necessary
* Perform any other duty related to inspections and monitoring of drug outlets as may be assigned by higher authorities.

3.5.6: Mandate and limitations of inspectors

Assigned inspectors will be mandated to carry out inspection in all retail medicine outlets only. They are allowed to carry out inspections in different geographical areas as directed by DGDA. Their inspection mandate is defined by DGDA and approved by the MOHFW. District level inspectors will conduct inspection mainly in retail medicine outlets in their respective district but their mandate can be extended to other premises where medicine is stocked, sold, distributed or displayed. District inspector’s mandate will be defined by the official circular based on GO/MOU/Letter of Collaboration but they will be able to take actions like written warnings or temporary closure of premises while reporting to DGDA in case of serious offences. Upazila level inspectors will be limited to medicine outlets within the upazila and limitation of their mandate will be also as per GO/MOU/Letter of Collaboration.

3.5.7: Inspection tools to be used for carrying out inspection

In the process of inspections, two types of inspection and monitoring tools/checklist will be used for two types of retail medicine outlets (Model Pharmacy and Model Medicine Shop). For preliminary, final and routine inspection contents of checklist will remain same but will differ in case of Model Pharmacy and Model Medicine Shop.

1. *Application Forms for Drug License*

This form will be used by all applicants intending to open a medicine outlet business. The form will be available at district level and at DGDA. They can also be downloaded at the DGDA website.

1. *Application Form for Renewal License*

Drug outlets will be required to apply for renewal license to DGDA through the district committee. Renewal license are issued every two years. They will be required to fill the application form and submit to the district with a proof that they have made payment for the permit. The DGDA office at district level will issue renewal license and medicine outlets owner will collect the license at the district level.

1. *Preliminary, final and Routine Inspection Checklist*

The *Preliminary, final and Routine Inspection Checklist* will be used by inspectors from Upazila, District and Central levels for the purpose of inspecting and providing instruction to a new premise intending to open a Model Pharmacy or Model Medicine Shop business. The checklist provides guidance to inspectors on what to inspect in relation to premise condition, storage of medicines, personnel to operate the outlet and materials to be made available to the new outlet as per standards.

Routine inspection checklist will be used by all levels of inspectors. It is mainly intended to be used for routine monitoring of drug outlets operation with focus on ensuring that standards for premise, personnel working in the outlets, storage conditions of medicines, record keeping and documentation and products stored for dispensing are maintained.

1. *Inspection Reporting Forms*

Inspection reporting forms are designed to be used for summarizing information/findings from the inspection activity at each level. The input for the report forms will be given electronically and the output report will be auto generated and then it will be submitted electronically by the inspectors and this output report will be accessible to respective district superintendent of drugs and DGDA HQ electronically. Respective district superintendent of drugs will review the report and provide his/her comments/inputs (If any) and submit it electronically. Central DGDA Inspection and Monitoring Cell/Unit will review the district report and provide input on actions to be needed and also provide decision for accreditation. The DGDA HQ decision on report will be accessible to respective superintendent of drugs. S/he will send a copy of inspected checklist and final report for to the respective retail medicine outlet by mail.

1. *Medicine Register/ Dispensing register*

Every accredited medicine outlet will be required to document all dispensed antibiotics in a medicine register. Medicine registers will be printed under guidance from DGDA and will be distributed through superintendent of drugs at district level to drug outlets. Information to be filled in the drug register will include:

* Date of sale
* Name/code number and address of the prescriber.
* Name of the facility from where the prescription was generated.
* Name of the patient and condition for which the prescription was written (if known).
* Name of the drug or preparation and the quantity supplied.

Some of the information filled in the registers may then be compiled and reported to the district and DGDA using reporting formats compatible with mobile technology (SMS) or on paper based summary reports.

1. *List of Approved Drugs for Sale in Medicine Outlets*

Drug outlets will be required to have the list of Over-the-Counter (OTC) medicines as guidance when purchasing, stocking and dispensing medicines. Inspectors will be required to be familiar with this list when inspecting drug outlets. They are also required to ensure that each medicine outlet has a printed copy of OTC list.

## 3.6: Review of Fees, Collection and Disbursement Mechanisms to Improve Inspection Activities

## To effectively manage inspection activities, financial resources are highly needed to enable inspectors meet inspection costs. Financial resources are also required to prepare the necessary documents and tools needed for inspections and to facilitate planned meetings to receive, discuss inspectors’ reports and recommendations. Collected fees by DGDA are currently deposited to government treasury under Ministry of finance. DGDA under MOHFW receives budget allocation from the government to manage its activities including inspections.

It is advisable that if financial systems of the government allow funds collected by DGDA from its other sources to remain within DGDA and used to support activities such as inspection as additional funds to the central government DGDA budget.

In order to determine for the adequacy of fees paid by medicine outlets, it is recommended to DGDA to facilitate an assessment to collect the following information related to fees paid by retail medicine outlets. The assessment should focus on the following areas:

* Types and level of fees paid by medicine outlets to DGDA and other authorities
* Collection mechanisms
* Mechanisms used to ensure that the collected funds reach DGDA and other authorities as required
* Cost associated with inspections and monitoring of retail outlets
* Any challenges associated with fees collection
* Possible matching between inspection cost and revenues collected and recommendations for adjustment of fees if needed as a way to improve inspection system
* Recommendations for use of the collected fees by DGDA

The assessment will provide useful information that can assist DGDA to discuss with the government on possibilities to use collected funds to support DGDA activities and also to determine possible measures that can be implemented to improve collection and use of fees.

## 3.7. Strengthening use of Information & Communication Technology by DGDA to Improve Inspection and Monitoring Systems

## Use of mobile technology communication system has shown promising improvement in monitoring operations of retail medicine outlets in other countries which have implemented similar initiatives. The BPMI initiative is developing a technology strategy which will highlight areas of possible improvement to the existing DGDA database which registers retail medicine outlets. Possible areas of consideration to enhance the technology component of retail medicine outlets are:

1. Improving the existing database to include other parameters as identified by the technology strategy.
2. Linking the database with a mobile phone communication platform to enhance the following
	1. Communication between drug outlets and District/DGDA through SMS, calls and emails
	2. Fees payment through mobile money
	3. Reporting on services provided by medicine outlets to DGDA and other Directorates e.g. DGHS, DGFP and public health partners
3. Conducting inspections/ assessments using customized free applications and linking them with central saver system.
4. Smart mobile phone or electronic tablet may be used to collect inspection data and auto-generate inspection report form.

3.7.1. Improving existing DGDA database to enhance Monitoring of Retail Pharmaceutical Services

With the intention to improve services in retail drug outlets in Bangladesh, the DGDA stopped issuing new licenses. This action would allow the authority to review the list of existing outlets, their licenses and operation status in terms of availability of trained personnel, premise condition and payments of license renewal fees. The DGDA has also established a web based database to improve visibility of information on the outlets including license renewal status, license number, personnel with PCB registration number, ownership and location. The ongoing BPMI technology strategy will build on the efforts made by the authority to develop the current database and add up other components which will be identified by this strategy. Such components may include but not limited to placing of the medicine outlets’ license and location information on Google maps and other types of maps. Currently BPMI has collected geocodes for each of all the retail medicine outlets in 7 districts of Bangladesh and Khilkhet thana of Dhaka city. The strategy will also highlight on possibility for linking DGDA database to MOHFW health information system for possible integration and sharing of information.

3.7.2. Use of mobile phones to enhance communication between drug outlets and DGDA/Districts through text messages, calls and emails

This feature relies on the fact that most of the drug shop owners and dispensers own mobile phone. The feature will be built on allowing DGDA to easily communicate with drug outlets when in need of sending information like reminders on payment of fees, attending meetings, recalling medicines and other important DGDA messages intended to reach out all or many drug shop owners and dispensers. The feature will also allow drug outlets owners and dispensers to send queries to DGDA and proposed District Drug Committees for clarification on medicines quality issues and other operational issues. The feature will be interactive enough to allow for sending information through text message and emails for those who can access internet connection. DGDA staff can respond through text message, email and can also make a direct phone call to the client as necessary.

By integrating this feature to its operations, DGDA will easily disseminate information which requires action to be taken by drug outlets countrywide within a very short time. DGDA will easily collect information needed to support its operations within a very short time and using very low cost and therefore serving time, resources and improve operation efficiency. Drug outlets can also enquire from DGDA any information related to license of premise and registration status of products.

