National Guideline
on
Accreditation of Model Pharmacy and Model Medicine Shop in Bangladesh

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

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Message from the
Director General
Directorate General of Drug Administration (DGDA)

I am delighted that the DGDA has prepared this very useful National Guideline on Accreditation of Model Pharmacy and Model Medicine Shop in Bangladesh, and its publication is a wonderful moment.

In 2016, DGDA took the lead to standardize the retail pharmacy sector in Bangladesh. Subsequently, the Ministry of Health and Family Welfare of the Government of the People's Republic of Bangladesh approved the Standards for the Establishment and Operations of Model Pharmacies and Model Medicine Shops to ensure their quality of services based on defined criteria and proposed grouping them into two categories with respect to infrastructure, floor space, shelving, qualification of technical personnel (pharmacist/pharmacy technician), and operations. The establishment of Model Pharmacies and Model Medicine Shops has continued since then. The initiative is popularly known as the medicine shop accreditation programme. A previous Management Sciences for health project, Accredited Drug Sellers, provided technical assistance to this initiative. After the end of that project, Better Health in Bangladesh (BHB) has been continuing the journey since 2019. BHB provided technical assistance to DGDA to develop the Inspection, Monitoring and Accreditation Strategy for Model Pharmacy and Model Medicine Shop in Bangladesh to enable the DGDA to enforce the standardisation of drug shops effectively.

This accreditation guideline will help DGDA officials and other stakeholders to improve the retail pharmacy sector in Bangladesh. I would like to thank the technical team of BHB, World Health Organization, and other review team members for developing the guideline.

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

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Abbreviations and Acronyms

ADLRS	Automated Drug Licensing and Renewal System
BHB	Better Health in Bangladesh
DG	Director General
DGDA	Directorate General of Drug Administration
GPP	Good Pharmacy Practice
HQ	Headquarters
MP	Model Pharmacy
MMS	Model Medicine Shop
MOHFW	Ministry of Health and Family Welfare
MSH	Management Sciences for Health
OTC	Over-the-Counter
PCB	Pharmacy Council of Bangladesh
SOP	Standard Operating Procedure
UHC	Universal Health Coverage

Using this Guideline

Objectives

This guideline is for DGDA officials and related stakeholders to accredit a retail medicine shop either as a Model Pharmacy (MP) or a Model Medicine Shop (MMS).

This guideline highlights the following:

- Current scenario of the retail pharmacy sector and its prospect for its potential improvement
- Pre-assessment process
- Good Pharmacy Practice (GPP) training process
- Post-assessment process
- Accreditation recommendation visit
- Accreditation-visit checklist
- Final accreditation
- Accreditation validity period

The MP and MMS accreditation process is one of DGDA's prime commitments. This guideline shows the steps of doing the whole accreditation process in pragmatic and effective way.

Scope

This guideline will be used for promoting regulation of model pharmacies and model medicines shops in Bangladesh in line with GPP.

This guideline will be used by:

- Directorate General of Drug Administration (DGDA)
- Retail medicine outlets
- Community pharmacies
- Hospital pharmacies
- Pharmacy Council of Bangladesh (PCB)
- Academia
- Other stakeholders

Terminology Used

Accreditation: A process of officially recognizing a retail medicine shop as either a model pharmacy or a model medicine shop that follows the Ministry of Health and Family Welfare- (MOHFW) approved standards. In 2017, to standardize the retail pharmacy sector, DGDA led the development of standards and an accreditation program for private retail medicine shops to become model pharmacies and model medicine shops, which the MOHFW eventually approved.

Accreditation certificate: Through a rigorous process that includes pre-assessment, training, post-assessment, accreditation recommendation visit, and the recommendation of the DGDA Inspector of Drugs or Superintendent of Drugs or Assistant Director, the Director General (DG), DGDA approves accreditation by issuing an accreditation certificate either as a MP or MMS. The accreditation certificate is valid for two years and subject to renewal.

Model Pharmacy: A retail medicine shop accredited by the DGDA as a model pharmacy complies with DGDA-recommended and MOHFW-approved standards for the establishment and operation of Model Pharmacies. MP will meet some minimum criteria such as floor space of at least 300 square feet,

air-conditioning system, pharmacy-grade refrigerator, and a university graduate pharmacist (Grade A) to dispense medicines and provide counselling.

Model Medicine Shop: A retail medicine shop accredited by the DGDA as a model medicine shop complies with DGDA-recommended and MOHFW-approved standards for the establishment and operation of MMS. An MMS will meet minimum criteria such as a minimum of 120 square feet of floor space and at least a grade C pharmacy technician to dispense medicines and provide counselling.

ADLRS: ADLRS stands for DGDA's Automated Drug Licensing and Renewal System. Accredited medicine shops and pharmacies are required to use the ADLRS to receive a new licence or renew an existing licence.

PMS: PMS stands for Pharmacy Management Software, which should be used in both MP and MMS. The MP must maintain computer(s) and use DGDA-provided PMS or commercially available software for running its day-to-day operations. It is better to have computer(s) in the MMS but not mandatory; however, the MMS may use android version of the DGDA-provided PMS by using smart phone(s) for its purchase, sales, profit, stock-in, stock-out, expired medicine(s) alert etc.

Window Period: The period after the pre-assessment that DGDA allows for conversion of the old medicine shop into either a model pharmacy or a model medicine shop. It is up to one-year.

Background

DGDA is the only government regulatory body of Bangladesh in the pharmaceutical sector. DGDA started an initiative named Bangladesh Pharmacy Model Initiative (BPMI) in 2016 to improve the standards of the retail medicine sector in Bangladesh with respect to infrastructure and service quality. If the medicine shops fulfil the criteria during the final inspection visits, DGDA gives the medicine shops the accreditation certificates as either MMS or MP.

To accredit retail medicine shops, DGDA developed a guideline with a set of criteria for infrastructure/ premises, personnel, and operations:

1) Pre-assessment of the medicine shops
2) Training of dispensers
3) Window period for owners and dispensers to upgrade medicine shop environment
4) Post-assessment for finalization
5) Final inspection by DGDA district officials
6) Issuance of accreditation certificate
7) Regular supervision and monitoring of accredited MP/MMS

The parliament passed the Drug and Cosmetics Act 2023, which was published as the government gazette on 18 September 2023. Clause 17. 1. advises that the company producing or selling medicines should follow the World Health Organization's Good Practices (GXP) guidelines in production, quality control, distribution, supply, and storage. Subclause 17.1.2 further explains that the Government may formulate guidelines regarding the production and quality control, distribution, supply, and storage of medicines as per the guidelines formulated by the World Health Organization or other recognized international organizations. In this context, this national accreditation guideline will help DGDA officials to comply with the Drug and Cosmetics Act 2023.

The act also highlights safe and appropriate antimicrobial sales and dispensing as part of the Government's strict policy to contain antimicrobial resistance as follows:

"Except over-the-Counter (OTC) medicines, antimicrobials or any other medicines should not be dispensed without prescription from a registered physician."

Introduction of Accreditation of Medicine Shops in Bangladesh

The Bangladesh Pharmacy Model Initiative (BPMI) to convert retail medicine outlets to accredited MMS or MP started in 2016. The formal launch took place in December 2016, with the inauguration of two MPs and the unveiling of 'Standards for Establishment and Operations of Model Pharmacy and Model Medicine Shop in Bangladesh' by the former Minister, Ministry of Health and Family Welfare. The DGDA has gradually scaled up the initiative across the country.

Strengths and Challenges in Inspecting and Monitoring of Retail Pharmacy Services

Automated systems: The Drug and Cosmetics Act 2023, under section 14, 15, and 16 specifies the requirement of drug license, renewal, and procedure to be followed. The Automated Drug Licensing and Renewal System (ADLRS) was developed by DGDA to automate the receipt and processing of applications and the issuance of new and renewal drug licenses. Similarly, Pharmacy Council of Bangladesh developed a system to automate the receipt and processing of applications and issuance of registration certificates to pharmacy professionals. Both systems increased efficiencies and

facilitated the applicants' processes and improved cross-checking and fraud detection through a computerized mechanism.

Standard operating procedure (SOP): DGDA developed a comprehensive SOP for inspecting retail and wholesale medicine shops. The SOP details the required qualifications, roles, and powers of inspectors and procedures related to inspection, random sampling, drug seizure, sample collection for quality control, report writing, follow-up, and regulatory decision-making. In 2021, DGDA developed the 'Inspection, Monitoring, and Accreditation Strategy for Model Pharmacy and Model Medicine Shop in Bangladesh' that provides inspection checklists and reporting formats for Model Medicine Shops and Model Pharmacies (Annex 2).

DGDA human resources and infrastructure: DGDA carries out its countrywide operation of post market surveillance along with inspection of MMS and MP through 55 district offices, and 720 MOHFW-sanctioned posts for DGDA including 266 first-class positions. However, there is a chronic shortage of qualified staff to cover thousands of medicine outlets across the country.

Pharmacy personnel: The Drug and Cosmetics Act 2023, under section 45 specifies what kind of qualification a pharmacy personnel must have to run a medicine shop. There is also a shortage of qualified pharmacy personnel leading to inadequately skilled staff working in outlets.

Lack of logistics and transportation facility: One of the many challenges for DGDA to conduct the accreditation process is, it lacks logistics and transportation facilities in the district offices. However, this challenge can be overcome with budget allocation.

Steps for Retail Outlet Accreditation

Accrediting a medicine shop to as either as MP or MMS requires the steps illustrated in Figure 1:

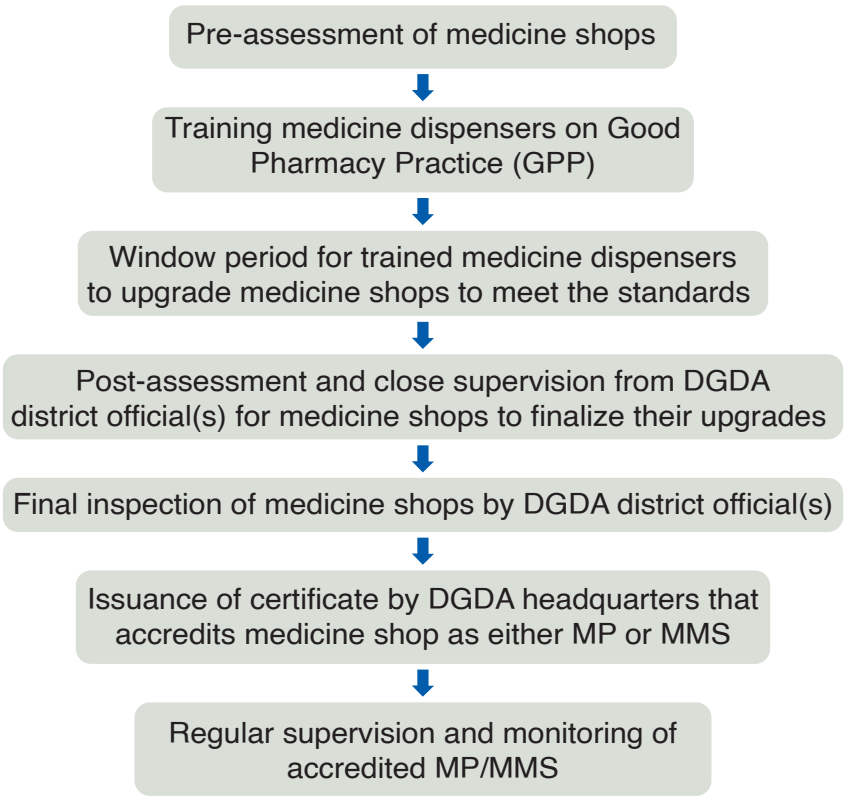

Figure 1: Flowchart of accreditation process for MP/MMS

1. Pre-assess Retail Medicine Shops

DGDA issues new license and renew licenses for Model Pharmacy and/or Model Medicine Shop according to the approved standards of MP and MMS.

Firstly, the local DGDA office will issue a circular to private retail medicine shops to upgrade to MP/MMS in its assigned area along with a form to complete by a deadline. The local DGDA office will review the applications to identify their suitability for upgrading to MP/MMS.

