དཔལ་ལྡན་འབྲུག་གཞུང་། གསོ་བ་ལྟན་ཁག་ འབྲུག་བཟའ་ཚས་དང་སྨན་རིགས་དབང་འཛིན།

ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY

APPLICATION FOR AUTHORIZATION TO IMPORT MEDICAL PRODUCT(S) FOR SALE/DISTRIBUTION

I/we hereby apply for authorization to import for following medical products in Bhutan for sale and distribution.

SN	Product Name	Registration No.	Registration Validity	Manufacturer	Pack size

Address of the premise(s)/Store(s):

Is the product registered by the applicant? Yes ☐ No ☐ *(Please tick the appropriate box)*

(*Please attach the following Documents*)

Note: The following documents are not required for Import Authorization for personal use, health camp, research purpose and special purpose

Documents required for registered medical products	Documents required for non-registered medical products
1. Proforma Invoice; 2. Evidence of route of import (Airway bill OR Transport consignee note) 3. No Objection letter from the Market Authorization holder in case the importer is different from the Market Authorization holder.	1. Certificate of Analysis (CoA) or performance data/report (in case of medical devices); 2. Manufacturing license; 3. cGMP certificate; 4. Specimen of packaging (package, label and insert); and 5. Route of import permit (Airway bill OR Transport consignee note) 6. Proforma Invoice; 7. Supply Order

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 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.

Date:

Signature of Applicant
Name, Address, Contact details