3.7.3. Use of mobile phone to improve fees collection from drug outlets

The mobile communication features also allows for collection of fees from drug outlets through mobile money. The application is usually linked with mobile phone network operators who also provide the mobile money services. Drug outlet fees are collected by DGDA and deposited to government treasury. It is still uncertain whether it is possible to collect central government fees through mobile phone technology. This will be explored by the technology strategy. Linking DGDA database with mobile money feature will allow drug outlets to pay their annual renewal fees through their mobile phones and their renewal status get updated on DGDA database. It is anticipated that the feature will ease the process of fees collection from owners, reduce unnecessary travels by either drug outlets owners to DGDA or district offices or banks to make payments. It will also encourage many owners to easily make payment and therefore improve revenue collection without hassle. The feature however will depend mostly on availability of mobile money services in Bangladesh. Details of this component will be provided on the BPMI technology strategy.

3.7.4. Reporting on services provided by drug outlets to DGDA and other public health partner

Using mobile application, drug shop owners/dispensers can be trained to record information on services provided in the outlets and later summarize some of the information on mobile application or SMS and send to a central server system. Such information can be aggregated and used to produce reports. Example of such services include, referral of TB cases, Kala Azar cases, malaria cases, Elephantiasis etc. The applications can also be used to conduct periodic surveys on availability of certain medicines of public health importance, price monitoring etc. Such reports can be well interpreted to elaborate various services provided by retails drug outlets and associated gaps which can then be strategically addressed.

3.7.5. Conducting inspections/ assessments using customized free applications and linking them with central server system

DGDA inspectors and other superintendents of drugs can also use the DGDA database and central server system to customize free applications available on the web like Open Data Kit (ODK) to develop inspection tools which can be uploaded in tablets or smart phones. Supervisors at central level can easily track inspectors in different parts of the country where inspection is being conducted because once the inspectors/superintendents of drugs submit the inspection summary in the server; they can easily be tracked on the exact time and location where the data was sent. Use of tablets or smart phones on inspection tools will ease the process of data transmission, analysis and reporting, and will also increase transparency and process decisions within shortest possible time. Inspection tools which can be customized to mobile applications include preliminary, final and routine inspection checklist/forms for retail drug outlets.

Chapter Four: Stakeholders Engagement and Participation to Improve Inspection System of Retail Medicine Outlets

For DGDA to institute and implement effective inspection and monitoring strategies for improving provision of services in retail drug outlets, a diverse and broad-based stakeholders-participation will be necessary. The following are the key stakeholders that can participate in the implementation of inspection and monitoring strategy:

1. Directorate General of Drug Administration (DGDA)
2. Pharmacy Council of Bangladesh (PCB)
3. Directorate General of Health Services (DGHS) at Central, District and Upazila level
4. Directorate General of Family Planning (DGFP) at Central, District and Upazila level
5. District Drug Committee and Upazila Drug Committee
6. Bangladesh Chemist and Druggist Samity (BCDS)
7. Bangladesh Association of Pharmaceutical Industries (BAPI)
8. Management Sciences for Health (MSH)
9. Academicians
10. Professional Associations like Bangladesh Medical Association (BMA) and Bangladesh Pharmacy Graduate Association (BPGA)
11. Directorate of National Consumer Rights Protection (DNCRP)
12. Consumers Association of Bangladesh (CAB)
13. Local Government at Division, District, Upazila and Union Level
14. Information technology organizations
15. General community

Overall Responsibilities of each stakeholder on strategies to improve inspection system for retail pharmaceutical services

