



**APPLICATION FOR VARIATION OF A
REGISTERED MEDICINAL PRODUCT
IN TANZANIA**



TMDA/DMC/MRE/F/005
Rev #:02
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1.0	DETAILS OF PRODUCT
1.1	Proprietary name:
1.2	Registration number:
1.3	International Non-proprietary Name (INN) of the Active Pharmaceutical Ingredient (API):
1.4	Strength of Active Pharmaceutical Ingredient (API) per unit dosage form:
1.5	Pharmacotherapeutic classification (Anatomic-Therapeutic Classification system):
1.6	Distribution category:
1.7	Dosage form:
1.8	Route(s) of administration (use current list of standard terms):
1.9	Packing/pack size:
1.10	Visual description:
1.11	Name and address (physical and postal) of FPP manufacturing facility: Name: Address: Country: Telephone: Telefax: E-Mail:



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2.0	DETAILS OF REGISTRANT
2.1	Name and address (physical and postal) of Applicant (Company): Name: Address: Country: Telephone: Telefax: E-Mail:
2.2	Name and address (physical and postal) of Local Technical Representative (Local Agent): Name: Address: Country: Telephone: Telefax: E-Mail:
3.0	DETAILS OF CHANGE
3.1	List of change(s) requested (<i>Please state all changes included in this application</i>) 1. 2. 3.





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3.2	Scope <i>(Please specify scope of the change(s) in a concise way)</i>
3.3	Type of change(s) <i>(State which type of Variation):</i> Minor: Major:
3.4	Other Application(s) <i>(Please provide brief information on any ongoing variation or other variation(s) submitted in parallel, or renewal application(s), or line-extension(s))</i>
3.5	Background for change & Justification for Consequential change(s) <i>(If applicable) Please give brief background explanation for the proposed change(s) to your marketing authorization as well as a justification in case of consequential change(s)</i>

3.6 Present <i>(Please specify precise present wording or specification)</i>	Proposed <i>(Please specify precise proposed wording or specification)</i>

	APPLICATION FOR VARIATION OF A REGISTERED MEDICINAL PRODUCT IN TANZANIA	 <p style="text-align: center;"> TMDA <small>Tanzania Medicines & Medical Devices Authority</small> TMDA/DMC/MRE/F/005 Rev #:02 Page 4 of 4 </p>
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In the case of changes to the Summary of Product Characteristics and/or package leaflet, applicants should always enclose a working model clearly showing the differences (new text and deleted text) between the proposed new version and the current text, previous version or reference text.

Declaration of the Applicant:

I hereby submit an application for the above Marketing Authorization to be varied in accordance with the proposals given above.

I declare that (Please tick the appropriate declarations):

- There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel; such parallel variations have to be specified under 'Other Application(s)');
- Where applicable, Variation fees have been paid;
- Change will be implemented from: Next production run/next printing

Name:

Qualification:

Position in the company:

Signature:

Date:

Official stamp: