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Guideline for approval of premises for sale and distribution of Medical Products

Licensing and Vigilance Section
Medical Product Division
Bhutan Food and Drug Authority

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1. Introduction

In accordance with section 24.1 of the Medicines Act of the Kingdom of Bhutan 2003, any premises utilised for the storage, sale, and distribution of medical products are required to obtain approval from the Authority. Furthermore, the premises intended for the sale and distribution of medical products must possess suitable facilities for the storage, sale, dispensing, and distribution of these products.

To ensure compliance and standardisation, this guideline outlines specific criteria for the approval of premises responsible for sale and distribution of medical products. These criteria are based on considerations such as location, structural requirements, and additional prerequisites. These minimum standards and requirements must be met for the establishment of new premises in order for the premises to be appropriately equipped and staffed at all times so as to adequately protect the health, safety and convenience of patients, public and staff.

Uniformity in the approval process is crucial in ensuring that all premises engaged in the sale and distribution of medical products meet the necessary standards and adhere to the stipulated requirements. Additionally, these guidelines serve as a reference tool for Regulatory Officials, ensuring uniformity in their decision-making processes.

2. Scope

2.1. Individual or entities intending to establish retail and/or wholesale premises dealing with sale and distribution of medical products.

3. Objectives

3.1. To standardise the requirements for premises dealing with sale and distribution of medical products

3.2. To provide the clients with guidance on the requirements for their premises.

3.3. To promote uniform enforcement of requirements for premises dealing with sale and distribution of medical products.

4. Normative reference

4.1. The Medicines Act of the Kingdom of Bhutan 2003

4.2. Bhutan Medicine Rules and Regulations 2019

4.3. Blood and Blood Product Regulation of Bhutan 2016

5. Definitions

5.1. **Authority:** It refers to the Bhutan Food and Drug Authority.

5.2. **Authorization inspection**: It refers to inspections undertaken to assess the suitability and adequacy of the new premise before technical authorization is issued. This can be an announced inspection.

5.3. **Competent Person**: It refers to any person who possesses the requisite qualifications and practical experience prescribed by the Board and is approved to

undertake:

5.3.1. Retail sale of medical products;

5.3.2. Sale by wholesale trade and distribution of medical products.

5.4. Contamination prone areas: It refers to sites or activities which emit obnoxious materials and wastes; open sewages; shops dealing with degradable items; or any other places as the Authority may deem unfit.

5.5. Medical products: It refers to pharmaceuticals & biologics for human and veterinary use, blood & blood products, medical devices and health supplements.

5.6. Premise: It refers to the establishment authorised by the Authority responsible for sale and distribution of medical products.

5.7. Technical Authorization: It refers to the Authorization issued to establishments responsible for sale and distribution of medical products.

6. Acronyms

6.1. BFDA: Bhutan Food and Drug Authority

6.2. BMRR: Bhutan Medicine Rules and Regulations

6.3. TA: Technical Authorization

7. General principles

7.1. As per section 66 of the Bhutan Medicines Rules and Regulations 2019, the Technical Authorization Holder shall conform to the conditions laid down in the Act, Regulation and any other conditions as deemed necessary by the Authority.

7.2. As per section 67 of the Bhutan Medicines Rules and Regulations 2019, the premises intended for sale and distribution shall have appropriate facilities to store, sell, dispense and distribute medical products.

7.3. TA is a prerequisite and not a substitute for a licence for sale from the Ministry of Industry, Commerce and Employment.

7.4. It has become of a high priority to set uniform standards for approval of premises dealing with sale and distribution of medical products to promote uniform implementation and enforcement.

7.5. During the location change and/or renewal of TA for sale and distribution, the applicant has to make sure that the requirements stated in the guideline are adhered to.

8. Minimum requirement for location

During inspection of location, Regulatory Officials of BFDA shall use several criteria to approve the new premise.

8.1. Proximity from contamination prone areas:

8.1.1. The premise should be exclusively dedicated for sale and distribution of medical products.and should not be located adjacent to any contamination prone areas.

9. Minimum requirement for structure

9.1. Building:

9.1.1. The premise should have a structurally permanent building.

9.1.2. Retail and wholesale premises and its operation should be carried out separately with separate entrances and exits.

9.2. **Dimension**: The premise should have an adequate space area that accommodates different categories of products. Minimum area of length of 5 metres, minimum breadth of 3 metres and height of 3 metres is mandatory to open both retail or wholesale premises.

9.3. **Security**:The premise should be secured with physical barriers such as window grille, shutter at the entrance and controlled access to the controlled area of the premise for unauthorised personnel.

9.4. **Ventilation:** The premise should have adequate ventilation

9.5. **Store:**

9.5.1. Wholesale premises should have a separate store facility.

9.5.2. Retail premises intending to have a dedicated store facility should notify the Authority during the application stage.

