



EVALUATIONS AND REGISTRATION DIVISION

VARIATION APPLICATION FORM FOR MAJOR VARIATION(S), MINOR VARIATION(S) OR IMMEDIATE NOTIFICATION(S)

Guideline: Please complete each section of this application form electronically as a signed Word document or a text-selectable PDF document. Please ensure that the electronic and the printed versions of the completed form accompany your submission.

SECTION 1: APPLICANT DETAILS

Company Name		
Address	Business	
	Postal	
Telephone		
Email Address		
Local Representative <sup>1</sup> agent details <i>i.e. name, address and contact details (if applicable and different from applicant)</i>		

<sup>1</sup>Please note that the contact listed as the local representative will be the primary contact for communication for this specific application.

**SECTION 2: PRODUCT (S) INFORMATION****2.1 Application Details****Variation type: (tick all applicable options)** Immediate notification (IN) Minor variation (Vmin) Major variation (Vmaj)**Grouping of variations** Single variation Grouped variations**2.3 Complete the Relevant Product(S) Details for Product(S) Applied for (*Add rows as necessary*):**

<b>Generic name, strength and pharmaceutical form</b>	<b>Trade name</b>	<b>File number</b>

**2.4 Summary of Proposed Changes**

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

**2.4.1 Variation title and number:**

*E.g. Minor variation:*

*Change in batch size of the finished product — up to and including a factor of ten (10) compared to the bio batch*

**2.4.2 Summary of current and proposed details:**

Pre-change details	Proposed Post-Change details	Justification

**SECTION 3.0: DOCUMENTATION CHECKLIST**

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

<b>Note: All documents must be provided for this application to be valid</b>	
<p><b>Supporting documentation</b>  <i>All parts of the dossier that are affected by a variation have been resubmitted according to the structure of the MC8 Form (Application for registration of a medicine) or CTD format as stipulated for the change(s) in the MCAZ Guideline for Submitting Applications for Variations to Registered Medicines.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p><b>Updated MC8 form</b>  <i>If applicable, for each amendment which alters any information on the MC8 form and CM1 form the revised, signed and dated form has been submitted</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
<p><b>Amendment fees</b>  <i>Applicable fees as per the fee schedule have been paid</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

**SECTION 4.0: DECLARATION** *(Please check all declarations that apply).*

I declare that:

- For each change all conditions as stipulated in the *MCAZ Guideline for Submitting Applications for Variations to Registered Medicines* for the change requested 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 separately.
  
- The information contained herein and in supporting documents is correct and true.

Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_