As shown in Figure 1, the accreditation of a MP/MMS requires seven steps. The first step is for a district DGDA officer to visit the outlet to see if it meets the three basic criteria below by having:

- An updated valid drug license for the premises
- A pharmacy professional will serve as medicine dispenser with an updated registration certificate from the Pharmacy Council of Bangladesh in one of three categories, viz., Grade A Pharmacist, Grade B Pharmacist, or Grade C Pharmacy Technician
- Floor space of at least 120 square feet for MMS and 300 square feet for MP

If the designated DGDA officer thinks that a pre-assessment will be required, then she/he can go for visit to verify the suitability of the potential medicine shop's conversion as either model medicine shop or model pharmacy.

Next, local DGDA office will compile the completed pre-assessment checklist (Annex-1) to produce a summary report. This report will be preserved as a reference document for the GPP training arrangements.

2. Train Medicine Dispensers

The purpose of the training is to produce skilled pharmacy personnel who can deliver GPP and thereby contributing to improve the quality, and usefulness of medicine dispensing to the population.

A training program should cover the following elements:

- Training plan
- Trainers / resource persons
- Training preparation
- Training report

Training Plan

The training plan should include at minimum the following elements:

- List of eligible trainees selected from pre-assessment
- Training schedule
- Training contents and methodology for delivery
- Name of trainer/ resource persons

A list of the eligible training participants will have to be collected from the pre-assessment results. Based on this, a participants' list according to batch will have to be prepared.

The list of training participants should have the following information:

- Name of medicine dispenser
- Age
- Sex
- Name of medicine shop
- Address of the medicine shop
- Drug license number
- Medicine dispenser's (pharmacy professional) PCB registration number
- Mobile number
- E-mail address (if any)
- Upazila
- District
- Division
- Other relevant information as required.

The schedule should describe the number of participants in each batch and total number of batches; what date and time the training of each specific batch will begin and end; and the program for each day's training including timeline, class duration, resource person(s), tools to be used, etc.

For in-person training, each batch should last for 4 days with usually 3 sessions per day. Each session should last for 1.5 to 2 hours. For online training, there will be one session per day that lasts for 1.5 to 2 hours. One day prior to the training should be reserved to orient participants on the online platform.

Training Material: The trainers and trainees can both use, *Establishment and Operations of Model Pharmacy and Model Medicine Shop* as reference training material. The training reference and basis for the contents is the grade C training material, "Establishment and Operation of Model Pharmacy and Model Medicine Shop". There will be a training handbook for the trainees. If funding can be made available, a hardcopy of the handbook is preferable. Otherwise, a digital book is also fine.

The trainer will decide on the training methodology based on its objectives and participants. For example—

- Brainstorming sessions
- Group discussions
- Interactive as well as question and answer sessions will be applicable for all trainings.
- Other appropriate display methods such as white board, flip charts, papers and posters, electronic media, practical demonstration, medicine shop visit, etc.

Trainers/ Resource Persons

Selection

The selection of trainers is a critical factor for the success of a training program. To obtain the best results, the trainer must have the following characteristics:

- Knowledge /experience with the subject
- Interested in training
- Communication skills
- Ability to get people to participate
- Strong desire to meet trainees' needs

The trainer must have training(s) on relevant topic(s) and/or be practically experienced. DGDA HQ will select the resource persons based on professional and educational background. Trainers / resource persons from pharmacy departments of different public and private universities will add value to the training and will be able to share updated knowledge and impart relevant skills to the participants. To enhance the trainers' pool, medical doctors, graduate pharmacists, Bangladesh Chemists and Druggists Samity leaders, etc. can also be included. The training organizer will prepare the list of trainers in consultation with the respective head of the function/department as required, which will be given final approval by Head of Quality Management System (QMS) and authorized by DG, DGDA.

Orientation

An orientation program for the trainers / resource persons will ensure consistency of the trainers'/ resource persons' deliberations and content delivery between batches and better adherence to planned contents of the training program.

All persons who are involved in conducting the GPP training event should receive a comprehensive orientation of the training purpose, contents, schedule, batches, and locations and how to engage with the participants, trainers / resource persons, stakeholders, etc. so that they can independently, efficiently, and comfortably execute the training program while maintaining quality standards.

Team meetings at the end of each day

All personnel engaged with implementing the training program should meet regularly to review the day's performance and get guidance on overcoming any problems and further improving the training quality. Specifically, they should review:

- Absence of trainees and their reasons and ways to improve attendance
- Trainers' daily evaluation
- Challenges faced (viz., mobile / internet connectivity, use of meeting platform like Zoom, etc.)
- Other issues as needed

Training Evaluation following completion of training of a batch

This meeting will be to review issues related to the entire batch series of trainings:

- Number of trainees who completed training
- Number of dropouts with reasons and ways to decrease dropouts
- Trainee attendance and ways to improve
- Trainers' evaluations overall
- Challenges faced and ways to overcome them
- Ways to further improve individual and collective training team member performance
- Preparation for training the upcoming batch
- Other issues as needed

Experience-sharing event(s)

The training plan may include organizing an experience sharing event following the completion of all batches of training. The event may be graced by dignitaries like Honourable Health Minister, Secretary of Health Services Division of MOHFW, DG, DGDA and other DGDA officials, and other stakeholders. Representatives from the trainees and trainers can also be invited to speak.

The discussion will cover experiences gathered from the training period including:

- Success stories
- Challenges
- Overcoming challenges
- Innovations
- Benefits of the training program
- Environment of the training program
- Stakeholders' involvement
- Field experience
- Recommendations for future training

Training Preparation

The training can be managed by either DGDA officials or outsourced professionals based on the decision of DGDA headquarters (HQ) and funding availability. The Preparation involves logistics, arranging a venue and refreshments for in-person training and the communication platform for online training as well as honoraria and other matters, such as timeline and training materials.

- Virtual/online trainings will be held when it is not possible for the trainer(s) or participant(s) to physically attend the training, pre/post evaluation, etc. In case of virtual/online training, the following information will be archived:
  - Printout of the training mail/circular stating that the training will be arranged online
  - Printout of the email containing link for the training
  - Printout of screenshot of participants attending the online training
- A standardized Pre-tests and post-tests should be conducted for each batch of training. Cover knowledge, information on practice and attitude on the training contents, viz., GPP, DGDA's Standards of Model Pharmacy and Model Medicine Shop, prerequisites for drug licensing, PCB registration, ADLRS, PMS, PCB automation system, etc.
- The training organizer should already have a batch-wise list of training participants. Invite them to the training by email, phone, text message, WhatsApp etc. Confirm their participation.

