**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.

| 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/authorized to communicate with SA Regulatory Authority*** | |
|---|---|
| *Name:* | |
| *Business address:* | |
| *Telephone no:* | |
| *Fax no:* | |
| *E-mail address:* | |

### b) *Particulars of the vaccine*

| ***Product*** | |
|---|---|
| *Category:* | |
| *Proprietary name:* | |
| *Pharmacological classification:* | |
| *Dosage form:* | |
| *Approved name(s):* | |

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| | |
|---|---|
| *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):*** | |
| | |
| | |

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| | |
|---|---|
| *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:* | |

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| | |
|---|---|
| *Date of issue:* | |

***c) Declaration and signature***

☐ *It is hereby confirmed that there are no pending or outstanding variations approvals by SAHPRA with respect to Lot release applied for.*

*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*

***d) Type of application***

Indicate the lot release process required *as well as material and documentation availed for the submission (✓) or a cross (X):*

| ***Human Medicine:*** | | ***Release process:*** | | ***Material and documentation:*** | |
|---|---|---|---|---|---|
| *Biological* | | *First Release* | | *Samples*[i] | |
| | | *Further Release* | | *Lot summary protocol* | |
| | | *Expedited Release*[ii] | | *Vaccine arrival report* | |
| | | | | *Release certificate of releasing NCL (if applicable)* | |
| | | | | *Proof of secondary packaging (if applicable)* | |

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| | | | | | |
|---|---|---|---|---|---|
| | | | | *Proof of lot release fee payment (if applicable)* | |
| | | | | *Motivation / Justification for expedited releaserequest* | |
| | | | | *Section 36 Exemption approval letter (if applicable)* | |

### *e) 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)* | |

[i] Samples are to be submitted to the SANCLBP as instructed by the Sahpra Service Desk System request
[ii] When a request for expedited review is made it is to be supported by the necessary motivation

Approved for use!