



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

Table with fields: Company Name, Address (Business, Postal), Telephone, Email Address, Local Representative agent details.

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

2.2 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):*

Generic name, strength and pharmaceutical form	Trade name	File number

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

3.0 DOCUMENTATION CHECK LIST

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

Note: All documents must be provided for this application to be valid	
Supporting documentation <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>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Updated MC8 form <i>If applicable, for each amendment which alters any information on the MC8 form and CMI form the revised, signed and dated form has been submitted</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Amendment fees <i>Applicable fees as per the fee schedule have been paid</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No

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 for separately.
- The information contained herein and in supporting documents is correct and true.

Name: _____

Signature: _____ Date: _____