When the preparations have been completed, the training organizer should check whether everything has been done correctly, anything was missed, or if anything needs to be finetuned to improve the training, if feasible. Now if everything is ready, just start.

Training Management To-Do List

Before the training starts	
Communicate with the trainees 1.Collect list of trainees 2.Communicate with the trainees to invite them to the training 3.After confirming his/her participation in the specific batch, crosscheck/update the information of the trainee with the trainee list: Trainee's name with correct spelling according to his/her SSC certificate, medicine shop's accurate location/ address, drug license number, trainee's PCB registration number	**Communicate with the trainers / resource persons** 1.Collect training materials and training event schedule 2.Discuss date, time, topic of session with the trainers 3.Confirm participation, reschedule if needed and possible

<table>
<tr><th colspan="2">Before the training starts</th></tr>
<tr><td>4.Issue a DGDA circular announcing the commencement of the training
5.Prepare the completion certificates and get them signed by the appropriate authority
6.Emphasize that trainee must arrive at each training session at least 30 minutes ahead of the start for in-person training
7.Inform trainee that if two or more days are missed, s/he will not get the certificate
8.Send text SMS two days prior to when the training will begin</td><td>4.Send training materials to the trainer when schedule is confirmed
5.Remind the trainer one day prior and on the same day of his/her session (well ahead of the session)
6.Follow up with the trainer during his/her travel and upon reaching the training venue if training is in-person
7.Save trainer’s phone number and request that they save your number on his/her phone</td></tr>
<tr><th colspan="2">During the training event</th></tr>
<tr><td>Role of training organizer about the trainees

1.Arrive at the training venue at least 30 minutes ahead
2.On the first day, explain the entire schedule
3.Confirm on each day the trainees' attendance, fill in the form, and archive it
4.Administer the pre-test on the first day before the first session starts. Score the responses, prepare a result sheet, and inform the trainees of their scores only. However, the top score, bottom score, average score can be shared without disclosing trainee names
5.Take photos of each day’s training session(s) including the trainer and archive
6.Randomize the questions from the pre-test for the post-test, which must not exceed 30 minutes. Score the responses as in #4
7.Distribute completion certificates
8.Start communicating with the new trainees and trainers for the next batch</td><td>Role of training organizer about the trainer / resource persons

1.Ensure timely presence of the trainer
2.Ensure trainer has the PowerPoint slide sets to conduct the course
3.Monitor adherence to session schedules
4.Make an attendance sheet with the trainer’s signature</td></tr>
</table>

Training Completion Reports

The training organizer should prepare a completion report after each batch is trained that includes following information on each trainee:

- Name
- Age (years)
- Sex
- Name of the medicine shop

- Address of the medicine shop
- Floor space (square feet) of the medicine shop
- Division
- District
- Upazila
- Mobile No.
- WhatsApp No.
- Email address
- Drug License No. with validity date
- PCB Registration No. and validity date
- Grade of pharmacy professional
- Pre-test score
- Post-test score
- Duration of training (days)
- Number of days present at the training
- Post-test result sheet for comparing with the pre-test result

In addition, the organizer should draft a batch-wise training report using the specific format. It should include an overall summary of the complete set of training batches as well as the pre and post test results.

3. Window Period

The window period (which is up to one-year) is the time that the medicine shop owner and/or the dispenser has to fill the gaps in meeting the government standards for a Model Pharmacy or Model Medicine Shop after the pre-assessment. The DGDA's accreditation team, either from HQ or from district office, will stay in communication with the respective medicine shop to learn their progress and guide them how to close the gaps and achieve the standards. If during the window period, one or more medicine shops have achieved the required standards, DGDA may make an in-person visit(s) to confirm. If there is still gap, the medicine shops and dispensers may be given support such as guidance and on-site training to comply with the standards.

4. Conduct Post-assessment Visit

DGDA officials or outsourced service providers (depending on funds) conducts a post-assessment, which can take place immediately after the medicine shop dispenser completes training on Good Pharmacy Practice as described above or up to one year later. The same data collection form used for pre-assessment is also designated for the post-assessment (Annex 1). This form tracks how many and which of the standards have been met.

5. Final Accreditation Inspection and Certification

During the post-assessment visits and as per the post-assessment data collection form, when a medicine shop complies with all of the required standards of either a Model Medicine Shop or a Model Pharmacy, a designated DGDA district officer will pay a final in-person visit to inspect the medicine shop for accreditation.

Annex 2 is the accreditation inspection form, issued by the DG, DGDA. If the inspector is satisfied with the results, she or he will recommend to DGDA HQ for issuing a certificate accrediting it as either a Model Pharmacy or Model Medicine Shop depending upon the criteria the medicine shop fulfils. If the shop does not fulfil the requirements, then private retail medicine shops may reapply for the next round of accreditation.

6. Issuance of Accreditation Certificate

DGDA HQ will go through the following process to issue an accreditation certificate:

- Constitute an Accreditation Cell at the DGDA HQ to review the recommendation for issuance of Accreditation Certificates to medicine shops and take final decision.
- This cell may be headed by a Director of DGDA and an Assistant Director or Superintendent of Drugs as the member secretary and three other DGDA officials at the level of Deputy Director, Assistant Director, and Superintendent of Drugs and Drug Inspector as members.
- The Accreditation Cell will sit at least monthly to evaluate the documents for the accreditation of recommended medicine shops and on satisfaction will recommend to the DG of DGDA to provide final approval and sign an Accreditation Certificate in the respective category (Model Pharmacy or Model Medicine Shop). A sample accreditation certificate is in Annex-3. If the cell members do not agree with the recommendation, the cell will send feedback to the recommending officer with the reason why the recommendation was not approved.
- The Accreditation Cell will distribute the Accreditation Certificate and will ensure that it has reached the correct medicine shop.
- The Accreditation Cell will update the accreditation database to make the information available on the DGDA website.
- The Accreditation Cell and/or DGDA may also consider organizing formal accreditation events to issue the accreditation certificates to a group of Model Pharmacies and Model Medicine Shops.

