

# Online Pharmacy Criteria

## 1) Validity of License and Renewal of License

The validity of Online Pharmacy License will be 02(Two) years from the date of issue. The Licensee should apply for renewal with required fee and documents at least 90 (Ninety) days before the expiry date.

## 2) Personnel:

The pharmacy should be operated by the presence of Grade 'A' Pharmacist. There may be presence of B, C grade pharmacist as associate.

## 3) Pharmacy Premises:

- a) Area of the premises should not be less than 300 sq. feet.
- b) The pharmacy premises must have Air conditioning (AC) systems for maintaining room temperature and refrigerator for temperature sensitive products.
- c) Mechanisms should be in place to protect medical products from light, moisture, heat, contamination and pest infestation.
- d) Dedicated area for patient counselling.

## 4) Electronic Platform and Security:

- a) Web address should be hosted on Bangladesh Domain name.
- b) The applicants must have adequate electronic support/software/E-system for properly managing all the functions (secured data maintaining) of online Pharmacy.
- c) Home page of website or app of the pharmacy should display online pharmacy license, physical address of the pharmacy, contact information, return policy for medical products, service hour, name of responsible pharmacists with registration number, picture of pharmacist, details of logistic service provider, ownership details etc. and any other order/direction from the Licensing Authority of Drugs.
- d) The online pharmacy infrastructure, such as hardware (e.g. computers, scanners, printers, server, router etc.) and software (e.g. dispensing system, inventory system etc.) should be appropriately set up, and processes must be robust and secured for the pharmacy operations.
- e) System must have traceability of the pharmacy activities.
- f) DGDA must have access to the database of the online pharmacy.

## 5) Documentation and Records:

- a) Applicants must have a retail license of Pharmacy premises with physical address.
- b) All prescriptions should be preserved in soft copy for at least 02(Two) years.
- c) Patient information should be preserved, and patient information should not be disclosed without the prior approval of DGDA.

- d) All information about medical products purchase, store and supply should be preserved in both soft copy and hard copy.
- e) Adverse Drug Reaction (ADR) of Medicines and Adverse Event Following Immunization (AEFI) in case of vaccines should be recorded and preserved. The Licensee should inform DGDA about ADR and AEFI.
- f) There should be Standard Operating Procedure (SOP) for receiving, storing and supplying medical products. The SOP should be followed.
- g) Sales invoices (Cash memo) of medical products should be preserved. Sales invoices should have followed information:
  - Name, address, phone number and license number of the pharmacy.
  - Details of the owner of the pharmacy.
  - Serial number and date of the invoice.
  - Name of the drug, name of the manufacturer, Marketing Authorization (M.A.) No./Drug Administration Registration (DAR) No., batch number or lot number, date of manufacture, date of expiry and quantity.
  - Name, signature and registration number of pharmacist (A Grade Pharmacist) who dispensed the medical products.
- h) All documents (Invoice. Cash memo, Prescription etc.) must be stored in database for at least 02 (Three) years.
- i) Internal and External audit record should be preserved.
- j) There should be back up of sales and purchase data, patient data, prescriptions. The licensee cannot sell or transfer these data abroad.

**6) Prescription Receiving & Dispensing of Medical Products:**

- a) Prescription of only authorized persons (registered physician) should be acceptable. This service can be provided only against the prescription sent by the consumer online. The prescription should be verified by the registered pharmacist.
- b) Prescription should have included name of the physician, designation, registration number, contact address, date etc. of the prescription.
- c) Only intended user or legal guardian of the user should be able to place order against a prescription.

- d) The licensee should purchase medical products from authorized manufacturers, importers, or distributors in Bangladesh.
- e) Online pharmacy will ensure an automatic feedback message system with notification against any purchase order mentioning delivery time.
- f) Instructions for use of medical products should be duly written on the supplied medical product's packages or on separate paper.

**7) Medical Products That Cannot be Delivered Online:**

- a) Only DGDA registered medical products can be supplied.
- b) Proper and exact brand name, dosage forms of medical products mentioned in the prescription and Full course of antibiotic should be supplied to the consumer.
- c) Unregistered, misbranded, counterfeit, govt. medical products of any kind should not be supplied.
- d) Prescription for Controlled Drugs (CDs) should not be supplied. The licensee should follow the Narcotics Control Act 2018(Act No 63 of 2018) and the rules made there under.

**8) Handling, Storing & Packing of Medical Products:**

- a) **Medical Products Handling and Storing:** The retail online pharmacy must comply with Good Storage & Distribution Practice (GSDP) requirements for the handling and storage of medical products.
- b) **Packaging of Medical products:** All medical products undergoing packing for supply through online pharmacy service should comply with good packaging standards to ensure proper labelling and maintenance of records to provide traceability.

**9) Delivery of Medical Products:**

- a) Good Distribution Practice (GDP) should be maintained. Cold chain management system should be available to supply temperature sensitive medical products.
- b) Medical products should be delivered from the licensee's Premises. If the Licensee have multiple licensed pharmacy with similar Name and Ownership, then the medicinal products can be delivered from there suitable premises.
- c) Online pharmacies using third party platforms shall have agreement and service level agreement showing responsibility of each party and it should maintain product quality in the whole supply chain.
- d) Medical products delivery systems should comply with the storage and delivery requirements according to GSDP.
- e) There should be a Complain Handling Procedure. All the complaints should be handled and disposed of within 07(Seven) days, and record must be kept at least 02 (Two) years.

**10) Change Control:**

- a) The Licensee cannot made any changes (Physical Structure of the pharmacy, Selling procedure, Delivery System, Hosting Domain etc.) without the prior approval of Licensing Authority.
- b) The Licensee cannot transfer ownership or change ownership, name of the pharmacy, address of the pharmacy, contact details of pharmacy, registered pharmacist, internet/web-based procedure (ex. Website to Mobile app) etc. without the prior approval of Licensing Authority.

**11) Others:**

- a) The licensee should be obligated to disclose all information requested by the inspector of DGDA and to provide all kinds of cooperation in the examination, inspection, and verification of records and registers such as relevant information, prescription, cash memos, invoices, etc.
- b) The licensee should not, without obtaining prior approval from the licensing authority, broadcast or publish any kind of advertisement related to medical products in radio, television, internet, social media, print media, or any other media.
- c) The licensee should comply with all the conditions imposed on this retail drug license, including the conditions mentioned above, as well as any other conditions imposed from time to time by the licensing authority through office orders.