Government of the People's Republic of Bangladesh
Ministry of Health and Family Welfare (MOHFW)
Directorate General of Drug Administration (DGDA)

STANDARDS FOR THE ESTABLISHMENT AND OPERATIONS OF MODEL PHARMACIES AND MODEL MEDICINE SHOPS

Dhaka 2016

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ACRONYMS

BAPI	Bangladesh Association for Pharmaceutical Industries
BCDS	Bangladesh Chemist and Druggist Samity
BMA	Bangladesh Medical Association
CAB	Consumers Association of Bangladesh
DFID	Department for International Development [UK]
DG	Director General
DGDA	Directorate General of Drug Administration
DNCRP	Directorate of National Consumer Rights Protection
DMC	Dhaka Medical College
DU	Dhaka University
ID	identification
JDTAF	Joint Donor Technical Assistance Fund
JU	Jahangirnagar University
MDGs	millennium development goals
MOHFW	Ministry of Health and Family Welfare
MRP	maximum retail price
MSH	Management Sciences for Health
NGO	non-governmental organization
OTC	over-the-counter
PCB	Pharmacy Council of Bangladesh
TIN	tax identification number

Mohammed Nasim, MP
Minister
Ministry of Health & Family Welfare
Govt. of the People's Republic of Bangladesh

মোহাম্মদ নাসিম, এমপি
মন্ত্রী
স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়
গণপ্রজাতন্ত্রী বাংলাদেশ সরকার

Message

I am pleased to know that the Bangladesh Pharmacy Model Initiative has successfully completed all the Phase-1 activities, and that the National Steering Committee, chaired by the Secretary of the Ministry of Health and Family Welfare, has approved the classification of all private retail drug outlets into two types, Pharmacy and Medicine Shop. The approved standards will be the ultimate guide for implementing and evaluating the Bangladesh pharmacy model in target districts during phase-2, which is a pilot phase.

In the last few years, Bangladesh has made tremendous progress in the health sector under the pro-people government led by our Honorable Prime Minister Sheikh Hasina. The pharmaceutical sector has been one of the major success stories. I am expecting that the standardization of the retail pharmacy sector and accreditation of each outlet through the Bangladesh Pharmacy Model Initiative will be another success to add to the list. Through wise planning, careful implementation, and good monitoring and evaluation, the retail pharmacy sector of Bangladesh will soon be standardized. In addition to strengthening regulatory oversight and promoting consumer advocacy and sensitization, the initiative will brand pharmacies and medicines shops that meet the standards with an accreditation logo.

Bangladesh has become a role model for many other developing countries in achieving MDGs and other health targets. I hope the country will continue to perform in improving consumer access to and appropriate use of quality medicine and pharmaceutical services through this new system of accrediting retail drug outlets. This will also increase consumer awareness, strengthen regulatory oversight, increase investments and employment opportunities for pharmacy professionals-both men and women and ultimately improve health outcomes.

I am happy to know that under Director General, DGDA the technical support for the Bangladesh Pharmacy Model Initiative has been provided by Management Sciences for Health, a nonprofit international NGO, with DFID funding through JDTAF. I congratulate everybody who contributed to this initiative that will help common people achieving the right to health by improving pharmacy services. I am also hopeful that development partners will continue their support and share the success.

Joy Bangla, Joy Bangabandhu
Long live Bangladesh.

Mohammed Nasim
15/11/16

Zahid Maleque, MP
State Minister
Ministry of Health & Family Welfare
Govt. of the People's Republic of Bangladesh

জাহিদ মালেক, এমপি
প্রতিমন্ত্রী
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গণপ্রজাতন্ত্রী বাংলাদেশ সরকার

Message

I am pleased to hear of the publication of standards for drug outlets of Bangladesh, developed by the Directorate General of Drug Administration along with national and international technical experts and sector stakeholders with support from Management Sciences for Health, an international nonprofit NGO, with DFID funding through JDTAF. In these standards, drug outlets are classified as either Pharmacies or Medicine Shops. The standards describe the personnel qualifications and the premises requirements for both levels that have to be met for the outlet to achieve accreditation as a Pharmacy or a Medicine Shop.

The Ministry of Health and Family Welfare is working towards improving the accessibility, quality, and affordability of healthcare to meet the needs of our population. Pharmacists, who are part of the healthcare team, play an integral role in attaining this goal. Under the strong leadership of our Honorable Prime Minister Sheikh Hasina, Bangladesh is now considered a role model for developing countries in having successfully reached MDGs and other health targets; still, our health care system is slanted mostly towards hospital care rather than community-based care. The Bangladesh Pharmacy Model Initiative is a project that works with the retail private pharmacy sector of Bangladesh, which is a popular source of medicines for the community. Since its inception, the initiative has seen significant gains in marshaling the support of stakeholders, while working side-by-side with DGDA to lead the development of pharmaceutical regulations, standards, and an accreditation strategy.

I am sure the publication of these standards will help us move toward improved patient care and ultimately improved health outcomes. I congratulate the Director General, DGDA Major General Md. Mustafizur Rahman and his team, whose responsiveness resulted in the publication of these standards.

Joy Bangla, Joy Bangabandhu
Long live Bangladesh.

Zahid Maleque

(Zahid Maleque, MP)

MD. SIRAZUL ISLAM
Secretary
Ministry of Health and Family Welfare
Government of the People's Republic of Bangladesh

মোঃ সিরাজুল ইসলাম
সচিব
স্বাস্থ্য ও পরিবার কল্যাণ মন্ত্রণালয়
গণপ্রজাতন্ত্রী বাংলাদেশ সরকার

Message

The most common source of medicine in many developing countries like Bangladesh is the private sector drug seller. I am privileged and delighted to be the chair of the National Steering Committee for the Bangladesh Pharmacy Model Initiative. This is an initiative of the Government of the People's Republic of Bangladesh under Director General of Drug Administration to improve the products and services in private retail drug outlets.

We know the pharmacy sector is strictly regulated all over the world. The purpose of this regulation is to safeguard and promote good public health. I must thank the representatives from DGDAand all other organizations who have recommended that drug outlets be classified into two groups based on personnel, premises, and provision of services, and who have actively participated in developing the new standards for pharmacies and medicine shops. I hope this milestone decision will create immense public health value by increasing the quality of pharmaceutical services in Bangladesh.

Management Sciences for Health, a nonprofit international health organization, has provided technical assistance to Uganda, Liberia, Zambia, and now Bangladesh to adopt the original Tanzanian drug outlet accreditation model to each country's specific context. I am happy to hear about the results of the initiative's first phase including the development of a pharmacy model and implementation strategies, that cover standards, laws, and regulations, regulatory and inspection capacity, and program oversight. I am hopeful that a successful pilot of the accreditation model in the initiative's second phase will lead to countrywide scale-up.

I also acknowledge the financial support of DFID through JDTAF for this important public health initiative.

(Md. Sirazul Islam)

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

FOREWORD

I am delighted to present this set of standards for the establishment and operation of Pharmacies and Medicine Shops to policy makers, planners, health managers, and field officers. Based on these standards, a pilot project will be conducted with 30 level 1 pharmacies, which will be selected from Dhaka, Rajshahi, Khulna, Barisal, and Sylhet divisional towns and Gazipur District Town. In addition, around 2000 level II medicine shops in six upazilas from three districts (two upazilas from each pilot district) will go through the accreditation process. These standards will be a guiding document for pharmacy owners, dispensers, and regulators, as well as entrepreneurs.

The objective of these standards is to reinforce regulations in the retail pharmacy business and achieve service uniformity among pharmacies and medicine shops, thereby maximizing patient care while minimizing health hazards.

The Directorate General of Drug Administration has been continuously working to gather field information with support from Management Sciences for Health, an international nonprofit NGO, to analyze existing practices. We had a series of stakeholder consultation meetings, individual key person consultation sessions, dissemination workshops, technical working group meetings, and national steering committee meetings to develop the standards. Hence, through this rigorous process, the final standards are now realistic and achievable. This is an enormous and difficult task, but I am happy that my colleagues at the DGDA and MSH are doing their jobs efficiently, even with limited resources.

I am grateful to the Honorable Minister, State Minister, and Secretary for the Ministry of Health and Family Welfare, for their constant support and guidance. I extend my heartiest congratulations to the team and to all the participants who have been working hard to develop and prepare these standards since the inception of this project. We appreciate DFID/JDTAF for their funding support.

Major General Md. Mustafizur Rahman

CATEGORIZATION OF RETAIL DRUG OUTLET OPERATIONS IN BANGLADESH

All drug outlets should operate on the principle of making the safety and welfare of customers the prime concern. All pharmaceutical service providers are required to operate in a secure and safe environment in accordance with legal and professional requirements and present an image that enhances pharmaceutical service.

A two-tier categorization of retail pharmaceutical service levels is based on training qualifications, skills and competencies, premises condition, and category of medicines/products to be handled. To be called a "model" outlet, it must meet the appropriate standards to be accredited by the Directorate General of Drug Administration (DGDA).

Model Pharmacy (Level I): This level of service will be provided, managed, or supervised by an A grade pharmacist who is present on the premises. B or C grade pharmaceutical personnel may assist with dispensing under the supervision of the A grade pharmacist.

Model Medicine Shop (Level II): This level of service will be carried out, at a minimum, by a person with C grade qualification.

Once an outlet has received a pre-accreditation inspection, the owner will be given a grace period of one year by the DGDA to renovate the premises and otherwise meet the specified standards for a Model Pharmacy or Model Medicine Shop. Owners of drug outlets that fail to meet Model Pharmacy or Model Medicine Shop standards by the end of the grace period will be required to close their business. Model Medicine Shops can also be upgraded to Model Pharmacy status if they meet the appropriate standards.

The standards for Model Pharmacies and Model Medicine Shops follow these principles:

- The governance arrangements are made with the aim of safeguarding the health, safety, and well-being of patients and the public.
- The personnel are empowered and competent to provide desired services to safeguard the health, safety, and well-being of patients and the public.
- The environment and condition of premises from which pharmaceutical services are provided and any associated premises, regardless of level of service, safeguard the health, safety, and well-being of patients and the public.
- The way in which pharmaceutical services are provided and medicines and medical devices are managed and delivered safeguards the health, safety, and well-being of patients and the public.
- The equipment, facilities, or utilities used during the provision of pharmaceutical services safeguard the health, safety, and well-being of the patient and the public.

STANDARDS FOR MODEL PHARMACIES (LEVEL I)

These standards are for the establishment and operation of Model Pharmacies. The standards consider the skills and competencies of dispensers and the A grade pharmacists overseeing this service level, types of medicines to be sold, and the infrastructure of the physical premises.

1. Standards for Personnel

Personnel at every Model Pharmacy shall fulfil the following requirements.

1.1 Owners

Every Model Pharmacy owner must:

- Have a Bangladesh national ID.
- Have a tax identification number (TIN).
- Have a trade license.
- Take the Pharmacy Council of Bangladesh (PCB)-approved business training course and pass the post-course examination.

Every Model Pharmacy owner shall:

- Ensure that the Model Pharmacy staff has the appropriate skills, qualifications, and competencies for their role and for the tasks they carry out.
- Prominently display the Pharmacy accreditation certificate, dispenser registration certificate(s), and trade license.
- Prominently display the name of the pharmacist–in-charge for the premises and his/her registration certificate in the professional service area.
- Notify the DGDA in writing within 30 days after the Model Pharmacy permanently closes; in so doing, the authority shall inspect the inventory and provide advice for proper disposal of medicines and other products.
- Notify the DGDA in writing within 30 days after the Model Pharmacy temporarily closes with the anticipated date of re-opening, which should also be publicly displayed in front of the premises. Should a Model Pharmacy close for one year, it shall be considered a new applicant for accreditation.
- Notify DGDA in writing within seven days for any change in approved personnel including when a notice for termination of contract with pharmacist-in-charge is issued.
- Report any thefts or unexplained losses of drugs or records immediately to the nearest police station and to DGDA.

1.2 Technical Personnel Responsible for Medicines Dispensing

All A, B, and C grade pharmaceutical personnel working in the Model Pharmacy must undergo a PCB-approved 30-hour orientation (A and B grade) or 80-hour dispensing training course (C grade) and pass the related exam. Any secondary school certificate holder in science who undergoes the PCB-approved 80-hour dispenser training course and passes the training exam may also be registered as a C grade dispenser.

The technical personnel working in a Model Pharmacy shall comply with the following:

- Maintenance of a high standard of personal hygiene.
- Guidelines on dispensing, ethics, and other issues related to the provision of pharmaceutical services.
- Completion of continuing education if required by the PCB.
- Code related to personal identification and dress.

1.3 Supervision of Model Pharmacy

- Every Model Pharmacy will be managed or supervised on-site by an A grade pharmacist registered by the PCB (pharmacist in-charge).
- Model Pharmacy dispensers must work under the on-site supervision of an A grade pharmacist (pharmacist in-charge).
- Non-pharmaceutical personnel employed by the Model Pharmacy can be on the premises, but shall not keep the business open without a pharmacist in-charge on the premises.

1.4 Contract between Model Pharmacy Owner and Pharmacist-in-charge

- Every owner and pharmacist-in-charge must sign a legally binding contract.
- The contract will describe the roles and responsibilities of each party including terms and conditions.
- A generic template contract will be provided by DGDA to be used by each Model Pharmacy.

2. Standards for Premises

2.1 Premises

Every Model Pharmacy premises must meet minimum requirements as follows:

- Be a permanent structure that is not at risk from floods.
- Have a roof and ceiling free from leakage.
- Provide adequate seating for customers waiting for service.
- Have surfaces/floors/walls with smooth finish that can be washed with disinfectants.
- Assure good hygiene inside and outside the premises.
- Have a source of potable water.

- Have space with dimensions of at least 300 square feet and a ceiling height of at least 8 feet.
- Have a source of electricity such as a direct connection to an electrical grid, generator, instant power supply, or solar panels.
- Have a sink with running water dedicated to support hand hygiene practices.
- Where a Model Pharmacy prepares extemporaneous products, the sink must have sufficient space for cleaning related equipment.
- The sink should not be used for disposal of mop water and other liquid wastes.
- The building must be constructed and maintained to minimize entry of animals, such as rodents and birds.

