

Form: BMRR III-PAM

APPLICATION TO SET UP A MANUFACTURING PLANT FOR MEDICINAL PRODUCTS

I/We.....
of..... hereby apply for the
grant/renewal of a provisional authorization to set up a manufacturing plant for medical products and
I/we have attached the following documents (circle the appropriate one):

1. Proposal to manufacture medical products
2. Detailed Plant Layout with description

The plant is expected to be operational with effect from
.....

Application fee has been deposited to the Royal Government of Bhutan (please submit a copy).

Declaration (please tick the boxes)

- ☐ I hereby declare that the documents submitted above/all information provided in the documents 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 provisions of the Act and Regulations thereunder.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority

Signature of Applicant
Name, Address, Contact No.

Date: