INSTRUCTION: The application form shall be used for an application for lot release of a human vaccine submitted to the South African Health Products Regulatory Authority.

This application form shall be included in the documentation submitted to the South African National Control Laboratory for Biological Products.

Application/Reg/Ref Number	Lot Number/Batch Number

a) Particulars of the Applicant/Holder of the certificate of registration (HCR)

Name:	
Business address:	
Postal address:	
Telephone no:	
Fax no:	
E-mail address:	
Site/Applicant Master File Number:	

Lot Release Responsible Person/authorised to communicate with SA Regulatory Authority	
Name:	
Business address:	
Telephone no:	
Fax no:	
E-mail address:	

a) Particulars of the vaccine

Product	
Category:	

Proprietary name:	
Pharmacological classification:	
Dosage form:	
Approved name(s):	
Strength(s) per dosage unit:	
Descriptive name of Biological product:	
Route of administration:	
Country of origin (country in which the original development was carried out):	

Manufacturing, packaging, testing sites[2]	
Manufacturer(s):'	
Physical address of site(s):	
Site Master File reference number(s):	
Date of submission	
Licence number:	
Date of issue:	
Manufacturer(s):	
Physical address of site(s):	

Site Master File reference number(s):	
Date of submission	
Licence number:	
Date of issue:	

***Primary Packer (Filling)**:*	
Physical address of site(s):	
Site Master File reference number(s):	
Date of submission	
Licence number:	
Date of issue:	

Secondary Packer:	
Physical address of site(s):	
Site Master File reference number(s):	
Date of submission:	
Licence number:	

***Finished product release control (FPRC)(s)**:*	
Physical address of site(s):	
Site Master File reference number(s):	
Date of submission:	
Licence number:	

Date of issue:	

***Finished product release responsibility (FPRR)(s)**:*	
Physical address of site(s):	
Site Master File reference number(s):	
Date of submission:	
Licence number:	
Date of issue:	

☐ *It is hereby confirmed that the South African National Control Laboratory for Biological Products were notified of all amendments and exemptions granted relevant to the lot and copies of the SAHPRA approval letters were submitted*

b) Declaration and signature

The undersigned hereby declares that all the information herein, and in the Annexes and Modules hereto, are correct and true and are relevant to this particular medicine, and that all existing data which are relevant to the quality, safety and efficacy of the product have been supplied in the dossier, as appropriate.

☒ *It is hereby confirmed that fees have been paid according to current legislation, and proof is attached:*

.....	.....
Signature of Responsible Person	*Date of application*
.....	.....
Name in block letters	*Date of registration*
.....	.....
Designation	*Date of current amendment*

c) Type of application

Indicate the type of medicine, the lot release process *and material and documentation submitted to the South African National Control Laboratory for Biological Products using a check mark (✓) or a cross (X):*

Human Medicine:		***Release process:***		***Material and documentation:***	
Biological		*First Release*		*Samples*	
		Further Release		*Lot summary protocol*	
		Expedited Release		*Vaccine arrival report*	
		Parallel Testing procedure		*Release certificate of releasing NCL (if applicable)*	
				Proof of secondary packaging (if applicable)	
				Proof of lot release fee payment (if applicable)	
				Expedited release approval letter	
				Exemption approval letter (if applicable)	

a) Particulars of the lot

Product	
Final container lot number:	
Secondary packaging lot number :	
Type of container (Vial/syringe)	
Number of doses per container:	
Number of commercial shipments imported:	
Number of containers submitted for release:	
Date of start of period of validity:	
Expiry date:	
Country of origin (country in which the lot was manufactured):	
First release certificate number (if applicable)	