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|  The People’s Republic of BangladeshMinistry of Health and Family Welfare (MOHFW)The Directorate General Drug of Administration (DGDA)-BangladeshINSPECTION GUIDE FOR ACCREDITED MEDICINE SHOPS AND MODEL PHARMACIES 2nd DraftNovember 2016 |

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# Foreword

Medicines are vital goods for any health-care delivery system. Therefore, one objective of the national medicines policy is assurance of the safety, quality and efficacy of the medicines circulating in the market. An essential part of any medicine control system is the provision of an inspection body with the responsibility and authority to inspect all of the activities involved in research, development, manufacture, control, distribution, sale and supply of medicines. Qualified and experienced drug inspectors constitute an indispensable component of the inspection system.

Drug inspectors serve as the eyes and ears of the medicines control authority and shall be the front liners in maintaining the quality, purity, and efficacy of medicines manufactured and marketed in any country. In this respect, drug inspectors have an important role in protecting and promoting public health by ensuring that medicines and medical supplies circulating in the market meet safety and quality standards. Succinctly, the inspector’s job is law enforcement. A drug inspector is empowered by the law, at all reasonable times, to enter any premises that is on the register or any premises in which he/she has reasonable cause to suspect that the law has been or is about to be contravened. The functions and duties of DGDA in relations to ensuring safety, quality and effectiveness of medicines are well stipulated in respective Drug Acts, Rules and Ordinances of the People’s Republic of Bangladesh.

Drug inspectors should perform their duties according to the guidelines. This guideline has been prepared to guide inspectors while preparing for and performing establishment or routine (monitoring) inspections for AMS and Pharmacies.

Director General DGDA

# Acknowledgments

# Acronyms

|  |  |
| --- | --- |
| AMS | Accredited Medicine Shops |
| CCTV-Camera | Closed Circuit Television - Camera |
| DDC | District Drug Committee |
| DDLC | District Drug Licensing Committee |
| DGDA | Directorate General of Drug Administration |
| MOHFW | Ministry of Health & Family Welfare |
| MSH | Management Sciences for Health |
| NMP | National Medicines Policy |
| PCB | Pharmacy Council of Bangladesh |
| SOP | Standard Operating Procedures |

# Section 1: Definitions

1. Medicines’ means any substance or mixture of substances intended for use in the diagnosis, treatment, mitigation, or prevention of a disease, disorder, abnormal physical or mental state, or symptoms thereof, in man or animal, or, restoring, correcting, or beneficial modification of organic or mental functions in man or animal.
2. Authority-herein means the Directorate General of Drug Administration of Bangladesh.
3. Dispense- means to give or prepare and give (especially a medicine) out based on a legal prescription or based on the judgement of the dispenser as directed by the existing law.
4. Dispenser-means one who is trained and licensed or registered to dispense (medicines).Practically**,** one who, though not a (graduate) pharmacist, is trained to prepare and distribute, to a patient, a course of medication on the basis of either an oral or written prescription; to manage stocks and to maintain records of some of drugs and non-drug therapeutic items;
5. Pharmacy - means a shop wherein medicines are sold conventionally under the superintendence of a l**ic**ensed pharmacist; also a hospital dispensary;
6. Pharmacy as a profession, is that science that deals with the recognition and isolation of drug substances (in the case of plants-derived medicines); the synthesis of drugs (in the case of synthetic drugs); the compounding, storage, and dispensing of drugs; and also imparting of drug information to both the prescriber and the patient, etc
7. Pharmacist-means a holder of a degree or diploma in pharmacy from a recognized higher (usually a tertiary level) institution of learning and is registered or licensed to practice pharmacy
8. Pharmaceutical personnel-means anyone licensed to practice any aspect of pharmacy proper or of sub­-pharmacy (a pharmacist or a dispenser, respectively).
9. Pharmaceutical product- means a pharmaceutical dosage form (i.e. the raw active ingredient made into a particular dosage form).

# Section 2: Background

The Bangladesh Directorate General Drug Administration was established under the Bangladesh Ministry of Health and Family Welfare. The Authority supervises and implements all prevailing Drug Regulations in the country and regulates all activities related to import, procurement of raw and packing materials, production and import of finished drugs, export, sale, pricing, etc. of all kinds of medicine including those of Ayurvedic, Unani, Herbal and Homoeopathic systems.

The Directorate General of Drug Administration’s mission is to ensure that the common people have easy access to useful, effective, safe and good quality essential and other drugs at affordable price.

The regulation of medicines involves among other things, inspection of medicines’ outlets of which in Bangladesh will include wholesale pharmacies, retails pharmacies and accredited medicine stores or Medicine Shops. Conducting inspection activities is very important in ensuring that medicines and health products circulating in the market meet the prescribed safety and quality standards and the services provided are of sufficient quality and meet the set standards. In order to achieve this goal, inspectors need to be provided with sufficient knowledge and skills, working tools and ample time to exert their expertise in observing, investigating and reaching conclusions on the quality of a particular medical product and services.

The guide has been prepared to support inspectors while preparing for and performing various types of inspection activities. The guide also sets standards of inspection performance and thus eliminating great variations between inspections done by different groups of inspectors. It also serves as a reference for inspectors prior to and during inspection.

The guide highlights general conditions and other pertinent requirements that are necessary for carrying out new or routine inspections for applying or already registered premises. The guide has seven sections:

1. Basic definitions
2. Background
3. Introduction to Medicines Inspection
4. Inspection of AMS and Pharmacies for establishment
5. Routine Inspection – Compliance Monitoring
6. Reporting
7. Inspection checklists and reporting forms for higher level inspectors

This guide covers only the inspection of drug outlets (later Accredited Medicine Shops) and Pharmacies. However inspectors may apply similar techniques and processes while inspecting wholesale pharmacies or storage facilities for medicines once standards are developed.

It is also expected that the guide shall help inspectors to conduct pharmacies and AMS inspection with integrity and diligence and have a consistent reporting format and improved transparency.

# Section 3: Introduction to Drug Inspection

The section describes what inspection is, what needs to be inspected, the different types of inspection, code of ethics and conduct for Inspectors and what is expected of inspectors. It is important for inspectors to go through this section first, especially during the preparatory phase of inspections.

### 3.1 What is Inspection?

To “inspect” is “to look closely at something, especially to check that everything is in good order.” “Inspection” is, therefore, the act of looking closely at something to ensure that it meets certain prescribed or known standards and specifications.

In relation to drug and premise inspection involves the act of examining or looking closely at all the medicines attributes and the condition of the facilities or premises responsible for storage and distribution/dispensing medicines. It also looks at how services and processes are carried out in the premise. The objective of conducting medicine, services and premise inspection is to ensure that medicines and related supplies either locally manufactured or imported from outside the country, meet set quality standards so as ensure patients safety and the public health at large. It also looks at the premise in which medicines are stored and services provided that if it meets established premise and operation standards.

Safety of medicines can be assured by enforcing medicines laws and regulations governing manufacturing, compounding, distributions, importation, exportation, sale, storage and use of medicines.

### 3.2 What Needs to be Inspected?

To ensure the quality of medicines entering or circulating in the Bangladesh market, the following establishments associated with medicines supply and the distribution chain should be legally established and inspected regularly:

1. New premises or facilities for wholesale and retail Pharmacies and Accredited Medicines Stores\* before they are licensed;
2. Operating wholesale and retail pharmacies;
3. Operating Accredited Medicines Shops (AMS);
4. New and old local manufacturing facilities before they are licensed and after being licensed respectively;
5. Overseas pharmaceutical manufacturing facilities before they are approved to import medicines to Bangladesh.

However, the scope of this guideline will be limited to the inspection of medicines, services and premises under a, b and c only. Nevertheless inspection of wholesale outlets will not be discussed in this guide although inspectors are expected to apply similar approaches when inspecting wholesale premises.

### 3.3 Types of Inspection

Generally, there are five types of inspections as outlined and described below;

* Preliminary
* Follow-up and Final
* Routine
* Concise
* Special
* Investigative

#### 3.3.1 Preliminary Inspection

The term preliminary inspection is very much linked with the process of drug outlets accreditation process. It describes the preliminary action taken by the regulatory body to send inspections to evaluate its compliance status one an application has been received. The major objective of this inspection is to evaluate the status of an existing premise, identify in-compliances if any and advice the owner/applicant what steps needs to be taken so that the premises complies with the existing regulatory requirements. If the premise does not exist yet inspectors will advice the applicant how to establish a premise that will be in compliance with the requirements. Preliminary inspection is therefore not a compliance inspection.

#### 3.3.2 Follow Up and Final Inspection

In ordinary routine inspection system a follow up (also referred to as re-inspection or re-assessment) inspection is normally carried out to ensure that corrective measures have been undertaken following advice and notice given during a previous inspection. Where a time limit was given for applying the corrective measures, the inspection should be unannounced. Depending on the nature of the defect and work required and the risk associated with the non-conformances adequate time to rectify the defect should be provided.

However in accreditation process, usually after preliminary inspection, inspectors leave behind a list of things that the applicant has to do within a given period to comply with the requirements. However it is advisable that instead of waiting up to the end of the set period to carry out final inspection, follow up inspection needs to be done to determine the progress of the process and discuss with applicants if they are facing any problems in the process.

Final inspection is done at the end of the agreed period and it is more comprehensive than the follow-up inspection. The final inspection is therefore a comprehensive compliance inspection. Applicants who do not totally meet the requirements will not go for accreditation but asked to continue working until all requirements have been met.

#### 3.3.3 Routine Inspection

Routine inspections are generally intended for a new establishment (new premises) or for an establishment that has applied for a permit to extend its scope of operations, made important changes in its key personnel, changed to a new premises, or has not been inspected for a long time. A routine inspection is a full review of all aspects and components of compliance within a premise. The inspector should also be aware of the licensing provision for the given premise.

Routine inspections may be announced or unannounced, depending on the history of the premise, experiences of previous inspections and the policy of the regulatory body.

#### 3.3.4 Concise Inspection

A concise inspection is the evaluation of limited aspects relating to premise compliance to regulations and standards of practice. It is usually done to a premise that has been found to comply with standards and regulations during previous inspections. It is sometimes known as an “abbreviated” inspection in some countries. Usually during concise inspection a limited number of operation standards or requirements are selected by the inspector to serve as indicators of overall practice compliance by the outlet. The inspector also takes opportunity to identify and evaluate any significant changes that could have been introduced since the last inspection.

Depending on authority’s practice, a premise would normally not be warned in advance about a concise inspection.

A concise inspection is applicable under the following circumstances:

* Where a premise has a consistent record of total compliance through routine inspections in the past and
* Where a sample of aspects can be taken as a good indication of the overall level of compliance

However, if the concise inspection uncovers evidence that the level of compliance has deteriorated a more comprehensive or full inspection should then be performed soon after the concise inspection.

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#### 3.3.5 Special Inspection

There are a number of circumstances in which special visits or inspections may be necessary. A special inspection is undertaken to do spot checks. Spot checks could focus on one some compliance elements of standards or requirements or the type of service being provided. The outlet may or may not be aware in advance of the inspection, depending on the reason for it. If there have been complaints about the services being provided for example sale of substandard or none registered products or services being provided by non qualified personnel, then a special inspection could be performed to investigate the complaints. In such cases the outlets may not be warned in advance.

A special inspection could also be performed to gather specific information, or to investigate specific issue or issues of the premise. This opportunity can also be used to advise the provider on specific regulatory requirements.

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#### 3.3.6 Investigative Inspection

An investigative inspection is undertaken to deal with specific complaints received about lapses or noncompliance with standards of professional practice. The inspection should be unannounced. This type of inspection does not differ much from special inspection.

### 3.4. Inspectors and Inspection

#### 3.4.1 Code of Ethics and Conducts for Inspectors

1. Inspectors shall behave, have desirable conduct and observe the code of ethics and conduct as stipulated herein below;
2. Strive to achieve the highest ethical and performance standards in carrying out inspection activities;
3. Uphold the honour and dignity of an inspector and avoid association with any enterprise of questionable character or apparent conflict of interest;
4. Protect and promote the interests of the Authority to the best of his/her ability and knowledge, recognizing that the Authority has placed trust and confidence onto him;
5. Strive to acquire new knowledge and skills continuously and use them effectively;
6. Conduct inspection in a manner that will assure independence from outside influence and interest, which would otherwise compromise his ability to render a fair and impartial opinion regarding any inspection conducted;
7. Promptly disclose to the Authority any interest in any business which may affect the quality, or the result of his/her work or remediation;
8. Not use his/her position for personal gain;
9. Make every effort to uphold, maintain and improve the integrity and reputation of the Authority and the Government of Bangladesh;
10. Perform duties tactfully, honestly and impartially to avoid circumstances that may lead to conflict of interest;
11. Maintain confidentiality whenever accessing confidential information as a result of inspection;
12. Assess facts quickly and take rational and sound decisions without delay;
13. Not solicit, force or accept bribes from a person whom he/she is serving, already served or will be serving either by doing so in person or by using another person;
14. Not receive presents in form of money, entertainments or any service from a person that may be regarded as geared towards compromising his/her integrity;
15. Disclose fraud or abuse of power and corruption to the Authority;
16. Avoid the use of rude and abusive language;
17. Maintain personal hygiene and dress in respectable attire in accordance with acceptable norms of the office;
18. Make decisions in line with authorized standards and procedures and
19. Report inspection findings truthfully and accurately
20. Committed to work hard and for long hours
21. Not without prior approval by Authority, engage in outside employment or activities and shall not seek or negotiate for employment that will directly conflict with the duties/interests of the Authority.
22. Conserve Authority property and shall not use it for private gain.
23. Endeavor to avoid any actions that create an appearance, circumstance that are violating the law or ethical standards as determined by the perspective of a reasonable person with the knowledge of the relevant facts.
24. Adhere to the laid down rules, regulations and standard operating procedures in executing his/her functions.

### 3.5. Inspectors’ Basic Qualification

Based on the current situation in Bangladesh and the critical shortage of inspectors to effectively monitor the high number of expected drug outlets (AMS and Pharmacies) inspectors of different qualifications will have to be created and used.

Currently the DGDA has inspectors that are known as superintendent most of them with graduate education and substantial experience in the field of inspection. Nevertheless these are few and therefore are not able to effectively carry out inspections as expected (twice per year).

With the BMPI project in place more AMS and pharmacies are expected to be created even in remote areas. The current numbers of inspectors will not be able to cover an effective compliance monitoring in areas were the project has established accredited model pharmacies and AMS. It will therefore be necessary to establish an inspectorate system at lower level to support the superintendents by carrying out basic compliance monitoring. Creation of lower inspectorate system will require training of those supporting the system.

### 3.6. Inspectorate System

Based on the inspection strategy, effective compliance monitoring can only be achieved if a network of inspection system is created from the central DGDA to the grassroots – lower level where most of the AMS will be operating. According to the MOHFW Memo (Ref. MHFP Memo: No D. A/D-43/88/284 Date 17.5.1989 and Ref. DGDA, dated 19-11-88 DA/AD-1/48/87/6193, and dated 23-11-88 DA/RL-1/79 (part)/83/6283) a special committee has been formed at district level (District Drug Licensing Committee – DDLC) with one of its responsibilities being to issue or withdraw license of drug outlets. The Memo also establishes Task Forces at Upazila with the responsibility of carrying out inspections of drug shops and taking necessary actions. As Task Forces are usually appointed for a short tem activity, we suggest that they be called Upazila or City Corporation Drug Committees and the committee at district level be renamed to District Drug Committee with a wider range of responsibilities as indicated in the inspection strategy. The Upazila and City Corporation Drug Committees will be answerable to the district drug committee and one of their responsibilities will be to carry out local inspections to support the superintendent as shall be described in the inspection strategy. The members of the district, Upazila and City Corporation will have different educational background in terms of inspection, training and experience. They will also need to be trained and oriented to carry out basic inspections and monitoring activities.

**(a) Central Inspectors**

These are inspectors currently and directly working under DGDA that include those at the head office and at district level. Most of these are graduates not necessarily in Pharmacy and have substantial experience in the field of inspection. This group although has sufficient knowledge and skills in the field of inspection will need to be reoriented to effectively understand the compliance requirements upon the model pharmacies and Accredited Medicine Shops. Furthermore continuous training shall be provided to inspectors to keep them abreast with the current knowledge and techniques in carrying out inspections. This shall be through attending training programs, seminars, scientific meetings, conferences and exhibitions organized either locally by DGDA or international organizations.

**(b) Members of the District/Upuzila Drug Committee**

This is not a new group as it was already formed by the Ministry (see ref. above) but unfortunately this order has not been put into practice up to date. Review carried out at District and Upuzila shows that there is no Task Force responsible for inspections of drug outlets as specified in the task Force formation Order. Creation of inspectorate system supported by the Task Force (committee) will be necessary for the DGDA to maintain an effective compliance monitoring by being able to comprehensively carry out inspection to cover most of the outlets and at acceptable frequency.

Since the members of the Task Force (committee) will have different education background that they will need to have a special training on basic inspections and oriented on the various inspection checklist as suggested in this guide.

The basic education of inspectors in this category may be different depending on the type of work a member is doing at present and at what level. For example, in this group the following can be included; Pharmaceutical technicians, C-Grade holders with several years of practical experience at retail level and others with sufficient basic education in science subjects, public health officers, clinicians, nurses or any other civil servant currently working within the health sector at District, City Corporation, Upuzila or Union. This Task Force (Committee) will form a core inspectorate system at local level and will support the superintendent at the district, City Corporation, Upuzila and Union by carrying out basic compliance monitoring inspections periodically and giving reports to the district Drug Committee where the District Superintendant is a secretary for the Committee to take actions where necessary.

The members of the Task Force (Committee) will be trained by the experienced central inspectors initially and then on the job by carrying out inspections with the experienced inspectors before they are left on their own.

This is the area that the DGDA needs to directly collaborate with the MOHFP staff at District and Upazila level.

In addition to this training, continuous training shall be provided to this group to keep them abreast with the current knowledge and techniques in carrying out inspections and to cover any new staff joining the inspectorate team by victual of their position in the health sector at that level

### 3.7. Conducting Inspections

Inspectors shall conduct the inspection systematically using preliminary drug outlets inspection Form (DGDA form- Template No….) as a checklist for new applications to become AMS/Pharmacy facilities. They will also use AMS/Pharmacy routine inspection (DGDA form – Template No--) as checklist for already accredited and operating AMS/Pharmacy and record their findings and observations accordingly. At least two inspectors, one being the lead inspector shall constitute the inspection team however the current law allows inspectors to carry out inspection even when he/she is alone. Although this can be possible for central inspectors at local level we would encourage inspectors to carry out inspections at minimum in a pair. This improves transparence, accountability and security for the individual.

