MPD-G-MA-MASR-02

Guideline for Market Authorization of medicinal products via standard route, 2024 - Book I

Drug Evaluation Section
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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 , 2019 and 2025. 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, 2025.

This guideline is developed to guide the applicant in the preparation and submission of application for Marketing Authorization of medicinal products. This guideline focuses on the requirements and procedures for Market Authorization of medicinal products through Standard route. The guideline is based on the ASEAN Common Technical Document (ACTD) and ICH Common Technical Documentation (CTD) with inclusion of specific requirements for Bhutan.

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

2. Scope

2.1. This guideline shall apply to the following categories of medicinal products:

2.1.1. Allopathic Pharmaceuticals Medicines for Human and Veterinary Use

2.1.2. Active Pharmaceutical Ingredients

2.2. This Guideline shall not apply to any of the following:

2.2.1. Health Supplement

2.2.2. Vaccine

2.2.3. Biologics and Biotechnology product

2.2.4. Medical Device

2.2.5. General Sale List and borderline product

2.2.6. New Chemical Entities.

2.2.7. Traditional Medicines

2.2.8. Complementary Medicines and Herbal Medicines

3. Objectives

3.1. The objectives of this guideline encompasses the following:

3.1.1. To describe the process of market authorization of medicinal products via the Standard route.

3.1.2. To provide guidance to the applicant for the preparation, compilation and submission of product dossiers for Market Authorization.

3.1.3. To provide guidance to the authority during assessment of product dossiers.

4. Normative references

4.1. The Medicine Act of the Kingdom of Bhutan 2003

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** refers to the Bhutan Food and Drug Authority, Royal Government of Bhutan.
5.3. **Abridged route of Market Authorization** refers to a procedure for Market Authorization where documents requirements in the dossier are not extensive as compared to the Standard route in merit of fulfilling reliance criteria set by the Authority.
5.4. **Complementary and Herbal Medicines:** Complementary medicine refers to 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.
5.5. **Drug Product** refers to the dosage form (the finished pharmaceutical product) in the final packaging intended for marketing.
5.6. **Drug Substance (or Active Pharmaceutical Ingredient- API)** 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.
5.7. **Excipient (or inactive ingredient)** 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.
5.8. **Evaluation** refers to the assessment of the dossier and product sample submitted by the applicant using a predefined set of criteria.
5.9. **Fixed Dose Combination** refers to the combination of more than one drug at a fixed ratio in a single dosage form for a particular indication.
5.10. **Generic Drug** refers to a pharmaceutical drug that contains the same chemical substance as a drug that was originally protected by chemical patents. Its authorisation is based on efficacy and safety data from studies on an authorised medicine.
5.11. **Generic Drug Application(GDA)** refers to the application for Market Authorization of a generic version of the Innovator medicine.
5.12. **New Drug Application** 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** refers to any novel chemical entity proposed to have medicinal value and has not been approved by any Medicine Regulatory Authority.
5.14. **Standard Route of Registration** refers to the procedure for Market Authorization where documents as per the ICH CTD or ACTD must be submitted.
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.

6. Acronyms

6.1. **ASEAN**: Association of Southeast Asian Nations
6.2. **ACTD:** ASEAN Common Technical Documentation
6.3. **BFDA**: Bhutan Food and Drug Authority
6.4. **BMRR**: Bhutan Medicines Rules and Regulation
6.5. **COA**: Certificate of Analysis
6.6. **CTD**: Common Technical Document
6.7. **FPP** : Finished Pharmaceutical Product
6.8. **ICH**: International Council on Harmonisation
6.9. **MA**: Market Authorization
6.10. **MAH**: Market Authorization Holder
6.11. **MRP** : Maximum Retail Price
6.12. **NRA** : National Regulatory Authority
6.13. **PIC/S**: Pharmaceutical Inspection Co-operation Scheme
6.14. **SMF** : Site Master File
6.15. **WHO** : World Health Organisation
6.16. **WLA**: WHO Listed Authority
6.17. **LoQs:** List of Queries
6.18. **GDE:** General Document Evaluation
6.19. **TDE:** Technical Document Evaluation
6.20. **BCS**: Biopharmaceutics Classification system
6.21. **ICH**: International Council for Harmonisation o

7. General Principles for Market Authorization

7.1. Exclusivity of Generic Medicines

7.1.1. The Authority will accept only Generic Drug Applications for Market Authorization in case of allopathic pharmaceutical medicines.

7.1.2. New Drug Applications of New Chemical Entities or formulations that have not been approved by any other NRA will not be accepted for Market Authorization except in public emergencies or other similar cases.

7.2. Recognized Standards

7.2.1. Finished pharmaceutical Products applied for Market Authorization must comply with the specifications in any one of following Pharmacopoeia:

i. British Pharmacopoeia
ii. United States Pharmacopoeia
iii. Indian Pharmacopoeia
iv. International Pharmacopoeia
v. Japanese Pharmacopoeia
vi. European Pharmacopoeia

7.2.2. For Type-2 FDCs, where FPP is not in any pharmacopoeia, it will be assessed on a case by case basis.

7.3. Routes of Market Authorization

7.3.1. The Authority will issue Market Authorization via two routes:

i. Standard Route of Market Authorization
ii. Abridged Route of Market Authorization

7.3.2. This Guideline will focus on the Standard Route of Market Authorization

7.3.3. For Abridged Route of Market Authorization please refer *Guideline for Market Authorization of medicinal products via abridged route, 2023- Book II.*

8. General Requirement for MA Application Dossier (For Standard Route)

8.1. Document Organization

The dossier should be submitted as per the Asean Common Technical Documentation (ACTD) or ICH Common Technical Documentation (CTD) format.

Document	**Location in**	
	ICH CTD	**ACTD**
Administrative Documents and Product Information	Module 1	Part I
Common Technical Document Overview and Summaries	Module 2	*Incorporated in Part II*
Quality Documents	Module 3	Part II

8.2. Electronic Format

The complete MA application dossier – i.e. Modules 1 to 3 of the ICH CTD or Parts I to II of the ACTD – must be submitted in an electronic format.

Electronic Dossier Format Requirements:

i. The electronic Dossier must be compiled in a folder template organised in either ICH CTD or ACTD. *Refer Figure 1a & 1b*
ii. All documents must be submitted in PDF and the whole electronic dossier must not exceed **250 mb**.
iii. The e-dossiers folder is required to be zipped before submission and named in the following format **Generic name & Strength (Brand Name)** before submission.
iv. The e-dossier must be submitted via an identified online portal.

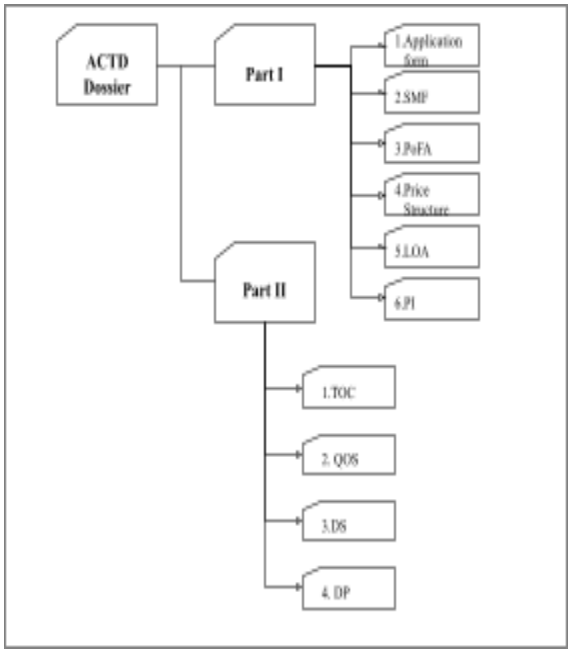


Figure 1a: Folder Template as per ACTD documentation

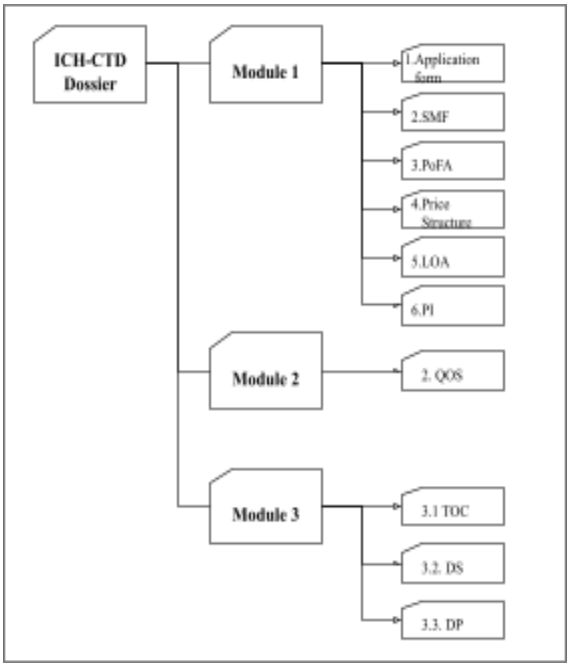


Figure 1b: Folder Template as per ICH-CTD documentation

For Module 1/Part I: 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

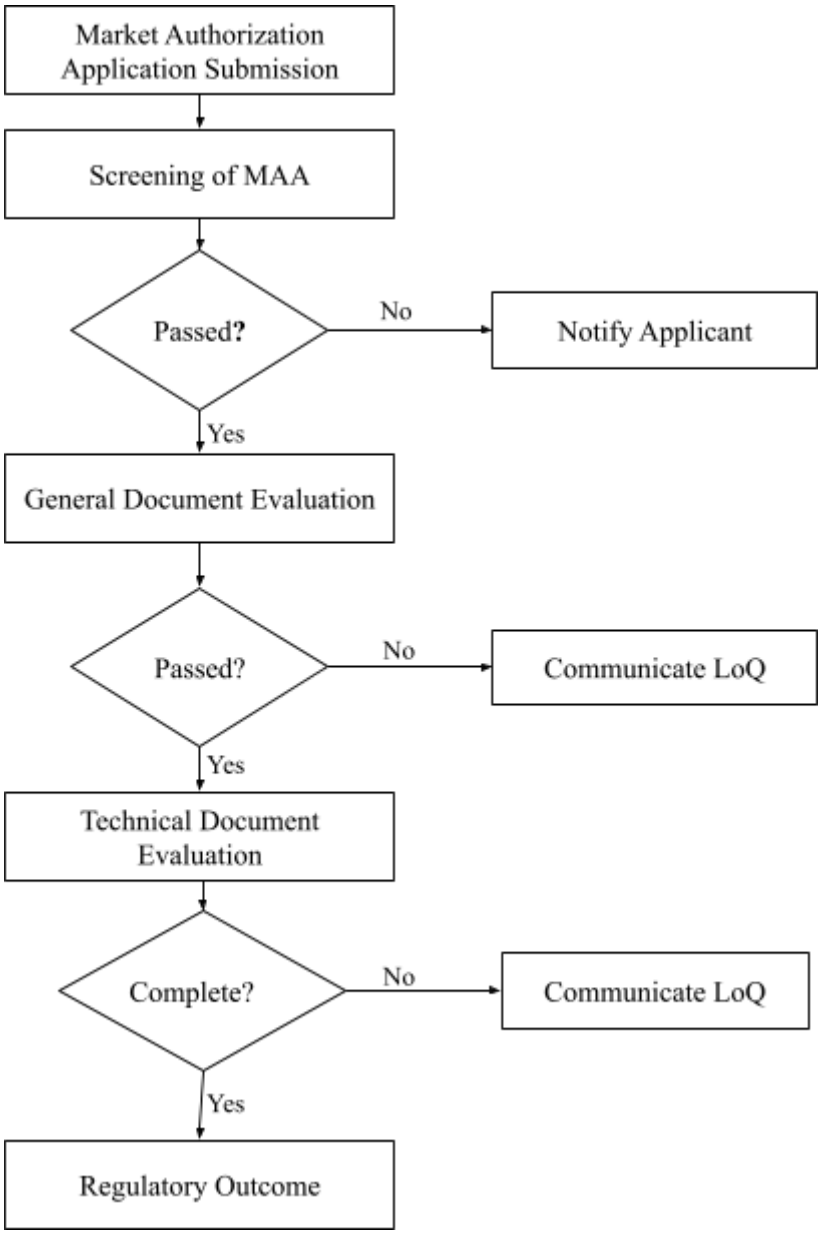
For Module 2 to 3/Part II:Applicants must submit the documents in soft copy that is **text searchable** or **OCR enabled.**

8.3. **Language and Translation**

All documents submitted must be in English and/or in Dzongkha. For documents in their original language which is not English or Dzongkha, a **certified translatio**n may be acceptable.

9. Market Authorization Procedure

9.1. Process flow of the Market Authorization Application



9.2. Description of Market Authorization Procedure

9.2.1. Application Submission

i. The applicants will submit the application dossier in the required format via the identified online portal.
ii. Ensure that the dossier folder is named as per the required format.

9.2.2. Screening of Application

i. Upon successful submission of the application by the clients, the authority will screen the e-dossiers.
ii. Screening of the dossier involves evaluation of the format of the E-dossier.
iii. After screening, the authority will notify the applicant of the outcome.
iv. Rejection during screening shall require resubmission of the application with the requisite amendments.
v. Approval during screening shall require the payment of application fee **(certificate fee)** and the submission of the product samples
vi. The Turnaround Time for screening of application will be **3 working days** from the date of submission.

9.2.3. General Document Evaluation of Application

i. Upon payment of application fee and submission of Product samples the General Document evaluation(GDE) of the dossier will commence.
ii. During the GDE the administrative and Regulatory Documents i.e Module 1/Part I will be evaluated.
iii. The date of payment of application fee and Product sample submission will be considered as the starting date of the GDE timeline.
iv. The turnaround time for GDE will be **15 Calendar days** considering Stop Clock Principle.
v. If deficiencies are identified in the application, a **General List of Queries** (**LoQ**) will be sent to the applicant.
vi. If the applicant fails to address the deficiencies raised during GDE, the application will be rejected.
vii. The stop-clock starts when LoQ is sent and ends upon receipt of a complete and satisfactory response to the query from the applicant.
viii. The total number of rounds of LoQs sent during GDE will be capped at two.
ix. An applicant has fifteen (15) **calendar days** to respond to each round of query starting from the date of dispatch of the query.
x. The application will only be accepted when all the LoQs have been adequately addressed and the Authority is satisfied that the dossier is complete for Technical Document Evaluation (TDE).
xi. The application may be rejected during this stage if the applicant fails to submit a query response within **15 calendar** days from the dispatch of the LoQ.

xii. If the application is subsequently re-submitted, it will be processed as a new application.

9.2.4. Technical Document Evaluation of Application

i. Once the application has passed the GDE, the application will commence to the Technical Document Evaluation (TDE) stage.
ii. TDE involves the evaluation of Quality Documents under Module 2 to 3/Part II of the Dossier.
iii. **Technical LoQ** may be issued to the applicant if clarification or additional information is required. The maximum number of rounds for communication of Technical LoQs from the Authority will be capped at two.
iv. The Turnaround time for TDE will be 60 calendar days considering Stop-clock principle and commences on the date of approval of the Technical Dossier evaluation plan.
v. The TAT count will stop when the Authority Issues Technical LoQs to the applicant and will restart upon the submission of COMPLETE and SATISFACTORY response from the applicant.
vi. The applicant has 6 months to address the Technical LoQs in each round of the communication. (Total 1 Year)
vii. After completion of TDE, the authority will issue regulatory outcomes in the form of rejection of application or Approval of the Product.
viii. Applications that pass the TDE will be issued with the Market Authorization certificate .
ix. The calculation of TAT ceases on the date of regulatory outcome.
x. The application shall be rejected due to the following:
    - Entire **sections or Subsections** of the dossier are missing.
    - Mismatch of information provided between Module 1/Part I and Module 2 to 3/ Part II.
    - Mismatch of information among different sections under Module 2 to 3/ Part II.
    - Discovery of data manipulation during the communication of LoQs and Query responses.
    - The product sample fails the pre-market testing.
    - Failure of the applicant to submit a Query Response within 6 months from the date of communication of technical LoQs.
xi. The Authority may engage external evaluators, experts and advisory committees in the evaluation process, when deemed necessary. These experts may be included from both local or/and overseas institutions. All external evaluators and experts are bound by conflict of interest and Non-disclosure agreement to protect the information made available to them.
xii. The qualification and experience of the evaluators shall be based on the provision of the Quality Manual of the Authority.

10. Specific Document Requirement for MA Application Dossiers

The Specific document requirements for Market Authorization will be based on the guidance documents published by the WHO and the ICH. This Guideline will focus on Allopathic Pharmaceutical Medicines for Human and Veterinary use.

Allopathic Pharmaceutical Medicine For Human And Veterinary Use

1. **PART I/Module 1** : Administrative Data And Product Information
2. **PART II/Module 2-3**: Quality Data

PART I /MODULE 1:ADMINISTRATIVE DATA AND PRODUCT INFORMATION

The following documents must be submitted under this Dossier Section

1. Application Form
2. Site Master File (*Exempted for local Manufacturers*)
3. Proof of Foreign Approval (*Exempted for local Manufacturers*)
4. Letter of Authorization (*Exempted for local Manufacturers*)
5. Price Structure (*considerations on applicability for Local industry)*
6. Artwork and Specification of Package, Label and Insert
7. Product Information
8. Product Sample
9. Regulatory status and rationale for combination (For FDCs only)

1. Application Form

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

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

2. Site Master File

2.1. The applicant must submit the Site Master File as per the WHO format including the Annexes (1 to 8).

2.2. The SMF must be of the latest effective version.

2.3. The submission of SMF is not applicable for the in-country manufacturers

3. Proof of Foreign Approval

3.1. The applicant must submit documents that show that the product is approved from the country of origin. Any of the following documents will be accepted as Proof of Foreign Approval.

3.1.1. Assessment report of the product by the Country of Origin; or

3.1.2. Market Authorization Certificate **or equivalent documents** from the country of origin; or

3.1.3. Certificate of Pharmaceutical Product (In WHO format) issued by the Country of origin; or

3.1.4. Free Sale Certificate (Veterinary Medicines only)

4. Letter of Authorization

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

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

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

4.4. In case 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.

5. Price Structure

5.1. The price structure should be submitted as per **Annexure 4**.

5.2. The Currency of the price structure should be in USD, INR or Nu.

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

6. Artwork and Specification of Package, Label and Insert

6.1. Artwork and Specification of the packaging including primary label, secondary label and product insert/patient information leaflet where applicable should be submitted.

6.2. The artwork submitted must contain the the following details

- 6.2.1. Dimensions of the packaging, labels and inserts
- 6.2.2. Colour palette of the packaging, label and inserts

6.3. The specifications of artwork submitted during evaluation must be the same as the commercial version of the product.

6.4. The product label should contain the following information:

- 6.4.1. Product name
- 6.4.2. Dosage form
- 6.4.3. Name and strength of active ingredient(s)/ content of formulation with quantity of ingredients per dosage unit
- 6.4.4. Batch no.
- 6.4.5. Date of manufacture
- 6.4.6. Date of expiry
- 6.4.7. Compendial standard where applicable
- 6.4.8. Route of administration (where applicable)
- 6.4.9. Storage conditions
- 6.4.10. Name and address of the manufacturer
- 6.4.11. Pack size (unit/volume)
- 6.4.12. Warnings/ cautions/precautionary information (where applicable)
- 6.4.13. The words “For animal use only” or words bearing similar meaning (For Veterinary Medicines)
- 6.4.14. Directions for handling, where applicable.

6.5. If the product is without an outer carton, the inner label should bear all the information that is required.

6.6. 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:

- 6.6.1. Product name
- 6.6.2. Name and strength of active ingredient(s)
- 6.6.3. Lot/batch number;
- 6.6.4. Name of the manufacturer,
- 6.6.5. Date of expiry

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

- 6.7.1. Product Name
- 6.7.2. Name and strength of active ingredient (s)
- 6.7.3. Product description

6.7.4. Pharmacodynamics / Pharmacokinetic
6.7.5. Indication
6.7.6. Recommended dose
6.7.7. Mode of administration
6.7.8. Contraindication
6.7.9. Warnings and precautions
6.7.10. Drug interactions
6.7.11. Pregnancy and lactation
6.7.12. Undesirable effects
6.7.13. Overdose and treatment
6.7.14. Storage condition
6.7.15. Dosage forms and Type of packaging
6.7.16. Withdrawal Period for food producing animals (For Veterinary Medicines)

6.8. The information provided in the label should be consistent with the information in the dossier for market authorization.

7. Product Information

7.1. The product information should contain the following information on drug product:

7.1.1. Generic or International Nonproprietary name (INN)
7.1.2. Brand name or trade name (if applicable)
7.1.3. Dosage form
7.1.4. Strength
7.1.5. Compendial/ In-house specifications
7.1.6. List of all the ingredients in the dosage form and their amount on a per unit basis, as per the label claim and batch quantities
7.1.7. Description of the organoleptic characteristics
7.1.8. Commercial presentation of packaging and pack size
7.1.9. The therapeutic category/pharmacological classification to which the pharmaceutical product belongs
7.1.10. Indication
7.1.11. Dose and directions for use for each indication
7.1.12. Mechanism of Action(s) for the claimed indication
7.1.13. List of all the major and common side effects. Side effects specific to the particular drug including newly recognized side effects should be identified.
7.1.14. Information on use in pregnancy, breastfeeding and other special group of patients including known contraindications and compatibility of use of the finished product during pregnancy and breastfeeding.
7.1.15. Withdrawal Period for food producing animals (For Veterinary Medicines)

8. Product Sample

8.1. Applicants must submit the product sample upon passing the screening phase of the application.

8.2. 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.

8.3. 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.

8.4. 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.

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

8.6. It is recommended that the sample must have a remaining shelf-life of at least 6 months at the time of submission.

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

9. Regulatory Status and rationale for combination

For the registration of FDCs, the applicant must submit:

9.1. Rationale of combination which must demonstrate a positive/synergistic effect as compared to individual administration

9.2. Evidence of prior approval by at least two National Regulatory Authorities.

PART II/MODULE 2-3: QUALITY DATA

1. QUALITY DOCUMENTS REQUIREMENTS

The data under this section must be submitted as per the following Guidelines:

1. ICH M4Q: COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE QUALITY OVERALL SUMMARY OF MODULE 2 AND MODULE 3: QUALITY

   OR

2. THE ASEAN COMMON TECHNICAL DOSSIER (ACTD) FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE Part II: QUALITY

2. Product Interchangeability data

In addition to the quality documents, some products will be required to submit product interchangeability data via in-vivo bioequivalence study or In-vitro comparative dissolution studies. The requirements for product interchangeability will be as per the following technical guidance documents;

WHO Expert Committee on Specifications for Pharmaceutical Preparations: *Guidance for organisations performing in vivo bioequivalence studies*
ICH M13 *Bioequivalence for immediate release solid oral dosage forms*

2.1. Products requiring Bioequivalence Study data

The list of products requiring bioequivalence will be published by the Authority via its official website.

2.2. Products not requiring Bioequivalence study data

The following products do not require the submission of bioequivalence study data.

1. Simple aqueous intravenous solutions or powders for reconstitution.
2. Orally administered suspensions and solutions
3. Products containing therapeutic substances which are not systemically or locally absorbed (eg, antacids, anthelmintics, barium sulphate enemas or oral suspensions, nonbiodegradable ion exchange resins or other non-biodegradable long chain polymers, powders in which no ingredient is absorbed).
4. Vaccines
5. Topical medicines

6. Products containing exclusively Vitamins and Minerals
7. Nebuliser solutions.
8. Nasal sprays intended for local action.

2.3. Biowaivers

Applicants can request for exemption of in-vivo Bioequivalence study as per the following guidelines.

1. WHO guideline on biopharmaceutics 5 Classification System -based Biowaivers
2. ICH M9 guideline on biopharmaceutics classification system-based biowaivers

Note: The requirements will be subject to changes as and when these guidelines are updated and the latest versions shall apply

11. RENEWAL OF MARKET AUTHORIZATION

11.1. General principle for Renewal of Market Authorization

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

11.1.2. 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.

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

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

11.1.5. Upon the completion of the grace period or failure to provide the evidence of having carried out the renewal process, the product registration shall be cancelled.

11.2. Procedure:

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

11.2.2. The application must contain the following documents;

11.2.2.1. Duly filled application form for renewal.

11.2.2.2. Declaration Letter (*as per Annexure 3)*

11.2.2.3. Updated Letter of Authorization from the Manufacturer (*if applicable*)

11.2.2.4. Application fee

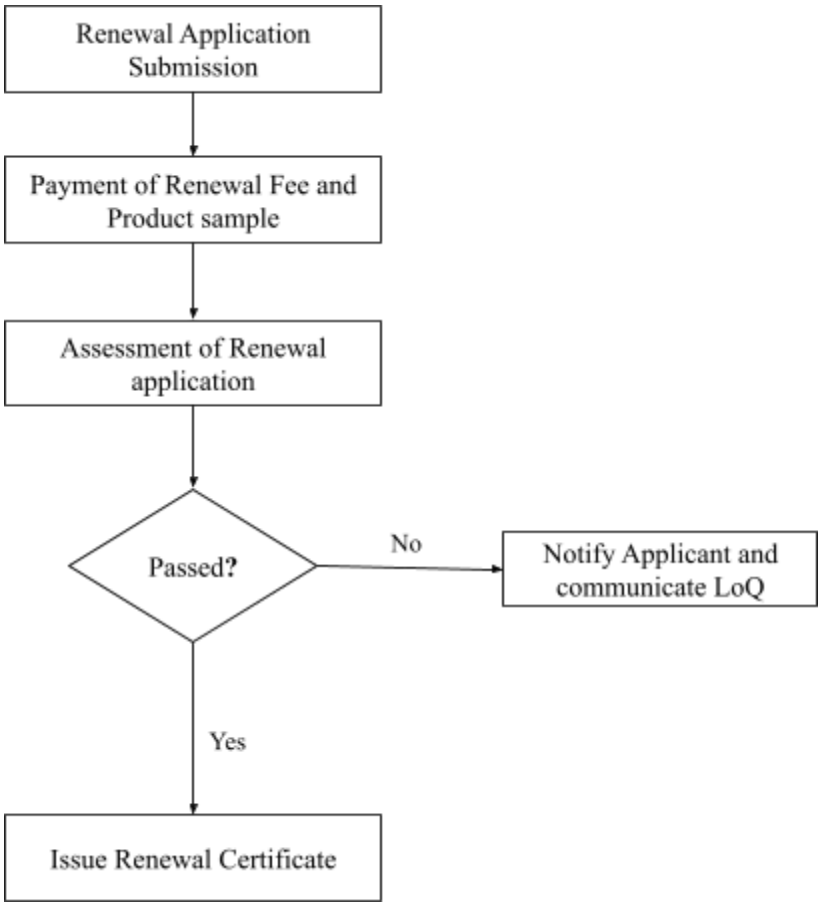
11.2.3. The application documents will be reviewed by the authority and if there are discrepancies, LoQ will be communicated to the applicant. The Turnaround time for the renewal of market authorization will be 60 calendar days.

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

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

- The renewal fee will be as per the prescribed amount in the current Regulation
- 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.

11.3 Process flow for renewal of Market Authorization



Annexure 1: Application form

APPLICATION FORM FOR STANDARD ROUTE OF REGISTRATION OF MEDICINES

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

Product	Pack	Composition (With Strength)	Manufacturer

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

Letter Head of the company

Date:.....

Declaration Letter

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.

☐ 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.
A copy of of the import authorization of the product is submitted along with this declaration(*if first checkbox is selected*)

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

(Seal and logo of the company)

Annexure 4: 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, Bhutan Food and Drug Authority

"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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