GUIDELINE FOR REGISTRATION OF MEDICINAL PRODUCTS

2020

ADDENDUM 2021

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Version: 02

Registration Division
Drug Regulatory Authority

Developed By:

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Introduction

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The Guideline for registration of Medicinal Products 2020 was developed to guide applicants in preparation and submission of drug registration applications in the form of dossies or to make changes to existing registered medicinal products. The guideline mentions three routes of registration, their eligibility criterias and the document requirements.

This Guideline serves as an addendum to the Guideline for registration of medicinal products 2020 and should therefore be read in conjunction with the said Guideline. This Guideline introduces a new route of product registration which is the Registration of Medicinal products via Company recognition.

PRODUCT REGISTRATION VIA COMPANY RECOGNITION:

1. A generic drug may be registered via company recognition provided the drug is included in the Essential Medicines List published by the Ministry of Health.

2. Only those generic drugs which are manufactured by companies recognized by the Drug Regulatory Authority (DRA) are eligible. Company recognition is based on cGMP audit report issued by the DRA.

3. The products registered via Company recognition will entail the same application fee and process as other routes of registration.
4. The DRA will maintain a list of companies that are eligible to apply for registration of their products.

5. Documents required for Registration Via Company Recognition:
    a. Application form (Checklist 5)
    b. Product Sample
    c. Packaging Specimen
    d. Price structure
    e. Letter of Authorization

**Note: Additional documents may be asked as and when deemed necessary.*

Criteria for Disqualification

Products registered via Company Recognition route may have their registration status revoked if:

1. The cGMP audit report during subsequent inspection of the recognized company finds that the company no longer falls unders ‘Very good” rating.
2. The company is no longer operational.
3. If product defect incidence occurs due to severe lapse in the quality from the recognized company.
4. Any other reasons as deemed necessary by the DRA.

Annexure 1: Application forms

APPLICATION FOR REGISTRATION OF MEDICINES VIA COMPANY RECOGNITION

M/s

……hereby apply for registration of the product specified below for sale/distribution in Bhutan.

Type of medicines (*Circle the appropriate one*):

- Human Allopathic
- Veterinary Allopathic
- Herbal Medicine
- Traditional Medicine
- API for extemporaneous preparation

Product Name	Pack Size	Composition (With Strength)	Manufacturer

Documents Required:

- ☐ Letter of Authorization
- ☐ Price Structure
- ☐ Packaging Specimen(*picture of the primary container/package, primary label, secondary label and insert/leaflet if applicable*)
- ☐ Product sample

**Note: Additional documents may be asked as and when deemed necessary.*

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the document above is 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 contravene the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Dated Signature of applicant

with name and contact Number.

Annexure 7: Checklist for compiling dossier

Checklist 5: Checklist for preparation of the application for Registration of medicinal product via company recognition

Documents Required	Tick Mark if it is Available
Application Form	
Packaging Specimen	
Product Sample	
Price structure	
Letter of Authorization	

Drug Regulatory Authority:
Promoting availability of quality, safe and efficacious medicinal products for consumers

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