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**

Is Product Insert Applicable? Yes ☐ No ☐

State the type of packaging: …….

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 circle the dots):*

- 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.

Name & Signature: ……
Address……
Phone Number: …….

Date of Application: ……..