7. Regular Supervision and Monitoring of Accredited MP/MMS

The value and need of monitoring and evaluation as a routine work must not be underestimated. Conduct on-site field visit as a part of monitoring.

The DGDA has an Inspection, Monitoring and Accreditation Strategy that can be an effective tool for inspection, monitoring, reporting, and regulation of the accredited model pharmacies and model medicine shops. It is to ensure that the model pharmacies and model medicine shops maintain their standards. The validity of accreditation is for two years and then subject to renewal.

Link: Inspection, Monitoring and Accreditation Strategy

http://dgdagov.info/index.php/information-center/guidance-documents/1419-inspection-monitoring-and-accreditation-strategy-for-model-pharmacy-and-model-medicine-shop-1/file

Conclusion

This is DGDA's guideline to carry out its retail medicine outlet accreditation programme; however, DGDA may seek assistance and collaboration from other partners to expedite the accreditation process. This guideline is a dynamic tool that can be modified over time to suit current needs and respond to continuous experience and learning.

An accreditation programme to identify eligible medicine shops and help them rise to meet standards as Model Pharmacies or Model Medicine Shops is undisputedly important because countries should not have medicine shops that run at substandard level. Medicines are needed to prevent and treat disease, maintain good health and save lives, and therefore, compromising medicine quality and safety is not acceptable. Only medicine shops operated in accordance with standard guidelines can meet these requirements.

Ensuring availability and accessibility of quality and safe medicines are also key components of reaching Sustainable Development Goal 3.8, i.e., universal health coverage (UHC). At the 2023 High-Level Meeting of United Nations on UHC, Heads of States recommitted to realizing universal health coverage and its components including access to quality and safe medicines.

References

1) Standards for the establishments and operations of Model Pharmacies and Model Medicine Shops; DGDA, MOHFW 2016, Bangladesh.

2) Inspection, Monitoring and Accreditation Strategy for Model Pharmacy and Model Medicine Shop in Bangladesh; DGDA 2021, Bangladesh.

3) Annual Report 2021-2022; DGDA, Bangladesh.

4) NRS-RS-017; Version-03; Standard Operating Procedures (SOP) for the development, adoption, and update of Guidelines; August 2023, DGDA, Bangladesh.

ANNEXURE

Annex 1: Pre-assessment and Post-assessment Checklist

(Please put tick mark where applicable)

SN	Subject	Findings			
1	Name of Pharmacy				
2	Address of Pharmacy				
3	Drug License No. (Valid DL)			DL Valid till:	
4	Pharmacy personnel's PCB Registration No. (Valid PCB RN)			PCB RN Valid till:	
5	Area of medicine shop in square feet (Length in feet x Width in feet) = SqFt				
		Pre-assessment		**Post-assessment**	
	Area to check	**Yes**	**No**	**Yes**	**No**
6	Does the shop preserve temperature sensitive medicine(s)				
7	Is shop having the right shelving system				
8	Does the shop have the facility of monitoring system of temperature sensitive medicine(s)				
9	Does the shop keep the OTC medicines' list				
10	Is the shop air-conditioned				
11	Does the shop have the right management system for expired medicines				
12	Is the pharmacy pharmacist or pharmacy technician trained on establishment and operations of MP or MMS				
13	Is there counselling corner inside the shop				
14	Does the shop maintain the antibiotic register of sold antibiotics				
15	Are antibiotics sold without valid prescription				
16	Does the shop fulfil the criteria for MP				
17	Can the shop be recommended for MP				
18	Does the shop fulfil the criteria for MMS				
19	Can the shop be recommended for MMS				
20	Any note/comment				
21	Date of inspection				
22	Name of DGDA official				
23	Signature of DGDA official				

Annex 2: Accreditation Inspection Visit Form (also used for recommendation)

সুপারিশ ফরম:

বিবরণ		তথ্যাদি		বিবরণ		তথ্যাদি	
১	ফার্মেসির নামঃ			২	ফার্মেসির ঠিকানাঃ		
৩	ড্রাগ লাইসেন্স নং-			৪	ড্রাগ লাইসেন্সের মেয়াদঃ		
৫	ঔষধের দোকানের মালিকের নামঃ			৬	ফার্মাসিস্টের নামঃ		
৭	PCB রেজিস্ট্রেশন নং-			৮	PCB রেজিস্ট্রেশনের মেয়াদঃ		
৯	ফার্মেসির ক্ষেত্রফল {দৈর্ঘ্য (ফুট) X প্রস্থ (ফুট)}	..... বর্গফুট		১০	তাপসংবেদনশীল ঔষধ বিক্রির জন্য সংরক্ষণ করে কি না	হ্যাঁ	না
১১	সঠিক শেলভিং ব্যবস্থা আছে কি না	হ্যাঁ	না	১২	তাপসংবেদনশীল ঔষধ সংরক্ষণে তাপমাত্রা মনিটরিং ব্যবস্থাসহ রেফ্রিজারেটর আছে কি না	হ্যাঁ	না
১৩	OTC ঔষধসমূহের তালিকা আছে কি না	হ্যাঁ	না	১৪	ফার্মেসি শীততাপ নিয়ন্ত্রিত কি না	হ্যাঁ	না
১৫	মেয়াদোত্তীর্ণ ঔষধের সঠিক ব্যাবস্থাপনা আছে কি না	হ্যাঁ	না	১৬	কর্মরত ফার্মাসিস্ট/ ফার্মেসি টেকনিসিয়ান মডেল ফার্মেসি অথবা মডেল মেডিসিন শপ স্থাপন ও পরিচালনা-র প্রশিক্ষণপ্রাপ্ত কি না		
১৭	রোগীদের কাউন্সেলিং কর্ণার আছে কি না	হ্যাঁ	না	১৮	বিক্রিত এন্টিবায়োটিকের রেজিস্ট্রার ব্যবহৃত হয় কি না	হ্যাঁ	না
১৯	প্রেসক্রিপশন ছাড়া এন্টিবায়োটিক বিক্রয় করা হয় কি না	হ্যাঁ	না	২০	মডেল ফার্মেসির ক্রাইটেরিয়া পূরণ করে কি না	হ্যাঁ	না
২১	মডেল মেডিসিন শপের ক্রাইটেরিয়া পূরণ করে কি না	হ্যাঁ	না	২২	মডেল ফার্মেসিতে উন্নীত হওয়ার যোগ্য হিসেবে সুপারিশকৃত কি না	হ্যাঁ	না
২৩	মডেল মেডিসিন শপে উন্নীত হওয়ার যোগ্য হিসেবে সুপারিশকৃত কিনা	হ্যাঁ	না	২৪	পরিদর্শনের তারিখঃ		
পরিদর্শনকারী কর্মকর্তার স্বাক্ষর ও সিল							

Annex 3: Accreditation Certificate Template for Model Pharmacy

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
ঔষধ প্রশাসন অধিদপ্তর
ঔষধ ভবন, মহাখালী, ঢাকা-১২১২

এ্যাক্রেডিটেশন সনদপত্র

এ মর্মে প্রত্যয়ন করা যাচ্ছে যে, ...
ড্রাগ লাইসেন্স নং ..... মালিকের নাম:.....
ঠিকানা:.....
.....,
স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয় কর্তৃক নির্ধারিত **মডেল ফার্মেসির** আদর্শমান পরিপূর্ণভাবে বাস্তবায়ন করে পরিচালিত হচ্ছে।

বিগত ..... তারিখে ঔষধ প্রশাসন অধিদপ্তরের পরিদর্শনের ভিত্তিতে নিম্নবর্ণিত শর্তে ..... কে এ্যাক্রেডিটেশন প্রদান করা হল।
এ্যাক্রেডিটেশন নং **MP-** .....

শর্ত:

১. বিগত ২৩ জুন ২০১৬ তারিখে স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ে এতদ্‌সংক্রান্ত স্টিয়ারিং কমিটি কর্তৃক নির্ধারিত আদর্শমান বজায় রেখে সেবা পরিচালনা করবেন অন্যথায় এ্যাক্রেডিটেশন স্থগিত অথবা বাতিল করা হবে।
২. এ্যাক্রেডিটেশন ছাড়া মডেল ফার্মেসির লোগো ব্যবহার করা যাবে না।
৩. ঔষধ প্রশাসন অধিদপ্তরের পূর্বানুমোদন ব্যতিরেকে প্রতিষ্ঠানের মালিকানা পরিবর্তন করা যাবে না।
৪. নিয়োজিত ফার্মাসিস্ট পরিবর্তন হলে ঔষধ প্রশাসন অধিদপ্তরকে অনতিবিলম্বে অবহিতকরতঃ অনুমোদন গ্রহণ করতে হবে।
৫. এ্যাক্রেডিটেশনপ্রাপ্ত প্রতিষ্ঠান হিসেবে আপনারা সাইনবোর্ডে, অনুমোদিত জনবলের এ্যাপ্রোনে, ক্যাশমেমো/ইনভয়েসে এবং ঔষধ সরবরাহের প্যাকেটে/ব্যাগে মডেল ফার্মেসির লোগো ব্যবহার করতে পারবেন।
৬. প্রতিষ্ঠানের অনুকূলে ইস্যুকৃত ড্রাগ লাইসেন্স-এর সকল শর্তাবলী প্রতিপালন করে ব্যবসা পরিচালনা করতে হবে।
৭. এ্যাক্রেডিটেশন সনদপত্রের বৈধতার মেয়াদ দুই বছর।

MODEL PHARMACY

প্রদানের তারিখ

মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তর

Annex 4: Accreditation Certificate Template for Model Medicine Shop

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
ঔষধ প্রশাসন অধিদপ্তর
ঔষধ ভবন, মহাখালী, ঢাকা-১২১২

এ্যাক্রেডিটেশন সনদপত্র

এ মর্মে প্রত্যয়ন করা যাচ্ছে যে, ...
ট্রাড লাইসেন্স নং ..... মালিকের নাম:.....
ঠিকানা:.....
.....
স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয় কর্তৃক নির্ধারিত মডেল মেডিসিন শপের আদর্শমান পরিপূর্ণভাবে বাস্তবায়ন করে পরিচালিত হচ্ছে।

বিগত ..... তারিখে ঔষধ প্রশাসন অধিদপ্তরের পরিদর্শনের ভিত্তিতে নিম্নবর্ণিত শর্তে ..... কে এ্যাক্রেডিটেশন প্রদান করা হল।
এ্যাক্রেডিটেশন নং MMS-.....

শর্ত:

১. বিগত ২৩ জুন ২০১৬ তারিখে স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়ে এতদসংক্রান্ত স্টিয়ারিং কমিটি কর্তৃক নির্ধারিত আদর্শমান বজায় রেখে সেবা পরিচালনা করবেন অন্যথায় এ্যাক্রেডিটেশন স্থগিত অথবা বাতিল করা হবে।
২. এ্যাক্রেডিটেশন ছাড়া মডেল মেডিসিন শপের লোগো ব্যবহার করা যাবে না।
৩. ঔষধ প্রশাসন অধিদপ্তরের পূর্বানুমোদন ব্যতিরেকে প্রতিষ্ঠানের মালিকানা পরিবর্তন করা যাবে না।
৪. নিয়োজিত ফার্মাসিস্ট পরিবর্তন হলে ঔষধ প্রশাসন অধিদপ্তরকে অবিলম্বে অবহিতকরত: অনুমোদন গ্রহণ করতে হবে।
৫. এ্যাক্রেডিটেশনপ্রাপ্ত প্রতিষ্ঠান হিসেবে আপনারা সাইনবোর্ডে, অনুমোদিত জনবলের এ্যাপ্রোনে, ক্যাশমেমো/ইনভয়েসে এবং ঔষধ সরবরাহের প্যাকেটে/ব্যাগে মডেল মেডিসিন শপের লোগো ব্যবহার করতে পারবেন।
৬. প্রতিষ্ঠানের অনুকূলে ইস্যুকৃত ট্রাড লাইসেন্স-এর সকল শর্তাবলী প্রতিপালন করে ব্যবসা পরিচালনা করতে হবে।
৭. এ্যাক্রেডিটেশন সনদপত্রের বৈধতার মেয়াদ দুই বছর।

MODEL MEDICINE SHOP

প্রদানের তারিখ

মহাপরিচালক, ঔষধ প্রশাসন অধিদপ্তর

Annex 5: Over-the-Counter (OTC) Medicines/Drugs

OTC drugs are medicines/drugs that can be dispensed from a pharmacy by a pharmacist without a prescription.

Prescription-only medicines/drugs must be dispensed from a pharmacy by a pharmacist with a valid prescription.

A valid prescription originates from a practicing registered physician and/or dentist. In Bangladesh, physicians are registered with the Bangladesh Medical and Dental Council (an autonomous government regulatory body). Valid prescribers in Bangladesh usually hold degrees such as MBBS, FCPS, MCPS, MD, MS, DOpth, DO, DCard, DDV, DTCD, DGO, DCH, BDS, DMF from Medical Assistant Training School (MATS), etc.

The DGDA has authorized thirty-nine (39) OTC medicines/drugs that can be dispensed without a prescription.

The list of the DGDA authorized OTC medicines is as below:

List of OTC Drugs (Allopathic)

1. Albendazole Chewable Tablet
2. Antacid Chewable Tablet/ Suspension
3. Ascorbic Acid Chewable Tablet/ Syrup
4. Benzyl Benzoate Lotion
5. Calcium Tablet
6. Chloramphenicol Eye/Ear Ointment/Drops
7. Chlorhexidine Lotion/ Cream
8. Chloroxylenol Lotion/ Cream
9. Chlorpheniramine Maleate Tablet/ Syrup
10. Condoms
11. Diclofenac Gel
12. Dextromethorphen Syrup
13. Ferrous (Sulphate, Gluconate & Fumarate) Tablet/ Capsule/ Syrup
14. Gentian Violet
15. Glycerine Suppository
16. Low-Dose Contraceptive Pills
17. Mebendazole Tablet
18. Metronidazole Tablet/ Suspension
19. Methyl Salicylate Gel
20. Milk of Magnesia Suspension
21. Mouthwash Preparations
22. Multivitamin Tablet/ Capsule/ Drops
23. Neomycin/ Gentamycin/ Bacitracin or combination Ointment/ Cream/ Dusting Powder
24. Omeprazole capsule
25. Oral Rehydration Salt (with or without glucose or flavours) Sachets

26. Paracetamol /Acetaminophen Tablet/ Syrup/ Suspension/Suppository
27. Permethrin Ointment/ Cream
28. Potassium Permanganate Granules for Gargle
29. Povidone Iodine
30. Promethazine Theoclate Tablet
31. Ranitidin Tablet
32. Riboflavine tablet
33. Salbutamol Tablet
34. Salicylic Acid+ Benzoic Acid Ointment
35. Silver Sulphadiazine Ointment
36. Sunscreen Preparations
37. Vitamin A Capsule
38. Vitamin B Complex (individual or combinations) Tablet/ Syrup/ Drops
39. Xylometazoline 0.1 % Nasal Drops

Annex 6: Accreditation Guideline Review Committee

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
ঔষধ প্রশাসন অধিদপ্তর
ঔষধ ভবন, মহাখালী, ঢাকা -১২১২
www.dgda.gov.bd

স্মারক নং-ডিজিডিএ/আরএস/কমিটি/১/ ১২৭৫৫ তারিখঃ ০২.১১.২০২৩খ্রিঃ

বিষয়ঃ মডেল ফার্মেসি এবং মডেল মেডিসিন শপ এক্রেডিটেশন গাইডলাইন রিভিউ এবং চূড়ান্তকরণ বিষয়ক কমিটি গঠন প্রসঙ্গে।

উপর্যুক্ত বিষয়ের পরিপ্রেক্ষিতে জানানো যাচ্ছে যে, ঔষধ প্রশাসন অধিদপ্তরের সার্বিক তত্ত্বাবধানে ও বেটার হেলথ ইন বাংলাদেশ (BHB) প্রকল্পের সহায়তায় মডেল ফার্মেসি এবং মডেল মেডিসিন শপ এক্রেডিটেশন কার্যক্রম চলমান রয়েছে। দাতা সংস্থার সহযোগীতা ব্যতিরেকে নির্বিঘ্নে এক্রেডিটেশন কার্যক্রম বহাল রাখার জন্য একটি এক্রিডিটেশন গাইডলাইনের খসড়া তৈরী করা হয়েছে। উক্ত খসড়া গাইডলাইনটি রিভিউ এবং চূড়ান্তকরণের নিমিত্তে নিম্নবর্ণিত সদস্যদের সমন্বয়ে একটি কমিটি গঠন করা হলো। কমিটিকে আগামী ০৩(তিন) মাসের মধ্যে গাইডলাইন চূড়ান্তকরণের জন্য বলা হলো।

সংখ্যাক্রম কর্মকর্তার নাম, পদবী ও কর্মস্থল

১. মো. ইয়াহইয়া	পরিচালক (চ. দা.), ঔষধ প্রশাসন অধিদপ্তর, ঢাকা	সভাপতি
২. মোঃ রাজিবুল হাবিব	সহকারী পরিচালক, জেলা কার্যালয়, ঔষধ প্রশাসন, মুন্সিগঞ্জ	সদস্য
৩. ফারজানা শবনম বৈশাখী	সহকারী পরিচালক, ঔষধ প্রশাসন অধিদপ্তর, ঢাকা	সদস্য
৪. মোঃ মওদুদ আহমেদ	ঔষধ তত্ত্বাবধায়ক, ঔষধ প্রশাসন অধিদপ্তর, ঢাকা	সদস্য
৫. মোঃ আরাফাত হোসেন	সহকারী প্রোগ্রামার, ঔষধ প্রশাসন অধিদপ্তর, ঢাকা	সদস্য
৬. মোঃ সহিদুল ইসলাম খান	প্রশাসনিক কর্মকর্তা (চ. দা.) ঔষধ প্রশাসন অধিদপ্তর, ঢাকা	সদস্য
৭. মোঃ রাকিবুল হাসান	পরিসংখ্যান কর্মকর্তা, ঔষধ প্রশাসন অধিদপ্তর, ঢাকা	সদস্য
৮. ডা. মো. ইফতেখার হাসান খান	মুখ্য কারিগরী উপদেষ্টা, বিএইচবি	সদস্য
৯. রাইয়ান আমজাদ	জেষ্ঠ্য কারিগরী উপদেষ্টা, বিএইচবি	সদস্য
১০. সারা সাফরীন	আইসিটি কনসালটেন্ট, বিশ্ব স্বাস্থ্য সংস্থা	সদস্য
১১. পরিতোষ চাকমা	ন্যাশনাল কন্সাল্টেন্ট, বিশ্ব স্বাস্থ্য সংস্থা	সদস্য
১২. শায়লা নওশাদ	সহকারী পরিচালক, ঔষধ প্রশাসন অধিদপ্তর, ঢাকা	সদস্য-সচিব