9.6. **Sign board:** Pharmacy sign boards must project the professional image of a pharmacy and should be displayed for easy identification. The sign board artwork should adhere to the requirement as per Annexure I.

9.7. **Pest control**: The premise should have pest control measures in place.

10. Other requirements

10.1. The premise should have temperature and humidity regulators like air conditioner or fan; this requirement will be determined by climatic zones.

10.2. The premise should have an identified Competent Person registered with the Authority. The Competent Person should have a tag and seal as per requirement in Annexure II.

10.3. Provision for appropriate shelving must be in place so that no medical products are stored on the floor, on stairs or passageways

11. Procedure for obtaining TA

11.1. The applicant has to apply to the Authority for Technical Authorization using G2C or application form as per Annexure III.

11.2. Self- inspection should be carried out by the premise applying for Technical Authorization (TA) using self inspection checklist (Annexure IV)

11.3. Authorization inspections will be undertaken by BFDA to assess the suitability and adequacy of the premise before TA is issued.

11.4. TA is issued with the validity of three years.

11.5. After the expiry of the TA, a grace period of fifteen working days shall be granted after which the renewal shall be done with a daily fine of Nu. 100 for further fifteen working days.

11.6. Non-renewal of TA within the period provided will lead to deregistration and new application from the same applicant will not be entertained for one year.

12. Reference

12.1. Guidelines for Community Pharmacy Practice. Sri Lanka FDA.

12.2. Procedure for approval of location of new Pharmacy, Tanzania.

12.3. Guidelines for Opening for Opening of Pharmacy of Pharmacies (Retail), Ministry of Health and Quality of Life, Mauritius, Africa

12.4. Requirements for Opening Medical Store, Gujarat, India

12.5. Pharmacy Business application Guidelines/forms, Pharmacy Council of Ghana

Annexure I: Sign board requirement for Pharmacy

1. For retail pharmacy dealing with medicine

Description of the signboard:

1. **Blue background with white font**
2. **Name of the pharmacy:**
   a. Should be both in Dzongkha and English
   b. It is mandatory to use the Dzongkha Language on the signage and should have greater or equal lettering size to English lettering and should be written above the English text.
   c. c. The name used on the signage must match the name mentioned on the trade license and TA certificate.
   d. The name in English text should be in Capital letters.
3. **Location**:
   a. The location should be written after the name of the pharmacy and should be in the capital. b. After the name of the location there should be a comma, followed by the Dzongkhag name
4. **Illumination:**

a. Signboards should be illuminated for anyone to read the sign during night and intense lighting should be avoided.
b. The use of neon, flashing, blinking, flickering or animated lighting, or any other highly reflective material is not permitted

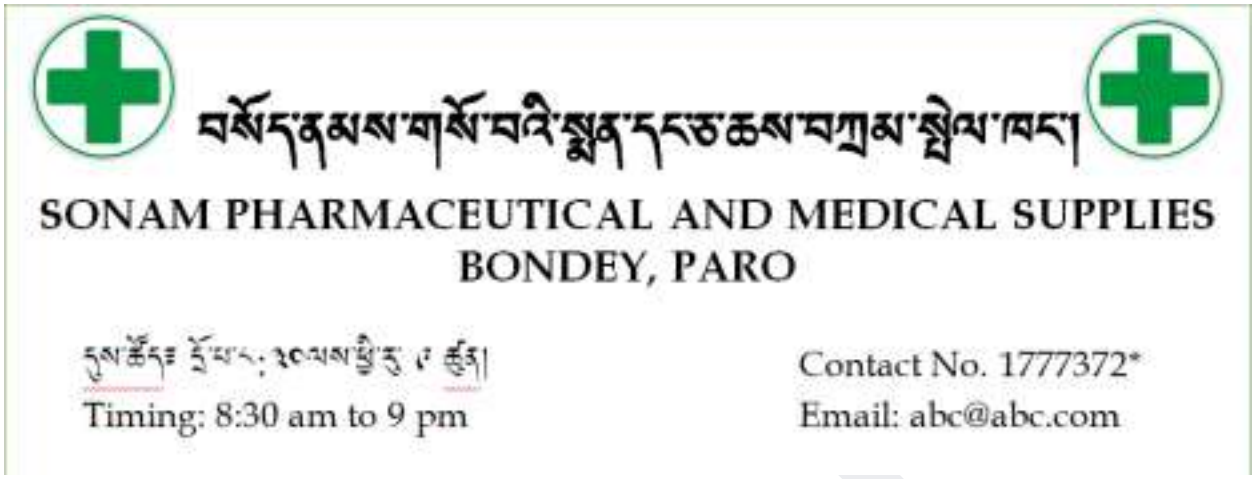
5. **Green Cross sign:** There should be two green cross signs on both the sides
6. **Business hour**: Business hour should be written in both Dzongkha and English
7. **Contact number:** Mandatory
8. **Email ID:** Mandatory
9. **Size of the signboard**

a. Minimum: 1 meter (100cm) in length and 60 cm in width
b. Maximum: Signage should not exceed the Maximum Allowable Signage Area (Calculation can be done as per the calculation of Maximum Allowable Signage Area given in Signage Guideline 2017 by Thimphu Thromde)