|  |  |
| --- | --- |
| Stakeholder | Overall Responsibilities |
| Ministry of Health and family Welfare (MOHFW) | * Development and approval of policies and guidelines to govern health services in the country
* Approval of regulations to govern establishment and operation of retail medicine outlets
* Agreement with Ministry of local government to collaborate on management of retail drug outlets
* Approval of fees charged by retail medicine outlets
 |
| National Steering Committee for Bangladesh Pharmacy Model Initiative | * Approval of strategies and materials developed for implementation of the project in Bangladesh
* Provide strategic and policy guidance to the project
* Review periodic project implementation and provide appropriate recommendations to Ministry of Health and Family Welfare (MOHFW)
 |
| Directorate General of Drug Administration (DGDA) | * National overseer of BPMI project
* Development of standards for establishment and operations of retail medicine outlets
* Development of list of Over-the-Counter (OTC) and prescription-only medicines for retail medicine outlets for the approval of the MOHFW
* Development of inspection tools, training materials and other materials needed for the project implementation
* Appointment/assignment of inspectors
* Training of inspectors
* Execute inspections
 |
| Pharmacy Council of Bangladesh (PCB) | * National overseer of technical personnel working in medicine outlets
* Providing technical inputs to the National Steering Committee (NSC) on project development
* Development of course curriculum, training materials and manage training for A, B and C grade pharmacist.
* Conduct registration examination for pharmacists. Maintain database for registered pharmacists.
 |
| Management Sciences for Health (MSH) | * Technical support to DGDA and other stakeholders on project implementation activities at National, district level and Upazila Level
 |
| Directorate General of Health Services (DGHS) | * Overseer of national health system under the MOHFW
* Provision of technical guidance on linkage of medicine outlets services to the National Health system
* Provision of human and financial resources to inspect and monitor retail medicine outlets in collaboration with DGDA
 |
| Directorate General of Family Planning (DGFP) |  |
| Bangladesh Chemist and Druggist Samity (BCDS) | * Umbrella organization for owners of medicine outlets
* Providing inputs to the National Steering Committee on matters related to owners during project implementation
* Safeguard interests of medicine outlets owners
* Encourage its members to comply with existing standards and regulations governing medicine outlets
* Collaborate with DGDA to implement self-inspection upon its members to establish peer supervision system;
* Collaborate with PCB on human resources development for retail medicine outlets
* Collaborate with MSH in implementing BPMI project in Bangladesh
 |
| District Drug Committee and Upazila Drug Committee | * Overseeing operations of retail medicine outlets at district and Upazila level
* Supervising district and upazila level inspectors
* Participation in project implementation at district and Upazila level
* Resource mobilization at district and Upazila level to support project implementation and maintenance
* Manage inspections at district and Upazila level
 |
| Bangladesh Association of Pharmaceutical Industries (BAPI) | * Provision of quality pharmaceutical products in the country
* Providing inputs to the NSC on project issues related quality of products
* To comply with the medicines category distribution based on the standards and regulations.
* Supply medicines to licensed retail medicine outlets
* Support implementing BPMI project in Bangladesh
 |
|  |  |
|  |  |
| Academicians | * Provide technical inputs to the NSC and Technical Management Committee (TMC) on project development and implementation
* Review the training of pharmacists with respect to provision of retail services
* Provide technical review and inputs to PCB in developing course curriculum and training materials for pharmacists
* Support implementing BPMI project in Bangladesh
 |
| Bangladesh Medical Association (BMA) | * Support BPMI project
* Participate in the NSC
 |
| Bangladesh Pharmacy Graduate Association (BPGA) | * Support BPMI project
* Motivate pharmacy graduates to contribute in retail pharmacy sector
 |
| Consumers Association of Bangladesh (CAB) | * Support BPMI project
* Raise awareness of consumers on quality pharmaceutical products and services
 |
| Directorate of National Consumers Rights Protection (DNCRP) | * Support BPMI project
* Raise awareness of consumers on quality pharmaceutical products and services
* Advocate any relevant legal matters related to quality pharmaceutical products and services
 |
| Local Government at Division, District, Upazila and Union Level | * Support BPMI project
* Raise awareness on quality pharmaceutical products and services
* Advocate any relevant legal matters related to quality pharmaceutical products and services
 |
| General Community | * Support BPMI project
* Procure quality pharmaceutical products and services
* Support any relevant legal matters related to quality pharmaceutical products and services
 |

Other levels suggested earlier should be included.

The following tables analyses stakeholders’ participation on implementation of the inspection strategy

|  |  |
| --- | --- |
| **Strategic Component** | **Participating Stakeholders** |
| STRATEGIC COMPONENT 1: Categorization of Retail Pharmaceutical outlets to optimize regulatory operations | MOHFW, DGDA, PCB, BAPI, BCDS, MSH, Academic Institutions  |
|  |  |
| STRATEGIC COMPONENT 2: Development of standards and regulations for establishment and operations of retail pharmaceutical services* Development of standards for establishment of Retail Drug outlets
* Development of regulations to govern establishment and operations of retail medicine outlets
 | MOHFW, DGDA, PCB, BAPI, BCDS, MSH, Academic Institutions |
|  |  |
| STRATEGIC COMPONENT 3: Strengthening the capacity of DGDA to conduct inspections of retail pharmaceutical services* Development of inspection guide for inspection of retail pharmaceutical services
* Development of inspection checklists and reporting forms
* Review the number and type of inspectors at central and local government level and categorize inspectors for different levels;
 | DGDA, , MSH, BCDS |
|  |  |
| STRATEGIC COMPONENT 4: Strengthening collaboration between DGDA, District Health Teams and lower levels to expand inspection of retail pharmaceutical services* Strengthening of the District Committee
* Establishment of Upazila inspection team
 | MOHFW, DGDA, DGHS, DGFP, District Health and FP Offices |
|  |  |
| STRATEGIC COMPONENT 5: Capacity building of inspectors at all levels* Type of Inspectors to be trained
* Appointment/assignment of inspectors
* Training materials for Inspectors
* Duration of training
* Roles of Inspectors
* Mandate and limitations of inspectors
* Inspection tools to be used during inspection
 | DGDA, MSH, BCDS |
|  |  |
| STRATEGIC COMPONENT 6: Review of fees, collection and disbursement mechanisms to improve inspection activities* Find the possibility to allow the DGDA to keep the fees and other charges collected within the DGDA to support inspection activities;
 | MOHFW, MOF, DGDA, District Health Offices, BCDS, MSH |
| STRATEGIC COMPONENT 7: Strengthening the use of DGDA data base and introduce use of mobile technology to support inspection, monitoring, communication and revenue collection | DGDA, DGHS, MSH, BCDS |
|  |  |

