Guideline for Market Authorization of Medicinal Products via abridged route 2025 - Book II

MPD-G-MA-MAAR-03

Drug Evaluation Section
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Bhutan Food and Drug Authority

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Version History

Version	Release Date	Version history	Revised by
00	2025	Original	See list of contributors

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1. Introduction

The Medicines Act of the Kingdom of Bhutan was enacted in 2003 and the Bhutan Medicines Rules and Regulations in 2005 with subsequent editions in 2008, 2012 and 2019. As per Chapter VI section 16.2 of the Act, "All medicinal products, manufactured, sold, and distributed and imported/ exported from Bhutan shall be registered under the provisions of this act." To facilitate the product registration process, this guideline is drawn up in accordance with Chapter IX of the Bhutan Medicines Rules and Regulation, 2019.

This guideline is developed to guide the applicant in the preparation and submission of drug registration for Abridged applications in the form of a dossier or to make changes to existing registered medicinal products.

The Authority and the Registration Committee for product registration adopts the principle of "Risk-based Approach" for product dossier evaluation which determines the product evaluation route.

The application for registration of the medicinal product can be made by any medicinal product manufacturer within Bhutan, a local wholesale pharmacy licensed firm or a government procurement agency. However, the applicant should ensure that all of the information given in the application form and supporting documents are true and valid at the time of filing application. The evaluation of the medicinal product dossier is done by the technical committee approved by the Board.

This guideline supersedes the Guideline for Registration of Medicinal Products 2020 which has now been divided into various separate guidelines. The guideline will be revised from time to time as deemed necessary by the Authority and the Committee for product registration.

2. Scope

2.1. This guideline shall apply to the following categories of medicinal products:
- 2.1.1. Allopathic Pharmaceuticals Medicine for Human and Veterinary use;
- 2.1.2. Vaccine; or
- 2.1.3. Biologics and Biotechnology products.

2.2. This Guideline shall not apply to any of the following:
- 2.2.1. Health Supplement;
- 2.2.2. Medical Device;
- 2.2.3. General Sale List and borderline product;
- 2.2.4. New Chemical Entities;
- 2.2.5. Herbal and Complementary medicine; and
- 2.2.6. Traditional medicine.

3. Objectives

3.1. The objectives of this guideline encompasses of followings:
- 3.1.1. To streamline and expedite the process of registration of medical products while ensuring safety, quality and efficacy;
- 3.1.2. To provide guidance to the applicant for the preparation, compilation and submission of product dossiers for Marketing Authorization via abridged route; and
- 3.1.3. To provide guidance to the authority during assessment of product dossiers submitted via abridged route.

4. Normative references

4.1. The Medicines Act of the Kingdom of Bhutan 2003; and
4.2. Bhutan Medicines Rules and Regulation 2019.

5. Definitions

5.1. **Act:** It refers to the Medicines Act of the Kingdom of Bhutan 2003.
5.2. **Authority:** It refers to the Bhutan Food and Drug Authority.
5.3. **Regulation:** It refers to the Bhutan Medicines Rules and Regulation.
5.4. **Borderline products:** It refers to products having combined characteristics of medicines along with foods, medical devices or cosmetics thus, the decision of the classification must be taken on a case-by-case basis.
5.5. **Complementary and Herbal Medicines:** Complementary medicine is a set of health care practices that are not part of that country's own tradition or conventional medicine and are not fully integrated into the national health-care system. Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products, that contain as active ingredients parts of plants, or other plant materials, or combinations.
5.6. **Drug Product:** It refers to the dosage form (the finished pharmaceutical product) in the final packaging intended for marketing.
5.7. **Drug Substance (or Active Pharmaceutical Ingredient- API):** It refers to any substance or mixture of substances intended to be used in the manufacture of a

medicinal product and that, when used in the production of a medicine, becomes an active ingredient of the finished product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

5.8. **Excipient (or inactive ingredient):** It refers to any substance other than the drug substance/Active Pharmaceutical Ingredient (API) that is intentionally included in an approved drug delivery system or a finished drug product.

5.9. **Evaluation:** It refers to the assessment of the dossier and product sample submitted by the applicant using a predefined set of criteria.

5.10. **Fixed Dose Combination (FDC):** It refers to the combination of more than one drug at a fixed ratio in a single dosage form for a particular indication.

5.11. **Generic Drug Application(GDA):** It refers to the application for Market Authorization of a generic version of the Innovator medicine.

5.12. **New Drug Application:** It refers to the application for Market Authorization of a New Chemical Entity where the API or formulation has not been approved in any other National Regulatory Authority.

5.13. **New Chemical Entity:** It refers to any novel chemical entity proposed to have medicinal value and has not been approved by any Medicine Regulatory Authority.

5.14. **Reference NRA**: It refers to National Regulatory Authorities that meet any of the following criteria:

5.14.1. They are designated as a WHO-Listed Authority (WLA) or a transitional WLA for the regulation of products covered under this guideline; or

5.14.2. The products within the scope of this guideline have been pre-qualified under the WHO Prequalification (WHO PQ) programme.

5.15. **Type 1 FDC**: It refers to the FDC that contains the same active ingredients in the same doses as an existing FDC available in pharmacopoeias.

5.16. **Type 2 FDC:** It refers to the FDC that contains the same active ingredients in the same doses as an established regime of single entity products, and the dosage regimen is the same. Alternatively the established regime may involve combinations of single entities and FDCs, for example, a single entity drug product combined with an FDC that contains two active ingredients. In all cases, the established regime has a well-characterised safety and efficacy profile, and all of the drug products used in obtaining clinical evidence have been shown to be of good quality.

5.17. **WHO-listed Authority (WLA):** It refers to a regulatory authority (RA) or a regional regulatory system (RRS) that complies with all the relevant indicators and requirements specified by WHO for regulatory capability as defined by an established benchmarking and performance evaluation process.

5.18. **WHO Pre-qualification:** It refers to a service provided by WHO to assess the quality, safety, and efficacy of medicinal products for priority diseases.

6. Acronyms

6.1. **ASEAN**: Association of Southeast Asian Nations
6.2. **BFDA**: Bhutan Food and Drug Authority
6.3. **BMRR**: Bhutan Medicines Rules and Regulation
6.4. **COA**: Certificate of Analysis
6.5. **CTD**: Common Technical Document
6.6. **ICH**: International Council on Harmonisation of technical requirements of pharmaceuticals for human use
6.7. **MA**: Market Authorization
6.8. **MAH**: Market Authorization Holder
6.9. **MAA** : Market Authorization application
6.10. **NRA** : National Regulatory Authority
6.11. **PIC/S**: Pharmaceutical Inspection Co-operation Scheme
6.12. **WHO** : World Health Organisation
6.13. **WLA**: WHO Listed Authority
6.14. **LoQs:** List of Queries
6.15. **GDE:** General Document Evaluation
6.16. **TDE:** Technical Document Evaluation
6.17. **BCS**: Biopharmaceutics Classification system

7. General requirements for the submission of a dossier

7.1. The electronic Dossier must be submitted in PDF and the whole electronic dossier must not exceed **100 mb**.

7.2. The e-dossiers folder is required to be zipped before submission and named in the following format **Generic name & Strength (Brand Name)** before submission.

7.3. The e-dossier must be submitted via an identified online portal.

7.4. The electronic Dossier must be compiled in a folder template organised as given in the *figure given* below.

7.5. For general administrative documents, colour scanned copies of the original documents should be submitted and original hardcopy of documents are not required. However, BFDA reserves the right to request for the submission of the original or certified true copy of the submitted document if there is any doubt that the submitted scanned document is not an accurate reflection of the original document.

7.6. The proof of foreign approvals furnished in the dossier must be valid and should have a validity of at least three months from the date of submission of the dossier.

7.7. All documents submitted must be in English. For documents in their original language which is not English, a certified translation may be acceptable.

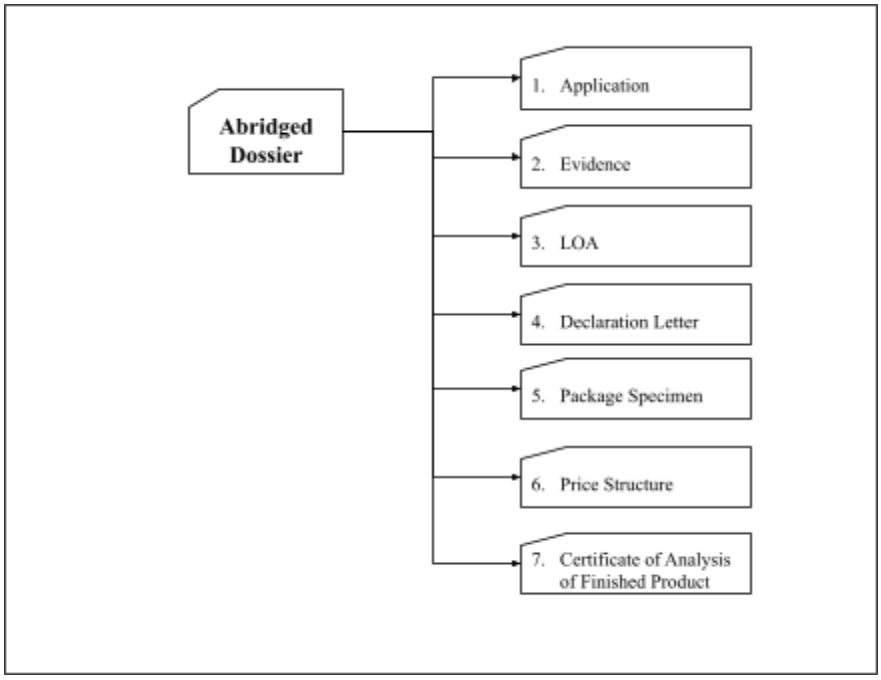


Figure 1: Folder Template for Abridged Dossier

8. Eligibility Criteria for abridged application

8.1.1. The product may be registered through the abridged route upon fulfilment of **ANY** of the following conditions:

8.1.1.1. Registered by WLA or transitional WLA.

OR

8.1.1.2. Pre-qualified by the World Health Organization (WHO) or World Organization of Animal Health (OIE).

OR

8.1.1.3. cGMP audit conducted for foreign manufacturers within the last 2 years and graded as Audit Level 1 by the authority for medicines included in the essential medicine list of Bhutan.

9. Market Authorization exemption

9.1. In accordance with section 5.13 of the Act, and Section 129 of the Regulation, medicines may be exempted from the registration requirement on the following grounds;

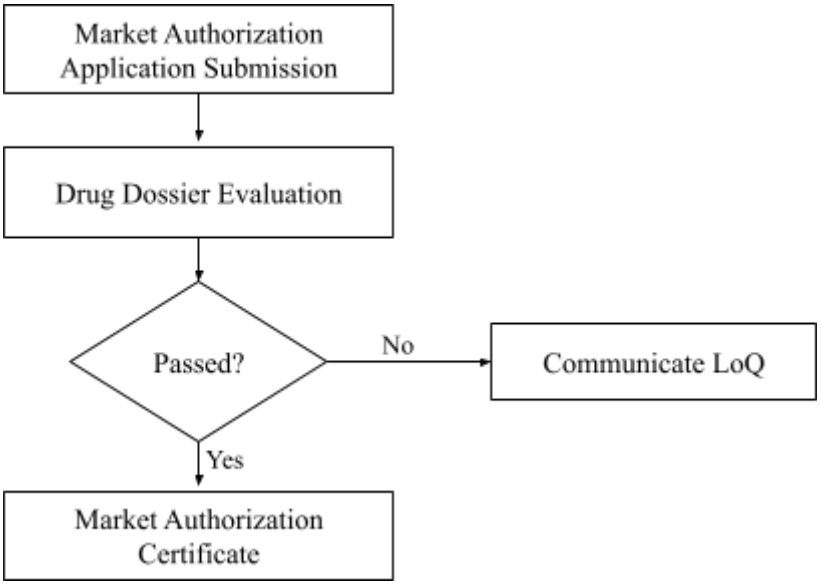
9.1.1. Medicinal product for the purpose of research as approved by the relevant agency or board;

9.1.2. Product sample for the purpose of registration not exceeding the quantities prescribed in this guideline;

9.1.3. Medicinal product for personal use, in a quantity not exceeding the amount stated in the prescription unless justified by a registered medical practitioner;
9.1.4. Limited quantities of medicinal products for specific diseases on a named-patient basis;
9.1.5. In public health emergencies as notified by relevant agencies;
9.1.6. Limited quantities of medicines required for approved medical camps;
9.1.7. All the imported raw materials for the manufacture of medicinal products in the country;
9.1.8. Products not registered but required in limited quantities for time bound government approved projects; or
9.1.9. Medicinal products donated to government agencies or international organisations/institutions.

10. Market Authorization Procedure

10.1. Process flow of the Market Authorization Application



10.2. Description of Market Authorization Procedure

10.2.1. Application submission

10.2.1.1. The applicants will submit the application dossier in the required format via the identified online portal.

10.2.1.2. Ensure that the dossier folder is named as per the required format.

10.2.2. Drug Dossier Evaluation

10.2.2.1. Once the applicant pays the fee and submit a product sample, the Authority will plan for the Drug Dossier Evaluation (DDE).

10.2.2.2. The DDE will be convened at least once a month involving external evaluators when deemed necessary. All external evaluators and experts are bound by conflict of interest and Non-disclosure agreement to protect the information made available to them.

10.2.2.3. The qualification and experience of the evaluators shall be based on the provision of the Quality Manual of the Authority.

10.2.2.4. After the evaluation of the Drug Dossier, the Authority will notify the applicant of the regulatory outcomes i.e. query, approval or rejection.

10.2.2.5. List of Query (LoQ) may be communicated to the applicant, if clarification or additional information is required. The maximum number of rounds for communication of LoQs from the Authority will be capped at two.

10.2.2.6. The applicant has 6 months to address the LoQs in each round of the communication.

10.2.2.7. The Turnaround Time (TAT) for DDE will be 60 calendar days considering Stop-clock principle and commences on the date of approval of the Drug Dossier Evaluation plan.

10.2.2.8. The TAT count will stop when the Authority issues LoQs to the applicant and will restart upon the submission of COMPLETE and SATISFACTORY response from the applicant.

10.2.2.9. The application shall be rejected if:

- 10.2.2.9.1. The Active Pharmaceutical Ingredient (API) is prohibited or banned in any WHO Listed Authority (WLA);
- 10.2.2.9.2. The product is a fixed-dose combination included in the Authority's published list of "Irrational Fixed Dose Combinations";
- 10.2.2.9.3. The documentation demonstrating eligibility for the abridged route of Marketing Authorization has not submitted;
- 10.2.2.9.4. Discovery of data manipulation during the review and evaluation of drug dossiers and its query responses;
- 10.2.2.9.5. The product fails the pre-market testing; or
- 10.2.2.9.6. Failure of the applicant to submit a query response within 6 months from the date of communication of LoQs.

10.2.2.10. Applications that pass the DDE will be issued with the Market Authorization certificate.

11. Document requirements

11.1. Application form

11.1.1. The application form should be submitted as per the prescribed format which will be annexed (i.e. annexure 1) in the guideline and also published on the website of the authority.

11.1.2. All the necessary information as asked by the application form should be filled and signed by authorised personnel of the firm.

11.2. Evidence to support abridged application

11.2.1. Any of the following evidence to support abridged route of registration should be submitted:

11.2.1.1. A copy of the assessment report generated by reference NRA where the product has been assessed and authorised for marketing or a copy of marketing authorization certificate; or

11.2.1.2. An evidence of the prequalification by the World Health Organization (WHO) or World Organization of Animal Health (OIE).

11.3. Letter of Authorisation

11.3.1. The letter of authorization from the manufacturer should be submitted in the specified format as per **Annexure 2**.

11.3.2. The regional offices or authorised marketer of the principal manufacturer may provide a letter of authorization. In such cases, the letter of authorization from the principal manufacturer to these offices/authorised marketer must be submitted.

11.3.3. In case of submission of more than one letter of authorization for the same product, the letter of authorization from the principal company shall be considered.

11.3.4. In case of submission of more than one letter of authorization from equivalent offices of the same manufacturer for the same product(s), the initial one shall be considered.

11.4. Declaration letter

11.4.1. The declaration letter is a document submitted from the manufacturer which mainly assures that the product submitted for registration is the **SAME** product that has been prequalified by the WHO or OIE; or registered and approved for marketing in the country (if WLA approved).

11.4.2. This letter is required only for the first two criteria for the abridged route.

11.4.3. The declaration letter should be submitted as per **Annexure 3** of this guideline.

11.5. Artwork and specimen of package, label and insert

11.5.1. Artwork and Specimen of the packaging including primary label, secondary label and product insert or patient information leaflet (where applicable) should be submitted.

11.5.2. The artwork submitted must contain the the following details:

11.5.2.1. Dimensions of the packaging, labels and inserts; and

11.5.2.2. Colour palette of the packaging, label and inserts.

11.5.3. The specifications of Artwork must be the same as the product sample submitted for registration.

11.5.4. The product label should contain the following information:

11.5.4.1. Product name;

11.5.4.2. Dosage form;

11.5.4.3. Name and strength of active ingredient(s)/ content of formulation with quantity of ingredients per dosage unit;

11.5.4.4. Batch number;

11.5.4.5. Date of manufacture;

11.5.4.6. Date of expiry;

11.5.4.7. Compendial standard where applicable;

11.5.4.8. Route of administration (where applicable);

11.5.4.9. Storage conditions;

11.5.4.10. Name and address of the manufacturer;

11.5.4.11. Pack size (unit/volume);

11.5.4.12. Warnings/ cautions/precautionary information (where applicable); and

11.5.4.13. Directions for handling, where applicable.

11.5.5. If the product is without an outer carton, the inner label should bear all the information stipulated in clause 11.5.4. of this guideline.

11.5.6. If the container label is too small, for example a label of small volume parenteral, not all the above requirements are applicable. The following information must be reflected on such labels:

11.5.6.1. Product name;
11.5.6.2. Name and strength of active ingredient(s);
11.5.6.3. Lot/batch number;
11.5.6.4. Name of the manufacturer, packer, or distributor; and
11.5.6.5. Date of expiry.

11.5.7. A product insert should contain the following information where applicable:

11.5.7.1. Product Name;
11.5.7.2. Name and strength of active ingredient (s);
11.5.7.3. Product description;
11.5.7.4. Pharmacodynamics / Pharmacokinetic;
11.5.7.5. Indication;
11.5.7.6. Recommended dose;
11.5.7.7. Mode of administration;
11.5.7.8. Beyond use date (Where applicable);
11.5.7.9. Contraindication;
11.5.7.10. Warnings and precautions;
11.5.7.11. Drug interactions;
11.5.7.12. Pregnancy and lactation;
11.5.7.13. Undesirable effects;
11.5.7.14. Overdose and treatment;
11.5.7.15. Storage condition;
11.5.7.16. Dosage forms and packaging; and
11.5.7.17. Withdrawal Period for food producing animals (For Veterinary Medicines).

11.6. Price structure

11.6.1. The price structure should be submitted as per **Annexure 4** of this guideline.

11.6.2. The Currency of the price structure should be either in USD, INR or BTN.

11.6.3. The MRP reflected in the price structure will be considered as the MRP of the product in the kingdom of Bhutan.

11.7. Sample

11.7.1. Applicants must submit the product sample during the payment of application fee.

11.7.2. The Product sample is used to verify the product with the information provided in the dossier. Product samples may be tested as part of the evaluation process by the Authority.

11.7.3. The product sample quantity required may vary depending on the type of packaging used. The applicant may consult the Authority on the quantity of samples to be submitted initially. In general, one commercial unit of the product should be submitted.

11.7.4. For the purpose of testing, additional samples should be submitted by the MAH at free of cost as per the sample size determined by the testing laboratory and/or as per sampling guideline of the Authority.

11.7.5. Sample must be intact, in the final commercial pack along with product insert or patient information leaflet (where applicable).

11.7.6. The product sample must have a remaining shelf-life of at least 6 months at the time of submission.

11.7.7. Controlled drugs or medicines requiring cold chain monitoring may be exempted from submission of samples.

11.8. **Certificate of Analysis (for third eligibility criteria only)**

11.8.1. The specification and method of analysis used for testing of the finished product should be provided.

11.8.2. For the In-Housed methods, the analytical method validation protocol and report should be submitted for those critical quantitative testing parameters used for the testing of finished products.

11.8.3. For the compendial methods, all test parameters performed should be as per the latest edition of the pharmacopoeia referred.

11.9. For the registration of FDCs, the FDC should not be in the "List of irrational FDCs" published by the Authority.

11.10. The applicant shall submit the rationale of FDC which must demonstrate a positive/synergistic effect as compared to individual administration.

11.11. Provision to furnish additional documents as and when required by the authority.

12. RENEWAL OF MARKET AUTHORIZATION

12.1. General principle for Renewal of Market Authorization

12.1.1. Market Authorization Certificates issued will have life long validity provided periodic renewal and timely post approval variations requirements are complied with.

12.1.2. The Market Authorization will be renewed every three years and Post approval variations shall be done prior to the renewal or during the renewal process.

12.1.3. Applicants can apply for renewal of their Product MA certificate within 90 days from the date of expiry of the MA certificate.

12.1.4. A grace period of one month may be granted after the expiry of the MA Certificate.

12.1.5. Upon expiry of the grace period, failure to renew the Market Authorization shall be dealt with in accordance with the provisions of the Act and Regulation thereunder.

12.2. Procedure:

12.2.1. The applicant must submit the application for renewal of the MA certificate to the Authority.

12.2.2. The application must contain the following documents;

- 12.2.2.1. Duly filled application form for renewal;
- 12.2.2.2. Declaration Letter (as per Annexure 3);
- 12.2.2.3. Updated Letter of Authorization from the Manufacturer (if applicable); and
- 12.2.2.4. Application fee.

12.2.3. The application documents will be reviewed by the authority and if there are discrepancies, LoQ will be communicated to the applicant. The Turnaround time for the renewal of market authorization will be 60 calendar days considering Stop-clock principle.

12.2.4. Applicants will need to provide a query response within 6 months from the date of communication of LoQs.

12.2.5. The number of communication for LoQs will be capped at two.

12.2.6. The MA certificate can be cancelled at any time if the Authority discovers grounds to believe that the product may be a potential threat to the public.

13. Market Authorization Transfer of Product

13.1. The marketing authorization of the registered product may be transferred if the manufacturer authorises a new MAH when the registered product has a remaining validity of at least one month.

13.2. An application to transfer the marketing authorization of a product shall be submitted with the prescribed fees.

13.3. Following are the documents required for transfer of MAH:

13.3.1. Letter of Authorization from the principal manufacturer to the new MAH specifying the name of the product; and

13.3.2. No Objection Certificate or letter from the current MAH.

14. Cancellation, suspension and withdrawal of Market Authorization

14.1. The cancellation, suspension and withdrawal of Marketing Authorization shall be done as per the *Guideline for Cancellation, suspension and withdrawal of Market Authorization of medical products*.

15. Issuance of duplicate Marketing Authorization certificate

15.1. The issuance of duplication marketing authorization certificate shall be done as per the provision under the Bhutan Medicine Rules and Regulation with the prescribed fees.

16. References

16.1.

ANNEXURES

Annexure 1: Application form

APPLICATION FORM FOR ABRIDGED REGISTRATION OF MEDICINES

M/s…… hereby apply for abridged registration of the product specified below for sale/distribution in Bhutan as per the Guideline.

Product	Pack	Composition (With Strength)	Manufacturer

I hereby declare that one of the following conditions are fulfilled (please tick the boxes):

☐ Registered by WLA or transitional WLA;

OR

☐ Pre-qualified by the World Health Organization (WHO) or World Organization of Animal Health (OIE);

OR

☐ cGMP audit report graded with "Very good" by the authority for a multinational manufacturer wherein registration is eligible only for medicines included in the essential medicine list of Bhutan.

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 fulfil 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 No.

Annexure 2: Letter of Authorisation

Letter Head of the company

Date:.....

Letter of Authorization

M/s ***(name of the firm).....*** having our registered office at ***(address of the firm including name of place, country)***……. hereby authorise ***(name of the authorization holder including government ministry, procurement agency, Market Authorization Holder).....*** having its office in Bhutan to apply and obtain registration certificate of the following medicinal products from Bhutan Food and Drug Authority.

1. (name of product)
2. (name of product)

(Name of authorization holder)…….. shall be sole dealer responsible for above product/s from the company and will be accountable for the performance of above products in Bhutan.

Further, the invoice will be generated from the (***name of the firm or regional office etc of the company)***…… which will be used for applying for Import Authorization.

This letter of Authorization shall be valid for a period of (number of years)…….. from above date unless suspended or revoked, the reason of which will be shared with Bhutan Food and Drug Authority.

This authorization cannot be assigned, transferred and/or sub delegated to any person or party without written approval from the principal manufacturer.

Authorised signatory
(Managing Director)
Name of the firm

(seal and logo)

Annexure 3: Declaration Letter for Abridged Route of Registration

Letter Head of the company

Date:.....

Declaration Letter for Abridged route of registration

M/s **(name of the firm)**..... having our registered office at **(address of the firm including name of place, country)**……. hereby declare that there is no change in any aspect of the product which is registered by WLA or tWLA/pre-qualified by WHO or OIE (tick).

The details of the registered medicinal product are as follows:

Generic Name:…….
Brand Name:…….
Registration/Pre-qualification Number:……..
Date of expiry of pre-qualifcation/registration:……

Authorised signatory
(Managing Director/Head of the Company)
Name of the firm

(Seal and logo of the company)

Annexure 4: Declaration Letter for renewal registration

Letter Head of the company

Date:.....

Declaration Letter for renewal registration

M/s **(name of the firm)**..... having our registered office at **(address of the firm including name of place, country)**……. hereby declare that there is no change in any aspect of the product which is registered with the Drug Regulatory Authority of Bhutan for the purpose of renewal of registration. The aspects shall include but not limited to quality, safety and efficacy of the medicinal product.

The details of the registered medicinal product are as follows:

Product Name:…….
Registration Number:……..
Date of expiry of registration:……

Tick appropriate box:

☐ The above product has been imported in the country during the validity of the initial registration with no cases of safety, efficacy or quality issues.

OR

☐ The above product has not been imported in the country during the validity of the initial because ……(*state reason and why applicant wants to renew*)…….

A copy of the medicinal product registration certificate is submitted along with this declaration letter.

Authorised signatory
(Managing Director/Head of the Company)
Name of the firm

(Seal and logo of the company)

Annexure 5: Price Structure

Letter Head of the company

Date:.....

Price Structure

Sl.no	Brand Name (Generic name) and Strength	Pack Size	Price to Distributor	Price to Retailer	MRP

Authorised signatory
(Proprietor of MAH)
Name of the firm

(Seal and logo of the company)

Authorised signatory
(Managing Director/Head of the Company)
Name of the firm

(Seal and logo of the company)

Quality Policy of Medical Product Division

"We commit to provide consistent regulatory operations with risk based planning and continual improvement in compliance with the recognized standards to meet our consumers' satisfaction and confidence".

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