Inspection, Monitoring and Accreditation Strategy for Model Pharmacy and Model Medicine Shop in Bangladesh

Directorate General of Drug Administration (DGDA)
Aushad Bhaban, Mohakhali, Dhaka-1212

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Acknowledgement

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About Management Sciences for Health (MSH)

Management Sciences for Health (MSH) works shoulder-to-shoulder with countries and communities to save lives and improve the health of the world's poorest and most vulnerable people by building strong, resilient, sustainable health systems. Together, we seek to achieve universal health coverage—equitable, affordable access to high-quality health services for all who need them—even in fragile, post-crisis settings. For more than 45 years in 150 countries, MSH has partnered with governments, civil society, the private sector, and thousands of health workers on locally-led solutions that expand access to medicines and services, improve quality of care, help prevent and control epidemics, support inspiring leadership and transparent governance, and foster informed, empowered, and healthier communities.

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Disclaimer

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"Inspection, Monitoring and Accreditation Strategy for Model Pharmacy and Model Medicine Shop in Bangladesh" Coordination Committee

A Coordination Committee on the "Inspection, Monitoring and Accreditation Strategy for Model Pharmacy and Model Medicine Shop in Bangladesh" maybe formed by DGDA if required. The committee members will be selected from among relevant stakeholders, along with DGDA officials.

The Coordination Committee will be responsible for suggesting amendments to the Strategy as required, for DGDA's approval.

Message from the

Director General

Directorate General of Drug Administration (DGDA)

Medicines are crucial for any health-care delivery system. Therefore, one objective of the National Drug Policy is assurance of the safety, quality and efficacy of the medicines circulating in the market. An essential part of DGDA is to inspect all of the activities involved in research, development, manufacture, control, distribution, sale and supply of medicines. This '*Inspection, Monitoring and Accreditation Strategy for Model Pharmacy and Model Medicine Shop in Bangladesh*' will facilitate the DGDA to effectively oversee the sale and supply of medicines to ensure the availability of safe and quality medicine.

The 'Inspection, Monitoring and Accreditation Strategy for Model Pharmacy and Model Medicine Shop in Bangladesh' has been developed by a team of international experts in 2017. Later, it has been revised and finalized in 2019 through a consultative workshop with DGDA officers, PCB officials, BCDS representatives, BHB technical team and development partners, i.e., FCDO (former DFID) and USAID-MTaPS.

Better Health in Bangladesh (BHB), MSH constantly oversaw the development process of this Strategy. I would like to highly appreciate and thank the officials and staff of BHB for their technical support.

Major General Md. Mahbubur Rahman
Director General
Directorate General of Drug Administration (DGDA)

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List of Acronyms

MOHFW	Ministry of Health & Family Welfare
DGDA	Directorate General of Drug Administration
DDA	Directorate of Drug Administration
PCB	Pharmacy Council of Bangladesh
ADDO	Accredited Drug Dispensing Outlet
BPMI	Bangladesh Pharmacy Model Initiative
ADS	Accredited Drug Seller
BCDS	Bangladesh Chemists & Druggists Samity
FCDO	Foreign, Commonwealth and Development Office
MSH	Management Sciences for Health
PV	Pharmacovigilance
BSTI	Bangladesh Standards and Testing Institution
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
USAID	United States Agency for International Development
DS	Drug Superintendent
SOP	Standard Operating Procedures
CAB	Consumer Association of Bangladesh
NGO	Non-Government Organization
BAPI	Bangladesh Association of Pharmaceutical Industries
DDLC	District Drug Licensing Committee
UHFPO	Upazila Health & Family Planning Officer
DGHS	Directorate General of Health Services

Chapter One: **Background**

1.1: Introduction

The Ministry of Health and Family Welfare (MOHFW) 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, targeted district implementation and evaluation, and capacity building of national institutions to implement the BPMI.

One of the major components of the BPMI is to support DGDA and Pharmacy Council of Bangladesh (PCB) to strengthen regulatory oversight and operations of retail medicine outlets in Bangladesh. The regulatory component includes sub components such as development of standards of operations of different medicine 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 update 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 MOHFW through the Directorate General of Drug Administration (DGDA) and Pharmacy education and practice is regulated by the Pharmacy Council of Bangladesh (PCB).

The Directorate of Drug Administration (DDA) was established in 1976 under MOHFW. Revision of the drug policy in 2005 recommended an upgrade to become Directorate General of Drug Administration (DGDA). Responsibilities of DGDA cover all medicines regulatory functions, such as registration, licensing, inspection, quality control, post- marketing surveillance and Pharmacovigilance (PV). Other responsibilities include pricing, import and export control, control of promotion and advertisement and control of clinical trials. DGDA 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, Bio-chemic, Unani, Ayurvedic, and Herbal products; Vaccines and Biologics; Medical devices; and Veterinary medicines. The scope of DGDA does not include food or cosmetics, which are currently regulated by the Bangladesh Standards and Testing Institutions (BSTI) (Ref: *Assessment of the Regulatory Systems and Capacity of the DGDA in Bangladesh SIAPS 2012*).

DGDA performs its primary responsibilities under the Drug policy 2005, Drug Acts 1940, Drug Rule 1945 and 1946, the Drug ordinance 1982 and other legal tools developed by the Government of Bangladesh.

The Pharmacy Council of Bangladesh is an autonomous organization under MOHFW responsible for regulation of practice of pharmaceutical personnel in the country. Operations of PCB are governed by the Pharmacy Ordinance of 1976 (Pharmacy Act 2013). 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 holders and C grade are Pharmacy Technician who pass a Pharmacy Certificate examination.

Grade A pharmacists are mainly found working in pharmaceutical manufacturing industries, B grade found mostly practicing in public and private hospital pharmacies while C grade are found working in retail pharmaceutical outlets.

1.3: Retail Pharmaceutical Services

Retail medicine outlets are registered by DGDA through application made under form No. 7 of the Drug Rules 1946. Applications are made to DGDA by applicants who wish to operate the retail 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 voter ID card. Registration of retail pharmaceutical outlet is issued with respect to availability of registered pharmaceutical personnel under the three PCB professional categories of which majority are C grade. Approved applications are issued with registration certificate upon payment of prescribed registration fee. The Drug Rules 1946 requires that licenses should be renewed every two years. The Drug Rules also requires having two types of licenses for retail sale of medicines; a license for sale of medicines under schedule C and a license for sale of medicines which are not under schedule C. In the year 2016, MOHFW has approved two types of private retail medicine outlets to be existed in Bangladesh: 1) Model Pharmacy (MP) and 2) Model Medicine Shop (MMS). So far, there are about 118,904 licensed retail medicine outlets in Bangladesh. (Ref: DGDA website, accessed on 31 December 2019). Out of these medicine outlets, the number of Model Pharmacy (MP) is 271 (Ref: DGDA records) and the number of Model Medicine Shops is 266 (Ref: DGDA records)) inaugurated by DGDA. DGDA stopped issuing new licenses for couple of years. Now DGDA is issuing new licenses only either for Model Pharmacy or Model Medicine Shop. Inspection of retail outlets is conducted by DGDA superintendents either from central level or those located at division and district level. The Drug Rules 1946 requires that retail medicine outlets are inspected at least twice in every year.

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

Two assessments previously carried out by a USAID funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program in Bangladesh in 2012 and 2015 identified some issues related to operations of retail pharmaceutical services in Bangladesh. This section will elaborate on the various areas of strength, weakness, opportunities, and challenges of retail pharmaceutical services.

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 pharmaceutical Outlets

The DGDA is responsible for licensing of retail medicine outlets in the country. An operation of retail medicine outlets is governed by the Drug Rules 1946. Currently DGDA has staff dedicated to inspection of retail pharmaceutical outlets and other premises. The authority has about 84 technical personnel, 61 being inspectors and of these are drug superintendents (DS) who are empowered to inspect private retail medicine outlets. DGDA has 50 offices at district which also oversee the remaining 14 districts without offices.

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

2.1.2: Existence of Inspection Checklist and Recently Developed Standard Operating Procedures (SOPs) to Support Inspection Activities

Standard Operating Procedures (Ref: SOPs for inspection of retail and wholesale medicine outlets have recently been developed with support from USAID/SIAPS program in Bangladesh (signed by DG-DGDA on 16 February 2016). The SOPs detail the qualifications and powers of inspectors, their duties, inspection process of retail and wholesale medicine outlets, random sampling, drug seizure, sample collection and procedure for quality control. Other areas described include report writing, follow up and regulatory decision-making.

Additional material will need to be developed to supplement the SOPs based on the new categorization of retail pharmaceutical services and associated standards. An inspection, monitoring and accreditation guide is an integral part of the developed standards of Model Pharmacy and Model Medicine Shop.

2.1.3: Support from Ministry of Health and Family Welfare, DGDA and Pharmacy Council

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) was formed to provide oversight on progress on implementation of Bangladesh Pharmacy Model Initiative aiming at improving services provided by retail medicine outlets in the country. Pharmacy Council has employed three (03) A grade pharmacists to strengthen its operations.

2.1.4: Contribution of Retail Medicine Outlets to Improving Access to Medicines and Pharmaceutical Services at Community Level.

The large network of licensed medicine outlets increases availability of medicines closer to where people live and hence complement the shortages experienced in public health facilities as well as inaccessibility of

public health facilities due to patient congestion, geographical distance from where people live and other factors. Improving services provided by retail medicine 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 Medicine Outlets.

2.2.1: Existing Gaps in the Current Legal Framework to Support Inspections of Retail Medicine Outlets

(a) The Drug Act 1940, Drug ordinance 1982 and Drug Rules 1946 did not categorize the operations of private retail pharmaceutical services based on their level of service, human resource qualifications and premise standards requirements. Since the inception of Bangladesh Pharmacy Model Initiative (BPMI), two types of retail medicine outlets detailing standards have been approved by MOHFW (2016) in order to serve the Good Pharmacy Practice (GPP) in Bangladesh both in urban and rural areas (Ref.: Standards for the Establishment and Operations of Model Pharmacies and Model Medicine Shops).

(b) For effective inspection system, standards of operation and premises must first be set so that inspectors uniformly follow the same standard while performing compliance monitoring. With limited human resource and in the absence of established inspection and monitoring guide, inspections are ineffective and adherence cannot be comprehensively monitored even though the current law requires that each medicine outlet must be inspected at least twice in every year.

(c) Collaboration between the two pharmaceutical regulatory bodies (DGDA and PCB) on inspection activities would increase the synergy and hence increase adherence to legal requirements and set standards e.g. ensuring presence of registered pharmacists in retail medicine outlets by PCB.

2.2.2: Inadequate Human Resource at DGDA and PCB to Manage Inspection Activities

DGDA doesn't have Superintendent of Drugs for all 64 districts. DGDA has positioned one district superintendent in some districts while other districts are shared by one superintendent. The role of district superintendents is to oversee all DGDA activities at district level including inspection of retail medicine outlets. At central level, the number of superintendents and inspectors is relatively low to manage all DGDA activities including pharmaceutical retail outlets inspections effectively and per schedule. Looking at the large population of Bangladesh and the number of retail drug outlets, it is evident that the number of inspectors is insufficient to meet the inspection requirements.

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

2.2.3: Large Number of Medicine Outlets in the Country Compared to Number of Registered Pharmaceutical Personnel

There are about 118,904 licensed medicine outlets operating in the country. There is also substantial number of unlicensed medicine outlets operating without DGDA license. PCB has registered about 115,003 C grade Pharmacists (Pharmacy Technicians), 4670 B grade Pharmacists and about 15887 A grade Pharmacists (Ref: PCB Official). The total number of professionals seems to be less than the number of licensed retail medicine outlets. This shows that there are a number of licensed medicine outlets operating without registered pharmacist posing a concern on the quality of service provided by these outlets.