Chapter Five: Monitoring and Evaluation of the Inspection System of Retail Medicine Outlets

Monitoring will be a critical and integral part of the BPMI project implementation. It will take place at all levels from the national level to the drug shops level. Coordination of the M&E will be one of the major responsibilities of DGDA in collaboration with MSHBPMI project. To make M&E effective and efficient, resources and capacities will also be strengthened at central district, upazila and union level.

It is important to point out that in the private sector the recording and reporting culture which is a back bone of M&E is either nonexistent or very weak. In order to establish and strengthen it a considerable amount of resources (skilled human, financial, time and materials) need to be allocated for the process. M& E system is a dynamic tool, bound to be reviewed, amended and changed as the situation of the Program parameters change. Monitoring and Evaluation will aim at:

* Determining the progress in the implementation of the BPMI project
* Continuously identifying and resolving any problems arising during the course of the project implementation
* Continuously tracking down the trends
* Tracking project outcomes and possible impact

## 5.1: Proposed Monitoring and Evaluation of Inspection System

BPMI will define a general M&E framework which shall monitor the retail drug outlets of which inspection system will be one of the components. As the inspection system ensures conformity to set standards and adherence to rules and regulations, monitoring mechanisms will need to be in place to ensure that inspections activities are conducted and documented to monitor outcomes.

Inspection Monitoring Tools

In order to make the monitoring system functioning, the following tools will need to be made available

* Inspection checklists;
* Inspection report forms
* Medicine outlet antibiotic dispensing registers
* Medicine outlet sales and purchase records

These tools have been elaborated in the inspection guide.

## 5.2: Development of inspection monitoring indicators

Inspection activities will be monitored upazila and district wise. Lists of indicators drawn from preliminary inspection checklist, final inspection checklist and routine inspection checklists which are proposed here. Performance of the system will be monitored on monthly basis at upazila level and quarterly and or annual basis at district level by using the selected indicators. The cumulative performance at the end of the year will be calculated centrally.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| S/No | Component | Indicator | Level | Data Source | Frequency of Collection |
|  | Coordination of inspection system | Number of functioning upazila committees | District | meeting minutes | annual |
|  | Coordination of inspection system | Number of functioning district committees | national | meeting minutes | annual |
| 1 |  |  |  |  |  |
|  |  |  |  |
| 2 | Inspection of medicine outlets | percent of medicine outlets inspected in each upazila | district | inspection reports | Monthly basis |
| percent of medicine outlets inspected in each district | National | inspection reports | quarterly basis |
|  |  |  |  |
|  |  |  |  |
| number of new premises established in each upazila | District | Inspection reports | quarterly |
| number of new premises established in each district | national | Inspection reports | Annually |
| number of premises accredited in each upazila | District | Inspection reports | quarterly |
| number of premises accredited in each district | national | Inspection reports | Annually |
| number of medicine outlets not in operation in each upazila | District | Inspection reports | quarterly |
| number of medicine outlets not in operation in each districts | national | Inspection reports | annual |
| 3 | Compliance to standards | percent of medicine outlets found with medicines not in the approved list | district | Inspection reports | quarterly |
| Percentage of medicine outlets with all recording and reporting tools | district | Inspection report | quarterly |
| Proportion of medicine outlets with a PCB registered dispenser  | district | Inspection report | quarterly |
| percentage of medicine outlets with expired medicines on shelves | district | Inspection reports | quarterly |
| percent of medicine outlets displaying DGDA licenses | district | Inspection reports | quarterly |
|  |  |  |  |

## 5.3: Monitoring of the indicators

All inspection indicators will be monitored through inspection activities. When inspection is carried out at any level, reports will be submitted at respective higher inspection level. Individual inspected premises will receive feedback after the completion of inspection. This will be provided both verbally and with a hard copy through postal service and will highlight areas that need improvement and action needed to be taken if any. Higher inspection levels will be required to provide inspection feedback to lower level both verbally through courtesy call and or with a hard copy through postal service.

**Upazila level inspectors** will conduct preliminary, final and routine inspections of all medicine outlets at their respective Upazila using preliminary, final and routine inspection checklists respectively. Routine inspection will be carried out on half-yearly basis while preliminary and final inspections will be carried out as needed when a new application for accreditation is submitted. Inspection results will be compiled in an inspection report form electronically and submitted to the district committee electronically as well.

**City Corporation level inspectors** will inspect preliminary, final and routine inspections of all drug shops at their respective city corporation using preliminary, final and routine inspection checklists respectively. Routine inspection will be carried out on half-yearly basis while preliminary and final inspections will be carried out as needed when a new application for accreditation is submitted. Inspection results will be compiled in an inspection report form electronically and submitted to the district committee electronically as well.

**District level Inspectors** will conduct preliminary, final and routine inspections. All inspections will be carried out jointly with upazila inspectors or separately. District inspectors will plan their inspection based on reports from upazila inspectors and in consultation with central level committee. When planning for an inspection they will focus on the following

* Locations which have not been reached by upazila inspectors
* Medicine outlets with serious in-compliances observed by upazila inspectors where district attention is needed
* Locations which have never been visited by district inspectors in the previous inspections

District inspectors will carry out routine inspections on half yearly basis and will carry out preliminary and final inspections as needed. They will also collaborate with DGDA inspection teams when visiting the district for inspection. District inspectors will prepare their inspection reports which will be discussed at the District Drug Committee meetings and then submitted to DGDA HQ electronically. The report will also include a summary of progress on the indicators which will be measured at district level.

**Central level DGDA Inspectors** will conduct inspection in any part of the country as may be needed. DGDA inspectors will collaborate with respective District and/or Upazila level inspectors wherever routine inspections will be conducted. Depending on the nature of inspection, DGDA inspectors may also carry out inspections without involving district and upazila levels. However, results or feedback of such inspections will be provided to the respective level for information and any action that may be required to be taken or followed up. Central level DGDA will have a responsibility of summarizing indicators that are monitored at district level through aggregation of reports from districts. They will also monitor some of the indicators that are measured centrally at DGDA.

**DRUG SHOPS INSPECTION REPORTING SYSTEM**

**CENTRAL LEVEL: DGDA HQ**

(DGDA Inspection Cell/Wing)

**DISTRICT DGDA OFFICE**

 (Superintendent of Drugs)

**UPAZILA HEALTH COMPLEX**

(Pharmacy personnel from Upazila Health Complex)

(Superintendent of Drugs from City Corporation)

Key:

* Reporting after inspection
* Feedback after inspection

**District Drug Committee meeting**

The District Drug Committee will hold meetings on quarterly basis. The meeting will be arranged by the Member Secretary in collaboration with the Chair and other members. Information about the meeting will be circulated to all members with the proposed agenda. District Drug Committee meeting will follow meeting procedures and rules as defined for all meetings in the district. The meeting agenda will include among other agenda, report and recommendations for new applications and routine inspection observations and recommended actions to be taken by the committee. Meeting minutes signed by both the Chair and the Member Secretary with attached list of members who attended will be forwarded to DGDA HQ with a list of new medicine outlets applications as well as inspection results for routine inspection accompanied by recommended actions.

**Upazila Drug Committee meeting**

The Upazila Drug Committee Drug Committeewill hold meetings on monthly basis. The meeting will be arranged by the Member Secretary in collaboration with the Chair and other members. Information about the meeting will be circulated to all members with the proposed agenda. Upazila Drug Committee Drug Committee meeting will follow meeting procedures and rules as defined for all meetings in the upazila/city corporation. The meeting agenda will include among other agenda, report and recommendations for new applications and routine inspection observations and recommended actions to be taken by the committee. Meeting minutes signed by both the Chair and the Member Secretary with attached list of members who attended will be forwarded to District Drug Committee with a list of new medicine outlets applications as well as inspection results for routine inspection accompanied by recommended actions.

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