2.2 Signage

Pharmacies will have the following signage:

- A sign board with the name of the outlet, registration number, address, and officially approved logo (brand) for a Model Pharmacy in accordance with DGDA's Model Pharmacy branding guidelines.
- A "NO SMOKING" sign conspicuously placed to prohibit smoking on the premises.
- A sign indicating operating hours.
- Upon closure or relocation, or loss of accreditation status, all signage indicating that the premises was a Model Pharmacy must be removed immediately.

2.3 Temperature Control

- The Model Pharmacy should have adequate air conditioner(s) with a power back-up source (e.g., generator, instant power supply, solar panel), so that the ambient temperature does not exceed 30°C.
- The Model Pharmacy must have a thermometer to monitor room temperature.

2.4 Refrigerator

- The Model Pharmacy must have, at minimum, one pharmacy-grade refrigerator that is large enough to store temperature-sensitive medicines.
- All refrigerators used to store medicines must be dedicated to the storage of pharmaceuticals only.
- Refrigerators used for storage of vaccines must comply with vaccine storage guidelines.

2.5 Security

- External walls should be of solid construction to ensure they cannot be breached.
- Measures need to be taken to prevent entry through the ceiling. The ceiling spaces above Model Pharmacies should be secured to ensure the crawl spaces cannot be accessed from adjoining areas.

- Walls must reach the roof line or security grills must be installed to cordon off the ceiling space.
- External doors must have a solid core. Where this is not possible, a heavy gauge roller door or security grill may be used in addition to a lockable door.
- All external entry points, including windows and skylights, must be lockable with additional security grills or roller doors. High security glass, equivalent in strength to a security grill or roller door, will be accepted. External bollards should be considered if the Model Pharmacy is at high risk of ram raid.
- Model pharmacies must be protected by a back-to-base electronic alarm system or CCTV security cameras to cover, at a minimum, areas where scheduled medicines are stored.
- All medicinal products, associated records, and recording equipment should be stored on the Model Pharmacy premises only.

2.6 Professional Services Area

- The Model Pharmacy must have a clearly delineated and marked professional service area restricted to the provision of therapeutic goods and services.
- The professional service area should be distinguishable from other areas of the Model Pharmacy; customers should readily be able to locate the dispensing area.
- The area should be designed and located such that consumers are able to access the advice of the pharmacist or other qualified pharmaceutical personnel to assist in their safe and effective use of therapeutic goods.
- The professional service area contains the dispensary, counselling area, prescription drop-off and collection points, and over-the-counter and prescription medicine storage areas. The professional service area must be free from information, products, and services that are not therapeutically related.
- Non-therapeutic items (e.g., toiletries, cosmetics) should not be displayed for sale within the professional area.
- No person other than a member of the Model Pharmacy staff is allowed behind the counter in the professional services area.
- The dispensary must have a dispensing counter with a clean and smooth surface.

3. Dispensing

3.1 Good Dispensing Practices

- Every pharmacist-in-charge shall bear professional responsibility for the pharmaceutical products and services provided by him or her or any other pharmaceutical technical personnel under his or her supervision.
- Patients whose conditions cannot be handled by the Model Pharmacy personnel should be referred to the nearest health facility.
- The pharmacist-in-charge shall ensure that:
  a. No damaged, counterfeit, substandard, or expired medicines are dispensed.
  b. Medicines dispensed are registered by the DGDA.

c. No physicians' samples are dispensed.
d. No medicines are dispensed directly to children under 12 years of age.
e. Prescription-only medicines are only dispensed against a prescription.
f. The patient is dispensed with the full course of treatment and directed to complete the full course of treatment.
g. Tablets and capsules are dispensed using an appropriate tool, such as a counting tray. They should not be handled with bare hands.
h. Every drug is dispensed in accordance with the Model Pharmacy dispensing and training guidelines/standards and in accordance with the existing DGDA laws, ordinances, and rules.

3.2 Counselling Patients

The pharmacist-in-charge shall ensure that:

- The customer receives dosing instructions and drug information before he or she leaves the premises.
- The customer understands the information and advice given (including directions on the labels of dispensed products) well enough to ensure safe and effective use of the medicine.
- Customers are warned to keep medicines well out of reach of children.
- Customer privacy is protected during counselling conversations through the use of a separate area or by requiring other customers to stand behind a line that allows for confidential conversations with the dispenser.

3.3 Dispensing Containers

- All oral liquid preparations must be dispensed in their original re-closable containers unless the product is supplied by the manufacturer in bulk.
- All dispensing containers for medicinal products must protect the medicine(s) from moisture, light, physical stress, and contamination.
- Dispensing containers should be labelled either by writing on the container or by using an adhesive sticker.