2.2.4: Inadequate Inspection Tools/Materials to Support Inspection Process

DGDA developed SOPs for use during inspection however inspection guide including inspection forms/ checklists have not been developed to capacitate inspectors at different levels to be able to carry out effective inspection. Inspection checklists for premises intending to operate the retail medicine outlets have not been made available. Standardized forms for preliminary and routine inspection will need to be developed to focus on the agreed categorization of premises and respective standards of retail medicine outlets. This document intends to provide a guide and checklist for inspection of retail medicine outlets (Annexure-1 & 2). Similar tools do not exist at Pharmacy Council to oversee the quality of services provided by pharmacists. There are no documented standards for pharmacy practice to be followed by pharmacy personnel in both public and private health sector.

Chapter Three: **Strategies for Improving Inspection System**

3.1. Establishment of a Model Pharmacy and Model Medicine Shop Wing/Inspectorate at DGDA

The BPMI project proposed establishment of a wing at DGDA headquarter to oversee activities related to Model Pharmacy and Model Medicine Shop. Structure, composition and responsibilities of the section are described below.

3.1.1. Structure of the Proposed DGDA Model Pharmacy and Model Medicine Shop Wing/Inspectorate

Short term measure

It is proposed to establish a wing to have the following staff composition;

- Headed by a Deputy Director
- One Assistant Director
- Two Drug superintendents
- One Inspector

The wing will report directly to DG, DGDA

Long Term measure

It is proposed to establish a Model Pharmacy and Model Medicine Shops Central Inspectorate with the following staff composition;

- Headed by a Director
- Two Deputy Directors
- Three Assistant Directors
- Six Drug Superintendents

At upazila level, one drug inspector is proposed under DGDA.

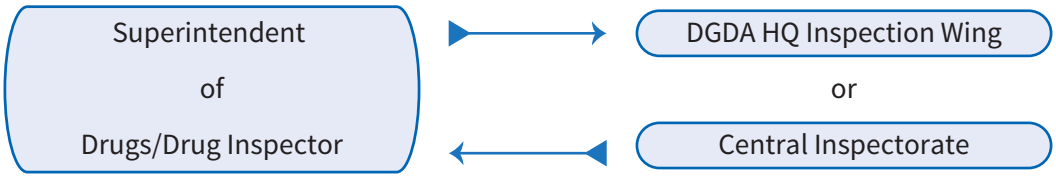
3.1.2: Responsibilities of the Proposed DGDA Model Pharmacy and Model Medicine Shop Wing/Inspectorate

The proposed wing/inspectorate will have the following responsibilities. Other responsibilities may be added from time to time as may be found necessary.

- Coordinate with Central/Divisional/District DGDA officials
- Coordinate and collaborate with MSH on all activities of BHB project in relation to inspection, monitoring and accreditation of Model Pharmacies and Model Medicine Shops
- Oversee the activities of pharmacy inspection of Divisional/District DGDA Officials.
- Coordinate licensing activities for retail medicine outlets within DGDA
- Provide legal support to Divisional/District officials about medicine outlets inspection
- Ensure availability of inspection tools at all inspection levels
- Take initiatives to resolve untoward situations as may be arising
- Provide continuous training to inspectors at all levels
- Cooperate with PCB and BCDS on training of medicine outlets owners and medicine outlets technical personnel

- To arrange awareness programs for the stakeholders and mass people
- Continuously update the training tools and materials for DGDA personnel related to inspection and monitoring
- Coordinate dissemination of information from DGDA to medicine outlets
- Liaison with relevant stakeholders

3.1.3: Reporting on Inspection Reporting flow:



Chapter Four: **Steps to be Followed for Accreditation**

4.1 Steps to be Followed Before, During and After Accreditation of Model Pharmacy and Model Medicine Shop

Before Accreditation

A. **Development of Human Resources:**

1. 30 hours orientation of graduate pharmacists (A Grade or B Grade)
2. 80 hours training of C-grade pharmacy personnel

B. **Activity at DGDA:**

Formation of Functional unit at DGDA for inspection, monitoring and accreditation

During Accreditation (Process of Accreditation)

1. Preliminary Inspection of retail medicine outlets: To identify areas of improvement to comply standards using the checklist
2. Time for improvement (grace period; maximum 12 months) and follow-up inspections based on approved standards
3. Final Inspection: Based on pre-inspection and follow-up inspection findings and necessary improvements made during given grace period, the inspection team will recommend for accreditation.
4. DGDA to issue Accreditation certificate and handover the Logo

After Accreditation

1. Regular supervision and monitoring by respective inspection team to ensure accredited Model Pharmacies and Model Medicine Shops comply with approved standards
2. Withdrawal of certificate and Logo from non-compliant existing Model Pharmacies and Model Medicine Shops.

References

1. Drugs Act 1940
2. Drug Rules 1945/1946
3. Drugs Ordinance 1982
4. Pharmacy Ordinance 1976
5. Assessment of the Regulatory Systems and Capacity of the Directorate General for Drug Administration in Bangladesh (USAID/SIAPS 2012)
6. Baseline Study of Private Drug Shops in Bangladesh: Findings and Recommendations (USAID/SIAPS 2015)
7. Tanzania Accredited Drug dispensing Outlets (ADDO) Implementation Guideline (2014)
8. Government of the People's Republic of Bangladesh (Ministry of Health and Family Welfare - Drug Administration Section) Memo: No. D, A/D-43/88/284
9. DGDA Presentation to National Stakeholders on Bangladesh Pharmacy Model Initiative in November 2015
10. DGDA Presentation to on study Tour - Tanzania Ministry of Health March 2016

ANNEXURE-1: **Inspection Checklist and Reporting**

Inspection & Monitoring Checklist for Model Pharmacy (Preliminary, Follow Up, Final and Routine)

Name of Proposed/Existing Premise: _____
Location and Physical Address: _____
Name of the premise in-charge (Dispenser): _____
Address: _____
Phone Number: _____
Qualification: _____
Owner's Name: _____
Owner's Phone Number: _____
Owner's Email address: _____
Date of last inspection: _____

Required Standards	Compliance Status		Remarks
	Yes	No	
1. Licensing Requirements			
1.1 Does the medicine outlet have a drug license issued by DGDA?			Drug License No.:
1.1.1 Is the drug license valid?			
1.1.2 Is the drug license displayed?			
1.1.3 Is the business operated by the drug license holder?			
1.2 Is the medicine outlet supervised by a registered pharmacist?			
1.3 Does the medicine outlet- in-charge has a valid PCB registration certificate and displayed?			PCB Registration No.:
1.4 Does the medicine outlet have an accreditation certificate displayed (only for routine inspection of accredited shops)?			
2. Standards for Personnel			
2.1 Has the pharmacist in charge received MP training?			
2.2 Is the registered pharmacist present in the medicine outlet at the time of inspection?			
2.3 Is the dispensing staff maintaining the dress code?			
3. Standards for Premises			
3.1 Does it have a minimum space as per standards 300 sqft for MP)?			Space: Length: Width:
3.2 Is there a source of power supply (National Grid, Back up IPS/generator/solar panels)?			Which One:
3.3 Is there functional air conditioner(s) for 24 hours with a power back-up source (for MP)?			
3.4 Is there a thermometer to monitor room temperature?			
3.5 Is the entire medicine outlet area clean and tidy?			
4. Signage			
4.1 Is there an officially approved logo (brand) for MP for existing outlets?			
5. Temperature maintenance and control			
5.1 Is the temperature in the medicine outlet compatible with recommended storage conditions?			
5.2 Is there at least one pharmacy grade refrigerator			
5.3 Is any medicine stored in the freezer/deep freezer?			
5.4 Is refrigerator working for 24 hours with power back up?			

Required Standards	Compliance Status		Remarks
	Yes	No	
5.5 Are any temperature-sensitive (recommended to store 2-8 degree Celsius) medicines found stored or displayed outside the refrigerator(s)?			
6. Status of Medicines & other products			
6.1 Is there expiry medicine container to store mentioning with marking as EXPIRED MEDICINE, NOT FOR SALE?			
6.2 Are there any-			Name (if any):
6.2.1 Expired			
6.2.2 Suspected counterfeit and suspected substandard			
6.2.3 Misbranded			
6.2.4 Unregistered			
6.2.5 Govt. Medicines			
6.2.6 Physician's Samples Medicines found for sale?			
6.3 Is there any expired medicine stocked or exhibited on shelves for sale?			Name (if any):
6.4 Are the medicines purchased from licensed anufacturers/importers/ wholesalers? (Check records)			Name (if not):
6.5 Are there separate shelving facility for OTC medicine and Prescription Only Medicine (including labeling)?			
6.6 Is there separate shelving facility for Alternative Medicine (including labeling)?			
6.7 Is there separate shelving facility for Medical Devices & Supplies (including labeling)?			
6.8 Is there separate shelving facility for Health and Hygiene Products (including labeling)?			
6.9 Is there any narcotic substance(s) found for sale in the medicine outlet?			Name (if yes):
6.10 Does the outlet have a narcotic license?			
6.11 Is there a separate area/space and shelving for veterinary medicines and properly labeled?			
7. Record Keeping			
7.1 Are there copies of proper receipts/invoices for the procurement of all the medicines and medical devices from manufacturers/importers/ wholesalers?			
7.2 Is any medicine procured without proper invoice?			
7.3 Does the medicine outlet maintain a register for selling Antibiotic?			
7.4 Does the medicine outlet have a narcotic medicine register (if narcotic medicine is available)?			
7.5 Is the purchase invoice kept for at least 2 years beyond the date of expiry?			
7.6 Does the medicine outlet maintain expired medicine register?			
7.7 Does the medicine outlet provide proper receipt/invoice/ cash memo to clients for selling medicines/products?			
8. Reference Materials			
8.1 Is standards (guideline) for MP available in the medicine outlet?			
8.2 Is list of approved OTC medicines available in the medicine outlet?			

Any other observation and remarks (Use separate sheet if required)

Recommendation and Action

Name of medicine outlet: Date: Address:		
Sl. No.	Issues that require attention and correction	Actions agreed to take and timeline
1		
2		
3		
4		
5		
6		
7		
8		

Comment

Not Recommended for New Accreditation (√ below)	Recommended for New Accreditation (√below)	Suspend Accreditation (for routine inspection) (√below)	Continue Accreditation (for routine inspection) (√below)
MP	MP	MP	MP
Geo Coordinates:			
Duty Station of Drug Inspector:			
Drug Inspector's Name:		Designation:	
Signature:		Date:	
Owner's Name:		Signature:	
Date:			

ANNEXURE-2: **Inspection Checklist and Reporting**

Inspection & Monitoring Checklist for Model Medicine Shop (Preliminary, Follow Up, Final and Routine)

Name of Proposed/Existing Premise: _____
Location and Physical Address: _____
Name of the premise in-charge (Dispenser): _____
Address: _____
Phone Number: _____
Qualification: _____
Owner's Name: _____
Owner's Phone Number: _____
Owner's Email address: _____
Date of last inspection: _____

