

Form: BMRR XII-PAV

APPLICATION FOR POST APPROVAL VARIATIONS OF MEDICINES

I/we.....hereby apply for post approval changes of the following product:

Product Registration Number:

Name of the Product:

Proposed Variations (*Circle the appropriate changes*):

- a. Shelf life or stability data,
- b. Packaging specification and pack sizes,
- c. Dosage regimen,
- d. Additional indication and target species,
- e. Price structure,
- f. Market authorization holder and/or
- g. other minor changes (*Please specify the details*)

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 thereunder.

☐ 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

Date:.....