3.4 Required Dispensing Tools

The following items must be available and in use in Model Pharmacies:

- Counting tray
- Spatula
- Measuring tools
- Mortar and pestle
- Scale for body weight measurement

3.5 Labelling Dispensed Medicines

- Labelling of dispensed medicines must be clear and legible and in the locally appropriate language or using pictographs.
- Dispensed medicines must bear the necessary cautionary and advisory labels.
- The label on the container must indicate:
  a. Name and address of the patient.
  b. Name of medicine.
  c. Directions for use, strength, dosage, and total quantity of the medicine supplied.
  d. If the medicine is for external application, the words "**For external use only**" must appear on the label.
  e. Expiry date.

4. Storage of Medicines

- Have a separate place within the professional area with no public access to keep approved prescription medicines, either in a separate room or on shelves with sliding glass or in a lockable cupboard or drawer.
- Have shelves with sliding glass to protect medicines from dust in dispensing area; arrange medicines alphabetically or according to therapeutic groups. Solid dosage forms to be separated from liquids and internal preparations to be separated from external preparations. All shelves with medicines shall be behind or under the dispensing counter.
- All pharmaceutical products held in inventory shall be stored in the manufacturer's original packaging and properly labelled with the manufacturer's original label and under the storage conditions that are specified by the manufacturer (e.g., refrigeration) until they are dispensed.
- Damaged or expired medicines shall be recorded, sealed, quarantined, and labelled with the statement in red ink "**Expired/damaged medicines–Not for sale**."
- No medicine should be stored on the floor or in passageways, toilets, or staff rest areas.
- Vaccines can be stocked if the Model Pharmacy is able to maintain cold chain standards.
- Over-the-counter (OTC) medicines may be stocked outside the professional service area, but must be stocked close enough to allow effective oversight by the pharmacist-in-charge or other qualified pharmaceutical personnel.

5. Hygiene

- Any dispenser or other personnel should not be allowed to work if he or she is suffering from a contagious disease condition, such as scabies, tuberculosis, leprosy, etc.
- Use of bare hands for counting tablets and capsules is prohibited.
- Buildings and fixtures must be kept clean, tidy, and well maintained. All cleaning equipment must be maintained to support good hygiene and infection control.
- The Model Pharmacy shall maintain regular general cleaning schedules. Floors shall be cleaned daily and when necessary. Shelves shall be regularly cleaned to maintain dust-free environment.

- The dispensing area should be tidy and free of clutter.
- Model Pharmacy staff should not eat while working in the dispensing area. Staff should have a separate area for eating available to them.
- Toilets must not open directly into the dispensing area. Hand-washing facilities with running water, soap, and clean towels must be provided in toilet areas with a conspicuous notice displayed that instructs users to wash their hands.
- Toilet areas must not be used for storage or as a source of water for dispensing.

6. Record Keeping and Documentation

- A record of all medicines dispensed shall be maintained in a register approved by the DGDA.
- For each prescription dispensed, a record shall be made as follows:
  a. Serial number of the entry.
  b. Date of sale.
  c. Name/code number and address of the prescriber.
  d. Name of the patient and condition for which the prescription was written (if known).
  e. Name of the drug or preparation and the quantity supplied.
- The Model Pharmacy should maintain automated (computerized) system to preserve all suppliers receipts and invoices for prescription and non-prescription medicines AND store all hard copies of the same supplier invoices and receipts on the premises for not less than two years.
- A purchase record book shall be kept, which shall minimally include:
  a. Name of supplier
  b. Date of purchase
  c. Name and quantity of the medicines
  d. Manufacturer, batch number, and expiry date.
- A record for expired products must be maintained.
- Every Model Pharmacy must maintain a file for all correspondence received from DGDA, Ministry of Health and Family Welfare, or other regulatory authorities (e.g., drug recall notices).
- The Model Pharmacy must maintain a book to record all inspections.
- The Model Pharmacy must maintain DGDA-approved adverse drug reaction forms and adverse drug reactions must be reported to DGDA regularly.

7. Disposal of Damaged/Expired Medicines

The disposal of damaged/expired medicines must strictly follow existing rules and procedures as provided by DGDA and other competent authorities.

8. Allowable Products and Services in Model Pharmacies

8.1 Prescription-only Medicines

Model Pharmacies will be allowed to stock and sell all prescription-only medicines registered by DGDA.

8.2 Non-prescription/Over-the-Counter (OTC) Medicines

Model Pharmacies will be allowed to stock and sell all non-prescription/ OTC medicines registered by DGDA.

8.3 Medical Supplies and Devices

- Model Pharmacies will be allowed to stock and sell medical supplies and devices other than medicines if they meet DGDA's established quality standards.
- All medical supplies and devices will be stocked separately from therapeutic products with distinct signage such as **"Medical Supplies and Devices."**

8.4 Non-pharmaceutical Products

- Model Pharmacies will be allowed to store and sell toiletries, cosmetics, and other hygiene and health promoting products.
- All non-pharmaceutical products will be stocked separately from therapeutic products with distinct signage such as "**Non-pharmaceutical Products."**
- DGDA approved/registered traditional /alternative medicines such as Ayurvedic, Unani, or bio-chemic medicines may be stored and sold, but must be stocked separately from therapeutic products with distinct signage such as "**Traditional/Alternative Medicines."**

8.5 Provision of other Health Services

- Model Pharmacy dispensers may check or monitor blood pressure, sugar level for diabetic patients, body temperature, body weight, nebulization, and perform rapid diagnostic tests for malaria and pregnancy and others as approved by appropriate bodies and DGDA, if this is within the legal framework of Bangladesh.
- Model Pharmacy dispensers are not allowed to conduct any medical/clinical services other than those listed above, including giving injections, unless they are legally authorized to do so and have the evidence of that authorization on hand and available for review.
- Stationing any medical practitioner or providing laboratory services within the Model Pharmacy premises is strictly prohibited.

9. Pricing of Pharmaceuticals

Model Pharmacies must comply with the DGDA's recommended maximum retail price (MRP) for pharmaceutical products.

10. Reference Materials

Each Model Pharmacy shall maintain the following reference materials:

- PCB-approved dispenser orientation and/or training manual
- British Pharmaceutical codex and/or Martindale
- Relevant legislation, including:
  a. Bangladesh Model Pharmacy standards, business acts, ordinances, rules, and regulations.
  b. List of prescription-only medicines registered by DGDA.
  c. List of non-prescription/OTC medicines registered by DGDA.

11. Offenses and Penalties

Model Pharmacies are subject to periodic regulatory inspection. Any person who violates any provision of these standards shall be liable upon conviction to a warning, fine, and/or imprisonment as specified under the existing acts, ordinance, and rules.

STANDARDS FOR MODEL MEDICINE SHOPS (LEVEL II)

These standards are for the establishment and operation of Model Medicine Shops. The standards consider the skills and competencies of the dispenser working at this service level, types of medicines to be sold, and the infrastructure of the physical premises.

1. Standards for Personnel

Personnel at every Model Medicine Shop shall fulfil the following requirements.

1.1 Owners

Every Model Medicine Shop owner must:

- Have a Bangladesh national ID.
- Have a tax identification number (TIN).
- Have a trade license.
- Take the Pharmacy Council of Bangladesh (PCB)-approved business training course and pass the post-course examination.

Every Model Medicine Shop owner shall:

- Ensure that Model Medicine Shop has staff with appropriate skills, qualifications, and competencies for their role and for the tasks they carry out.
- Prominently display the Medicine Shop accreditation certificate, dispenser registration certificate(s), and trade license.
- Notify the DGDA in writing within 30 days after the Model Medicine Shop permanently closes; in so doing, the authority shall inspect the inventory and provide advice for proper disposal of any inventory or medication.
- Notify the DGDA in writing within 30 days after the Model Medicine Shop temporarily closes with the anticipated date of re-opening, which should also be made public with notification displayed in front of the premises. Should a Model Medicine Shop close for one year, it shall be considered a new applicant for accreditation.
- Notify DGDA in writing within seven days for any change in approved personnel.
- Report any thefts or unexplained loss of drugs or records immediately to the nearest police station and to DGDA.

1.2 Technical Personnel Responsible for Medicines Dispensing

All A, B, and C grade pharmaceutical personnel working in the Model Medicine Shop must undergo a PCB-approved 30-hour orientation (A and B grade) or 80-hour dispensing training course (C grade) and pass the related exam. Any secondary school certificate holder in science who undergoes the PCB-approved 80-hour dispenser training course and passes the training exam may also be registered as a C grade dispenser.

The technical personnel working in a Model Medicine Shop shall comply with the following:

- Maintenance of a high standard of personal hygiene.
- Guidelines on dispensing, ethics, and other issues related to the provision of pharmaceutical services.
- Completion of continuing education if required by the PCB.
- Code related to personal identification and dress.

1.3 Contract between Model Medicine Shop Owner and Dispensers

- Every owner and dispenser must sign a legally binding contract.
- The contract will describe the roles and responsibilities of each party including terms and conditions.
- A generic template contract will be provided by DGDA to be used by each Model Medicine Shop.

2. Standards for Premises

2.1 Premises

The premises of every Model Medicine Shop must meet minimum requirements as follows:

- Be a permanent structure that is not at risk from floods.
- Have a roof and ceiling free from leakage.
- Provide seating for at least one customer waiting for service.
- Have surfaces/floors/walls with smooth finish that can be washed with disinfectants.
- Assure good hygiene inside and outside the premises.
- Have a source of potable water.
- Have space with dimensions of at least 120 square feet with a ceiling height of at least 8 feet.
- Have a source of electricity such as a direct connection to an electrical grid, generator, instant power supply, or solar panels.
- The building must be constructed and maintained to minimize entry of animals, such as rodents and birds.

2.2 Signage

The premises shall have the following signage:

- A sign board with the name of the outlet, registration number, address, and officially approved logo (brand) for a Model Medicine Shop in accordance with DGDA's Model Medicine Shop branding guidelines.
- A "NO SMOKING" sign conspicuously placed to prohibit smoking on the premises.

- Upon closure, relocation, or loss of accreditation status, all signage indicating that the premises was a Model Medicine Shop must be removed immediately.

2.3 Temperature Control

- The Model Medicine Shop should have adequate method to cool the premises (e.g., air conditioner, fans) with a power back-up source (e.g., generator, solar panel, instant power supply), so that the ambient temperature does not exceed 30°C.
- The Model Medicine Shop must have a thermometer to monitor room temperature.

2.4 Refrigerator

- The Model Medicine Shop must have, at minimum, one refrigerator that is large enough to store temperature-sensitive medicines.
- All refrigerators used to store medicines must be dedicated to the storage of pharmaceuticals only.
- Refrigerators used for storage of vaccines must comply with vaccine storage guidelines.

3. Dispensing

3.1 Good Dispensing Practices

- Every Model Medicine Shop dispenser shall bear professional responsibility for the pharmaceutical products and services provided by him or her.
- Patients whose conditions cannot be handled by Model Medicine Shop personnel should be referred to the nearest health facility.
- Every dispenser shall ensure that:
  i. No damaged, counterfeit, substandard, or expired medicines are dispensed.
  j. Medicines dispensed are registered by the DGDA.
  k. No physicians' samples are dispensed.
  l. No medicines are dispensed directly to children under 12 years of age.
  m. Prescription-only medicines are only dispensed against a prescription
  n. The patient is dispensed with the full course of treatment and directed to complete the full course of treatment.
  o. Tablets and capsules are dispensed using an appropriate tool, such as a counting tray. They should not be handled with bare hands.
  p. Every drug is dispensed in accordance with the Model Medicine Shop dispensing and training guidelines/standards and in accordance with the existing DGDA laws, ordinances, and rules.

3.2 Counselling Patients

The dispenser shall ensure that:

- The customer receives dosing instructions and drug information before he or she leaves the premises.
- The customer understands the information and advice given (including directions on the labels of dispensed products) well enough to ensure safe and effective use of the medicine.
- Customers are warned to keep medicines well out of reach of children.
- Customer privacy is protected during counselling conversations through the use of a separate area or by requiring other customers to stand behind a line that allows for confidential conversation with the dispenser.

3.3 Dispensing Containers

- All oral liquid preparations must be dispensed in their original re-closable containers unless the product is supplied by the manufacturer in bulk.
- All dispensing containers for medicinal products must protect the medicine(s) from moisture, light, physical stress, and contamination.
- Dispensing containers should be labelled either by writing on the container or by using an adhesive sticker.

3.4 Required Dispensing Tools

The following items must be available and in use in Model Medicine Shops:

- Counting tray
- Spatula
- Measuring tools
- Scale for body weight measurement

3.5 Labelling Dispensed Medicines

- Labelling of dispensed medicines must be clear and legible and in the locally appropriate language or using pictographs.
- Dispensed medicines must bear the necessary cautionary and advisory labels.
- The label on the container must indicate:
  f. Name and address of the patient.
  g. Name of medicine.
  h. Directions for use, strength, dosage, and total quantity of the medicine supplied.
  i. If the medicine is for external application, the words "**For external use only**" must appear on the label.
  j. Expiry date.

4. Storage of Medicines

- Have a separate place with no public access to keep approved prescription-only medicines, either in a separate room or on shelves with sliding glass or in a lockable cupboard or drawer.

- Have shelves with sliding glass to protect medicines from dust in dispensing area; arrange medicines according to dosage forms or therapeutic groups. Solid dosage forms to be separated from liquids and internal preparations to be separated from external preparations. All shelves with medicines shall be behind or under the dispensing counter.
- All pharmaceutical products held in inventory shall be stored in the manufacturer's original packaging and properly labelled with the manufacturer's original label and under the storage conditions that are specified by the manufacturer (e.g., refrigeration) until they are dispensed.
- Damaged or expired medicines shall be recorded, sealed, quarantined, and labelled with the statement "**Expired/damaged medicines–Not for sale.**"
- No medicine should be stored on the floor or in passageways, toilets, or staff rest areas.
- Vaccines can be stocked if the Model Medicine Shop is able to maintain cold chain standards.
- Over-the-counter (OTC) medicines may be stocked outside the professional service area, but must be stocked close enough to allow effective oversight by qualified pharmaceutical personnel.

5. Hygiene

- Any dispenser or other personnel should not be allowed to work if he or she is suffering from a contagious condition, such as scabies, tuberculosis, leprosy, etc.
- Use of bare hands for counting tablets and capsules is prohibited.
- Buildings and fixtures must be kept clean, tidy, and well maintained. All cleaning equipment must be maintained to support hygiene and infection control.
- The Model Medicine Shop shall maintain regular general cleaning schedules. Floors shall be cleaned daily and when necessary. Shelving shall be regularly cleaned to maintain a dust-free environment.
- The dispensing area should be tidy and free of clutter.

6. Record Keeping and Documentation

- A record of all medicines dispensed shall be maintained in a register approved by the DGDA.
- For each prescription dispensed, a record shall be made as follows:
  a. Serial number of the entry.
  b. Date of sale.
  c. Name/code number and address of the prescriber.
  d. Name of the patient and condition for which the prescription was written (if known).
  e. Name of the drug or preparation and the quantity supplied.
- All supplier invoices and receipts for prescription and non-prescription medicines shall be stored on the premises for not less than two years.
- A purchase record book shall be kept, which shall minimally include:
  a. Name of supplier
  b. Date of purchase
  c. Name and quantity of the medicines

d. Manufacturer, batch number, and expiry date.

- A record for expired products must be maintained.
- Every Model Medicine Shop must maintain a file for all correspondence received from DGDA, Ministry of Health and Family Welfare, or other regulatory authorities (e.g., drug recall notices).
- Every Model Medicine Shop must maintain a book to record all inspections.
- The Model Medicine Shop must maintain DGDA-approved adverse drug reaction forms and adverse drug reactions must be reported to DGDA regularly.

7. Disposal of Damaged/Expired Medicines

The disposal of damaged/expired medicines must strictly follow existing rules and procedures as provided by DGDA and other competent authorities.

8. Allowable Products and Services in Model Medicine Shops

8.1 Prescription-only Medicines

Model Medicine Shops will be allowed to stock and sell all prescription-only medicines registered by DGDA except the restricted group of medicines, medicines under schedule C and any other products that DGDA excludes.

8.2 Non-prescription/Over-the-counter (OTC) Medicines

Model Medicine Shops will be allowed to stock and sell all non-prescription/ OTC medicines registered by DGDA.

8.3 Medical Supplies and Devices

- Model Medicine Shops will be allowed to stock and sell medical supplies and devices other than medicines if they meet DGDA's established quality standards.
- All medical supplies and devices will be stocked separately from therapeutic products with distinct signage such as "**Medical Supplies and Devices**."

8.4 Non-pharmaceutical Products

- Model Medicine Shops will be allowed to store and sell toiletries, cosmetics, and other hygiene and health promoting products.
- All non-pharmaceutical products will be stocked separately from therapeutic products with distinct signage such as "**Non-pharmaceutical Products**".
- DGDA approved/registered traditional /alternative medicines such as Ayurvedic, Unani, or bio-chemic medicines may be stored and sold, but must be stocked separately from therapeutic products with distinct signage such as "**Traditional/Alternative Medicines**".

8.5 Provision of other Health Services

- Model Medicine Shop dispensers may check or monitor blood pressure and sugar level for diabetic patients, body temperature, body weight, nebulization, and perform rapid diagnostic tests for malaria and pregnancy and others as approved by appropriate bodies and DGDA, if this is within the legal framework of Bangladesh.
- Model Medicine Shop dispensers are not allowed to conduct any medical/clinical services other than those listed above, including giving injections, unless they are legally authorized to do so and have the evidence of that authorization on hand and available for review.
- Stationing any medical practitioner or providing laboratory services within the Model Medicine Shop premises is strictly prohibited.

9. Pricing of Pharmaceuticals

Model Medicine Shops must comply with the DGDA's recommended maximum retail price (MRP) for pharmaceutical products.

10. Reference Materials

Each Model Medicine Shop shall maintain the following reference materials:

- PCB-approved dispenser orientation and/or training manual
- Relevant legislation, including:
  a. Bangladesh Model Medicine Shop standards, business acts, ordinances, rules, and regulations.
  b. List of prescription-only medicines allowed for sale by Model Medicine Shops
  c. List of non-prescription/OTC medicines registered by DGDA.

11. Offenses and Penalties

Model Medicine Shops are subject to periodic regulatory inspection. Any person who violates any provision of these standards shall be liable upon conviction to a warning, fine, and/or imprisonment as specified under the existing acts, ordinance, and rules.

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