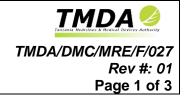


VACCINE VARIATION APPLICATION FORM



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 applicable options)				
	Notification (N)				
	Minor variation (Vm	in) Major variation (Vmaj)			
1.2	Grouping of variations				
	Single variation	Grouped variations			
1.3	Finished Product (FPP)				
Prop	rietary 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)					
regis	e and address(es) of the tered—manufacturer(s) of immunogenic/drug tance(s).				



VACCINE VARIATION APPLICATION FORM



(Add as <i>many</i> 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



VACCINE VARIATION APPLICATION FORM



2.3 Reason for change:

3. Documentation checklist

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

Supporting documentation All supporting documents as stipulated for the change in the Guidelines on Variations to a Registered Vaccine are included in this submission	Yes NA			
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 submission, except for possible editorial changes. Any be applied for separately.				
The information submitted is true and correct.				
Name:				
Title/Designation				
Signature: Date:				