MODULE 1: ADMINISTRATIVE INFORMATION	
1.0 PARTICULARS OF THE FINISHED PRODUCT	
1.1	Type of the medicinal product application New (Innovator) Generic (Traditional/Follow on vaccines) Renewal
1.2	Proprietary Name
1..3	International Non-proprietary Name (INN) of the immunogenic substance
1.4	Strength of immunogenic substance(s) per unit dosage
1.5	Name and address (physical and postal) of Applicant
(Company) Name: Address: Country: Telephone: E-Mail:	
1.6	Dosage form and route of administration
1.6.1	Dosage form:
1.6.2	Route(s) of administration
1.7	Packing/pack size:
1.8	Visual description (Add as many rows as necessary)
1.9	Proposed shelf life (in months):
1.9.1	Proposed shelf life (after reconstitution or dilution) (if applicable).

1.9.2	Proposed shelf life (after first opening container):
1.9.3	Proposed storage conditions:
1.9.4	Proposed storage conditions after first opening:
1.10	Other related Vaccine products registered or applied for marketing Authorization.
	Do you hold Marketing Authorization (s) of other Vaccines (s) Containing the same active Immunogenic (s) in the EAC? ▪ If yes state; Product name (s), strength (s), dosage form (s): ▪ Partner States where product is authorized: ▪ Marketing authorization number(s): ▪ Indication(s):
1.11	Pharmacotherapeutic group and ATC code:
1.11.1	Pharmacotherapeutic group:
1.11.2	ATC Code: (Please use current ATC code)
	If no ATC code has been assigned, please indicate if an application for ATC code has been made: ☐
1.12	Distribution category: POM (Prescription only Medicine) unless otherwise, provide justification)
1.13	Country of origin:
1.14	Product Marketing Authorization in the country of origin (Attach Certificate of Pharmaceutical Product from National Medicines Regulatory Authority). If not registered, state reasons
☐ Authorized	Withdrawn (by applicant after authorization) ☐

Country: Date of authorization (dd-mm-yyyy): Proprietary name: Authorization number: Refused ☐ Country: Date of refusal (dd-mm-yyyy): Reason for Refusal: SDRA-Documents to be attached:	Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal: ☐ Suspended/revoked (by competent authority) Country: date of suspension/revocation (dd-mm-yyyy): Reason for suspension/revocation: Proprietary name: SDRA-Documents to be attached:
1.15	List SRAs where the vaccine is approved. SDRA-Documents to be attached:
1.16	Name(s) and complete physical address(es) of the manufacturer(s)
1.16.1	Name(s) and physical address(es) of the manufacturing site of the finished product, including the final product release if different from the Manufacturer. Alternative sites should be also Declared here. All manufacturing sites involved in the manufacturing process of each step of the finished

	product, stating the role of each including quality Control / in-process testing sites should be listed. (Add as many rows as necessary
Name: Company name: Address: Country: Telephone: E-Mail:	
1.16.2	Name(s) and physical address(es) of the manufacturer(s) of the active immunogenic substance (Add as many rows as necessary) All manufacturing sites involved in the manufacturing process of each source of active immunogenic substance, including quality control / in-process testing sites should be listed.
Name: Company name: Address: Country: Telephone: E-Mail:	
1.17	Name and address (physical and postal) of the Local Technical Representative (if applicable)
Name: Company name:	

Address: Country: Telephone: E-Mail:			
1.18	Name and address (physical and postal) of the person or company responsible for pharmacovigilance		
Name: Company name: Address: Country: Telephone: E-Mail:			
1.19	State the reference/monograph standard such as British Pharmacopeia, United States Pharmacopeia, Ph. Eur, Japanese Pharmacopeia, In-house monograph e.t.c. used for Finished Product.		
1.20	Qualitative and Quantitative composition of the immunogenic substance(s) and excipient(s) A note should be given as to which quantity the composition refers (e.g. per ml).		
Name of immunogen(s) Quantity /	Quantity/ dosage unit	Unit of measure	Reference/ Monograph standard
1.			
2.			
3.			

e.t.c			
Name Excipient(s)			
1.			
2.			
3			
e.t.c			
Note: Only one name for each substance should be given in the following order of priority: INN, Pharmacopoeia, common name, scientific name.			
1.21	Name and address (physical and postal) of the Clinical Research Organization(s) where the clinical studies of the product were Conducted.		
Name: Company name: Address: Country: Telephone: E-Mail:			
2.0 DECLARATION BY AN APPLICANT			
	I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge. I further confirm that the information referred to in my application dossier is Available for verification during GMP inspection. I also agree that I shall carry out pharmacovigilance to monitor the safety of the product in the market and provide safety update reports to the Tanzania Medicines and Medical Devices Authority (TMDA).		

	I further agree that I am obliged to follow the requirements of Legislations and Regulations which are applicable to medicinal products. I also consent to the processing of information provided by the TMDA. I further agree that the TMDA can contact and share submitted confident content from the applicant and evaluation reports with Stringent Drug Regulatory Authorities (SDRAs) for scientific discussion and advice. It is hereby confirmed that fees will be paid/have been paid according to the Fees and Charges Regulations. Name: ..... Position in the company: ..... Signature: ..... Date: ..... Official stamp: ..... * Note: If fees have been paid, attach proof of payment