**BANGLADESH PHARMACY MODEL INITIATIVE (BPMI)**

**HOW TO CARRY OUT PRELIMINARY AND FINAL INSPECTION FOR SELECTED PHARMACIES BEFORE ACCREDITATION**

**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 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;
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 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.

#### 1.1: Procedures to carry out Preliminary Inspection for a new applicant intending to operate a Model Pharmacy

**1.2: Preparing for Inspection**

**1.2.1: Preparation Phase;**

The inspector should read and thoroughly understand the operational standards and regulations for Model Pharmacy 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 if the inspection involves both types of premises;

**1.2.2: 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 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 Health 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 lists;
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;

### 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 evaluate 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.

#### 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. 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.
3. 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;
4. 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;
5. 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;
6. 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.

#### 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 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.

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

### 3: INSPECTION REPORT

Inspection report 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.

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 that are considered to be non-compliance with existing operation standards and regulations or Laws for 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 resent inspections done in the area.

#### 3.1 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.

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

The preliminary inspection report 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 of which this report is part of. If you had inspected both Pharmacy Shop premises, make two separate files for each category;
2. Make a list of all premises in that area that you have inspected with details in terms of applicant, 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 DDLC 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 the 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 have different formats for reporting.

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| TEMPLATE 4: COMBINED PRELIMINARY AND FINAL INSPECTION CHECKLIST FOR PHARMACY PREMISES 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
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| 1. Counseling area
 |  |  |  |
| 1. Prescription drop off and collection points
 |  |  |  |
| 1. Over-the-counter medicine storage areas
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| 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? |  |  |  |
| 1. **Store Room for Storage of Medicines**
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| 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?  |  |  |  |
| **9.0. 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? |  |  |  |
|  |  |  |  |
| Names: 1. --------------------------------------------------signature: --------------------------------------- Date: --------------------------- 2.-------------------------------------------------- Signature: --------------------------------------- Date: -----------------------------Applicant’s (Owner’s) Name: ---------------------------------------------------- Signature: ----------------------------------- Date: -------------------------- |
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| TEMPLATE2: PRELIMINARY AND FINAL INSPECTION REPORT FORM FOR PHARMACY |
| S/N | Name of Applicant  | Proposed name of the Pharmacy | Premise location and Physical Address  | Contact Address/Telephone Number | List of areas of in-compliance to be addressed | Instructions provided for premise upgrade | Inspector’s comments and recommendation |
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| Reporting Inspector(s): Name: 1 ------------------------------------------------------------Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 2. ------------------------------------------------------- Signature: ------------------------------------------------Owner/Representative Name: ------------------------------------------------------------ Signature: --------------------------------------------- |