


<b>1.0</b>	<b>DETAILS OF PRODUCT</b>
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:

<b>2.0</b>	<b>DETAILS OF REGISTRANT</b>
2.1	<p>Name and address (physical and postal) of Applicant (Company):</p> <p>Name:</p> <p>Address:</p> <p>Country:</p> <p>Telephone:</p> <p>Telefax:</p> <p>E-Mail:</p>
2.2	<p>Name and address (physical and postal) of Local Technical Representative (Local Agent):</p> <p>Name:</p> <p>Address:</p> <p>Country:</p> <p>Telephone:</p> <p>Telefax:</p> <p>E-Mail:</p>
<b>3.0</b>	<b>DETAILS OF CHANGE</b>
3.1	<p>List of change(s) requested (<i>Please state all changes included in this application</i>)</p> <ol style="list-style-type: none"> <li>1.</li> <li>2.</li> <li>3.</li> </ol>
3.2	<p>Scope (<i>Please specify scope of the change(s) in a concise way</i>)</p>

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) (If applicable) <i>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>

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.

	<b>APPLICATION FOR VARIATION OF A REGISTERED HUMAN MEDICINAL PRODUCT IN TANZANIA</b>	<i>TMDA/DMC/MRE/E/005 Rev #:01</i>
---	--	--

**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: