

**Form: XX-ER**

**Regulation No.: BMB directives**

**APPLICATION FORM FOR EXPEDITED REGISTRATION OF MEDICINES**

I/We ..... hereby apply for expedited registration of the product specified below for sale/distribution in Bhutan as per the Product Registration Guideline.

In support of registration of medicinal product by above process, following documents are attached:

- i. Letter of Authorization from the Manufacturer.
- ii. Specimen of package, label and insert.
- iii. Product Samples
- iv. Price structure

Details of Medicinal Product *(Use one application per product)*

Product	Pack Size	Composition with Strength	Manufacturer

Name of the Market Authorization Holder:

Application Fee has been deposited to the Royal Government of Bhutan vide revenue receipt No..... (Attach copy)

All the following conditions of Expedited Registration are fulfilled *(please tick the boxes)*:

- Minimum of 5 products with valid registration status registered with DRA for minimum of 2 years at the time of application;
- No past record of product recall or withdrawal from Bhutan (voluntarily recalls by Manufacturers do not apply);
- Not more than 2 post registration change applied for a single product in one year;
- For parenteral, at least ONE parenteral product to be registered amongst the 5 valid.

Signature of Applicant: .....

Name: .....

Address.....

Phone Number: .....