Required Standards	Compliance Status		Remarks
	Yes	No	
1. Licensing Requirements			
1.1 Does the medicine outlet have a drug license issued by DGDA?			Drug License No.:
1.1.1 Is the drug license valid?			
1.1.2 Is the drug license displayed?			
1.1.3 Is the business operated by the drug license holder?			
1.2 Is the medicine outlet supervised by a registered dispenser?			
1.3 Does the medicine outlet- in-charge has a valid PCB registration certificate and displayed?			PCB Registration No.:
1.4 Does the medicine outlet have an accreditation certificate displayed (only for routine inspection of accredited shops)?			
2. Standards for Personnel			
2.1 Has the pharmacist in charge received MMS training?			
2.2 Is the registered pharmacist present in the medicine outlet at the time of inspection?			
2.3 Is the dispensing staff maintaining the dress code?			
3. Standards for Premises			
3.1 Does it have a minimum space as per standards 120 sqft for MMS)?			Space: Length: Width:
3.2 Is there a source of power supply (National Grid, Back up IPS/generator/solar panels)?			Which One:
3.3 Is there ceiling fan and/or exhaust fan			
3.4 Is there a thermometer to monitor room temperature?			
3.5 Is the entire medicine outlet area clean and tidy?			
4. Signage			
4.1 Is there an officially approved logo (brand) for MMS for existing outlets?			
5. Temperature Maintenance and Control			
5.1 Is the temperature in the medicine outlet compatible with recommended storage conditions?			
5.2 Is any medicine stored in the freezer/deep freezer?			
5.3 Is refrigerator working for 24 hours with power back up?			

Required Standards	Compliance Status		Remarks
	Yes	No	
5.4 Are any temperature-sensitive (recommended to store 2-8 degree Celsius) medicines found stored or displayed outside the refrigerator(s)?			
6. Status of Medicines & Other Products			
6.1 Is there expiry medicine container to store mentioning with marking as EXPIRED MEDICINE, NOT FOR SALE?			
6.2 Are there any-			Name (if any):
6.2.1 Expired			
6.2.2 Suspected counterfeit and suspected substandard			
6.2.3 Misbranded			
6.2.4 Unregistered			
6.2.5 Govt. Medicines			
6.2.6 Physician's Samples Medicines found for sale?			
6.3 Is there any expired medicine stocked or exhibited on shelves for sale?			Name (if any):
6.4 Are the medicines purchased from licensed manufacturers/ importers/wholesalers? (Check records)			Name (if not):
6.5 Are there separate shelving facility for OTC medicine and Prescription Only Medicine (including labeling)?			
6.6 Is there separate shelving facility for Alternative Medicine (including labeling)?			
6.7 Is there separate shelving facility for Medical Devices & Supplies (including labeling)?			
6.8 Is there separate shelving facility for Health and Hygiene Products (including labeling)?			
6.9 Is there any narcotic substance(s) found for sale in the medicine outlet?			Name (if yes):
6.10 Does the outlet have a narcotic license?			
6.11 Is there a separate area/space and shelving for veterinary medicines and properly labeled?			
7. Record Keeping			
7.1 Are there copies of proper receipts/invoices for the procurement of all the medicines and medical devices from manufacturers/importers/ wholesalers?			
7.2 Is any medicine procured without proper invoice?			
7.3 Does the medicine outlet maintain a register for selling Antibiotic?			
7.4 Does the medicine outlet have a narcotic medicine register (if narcotic medicine is available)?			
7.5 Is the purchase invoice kept for at least 2 years beyond the date of expiry?			
7.6 Does the medicine outlet maintain expired medicine register?			
7.7 Does the medicine outlet provide proper receipt/invoice/cash memo to clients for selling medicines/products?			
8. Reference Materials			
8.1 Is standards (guideline) for MMS available in the medicine outlet?			
8.2 Is list of approved OTC medicines available in the medicine outlet?			

Any other observation and remarks (Use separate sheet if required)

Recommendation and Action

Name of medicine outlet: Date: Address:		
Sl. No.	Issues that require attention and correction	Actions agreed to take and timeline
1		
2		
3		
4		
5		
6		
7		
8		

Comment

Not Recommended for New Accreditation (√ below)	Recommended for New Accreditation (√below)	Suspend Accreditation (for routine inspection) (√below)	Continue Accreditation (for routine inspection) (√below)
MMS	MMS	MMS	MMS
Geo Coordinates:			
Duty Station of Drug Inspector:			
Drug Inspector's Name:		Designation:	
Signature:		Date:	
Owner's Name:		Signature:	
Date:			

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