### 3.8. What is Expected of a Drug Inspector?

During facility inspection, Inspectors shall remember the following—

* Contact the person in-charge of the establishment by approaching him or her in a dignified, authoritative, and cordial manner. Avoid being arrogant.
* Present credentials (e.g., your identity card) and explain the purpose of your visit.
* Use diplomacy, tactics, and persuasiveness to acquire the necessary information and all necessary inspection details. Use the standard operating procedures (SOPs)/Inspection checklist to achieve this.
* In case of refusal to undergo inspection, explain that refusing is a criminal offense and courteously discuss the matter with the owner or responsible person on the premises.
* Upon completion of inspection, meet with the owner or person in charge to discuss the findings. Adopt a courteous attitude in calling attention to the practices or conditions observed at the time of inspection; make suggestions for minor corrections to be made as you perform the inspection.
* If any samples have been taken for testing, furnish a receipt for these samples to the person from whom samples are taken.

*Special Instructions*

The following forms, as part of this guide, shall be used to provide special instructions

1. Inspection checklists

2. Observation forms

3. Sample collection forms

4. Confiscation/quarantine forms

#### *Sample Collection and Testing*

The inspection may include the collection of samples for verification of quality parameter as deemed necessary by the inspectors. Normally, the sample size should be sufficient to carry out the test for investigated parameter(s). The quantities of medicines samples to be collected will follow the guide from the National Control Lab (NCL) as indicated below



# Section 4: Inspection of Drug Outlets for the Establishment of Accredited Medicine Shops or Model Pharmacy

In the process of establishing AMS and Model Pharmacies in Bangladesh, inspectors will be required to carry out at least two inspections before the insurance of approval and accreditation in case of AMS or Model Pharmacy. Underneath the two types of inspections are described.

### 4.1: Preliminary Inspection

Preliminary inspection is usually carried out as a reaction of the Authority to an application submitted by an owner intending to operate a Medicine Shop or Model Pharmacy business.

The inspection’s main objectives are:

1. Assess the status of premise and its location to see if it meets basic requirements as premises for either Model Pharmacy or Medicine Shop;
2. To advice the applicant if necessary to make some compliance changes to the premise so that it can meet the premises standards as spelt out in the Model Pharmacy or Medicine Shop operation standards and regulations;
3. To access the availability and qualifications of premises superintendent or in-charge as a standard requirement for operation of such business;
4. It is the opportunity to discuss and to inform the applicant the objective of the project, his/her participation and about the whole accreditation or licensing process;

It is therefore important that before going for the preliminary inspection, the inspector should acquaint her/him –self well with the developed standard to be met by a newly applicant before he/she is licensed to operate a Model Pharmacy or Medicine Shop.

#### 4.1.1: Procedures to carry out preliminary inspection for a new applicant intending to operate a Model Pharmacy or Medicine Shop

**4.1.1.1: Preparation Phase;**

The inspector should read and thoroughly understand the operational standards and regulations for Model Pharmacy or Medicine Shop and do the following;

1. Identify all applicants in the area planned for the preliminary inspection and develop a tentative schedule to estimate the time the inspection would take to cover all the premises to be inspected;
2. A least a week or two in advance, communicate with the applicant(s) the intention to visit the areas to carry out preliminary inspection as a reaction to his/her application to the authority. If possible share the schedule prepared above with applicants at the same time;
3. Communicate with any local health authority that you wish would be advantageous to participate in the process to build local skills and ownership. If there are local inspectors in the area, take this opportunity to work with them so that they are trained on the job and become acquainted with the inspection procedures;
4. Inform the applicant(s) about the necessary documents required to be present with him/her during the preliminary inspection visit and explain to the applicant(s) the main objective of the inspection;
5. Take with you sufficient copies of inspection checklists for model pharmacy and Medicine Shop if the inspection involves both types of premises;

**4.1.1.2: While at the Site**

Preliminary inspection is not a compliance inspection, but it is attempting to assess the status of the applicant’s ability to comply with the set operational standards before his/her approval to operate the desired business. Preliminary inspection is therefore an advisory inspection whereby the inspector is trying to help the applicant on how he or she can improve the premises to meet basic standards’ requirements before he/she is licensed to operate the business. This inspection should therefore create a friendly and convincing atmosphere for the applicant that the changes being advised to are meant for improved quality of service and safety to the patients. It is advisable to have a minimum of two inspectors do the preliminary inspection whenever it is possible.

 On arrival to the site, the inspector(s) should therefore do the following:

1. Where possible invite the Upazila/City Corporation drug committee members for them to understand the program so as to get more program local support but also this would be an opportunity for the committee members to learn the inspection process and standards’ requirements. Also in addition to the local committee members some of the District Drug Committee members may be invited to participate in this inspection.
2. Introduce yourself (if alone) and the rest of the team with you and show your official identification to the applicant;
3. Shortly explain the purpose of the visit and estimate the time the inspection would take;
4. Using a carbonated copy of a combined checklist for preliminary and final inspection ( see below) for the type of premise in question, start filling the checklist step by step as the checklist flows;
5. When you find any non compliance to a required standard, you should explain to the applicant what he/she should do to meet required standard. Always remember the purpose of this type of inspection, is to help the applicant meet the standards;
6. When the checklist is fully filled and fully explained to the applicant both the inspector and the applicant should sign the inspection checklist and hand over one copy to the applicant as a reference to be used to address the necessary changes that he/she should make before being approved for licensing;
7. Explain to the applicant on the tentative timeline suggested to carry out the compliance and indicate in the checklist copy when you are planning to visit the premise for final inspection. You should carefully listen to the opinion of the applicant especially on when he/she feels would be able to implement the in-compliances you have pointed out;
8. Emphasize that the authority will always be available to support in case the applicant comes to any problem that needs the authority guidance;
9. Provide a means of direct communication between the applicant and the authority and indicate the name of a contact person within the authority or at local level;

### 4.2: Follow Up and Final Inspection

After the preliminary inspection, applicants should be given sufficient time to address the issues pointed out during the preliminary inspection. They should be encouraged by ensuring them that even if they do not complete addressing the issues raised during the first follow up inspection they can still take their time to finalize them and they will be inspected in the consecutive follow up/final inspection. Their chances to get approval will still be there even after finishing addressing the issues late.

Between the preliminary and final inspection, there need to be follow up inspections whereby the inspector evaluates the status of implementation for recommendations made during preliminary inspection. At the end of the agreed period, a final inspection will be carried out. During the final inspection, inspectors will look for the issues that were not complying with the requirements during the preliminary inspection and the applicant was told to address them, to see if the applicant has complied.

Follow up inspections may be carried out by inspectors depending on availability of time and resources. Follow up inspections can be carried out to those who have made significant progress on their premises or those who need advice. Inspectors are also advised to collaborate with local inspectors when conducting follow up inspections. A final inspection checklist should be used in this inspection visit.

#### 4.2.1 Preparation for Final Inspection

As was for the case of preliminary inspection, while preparing for the final inspection the responsible inspector (s) should do the following:

1. Make a list of all applicants that were preliminarily inspected and indicate for each the anticipated completion time of meeting all operational standards requirements assigned to them during the preliminary inspection;
2. At least two weeks before the anticipated final inspection date, notify all of them on the intention to carry out final inspection and the planned date for the inspection;
3. Inform participating local committee members that had previously participated in the preliminary inspection and invite them to take part during the final inspection. This forms another opportunity for training them on the job;
4. Make a list of all necessary tools that you need to take along with you including sufficient carbonated copies of checklist for final inspection and the previous preliminary inspection checklist copies for each preliminarily inspected premise. Take other extra copies for preliminary inspection in case some new applicants would like to join the project and would like to be inspected;
5. Plan the logistic including transport and related logistics issues. Send the final inspection schedule to all applicants targeted for final inspection. If the schedule cannot be sent, then a least make an effort to communicate with each of them so that they are well ahead informed about the coming inspection. Remember that these inspections are costly and it will be cost efficient if you meet the majority of them ready and waiting for you.

#### 4.2.2 Carrying out Final Inspection

This is a compliance inspection; the applicant is required to have made all the necessary changes that were identified during the preliminary inspection in order to comply with the operational requirements before being approved for accreditation as Medicine Shop or Model Pharmacy or licensed model pharmacy.

Use the combined Preliminary and final inspection checklist which was previously used during the preliminary inspection to confirm compliance to operation standards for Model Pharmacy or Medicine Shop.

1. Using the copy of the checklist previously used during the preliminary inspection, follow the sequence of standard requirements listed in the checklist and indicate its compliance by either ticking YES or NO and make any relevant comments related to what you have observed.
2. Provide sufficient explanation to the applicant where necessary especially when non-compliance is still noted.
3. When you have gone through the whole checklist summarize your observation and give feedback to the applicant about the status of his/her premise and the prospects of being accredited or licensed;
4. Provide clear explanation on the next steps before accreditation or license is given and the issues/requirements that the applicant must fulfill towards that;
5. Leave with the applicant a copy of the final inspection checklist fully signed by both the inspector and the applicant, and provide an indication when could be the expected date for the accreditation or licensing if the applicant has met all requirements;

Provide any additional useful information about the next steps so that applicants are aware about the program/project development and the coming steps

#### COMBINED PRELIMINARY AND FINAL INSPECTION CHECKLIST FOR PHARMACY PREMISES

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| DIRECTORATE GENERAL OF DRUG ADMINISTRATIONP.O Box ----------------------Tel. -----------------**Mohakhali, Dhaka**COMBINED PRELIMINARY AND FINAL INSPECTION CHECKLIST FOR PHARMACY PREMISES |
| **GENERAL INFORMATION** |
| Name of proposed/existing premise: --------------------------------------------Location and physical address: -----------------------------------------------Contact address and phone number: ----------------------------------------Name of proposed/current premise pharmaceutical personnel in-charge and qualification: --------------------------------------------------------------------------------------------------------------Name of owner/Representative: -------------------------------------------------------------------- |
| **REQUIRED STANDARDS** | Compliance status | Remarks/steps to be taken |
| YES | NO |
| 1. **Licensing Requirements**
 |
| 1.1 Does the drug outlet have a DGDA registration and displayed?  |  |  |  |
| 1.2 Does the drug outlet have a business license? |  |  |  |
| 1.3 Does the Pharmacy have a current renewal license issued by DGDA? |  |  |  |
| 1.4 Is the drug outlet pharmacist in-charge’s PCB registration certificate available? |  |  |  |
| 1.5. Is the dispensing staff maintaining the dressing code? |  |  |  |
| 1.6. Does the drug outlet has a DGDA registration and displayed?  |  |  |  |
| **2. Standards for Personnel** |
| **2.1 Owner (**check to ensure the owner possess the following) |  |  |  |
| 2.1.1 Bangladesh National ID. |  |  |  |
| 2.1.2 Tax Identification Number (TIN). |  |  |  |
| 2.1.3 Trade License\*  |  |  |  |
| 2.1.4 Pharmacy owner training certificate\* |  |  |  |
| **2.2 Technical personnel responsible for medicines dispensing (**The Pharmacy business must be under the direct supervision of A grade Pharmacist with a valid PCB registered. Other pharmaceutical personnel to work in the Pharmacy must also be registered by PCB. Please observe to ensure the following; |
| 2.2.1 - Registered Pharmacist available |  |  |  |
| 2.2.2 Other pharmaceutical personnel are registered by PCB  |  |  |  |
| **3. Standards for Premises** |
| 3.1. Is it a permanent structure that is not at risk from floods? |  |  |  |
| 3.2. Are the roof and ceiling free from leakage?  |  |  |  |
| 3.3. Does the premise provide adequate seating for customers waiting for service?  |  |  |  |
| 3.4 Do surfaces/floors/walls have smooth finish that can be washed with disinfectants? |  |  |  |
| 3.5 Is the premise environment (inside and outside) clean?  |  |  |  |
| 3.6 Does it have a minimum surface area with dimensions of at least300 sq. ft. and a height of 8 ft? |  |  |  |
| 3.7 Is there a sink with running water dedicated to support hand hygiene practices? (the sink should not be used for disposal of mop water and other liquid wastes) |  |  |  |
| 3.8. Is there a source of power such as electricity, generator and or solar panels? |  |  |  |
| 3.9. Is there adequate air conditioner(s) with a power back-up source? |  |  |  |
| 3.10. Is there a thermometer to monitor room temperature? |  |  |  |
| 3.11 Is there a clean toilet facility within the premise or a nearby public toilet facility?  |  |  |  |
| **4. Refrigerator** |
| 4.1 Is there at least one pharmacy grade refrigerator to store temperature-sensitive medicines?  |  |  |  |
| **5. Security** |
| 5.1 Are external walls made of solid materials to ensure that they cannot be easily broken in? |  |  |  |
| 5.2 Is the ceiling well secured to prevent theft?  |  |  |  |
| 5.3. Do the external doors have solid cores or other security means in addition to lockable doors?  |  |  |  |
| 5.4. Is the Pharmacy protected by a back-to-base electronic alarm system or CCTV security cameras? |  |  |  |
| **6. Professional Services Area** |
| 6.1 Is there a clearly demarcated professional service area restricted to the provision of medicines and related services?  |  |  |  |
| 6.2 Is the professional service area distinguishable from other areas of the pharmacy?  |  |  |  |
| 6.3 Does the professional service area contain the following sub sections? |  |  |  |
| 1. Dispensing area
 |  |  |  |
| 1. Counseling area
 |  |  |  |
| 1. Prescription drop off and collection points
 |  |  |  |
| 1. Over-the-counter medicine storage areas
 |  |  |  |
| 1. Prescription medicine storage areas
 |  |  |  |
| 6.4. Does the dispensary have a dispensing counter with a clean and smooth surface?  |  |  |  |
| 6.5. Are medicines stored alphabetically or pharmacologically and in a tidy, orderly fashion?  |  |  |  |
| 6.6. Are medicines stored away from easy access by patients/customers? |  |  |  |
| 6.7. Are internal preparations separated from external preparations?  |  |  |  |
| 6.8. Are solid dosage forms separated from liquid dosage forms? |  |  |  |
| **7: Required Dispensing Tools** |
| 7.1. Are counting trays available? |  |  |  |
| 7.2. Are spatula available?  |  |  |  |
| 7.3. Are measuring devices available? |  |  |  |
| 7.4. Are Mortar and pestle available? |  |  |  |
| 7.5 Is a weighing scale for body weight measurement available? |  |  |  |
| **8: Store Room for Storage of Medicines** |
| 8.1 Is there a separate store room within the premise for storage of extra stock of medicines? |  |  |  |
| 8.2 Are there shelves or pellets with store room?  |  |  |  |
| **9: Storage of Products Other than Medicines** |
| 9.1. Is there a separate storage space for other supplies such as medical supplies and devices, nutritional products, cosmetics? |  |  |  |
|  |
| Inspectors names: 1. --------------------------------------------------signature: --------------------------------------- Date: --------------------------- 2.-------------------------------------------------- Signature: --------------------------------------- Date: -------------Applicant’s (owner’s) name: ---------------------------------------------------- Signature: ----------------------------------- Date: -------------------------- |

#### COMBINED PRELIMINARY AND FINAL INSPECTION CHECKLIST FOR ACCREDITED MEDICINE SHOPS PREMISES

|  |
| --- |
| **DIRECTORATE GENERAL OF DRUG ADMINISTRATION****P.O Box ---------------------- Tel. -----------------****Mohakhali, Dhaka****PRELIMINARY & FINAL INSPECTIONST CHECKLIST FOR AMS PREMISES** |
| **GENERAL INFORMATION** |
| Name of the Proposed / Existing Premise: --------------------------------------------Location and Physical Address: -----------------------------------------------Contact Address and Phone Number: ----------------------------------------Name of Expected/Current Premise In-charge and Qualification: -----------------------------Applicant/Owner’s Name: --------------------------------------------------------------------Date: ----------------------------------------------------------------------------------------- |
| Required standards | Compliance status | Steps to be taken//taken |
|  |
| YES | NO |
| 1. **Licensing requirements**  |
| 1.1 Does the outlet have a DGDA registration?  |  |  |  |
| 1.2 Does the outlet have a business license? |  |  |  |
| **2. Required Operational Standard for Personnel** |
| 2.1. Owner – A citizen of Bangladesh2.1. 1 Owner has TIN for Bangladesh  |  |  |  |
| **2.2 Technical Personnel** 2.2.1 Supervision of AMS – Is a Pharmaceutical personnel with minimum current and live C grade registration under the PCB available?2.2.2 Has he/she Undergone a PCB approved dispensing training course? |  |  |  |
| 3**. Operation Standards on Premise** |
| 3.1 A permanent structure that is not at risk from floods or other hazards. |  |  |  |
| 3.2 Has a roof and ceiling free from leakage.  |  |  |  |
| 3.3 Is well protected from entry of rodents, birds, vermin and pests; |  |  |  |
| 3.4 Walls cleanly painted with washable paint or as otherwise directed by the authority; |  |  |  |
| 3.5 Has surfaces/floors/walls with smooth finish that can be washed with disinfectants. |  |  |  |
| 3.6 Has seating space for at least one customer;  |  |  |  |
| 3.7 Is well ventilated with an electric exhaust fan or windows, fans or air-condition; |  |  |  |
| 3.8 Has adequate toilet facility or available clean public toilet facility within easy reach from the premise ; |  |  |  |
| 3.9 Has a total surface area of at least 120 square feet. (a minimum floor length and width of 10x12 feet, a minimum ceiling height of 8 feet) |  |  |  |
| 3.10 Has a separate storage facility/store for medicines and medical supplies; |  |  |  |
| 3.11 Has a source of potable water.  |  |  |  |
| 3.12Have a source of power such as electricity, generator and or solar panels |  |  |  |
| 3.13 Premise not shared with or established within the premise any medical/veterinary clinic or laboratory settings; |  |  |  |
| 3.14 Has a thermometer to monitor room temperature |  |  |  |
| 4. Refrigerator |
| 4.1 Is a pharmacy Refrigerator available? |  |  |  |
| 5. Required Dispensing Tools |
| 5.1 Counting tray |  |  |  |
| 5.2 Spatula |  |  |  |
| 5.3 Measuring device |  |  |  |
| 5.4 Mortar and pestle |  |  |  |
| 5.5 Weighing scale for body weight |  |  |  |
| **6. REFERENCE MATERIALS** |
| 6.1 Accredited Medical Shop Operation Standards |  |  |  |
| 6.2 Accredited Medicine Shops Training Manual |  |  |  |
| 6.3 Republic of Bangladesh Pharmacy Acts, Rules, Regulations and ordinances; |  |  |  |
| 6.4 Bangladesh National Formulary  |  |  |  |
| 6. 5 List of allowable prescription medicines; |  |  |  |
| Names: 1. --------------------------------------------------signature: --------------------------------------- Date: --------------------------- 2.-------------------------------------------------- Signature: --------------------------------------- Date: -----------------------------Applicant’s/Owner’s Name: ------------------------------------ Signature: ----------------------- Date: --------------- |

# Section 5: Routine Inspections – Compliance Monitoring

There is a substantial difference between inspection carried out for premise to be established (preliminary inspection) and the routine inspection. While preliminary and final inspection’s objective is to see if the applicant has met all the premise standards and basic legal requirements before being approved to establish the business, the routine inspection checks compliance to maintaining the premise and operational standards for the business. The routine inspection is therefore more comprehensive since it also wants to see how services have been provided in the past and now.

For a comprehensive compliance monitoring to be carried out routinely for AMS and Model Pharmacies special routine inspection checklists have been developed for AMS and Model Pharmacies.

An inspector after a short training should be able to use these checklists to monitor adherence to operating standards.

### 5.1 Carrying out Routine (Adherence Monitoring) Inspection

#### 5.1.1 Planning for Routine Inspection

Routine and effective inspection system is key to maintaining standards and high quality of retail pharmaceutical services in any country. However effective routine inspection system is highly demanding in terms of employed human resource, finance and logistics. It is therefore necessary that a well planned system of inspection is needed to effectively utilize available but limited resources to achieve the desired outcome. The planning process must take into account the existing technical human resources at all level and how they are going to be linked to avoid unnecessary duplications of effort and waste of resources.

During the planning phase, where possible, all levels of the established inspection system should be consulted; their roles and contribution in terms of resources should be identified and agreed upon.

Once the plan is approved, it will be advantageous to extract roles, responsibilities and resource contribution at each level within the inspection system and shared with the respective levels. Once the plan has been shared with the different levels, the levels should then integrate the plan into their local plans so that to use the limited resources rationally.

#### 5.1.2 Conducting Routine Inspection

For routine inspection to operate smoothly in a resource limited country like Bangladesh, a step wise inspection system would be advisable. Identify each step or level with its specific roles and responsibilities in the system.

### 5.2: Levels of Routine Inspection

It is suggested that the Authority, categorize three levels of inspection within the routine inspection system.

**5.2.1. Upazila Level**

It is advisable that the Authority create a new level of inspectors – in a form of Task Force in line with MOHFW Order of 1986 so that they can continuously monitor outlets’ adherence to basic standards that not necessarily need a highly qualified inspector to determine non-adherence. The local inspectorate system usually should have a limited decision making authority but should have the mandate to warn when in-compliances are noticed and when the provider does not respond accordingly, a higher level of inspectorate system is informed so that action can be taken against the provider that persistently continues to violet operational standards and existing regulations.

Local Task Force with an inspection responsibility can carry out local inspection with its members selected among basic health staff within the local health system and provided with a short training in basic inspection. To ensure the effectiveness of the local inspection system, the number of outlets to be monitored should be limited and easy to cover all outlets with minimum logistics, cost and other resources. A special local inspection checklist has been developed from the comprehensive routine inspection checklist by targeting very specific operation standards to be monitored at this level. Local inspection can be carried out quarterly.

***Which outlets should be monitored by Local Task Force Inspectors?***

Members forming local Task Force are mainly non-pharmaceutical personnel with limited education about medicines or pharmaceutical regulatory related issues. Also the aim of creating the TF at this level is to relief pressure on the central inspectorate system so that they concentrate more on areas that demand higher technical skills. The other reason is that the number of AMS is expected to be very high as compared to model pharmacies and spreading far into the remote areas. It is therefore rational to suggest that local TF should carry on monitoring inspections principally for AMS while inspectors at district/or national level spend more time to carry out routine inspections for model pharmacies, wholesalers and manufacturers.

***Incentives for Local TF-Inspectors***

It should be realized that routine inspection is basically the responsibility of the Authority at all levels and therefore should be budgeted for. However the use of local TF reduces the cost of routine inspections at lower levels and gives opportunity for experienced inspectors of the Authority to concentrate their inspections on more complex issues. As members of the local TF have other responsibilities, the time used for local inspections on behalf of the Authority should be acknowledged and where possible small financial budgets should be planned to cover inspection activities at this local level. Members of the TF should therefore be given a small inspection allowance every quarter after they have submitted their quarterly reports to the district. Experience from other countries has shown that where the financial incentive has been removed the local inspectors have no motivation to carry out inspections as scheduled effectively there is also a danger of them soliciting or demanding bribe to compensate their labour. .

***Local Inspection Checklist for AMS and Reporting***

To support local TF -inspectors, the Authority should develop a very short local inspection checklist that would cover few vital elements of standards and requirements that the Authority would like to be continuously monitored and reported at local level.

Parallel to the local inspection list, a local reporting format should also be developed that would provide uniform reporting from all local inspections carried out by local inspectors. Below is an example of a local inspection checklist that could be developed for this level. A reporting form template is included under reporting section.

**ROUTINE INSPECTION CHECKLISDT FOR ACCREDITED MEDICINE SHOPS PREMISES**

|  |
| --- |
| DIRECTORATE GENERAL OF DRUG ADMINISTRATIONP.O Box ----------------------Tel. -----------------**Mohakhali, Dhaka** **LOCAL MONITORING/INSPECTION CHECKLIST** **(ROUTINE INSPECTION)**(Two copies should be filled; one copy should remain in the premise and the other copy should be kept by the local TF-inspectors/monitors) |
| GENERAL INFORMATION |
| Name of Medicine Shop:  | Date: |
| Address | Phone Number |
| District  | Upazila  | Union |
| **1. LICENSING REQUIREMENTS** | Yes | No |
|  | Does the AMS have a DGDA registration (observe if it is displayed)  |  |  |
|  | Does the AMS have a business license (observe if and it is displayed) |  |  |
|  | Does the AMS have a current operation permit issued by DGDA (observe if it is displayed) |  |  |
|  | Does the AMS have an accreditation certificate (observe if it is displayed) |  |  |
|  | Is the PCB registration certificate of the AMS in-charge displayed? |  |  |
|  | Are the dispensing staff maintaining the dressing code? |  |  |
| 2. CONDITION OF THE PREMISES  | YES | NO |
|  | Is the floor clean?  |  |  |
|  | Are the walls inside clean and well painted? |  |  |
|  | Are the shelves clean and free from dust? |  |  |
|  | Is the ventilation sufficient?  |  |  |
|  | Is the light sufficient? |  |  |
|  | Is the roof ceiling in good condition? |  |  |
|  | Is there a hand washing facility with water in the premise? |  |  |
|  | Is the cleanliness of the surroundings of the premise adequate? |  |  |
|  | Is the premise temperature maintained below 30 degrees Celsius ? |  |  |
| 3. RECORD KEEPING |  |  |
|  | Are dispensed medicines recorded? |  |  |
|  | Are purchase invoices for all medicines bought well filed?  |  |  |
| 4. STORAGE OF MEDICINES |  |  |
|  | Are medicines properly stored? |  |  |
|  | Are all medicine shelves clean and tidy?  |  |  |
|  | Is the store clean and tidy? |  |  |
|  | Are expired medicines recorded and separately stored and marked “expired not for use”? |  |  |
| 5. RECOMMENDATIONS /ADVICE GIVEN TO S\DISPENSERS: |
|  |
| Local monitors/Inspectors: Name and signature1………………………. ….……….2…………………… …………... | Accredited Medicine Store personnel: Name and signature 1……………………………….. ………………………2……………………………….. ……………………… |

**5.2.2. District Level**

Current establishment is that the DGDA has one inspector/superintendent at the district level. His/her overall responsibility is to carry out inspection in the whole district. One inspector is not able to effectively carry out routine inspections at a frequency of every quarter or even twice a year covering the huge number of dug outlets. This explains why it is said that there are many outlets operating without DGDA license or not inspected for a long time.

It is suggested that the number of inspectors in the district to be increased. There are two possible ways to achieve that; either the DGDA directly employs new inspectors to support the superintendent or establish a District Drug Committee and draw some of its members to take some inspectorate role to boost the inspectorate system in the district. The DGDA can take the second option which is less costly and because it can use the District Task Force established by the MOHFW order which has not been implemented yet at that level. According to the order the Task Force has one of its responsibilities of inspection. The DGDA can provide a short inspection training course for the Task Force members.

*The Role of District Drug Committee*

The suggestion to establish the District Drug Committee goes back to the MOHFW Order of 1986. It is suggested that the naming and the composition of the committee members can be modified a bit to have a much more comprehensive committee with wider responsibilities including inspection and adherence monitoring. The District drug committee role and responsibilities and composition of members is discussed in the inspection strategy and monitoring document.

*The Role of the District TF-Inspectors*

The district TF-inspectorate team can be made from some of the members of the District Health Committee and health staff at district level and have two major responsibilities in terms of inspection. To support the local inspectorate system and to carry out at least two major routine inspections that cover the whole district. But since one expects more model pharmacies to be established in major cities, towns and busy commercial centres, the district TF-inspectors should concentrate on carrying routine inspections on the model pharmacies while at local level where most of the outlets will be AMS, the local TF-inspectors will do that. Also being part of the District Drug Committee (DDC) members they will review inspection reports from the local level and make some follow up if that would be necessary to take the necessary action. District TF-inspectorate team should make at least two routine inspections to cover all model pharmacies in their district and two to cover a substantial number or all drug outlets AMS in their district.

**5.2.3. The National Level**

The national level inspectors include the superintendents appointed by the DGDA at district level; nevertheless there are those who reside at the head office of the DGDA. These inspectors usually have a multiple of responsibilities and assignments to the extent that routine inspection is sometimes not equally implemented.

Since the importance of maintaining adherence to governing standards, requirements and regulations for the retail pharmaceutical services is equally important, it is suggested that a special unit within the inspectorate department be established and responsible for drug outlet inspections and establishment of new outlets. The unit will have the following responsibilities although not limited to only these:

1. Coordinate all inspection activities at all levels;
2. Review all inspection summaries reports submitted by the district and actions taken by the districts;
3. Acknowledge or respond to reports submitted by the district and local inspectors that need the attention of the head office;
4. Directly carry out routine inspections especially in big cities where most of the pharmacies will be situated;
5. Carry out at least one audit routine inspection in a sampled manner at district and local levels;
6. Provide continuous orientation/training of both local and district inspectors especially when new inspectors are appointed;
7. Compile quarterly reports that find their way to the management meetings for attention and action where needed by this high level;
8. Compile annual report on inspections’ outcome and the status of compliance to standing requirements by the operating drug outlets at different levels.

### Routine Inspection Checklist for Pharmacy Premises

This tool will be used by inspectors at district sand national level since they will be responsible for inspection of all pharmacies.

|  |
| --- |
| DIRECTORATE GENERAL OF DRUG ADMINISTRATIONP.O Box ----------------------Tel. -----------------**Mohakhali, Dhaka**ROUTINE INSPECTION CHECKLIST FOR PHARMACY PREMISES***(DISTRICT AND NATIONAL INSPECTORS ONLY)*** |
| **GENERAL INFORMATION** |
| Name of proposed/existing premise: --------------------------------------------Location and physical address: -----------------------------------------------Contact address and phone number: ----------------------------------------Name of pharmaceutical personnel in-charge and qualification: --------------------------------------------------------------------------------------------------------------Name of owner/Representative: -------------------------------------------------------------------- |
| **REQUIRED STANDARDS** | Compliance status | Remarks/steps to be taken |
| YES | NO |
| 1. **Licensing Requirements**
 |
| 1.1 Does the drug outlet have a DGDA registration and displayed?  |  |  |  |
| 1.2 Does the drug outlet have a business license? |  |  |  |
| 1.3 Does the Pharmacy have a current renewal license issued by DGDA? |  |  |  |
| 1.4 Is the drug outlet pharmacist in-charge’s PCB registration certificate available? |  |  |  |
| 1.5. Is the dispensing staff maintaining the dressing code? |  |  |  |
| 1.6. Does the drug outlet has a DGDA registration and displayed?  |  |  |  |
| **2. Standards for Personnel** |
| **2.2 Technical personnel responsible for medicines dispensing (**The Pharmacy business must be under the direct supervision of A grade Pharmacist with a valid PCB registration. Other pharmaceutical personnel to work in the Pharmacy must also be registered by PCB. Please observe to ensure the following; |
| 2.2.1 - Registered Pharmacist available |  |  |  |
| 2.2.2 Other pharmaceutical personnel are registered by PCB  |  |  |  |
| **3. Standards for Premises** |
| 3.1. Is it a permanent structure that is not at risk from floods? |  |  |  |
| 3.2. Are the roof and ceiling free from leakage?  |  |  |  |
| 3.3. Does the premise provide adequate seating for customers waiting for service?  |  |  |  |
| 3.4 Do surfaces/floors/walls have smooth finish that can be washed with disinfectants? |  |  |  |
| 3.5 Is the premise environment (inside and outside) clean?  |  |  |  |
| 3.6 Does it have a minimum surface area with dimensions of at least300 sq. ft. and a height of 8 ft? |  |  |  |
| 3.7 Is there a sink with running water dedicated to support hand hygiene practices? (the sink should not be used for disposal of mop water and other liquid wastes) |  |  |  |
| 3.8. Is there a source of power such as electricity, generator and or solar panels? |  |  |  |
| 3.9. Is there adequate air conditioner(s) with a power back-up source? |  |  |  |
| 3.10. Is there a thermometer to monitor room temperature? |  |  |  |
| 3.11 Is there a clean toilet facility within the premise or a nearby public toilet facility?  |  |  |  |
| **4. Refrigerator** |
| 4.1 Is there at least one pharmacy grade refrigerator to store temperature-sensitive medicines?  |  |  |  |
| **5. Security** |
| 5.1 Are external walls made of solid materials to ensure that they cannot be easily broken in? |  |  |  |
| 5.2 Is the ceiling well secured to prevent theft?  |  |  |  |
| 5.3. Do the external doors have solid cores or other security means in addition to lockable doors?  |  |  |  |
| 5.4. Is the Pharmacy protected by a back-to-base electronic alarm system or CCTV security cameras? |  |  |  |
| **6. Professional Services Area** |
| 6.1 Is there a clearly demarcated professional service area restricted to the provision of medicines and related services?  |  |  |  |
| 6.2 Is the professional service area distinguishable from other areas of the pharmacy?  |  |  |  |
| 6.3 Does the professional service area contain the following sub sections? |  |  |  |
| 1. Dispensing area
 |  |  |  |
| 1. Counseling area
 |  |  |  |
| 1. Prescription drop off and collection points
 |  |  |  |
| 1. Over-the-counter medicine storage areas
 |  |  |  |
| 1. Prescription medicine storage areas
 |  |  |  |
| 6.4. Does the dispensary have a dispensing counter with a clean and smooth surface?  |  |  |  |
| 6.5. Are medicines stored alphabetically or pharmacologically and in a tidy, orderly fashion?  |  |  |  |
| 6.6. Are medicines stored away from easy access by patients/customers? |  |  |  |
| 6.7. Are internal preparations separated from external preparations?  |  |  |  |
| 6.8. Are solid dosage forms separated from liquid dosage forms? |  |  |  |
| **7: Required Dispensing Tools** |
| 7.1. Are counting trays available? |  |  |  |
| 7.2. Are spatula available?  |  |  |  |
| 7.3. Are measuring devices available? |  |  |  |
| 7.4. Are Mortar and pestle available? |  |  |  |
| 7.5 Is a weighing scale for body weight measurement available? |  |  |  |
| 7.6 Are all the tools above used? |  |  |  |
| **8: Store Room for Storage of Medicines** |
| 8.1 Is there a separate store room within the premise for storage of extra stock of medicines? |  |  |  |
| 8.2 Are there shelves or pellets with store room?  |  |  |  |
| 8.3 Is the storage room clean and tidy? |  |  |  |
| **9: Storage of Products Other than Medicines** |
| 9.1. Is there a separate storage space for other supplies such as medical supplies and devices, nutritional products, cosmetics? |  |  |  |
|  |
| Inspectors names: 1. --------------------------------------------------signature: --------------------------------------- Date: --------------------------- 2.-------------------------------------------------- Signature: --------------------------------------- Date: -------------Owner’s name: ----------------------------------------Signature: ------------------------------- Date: ----------------------- |

#### ROUTINE INSPECTION CHECKLIST FOR ACCREDITED MEDICINE SHOPS

#### (DISTRICT AND NATIONAL INSPECTORS)

|  |
| --- |
| DIRECTORATE GENERAL OF DRUG ADMINISTRATIONP.O Box ----------------------Tel. -----------------**Mohakhali, Dhaka**ROUTINE INSPECTION CHECKLIST FOR ACCREDITED MEDICINE SHOPS***(DISTRICT AND NATIONAL INSPECTORS ONLY)***(Two copies should be filled; one copy should remain at the premise and the other copy should be kept by the inspectors) |
| **GENERAL INFORMATION** |
| Name of drug shop: | Date: |
| Address | Phone Number |
| union: | Upazila | District |
| **1. LICENSING REQUIREMENTS** | **Yes** | **No** |
|  | Does the AMS have a DGDA registration? *(see if it is displayed*)  |  |  |
|  | Does the AMS have a business license? *(see if it is displayed)* |  |  |
|  | Does the AMS have current permit issued by DGDA? *(see if it is displayed)* |  |  |
|  | *Does the AMS have an accreditation certificate? (see if it is displayed)* |  |  |
|  | Is the AMS in-charge’s PCB registration certificate displayed? |  |  |
|  | Is the dispensing staff maintaining the dressing code? |  |  |
| **2. SINAGE** |
|  | An officially approved accreditation logo (brand). |  |  |
|  | Name of the accredited medicine store conspicuously displayed on the wall or shop boards. |  |  |
|  |  A “NO SMOKING” sign conspicuously placed to prohibit smoking in the drug shop. |  |  |
|  | A sign indicating operating hours. |  |  |
| **3. CONDITION OF THE PREMISES**  | **YES** | **NO** |
|  | Is the floor clean?  |  |  |
|  | Are the walls inside clean and well painted? |  |  |
|  | Is there dust on the shelves? |  |  |
|  | Is the ventilation sufficient?  |  |  |
|  | Is the light sufficient? |  |  |
|  | Is the ceiling in good condition? |  |  |
|  | Is there a hand washing facility with water in the premise? |  |  |
|  | Is the cleanliness of the surroundings of the premise adequate? |  |  |
|  | Is the toilet clean and in good working condition? |  |  |
|  | Is the premise temperature maintained below 30 degrees Celsius? |  |  |
|  | Has a source of potable water  |  |  |
|  | Has a source of power such as electricity, generator and or solar panels |  |  |
|  | Premise not shared with or established within the premise any medical/veterinary clinic or laboratory settings; |  |  |
|  | Has a thermometer to monitor room temperature |  |  |
| **4. REQUIRED DISPENSING TOOLS** |
|  | Counting tray |  |  |
|  | Spatula |  |  |
|  | Measuring device |  |  |
|  | Mortar and pestle |  |  |
|  | Weighing scale for body weight |  |  |
| **5. RECORD KEEPING** |  |  |
|  | Are dispensed medicines recorded? |  |  |
|  | Are purchase invoices for all medicines bought well filed?  |  |  |
| **6. STORAGE OF MEDICINES** |  |  |
|  | Are medicines properly stored? |  |  |
|  | Are all medicine shelves clean and tidy?  |  |  |
|  | Is the store clean and tidy? |  |  |
|  | Are expired medicines recorded and separately stored and marked “expired not for use”? |  |  |
| **7. SERVICES OFFERED** |
|  | Are prescription medicines dispensed on prescription only?  |  |  |
|  | Are clients properly advised on use of medicines dispensed to them? |  |  |
|  | Is the list of approved prescription medicines displayed? |  |  |
|  | Are medicines sold at the fixed price? |  |  |
|  | Are there any clinical or laboratory services being offered within the premise? |  |  |
| **8. REFERENCES** |
|  | Accredited Medical Shops Operation Standards |  |  |
|  | Accredited Medicine Shops –Dispensers Training Manual |  |  |
|  | Republic of Bangladesh Pharmacy Acts, Rules, Regulations and ordinances; |  |  |
|  | Bangladesh National Formulary |  |  |
|  |  List of AMS Allowable Prescription Medicines; |  |  |
| **4. Recommendations /advice given to dispenser/Owner:** |
| Inspectors’ Signature1………………………. ….……….2…………………… …………... | Accredited Medicine Store personnel: Signature 1……………… ………………….2……………… …………………. |

# Section 6: Inspection Reporting

Inspection reports shall be written immediately after completing inspection. The compiled report shall be submitted to the respective level as described above within 7 calendar days upon completion of inspection. Where Regulatory action(s) are taken as stipulated in the Law, it shall be in the form of a letter from the authority at the respective level.

Inspection report shall be written using special inspection report form that is part of this guide. Sufficient details shall be provided to allow for an independent assessment, comprehension and easy decision making.

Observations made on what is considered to be non-compliance with existing operation standards and regulations or Laws for AMS/Pharmacies shall be listed in the report, and a clear distinction shall be made between “compliances” and “non-compliances”.

The reports document outcome of each inspection and they form reference sources for inspectors going to carry out inspections as a follow-up or as next routine inspection. Inspectors before travelling to respective areas for any type of inspection should acquaint themselves with reports from the most recent inspections done in the area. Whenever possible while higher level inspectors are visiting lower areas, local inspectors in that area should be involved. Where local inspectors constitute part of the problems experienced with the outlets, no pre-information may be provided to the local inspectors.

### 6.1. Preliminary Inspection Report

Once the preliminary inspection is done, it is important to have a documented report summary of all the findings including the challenges met during the inspection process. The report should also provide recommendations to address the challenges observed during the inspection.

***What to do with the Preliminary Inspection Report?***

Preliminary inspection is the initial stage in the process of accreditation or approving a pharmacy or drug shop to operate. The generated report therefore forms a reference for the inspectorate team and provides vital information on the status of compliance of the applying premise and what directives or advices have been given to the applicant to become compliant and the time frame agreed upon. If this inspection is documented in a form of a report, any appointed inspector can carry out the follow-up (Final Inspection) without any problem. On completion of writing the preliminary inspection report the inspector may do the following:

1. Open a new file for all the premises you have inspected in one area which this report is part of. If you had inspected both AMS and pharmacy premises make two separate files for each category;
2. Make a list of all premises in that area you have inspected with details such as applicant name , contact address, phone number of the applicant and location and file it together with the report;
3. Also make sure that all preliminary inspection checklists used during the inspection for each premise inspected are filed with the summary report;
4. Since you left a copy of the preliminary inspection checklist with the applicant with all the details on what to do, you need not share this summary report with the applicants;
5. Unless there are serious issues other than in-compliances that the applicant has agreed to address, this report need not be shared at higher level or at the DDC because there is no decision that will be taken at this stage yet. However it should be available if the committee would like to have it during their applications review meetings;
6. The file should be available to any other inspector who will be assigned to carry out final (Follow-up) inspection in the respective area(s).
7. For having a uniform reporting format, use the combined preliminary and final inspection report form (template provided). Remember that pharmacies and AMS have different formats for reporting.

### 6.2 Final Inspection Report Form

The final inspection report is the one that is submitted to the district drug committee for discussion and finally given recommendation to the national level for accreditation of applicants who have met requirements. The report should be well written so that any recommendations made to the national level the basis are well documented.

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| --- |
| **DIRECTORATE GENERAL OF DRUG ADMINISTRATION****P.O Box ---------------------- Tel. -----------------****Mohakhali, Dhaka****FINAL INSPECTION REPORT FORM FOR AMS/PHARMACY** |
| **GENERAL INFORMATION** |
| Name of Proposed Premise: --------------------------------------------Location and Physical Address: -----------------------------------------------Contact Address and Phone Number: ----------------------------------------Name of Proposed Premise In charge and Qualification: --------------------------------------Owner’s Name: --------------------------------------------------------------------Date: ---------------------------------------------------------------------------- |
| S/N | Name of Applicant/Owner | Name of Medical Store/Pharmacy | Location and Physical Address of Premises | Contact Address/Phone Number | Name of Proposed AMS/Pharmacy Supervisor and Qualification |  Status of Compliance | Inspector’s Comments and recommendation *(indicate in-compliance observed)* | Committee Decision or Action Taken |
|  |  |  |  |  |  | Complied | Not Complied |  |  |
| 1 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |
| n |  |  |  |  |  |  |  |  |  |
| Reporting Inspector(s): Name: 1 ------------------------------------------------------------Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 2. ------------------------------------------------------- Signature: ------------------------------------------------Owner/Representative Name: ------------------------------------------------------------ Signature: -------------------------------------------- |

### 6.3 Routine (Compliance Monitoring) Inspection Report

As previously mention in this guide, routine inspection main objective is to monitor compliance to the standards, rules and regulations by registered premises. Documenting the inspection carried out at all levels after the inspection is important because it forms the basis for the next inspection and also the Authority can measure the level of compliance country wide. As compliance inspection will be done at the three levels, two formats are suggested for local routine inspections and one for the district and national level.

As reports will be generated at different levels, a description on how the reports will be handled at each level is given below:

#### 6.3.1. Routine Inspection Reporting at Upazila and City Corporation Level

The monitoring inspection carried out at local level main objective is to observe that compliance is maintained and if it is noticed that serious violations are being committed, local inspectors with limited mandate would immediately report to higher level (district) for necessary action. Local inspection can be said to be whistle blower especially where there are serious violations being committed. Once the inspection has been done a report should be written using the suggested format below and then do the following with the report:

1. A special file should be created at the local level; one for keeping the inspection checklists used and filled during inspection and a second file for keeping all remaining copies of inspection reports;
2. At least two copies of inspection reports should be made; one is filed at the local level and the second one submitted to the district;
3. At each planned next inspection, the inspectors should review the report of the previous inspection before going for the next inspection. They should also review the previous copies of checklists for the previous inspection for each outlets that is planned to be inspected in the planned inspection;
4. Local Inspectors should note down all the in-compliances observed during the previous inspection for each outlet. This list is your follow-up list to see if the outlet has taken any steps to comply with the requirement(s).

**UPAZILA CITY CORPORATE INSPECTION REPORTING FORM**

**(ONLY FOR AMS)**

|  |
| --- |
| DIRECTORATE GENERAL OF DRUG ADMINISTRATIONP.O Box ----------------------Tel. ----------------- **Mohakhali, Dhaka****LOCAL MONITORING/INSPECTION REPORT FORM**(Two copies should be filled; one copy should remain at local level and the other copy should be submitted to the District Superintendent) |
| **GENERAL INFORMATION** |
| Name of the covered area  | District: |
| Address | Contact Phone Number: |

|  |  |  |
| --- | --- | --- |
| Reporting Period: | # of AMS | Comments |
| **INSPECTION OUTCOME** |
|  | Total number of AMs in this area |  | Indicate if there are any that have closed. |
|  | Number of AMS inspected during the this period |  |  |
|  | Number of AMS not inspected during this period |  | Give reasons why they were not inspected. |
|  | Number of AMS found in full compliance of all the elements in the inspection checklist |  |  |
|  | Number of AMS found with 1-5 in-compliances during inspection: (*List down the common in-compliances for this group)*1.--------------------------------------------------2.-------------------------------------------------3. ------------------------------------------------4.-------------------------------------------------5.------------------------------------------------- |
|  | The number of AMS found with more than 5 in-compliances |  |  |
|  | General action taken for AMS that were found not complying with requirements (*List down)*1. -----------------------------------------------

2.-------------------------------------------------3.------------------------------------------------ |
|  | Number of AMS found with the following serious in-compliances that have been suspended to provide services: (*Indicate the in-compliance by ticking it.)*1. Operating without registration
2. Operating without operation license issued by DGDA
3. Storage and sale of prescription medicines out of the allowable list
4. Operating without a qualified AMS In-Charge
5. -----------------
 |
| **OTHER ISSUES** |
|  | Challenges faced during inspections (*List down)*1. ------------------------------------------------
2. ------------------------------------------------
3. …………………………………………………………………….
 |
| 1. 9
 | Issues for which the decision or support of the district is needed with regards to inspection (*List the issues down.)*1.-------------------------------------------------2.------------------------------------------------3.------------------------------------------------ |
|  | Planned Inspection Activities for next period from --------------- to --------------(List here) |

Reporting Inspector(S): -----------------------------------------Signature------------------------

 ……………………………………………………Signature ………………………..

Date----------------------------------------------------

#### 6.3.2. Inspection Reporting Forms at National and District Levels

**(a) District Level**

The inspectorate team under the district superintendent also makes reports for the drug outlets inspected by the team. Therefore at the district level the following should be done:

1. Open files for reports from the local level. Since such areas may be multiple, it is advisable that each areas should have its file for easy retrieval of reports when required;
2. Since the district will be required to make summaries of all the reports submitted by the local inspectors into summary report to share with the DGDA head office and the DDC a separate file should be created to contain all quarterly summary reports from the local level;
3. Submit quarterly summary report on inspections carried out at local and district level to the DDC and at the DGDA head office;
4. Always acknowledge, even by phone to the head of the local inspectorate team that the district has received their report. Lack of acknowledgement discourages the lower level to continue doing the inspections and sending the reports that are not commented upon or even acknowledged;
5. Identify all issues raised by the local inspectors and for those falling under the district mandate actions should be taken immediately. Respond to the issues that local level has forwarded to the district for action and inform the actions taken. For issues that would need the mandate of the head office, forward them and follow-up for action;
6. Submit all inspection report summaries to the DDC and they should be part of the agenda during this committee’s meeting. Inform the lower levels on any directives or decisions made during the committee meeting for issues that are relevant to them or at that level.

**(b) National Level**

Like the district, the national level will receive summaries of reports from all the districts and reports generated by the head office’s own inspections carried out in each quarter. It is therefore obvious that the volume of reports received from all districts will be high and that is the essence of having a special unit at the head office to deal with all these reports and take necessary actions as shall be requested by the lower levels. In order to efficiently manage the high volume of coming reports and efficiently respond to lower levels’ expectations the following can be done:

1. An action oriented summary report format has to be developed so that the head office focuses its attention on issues that need its reaction; A sample format is suggested in this guide for summary reports from the districts to the head office;
2. It will be a priority to computerize the inspection system at the head office so that reports can be electronically submitted and stored per district and make easy retrieval;
3. For all received summary reports, the head office must immediately acknowledge receipt and once the reports have been reviewed decisions on issues raised by the reports have been identified, the head office must communicated with the respective districts without long delays. Non response is usually the killer factor of efficient inspection system at lower levels as it seriously demoralizes the inspectors at that level;
4. Where the presence of higher level inspector is needed, the head office should make effort to avail that inspector as this positive response motivates the local inspectors as they realize that they are supported by the head office in what they are doing. A response to action requested from the authority by the lower level has similar impact;
5. The unit at head office should prepare quarterly summary report that that covers all inspectorate activities at all levels and submit it to the respective director to be shared at management meetings;

**District Monitoring/Inspection Summary Report Form (1)- Accredited Medicine Shops (AMS)**

|  |
| --- |
| **DIRECTORATE GENERAL OF DRUG ADMINISTRATION****P.O Box ---------------------- Tel. -----------------****Mohakhali, Dhaka****DISTRICT MONITORING/INSPECTION SUMMARY REPORT FORM FOR (1)****Accredited Medicine Shops (AMS)** (Two copies should be filled; one copy should remain at the district level and the other copy should be submitted to the DGDA Head office) |
| **GENERAL INFORMATION** |
| Name of the District : |
| Name and designation of Reporting Inspector | Contact Phone Number: |

|  |  |  |
| --- | --- | --- |
| Reporting Period: | Number of AMS: | Comments |
| **INSPECTION ISSUES** |
| 1 | Total number of local inspectorate teams in the district |  |  |
| 2 | Number of local inspectorate teams that have submitted reports this quarter |  |  |
| 3 | Total number of AMs in the District |  | Indicate if there are any that have closed. |
| 4 | Total number of AMS inspected during the this period in the district |  |  |
| 5 | Number of AMS not inspected during this period in the district |  | Give reasons why they were not inspected. |
| 6 | Number of AMS found in full compliance of most of the elements in the inspection checklist in the district |  |  |
| 7 | Number of AMS found with 1-5 in-compliances during inspection in the District |  |  |
| 8 | Number of AMS found with more than 5 in-compliances in the District |  |  |
| 9.Common in-compliances at local level (list them) |
| 10. Serious in-compliances observed at local level (list them)  |
| 11. Common actions taken by local inspectorate teams to enforce Compliance (list them) |
| 12. Actions taken by the District to enforce compliance at local level (list them) |
| **OTHER ISSUES** |
| 13. Common challenges faced during inspections as reported by local inspectorate teams *(list them)* |
| 14. Issues addressed by the District in support to local inspectors *(List them)* |
| 15. Issues that the DGDA head office has to address *(List them)* |
| 16. Any other issues/comments |
|  |

Reporting inspector name: -----------------------------------------Signature------------------------

Date----------------------------------------------------

**District Monitoring/Inspection Summary Report Form (2)- Accredited Medicine Shops (AMS) and Pharmacies**

This report form will be generated by district or national inspectors once they carry out routine inspections. It can be remembered that district and national inspector’ inspection will cover both categories of outlets and that is why this form is combined.

|  |
| --- |
| DIRECTORATE GENERAL OF DRUG ADMINISTRATIONP.O Box ---------------------- Tel. -----------------Mohakhali, Dhaka**DISTRICT MONITORING/INSPECTION REPORT FORM (2)****Accredited Medicine Stores (AMS) and Pharmacies**(Two copies should be filled; one copy should remain at the district level and the other copy should be submitted to the DGDA Head office) |
| **GENERAL INFORMATION** |
| Name of the District : |
| Name and designation of reporting inspector | Contact Phone Number: |

|  |  |  |
| --- | --- | --- |
| Reporting Period: | Number of AMS | Comments |
| Number of Pharmacies |
| **INSPECTION ISSUES** |
| 1 | Total number of AMS in the District |  | (indicate if there any that have closed or newly opened) |
| 2 | Total number of Pharmacies in the District |  | (indicate if there any that have closed or newly opened) |
| 3 | Total number of AMS inspected during this period by the district Inspectors |  |  |
| 4 | Total number of Pharmacies inspected this period by the district |  |  |
| 5 | Number of AMS found in full compliance of all the elements in the inspection checklist by district Inspectors  |  |  |
| 6 | Number of Pharmacies found in full compliance of all the elements in the inspection checklist by district Inspectors |  |  |
| 7 | Number of AMS found with 1-5 in-compliances during inspection in the district |  |  |
| 8. | The number of AMS found with more than 5 in-compliances in the district |  |  |
| 9 | Number of Pharmacies found with 1-5 in-compliances during inspection in the district |  |  |
| 10 | The number of Pharmacies found with more than 5 in-compliances in the district |  |  |
| 11. Common in-compliances observed by District inspectors(list them) |
| 12. Serious in-compliances observed by District inspectors *(List them)* |
| 13. Common actions taken by District inspectors to enforce compliance *(List them)* |
| **OTHER ISSUES** |
| 14. Common Challenges faced during inspections at District level *(List them)* |
| 15. Issues addressed by the District in support to District inspectors *(List them)* |
| 16. Issues that the DGDA head office has to address *(List the)* |
| 17. Any other issues/comments |
| 18. Planned inspection activities in the coming Period----- *(list them)* |

Reporting Inspector name:-----------------------------------------Signature------------------------

Date----------------------------------------------------

## Section 7: Bibliography

1. Drug Act 1940, Drug Rules 1945, Drug Ordinances 1982:
2. Management Sciences for Health (MSH) and World Health Organization (WHO). (1997) Managing drugs supply: the selection, procurement, distribution and use of pharmaceuticals. West Hartford, Connecticut: Kumarin Press.
3. National Drug Policy (2005), Ministry of Health and Family Welfare: Republic of Bungladesh.
4. Draft Standards for Accredited Medicines Stores (AMS), and Pharmacy -Draft (April, 2016);
5. The Pharmacy Council of Tanzania (Standards and Code of Ethics for Duka la Dawa Muhimu) Regulations, 2004/2007/2015
6. Proposed Inspection Strategy for AMS (2016) Draft.