

The Pharmacy and Medicines Regulatory Authority Act, 2019

(Act No. 9 of 2019, Part IV Section 62)

APPLICATION FORM FOR VARIATION

Variation to a Registered Finished Medicinal Product Application form

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.

| 1. Application details | |
|--|--|
| 1.1 Variation type: (tick all a | applicable options) |
| ☐ Immediate notification (IN) | ☐ Annual notification (AN) ☐ Minor variation (Vmin) |
| ☐ Major variation (Vmaj) | |
| 1.2 Grouping of variations | |
| Single variation | Grouped variations |
| 1.3 Associated Finished Pha | armaceutical Product (FPP) Name: |
| | |
| 1.4 Name and Address of A | pplicant: |
| 1.5 Is the products registere | ed in Malawi through WHO or SRA CRP |
| Yes: WHO/SRA Number Include WHO/SRA approva | ☐ No |
| 2. Summary of proposed ch | anges |
| For multiple variations (groupe summaries for each proposed v | d variations), reproduce this section and provide separate ariation. |
| 2.1 Variation title and num | ber |

e.g. Minor variation # 30:

Minor change in the manufacture of the finished product

2.2 Summary of current and proposed details:

| Current details | Proposed d | letails | | |
|--|------------------------------|--------------|--|--|
| | | | | |
| | | | | |
| | | | | |
| 2.3 Reason for change: | | | | |
| | | | | |
| | | | | |
| | | | | |
| 2.4 Date of implementation (for Immediate Notifications only): | | | | |
| | | | | |
| 3. Documentation checklist | | | | |
| The following documents have been submitted | ed together with this applic | cation form: | | |
| Note: All documents must be provided for valid. | this application to be | | | |
| Supporting documentation All supporting documents as stipulated for the | e change in the Guidance | _ | | |
| on Post Approval Changes (Variations) are in | | Yes | | |
| | | | | |

4. Declaration

| Please o | check all declarations that apply. | | |
|----------|---|--|--|
| I declar | re that: | | |
| | or each change all conditions as stipulated in the nange requested are fulfilled. | e Variation Guidelines for Medicines for the | |
| | 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 | e information submitted is true and correct. | | |
| Name: | | | |
| Signatu | re: | Date: | |
| Stamp: | | | |