

APPLICATION FORM FOR VARIATION TO A REGISTERED HUMAN PHARMACEUTICAL PRODUCT

Please complete each section of this application form electronically as a Word Document and as a scanned signed PDF file. Please ensure that the electronic and the printed versions of the completed form accompany your submission, and note that the used watermark must remain intact in this form

1. Application details

1.1 Variation type: (tick all applicable options)

☐

Annual Notification (AN)

☐

Immediate Notification (IN)

☐

Minor variation (Vmin)

☐

Major variation (Vmaj)

1.2 Grouping of variations

☐

Single variation

☐

Grouped variations

1.3 Finished Pharmaceutical Product (FPP)

Proprietary Product Name	
Registration Number	
File Number	
International Non-proprietary Name (INN) of the Active Pharmaceutical Ingredient (API), strength, pharmaceutical form.	
Registered Pack Size(s)	
Name (s) and complete address (es) of the registered manufacturer (s) of the finished product (s), including the final product release if different from the manufacturer. (Add as many rows as necessary)	
Name and address (es) of the registered manufacturer(s) of the active pharmaceutical ingredient(s). (Add as many rows as necessary)	

Name of the Local Technical Representative (LTR)	
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1.4 Applicant (Marketing Authorisation Holder) details

Applicant	
Contact person responsible for this application	Title/Designation: First name: Surname name:
Contact person's job title	
Contact person's postal address	
Contact person's email address	
Contact person's phone number	

2. Summary of proposed changes

For multiple variations (grouped variations), reproduce this section and provide separate summaries for each proposed variation.

2.1 Variation title and number

e.g. *Minor variation # 34a:*

Change in the manufacturing process of the FPP

2.2 Summary of current and proposed details:

Current details	Proposed details

2.3 Reason for change:

2.4 Date of implementation (for Immediate Notifications and Annual Notifications))

3. Documentation checklist

The following documents have been submitted together with this application form:

<i>Note: All documents must be provided for this application to be valid.</i>	
Supporting documentation <i>All supporting documents as stipulated for the change in the Rwanda FDA Guidelines on Variations to a Registered Human Medicines are included in this submission</i>	☐ Yes ☐ NA

4. Declaration

Please check all declarations that apply.

I declare that:

- ☐ For each change, all conditions as stipulated in the ***Guidelines for Variation of Registered Human Pharmaceutical Products*** are fulfilled.
- ☐ There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied for separately.
- ☐ The information submitted is true and correct.

Name: _____ Title/Designation _____

Signature: _____ Date: _____