10. **Type of font:**

a. Dzongkha: Jomolhari
b. English: Book Antiqua

2. For wholesale pharmacies



Description of the signboard:

1. **White background with black font**
2. **Name of the pharmacy:**

a. Should be both in Dzongkha and English

b. It is mandatory to use Dzongkha Language on the signage and should have greater or equal lettering size to English lettering and should be written above the English text.

c. The name used on the signage must match the company name/operating name mentioned on the trade license and TA certificate.

d. The name in English text should be in Capital letter

3. **Location**: The location should be written after the name of the pharmacy and should be in capital.
4. **Green Cross sign:** There should be two green cross signs on both the sides
5. **Business hour**: Business hour should be written in both Dzongkha and English
6. **Contact number:** Mandatory
7. **Email ID:** Mandatory
8. **Size of the signboard**

a. Minimum: 1 meter (100cm) in length and 60 cm in width

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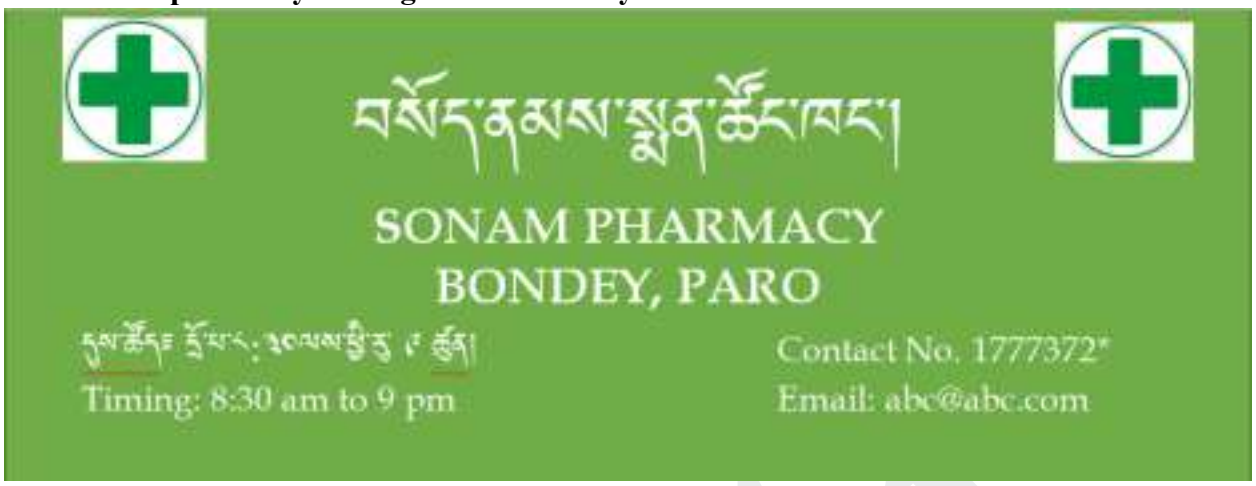
9. **Type of font:**

a. Dzongkha: Jomolhari

b. English: Book Antiqua

3. For retail pharmacy dealing with veterinary medicine



Description of the signboard:

1. Green background with white font

2. Name of the pharmacy:

a. Should be both in Dzongkha and English

b. It is mandatory to use Dzongkha Language on the signage and should have greater or equal lettering size to English lettering and should be written above the English text

c. The name used on the signage must match the company name/operating name mentioned on the trade license and TA certificate.

d. The name in English text should be in Capital letter

3. Location: The location should be written after the name of the pharmacy and should be in capital.

4. Green Cross sign: There should be two green cross signs on both sides.

5. Business hour: Business hour should be written in both Dzongkha and English.

6. Contact number: Mandatory

7. Email ID: Mandatory

8. Size of the signboard:

a. Minimum: 1 meter (100cm) in length and 60 cm in width

b. Maximum: Signage should not exceed the Maximum Allowable Signage Area (Calculation can be done as per the calculation of Maximum Allowable Signage Area given in Signage Guideline 2017 by Thimphu Thromde)

9. Type of font:

a. Dzongkha: Jomolhari

b. English: Book Antiqua

4. For retail pharmacy dealing with pre-determined list of veterinary medicine

Description of the signboard:

1. Green background with white font

2. Name of the pharmacy:

a. Should be both in Dzongkha and English

b. It is mandatory to use Dzongkha Language on the signage and should have equal lettering size to English lettering and should be written above the English text

c. The name used on the signage must match the company name/operating name mentioned on the trade license and TA certificate.

d. The name in English text should be in Capital letter

e. Mention of "FOR SALE OF PRE-DETERMINED LIST OF VETERINARY MEDICINES" in smaller font

3. Location: The location should be written after the name of the pharmacy and should be in capital.

4. Green Cross sign: There should two green cross signs on both the sides

5. Business hour: Business hour should be written in both Dzongkha and English

6. Contact number: Mandatory

7. Email ID: Mandatory

8. Type of font:

a. Dzongkha: Jomolhari

b. English: Book Antiqua

Annexure II: Seal and Tag sample for Competent Person

SEAL SAMPLE FOR COMPETENT PERSON

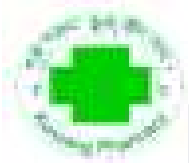
Name:.....
Competent Person
Sonam Pharmacy
CP Reg.no:.....

Required details on the seal

1. The inscription on the seal should be as per the above template.
2. There should be space after Name and CP Reg.no for the competent person to fill up. 3. Seal size:
    a. Length: 5cm
    b. Width: 3 cm
4. Front style: Arial
5. A blue ink should be used

TAG SAMPLE FOR COMPETENT PERSON

FRONT



Competent Person
Name: Kunzang Dorji
Pharmacy name: Kunzang Pharmacy
Location: Olakha, Thimphu
CID No.: 10103000524
Reg. No.: DRA/CP/REG/2018/01
Registration valid till: 03/2018

BACK

This identification certifies that

Mr. Kunzang Dorji

is registered as the Competent Person

as per Section 19.2 of

THE MEDICINES ACT OF THE

KINGDOM OF THE BHUTAN 2003.

This card is not transferable.

Annexure III: Application form

དཔལ་ལྡན་འབྲུག་གཞུང་། གསོ་བ་ལྡན་ཁག། འབྲུག་བཟའ་ཚས་དང་སྨན་རིགས་དབང་འཛིན།

ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY

APPLICATION FOR AUTHORIZATION TO SELL OR DISTRIBUTE MEDICAL PRODUCTS

I/we……hereby apply for New or renewal of authorization to sell medical products by Retail or Wholesale (Tick whichever is applicable).

i. Proposed name of the firm: …….
Location …….

ii. Category of medicinal products (please tick the appropriate category);
   a) Human allopathic medicines
   b) Veterinary medicines
   c) gSo-ba-rig-pa
   d) Medical Device
   e) Health supplements

iii. State the name of the Competent Person who shall supervise the sale of medical products.

Name(s): ……..

Competent Person Registration Number: ……..

Declaration (please tick the boxes):

□I hereby declare that the documents submitted are true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.

□I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provision(s) of the Act and regulations made there under.

□If my application is granted, I shall abide by the Act and the Regulations and any other standards set by the Authority.

Signature of applicant:

Name, address, contact no:

Date: dd-mm-yyyy

Annexure IV: Self inspection checklist

Sl. No.	Adequacy & Suitability of Premise	Yes	No	Remarks
Minimum requirement for location				
1.	Proximity from contamination prone areas: Is the premise not located adjacent to any contamination prone areas?			
	Is the facility separated from residential use, with a different entrance?			
Minimum requirement for structure				
1	Is there permanent structure?			
2	Does the premise have a minimum length of 5 metres, minimum breadth of 3 metres and height of 3 metres?			
3	Is the premise clean and tidy?			
4	Is the premise secured with physical barriers such as window grille, shutter at the entrance with controlled access to the controlled area of the premise for unauthorised personnel?			
5	Does the premise have a minimum of one window or vent to facilitate adequate ventilation?			
6	Are there pest control measures in place?			
7	Does the premise have a separate store facility? (where applicable)			
8	Is the sign board artwork of the premise as per requirement?			
Other requirements				
1	Are provisions for appropriate shelving in place?			
2	Does the premise have temperature and humidity regulators like air conditioner or fan?			

3	Does the premise have an identified Competent Person registered with Authority?			

Please tick the appropriate box.

☐ Self Inspection ☐ Inspected by BFDA

In case of "Self Inspection, tick the declaration box below"

☐ I (licensee) hereby declare that, all the information provided above is valid and in the event of discovery of any discrepancies or false information during subsequent inspection, I shall be held liable to any penalty dictated by the Authority.

Name and Address of the applicant	Dated Signature of the applicant

Decision of the Authority:

- o Recommended for issuance of Technical Authorization
- o Rejected

Comments:

1.
2.

Inspected by (Name & Signature)	**Verified by the Section Head**

Medical Product Division

Promoting availability of quality, safe and efficacious medicinal products for consumers

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