**APPLICATION FORM FOR EXPEDITED REGISTRATION OF MEDICINES**

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

| Product | Pack | Composition (With Strength) | Manufacturer |
|---|---|---|---|
| | | | |

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

Note: Out of three criteria, one must be fulfilled.

- ☐ 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.

OR

- ☐ cGMP compliant manufacturer verified from the GMP inspection report of the Authority and/or other MRA wherever applicable;

OR

- ☐ Registered by at least two other MRAs.

***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 contravenes 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.