



VACCINE VARIATION APPLICATION FORM



TMDA/DMC/MRE/F/027
Rev #: 01
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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 applicable options)

Notification (N)

Minor variation (Vmin)

Major variation (Vmaj)

1.2 Grouping of variations

Single variation

Grouped variations

1.3 Finished Product (FPP)

Proprietary Name	
Reference number	
Registration Numbers	
Name of immunogenic/drug substance(s), strength and dosage 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 immunogenic/drug substance(s).	



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(Add as many rows as necessary)	
Name of the Local Technical Representative (LTR)	

1.4 Applicant (Marketing Authorisation Holder) details

Applicant	Particulars
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 the entire section 2 (2.1, 2.2 and 2.3) and provide separate summaries for each proposed variation.

2.1 Variation title and number

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

Change in batch size of the finished product - Up to and including a factor of ten (10) compared to the bio-batch

2.2 Summary of current and proposed details:

Current details	Proposed details



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2.3 Reason for change:

3. Documentation checklist

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

Supporting documentation <i>All supporting documents as stipulated for the change in the Guidelines on Variations to a Registered Vaccine are included in this submission</i>	<input type="checkbox"/> Yes <input type="checkbox"/> NA
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4. Declaration

Please check all declarations that apply.

I declare that:

- For each change all conditions as stipulated in the **Guidelines on Variations to a registered Vaccine** 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 submitted is true and correct.

Name: _____

Title/Designation _____

Signature: _____ Date: _____