মেজর জেনারেল মোহাম্মদ ইউসুফ
মহাপরিচালক
ঔষধ প্রশাসন অধিদপ্তর, ঢাকা
ফোনঃ ০২২২২২৮০৮০৩
dgda.gov@gmail.com

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স্মারক নং-ডিজিডিএ/আরএস/কমিটি/১/ ১২৭৫৫ তারিখঃ ০২.১১.২০২৩খ্রিঃ

অবগতি ও প্রয়োজনীয় ব্যবস্থা গ্রহণের জন্য অনুলিপি প্রেরণ করা হলো (জেষ্ঠ্যতার ক্রমানুসারে নয়)

১. পরিচালক/ পরিচালক (চ. দা.)/ উপপরিচালক/ উপপরিচালক (চ. দা.) প্রধান কার্যালয়, ঔষধ প্রশাসন অধিদপ্তর, ঢাকা
২. উপপরিচালক/ উপপরিচালক (চ. দা.), সকল বিভাগীয় কার্যালয়।
৩. সহকারী পরিচালক/ ঔষধ তত্ত্বাবধায়ক / ঔষধ তত্ত্বাবধায়ক (ভারপ্রাপ্ত)/সহকারী প্রোগ্রামার/ঔষধ পরিদর্শক/পরিসংখ্যান কর্মকর্তা/প্রশাসনিক কর্মকর্তা (চ.দা.), এ অধিদপ্তর/ জেলা কার্যালয় (সকল জেলা)।
৪. জনাব অধ্যাপক ডা. আবুল কালাম আজাদ, প্রকল্প পরিচালক, বেটার হেলথ ইন বাংলাদেশ (বিএইচবি) প্রকল্প।
৫. জনাব ডা. মোঃ ইফতেখার হাসান খান, মূখ্য কারিগরি উপদেষ্টা, বেটার হেলথ ইন বাংলাদেশ (বিএইচবি) প্রকল্প।
৬. জনাব রাইয়ান আমজাদ, জেষ্ঠ্য কারিগরী উপদেষ্টা, বেটার হেলথ ইন বাংলাদেশ (বিএইচবি) প্রকল্প।
৭. জনাব পরিতোষ চাকমা, ন্যাশনাল কন্সাল্টেন্ট, বিশ্ব স্বাস্থ্য সংস্থা।
৮. সারা সাফরীন, আইসিটি কনসালটেন্ট, বিশ্ব স্বাস্থ্য সংস্থা।

মহাপরিচালক
ঔষধ প্রশাসন অধিদপ্তর, ঢাকা

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Annex 7: Images Relevant to Accreditation of Model Pharmacy and Model Medicine Shop

MODEL PHARMACY

MODEL MEDICINE SHOP

Logos of Model Pharmacy and Model Medicine Shop

Pharmacy Grade Refrigerator (With an exterior temperature-display) and
Ordinary Refrigerator with a Thermometer Inside

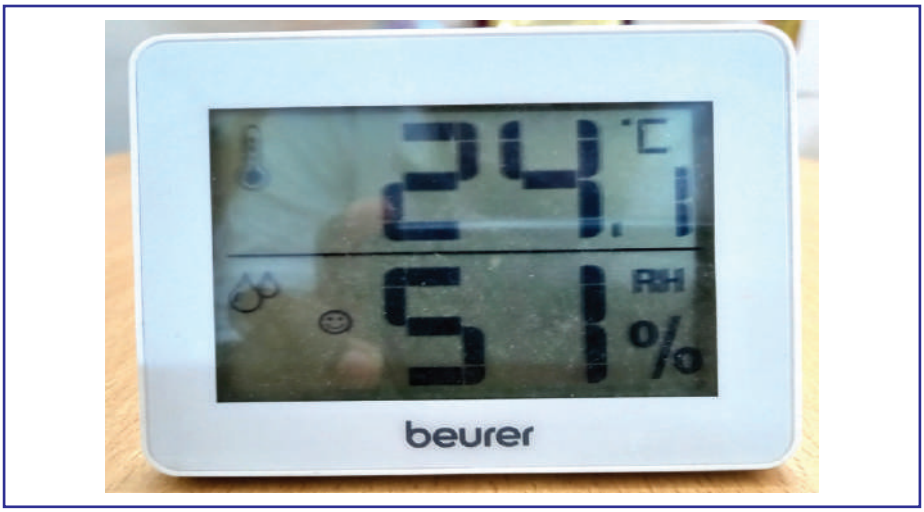
Expiry Medicine Bin with Message

White Apron for Grade-A Pharmacist

Sky Blue Apron for Grade-B Pharmacist

Pink Apron for Grade-C Pharmacy Technician

Dress code for Pharmacy Personnel working in a Model Pharmacy/Medicine Shop



Hygro-thermometer placed inside the shop premise to monitor room temperature and humidity

Ideal signboard for Model Medicine Shop

Ideal Signboard for Model Pharmacy

Counselling area, shelving of medicines, and displaying of drug license and PCB registration certificate etc.

মডেল মেডিসিন শপ স্থাপন ও পরিচালনা প্রশিক্ষণ ম্যানুয়াল

বাংলাদেশ ফার্মেসী কাউন্সিল

Manual for Establishment and Operations of Model Pharmacy and Model Medicine Shop

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

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