**REQUEST FOR USE OF AN UNREGISTERED PRODUCT IN TERMS OF SECTION 21 OF ACT 101 OF 1965**

**NB:** Please refer to the guideline SAHPGL-PEM-VET-01 Access to Unregistered Veterinary Medicine on the SAHPRA website.

**1A. APPLICANT DETAILS**

a) Name:

b) Postal / Street address:

c) Telephone / Cell number:

d) E-mail address:

e) Designation:

f) Qualification:

**1B. CO-APPLICANT DETAILS**

 Name:

b) Postal / Street address:

c) Telephone number / Cell phone:

d) Fax number:

e) E-mail address:

f) Designation:

g) Qualification:

h) SAVC Registration number:

**1C. INSTITUTION/FACILITY DETAILS (where product will be stored)**

a) Responsible Person:

b) Street address:

c) Contact details: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**2. PRODUCT INFORMATION**

a) Trade name:

b) Active substance: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

c) Composition:

d) Batch/Lot number:

e) **Total quantity required for** **6m**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

f) Dose, route, frequency, and duration of administration:

g) Has the product been approved for use in other countries, attach PI?

h) If approved, specify countries and conditions of authorisation:

i) Specify major side effects of this product:

**3. ADDITIONAL INFORMATION FOR USE OF VACCINES FOR INDIVIDUAL PATIENTS (when applicable)**

a) **Name of farm: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

b) **Coordinates: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

c) **Presenting Complaint: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

d) **Date of sample submission:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

e) **Date of positive sample: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

f) **Serotyping: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

g) **Surveillance data: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

h) **Interventions implemented: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

i) **Organisms identified: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

j) **Mode of transmission: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

k) **Environmental persistence: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

l) **Carrier status: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

m) **Biosecurity measures in place: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**4. MOTIVATION FOR USE OF THE UNREGISTERED PRODUCT:**

**5. REASON FOR NOT USING A LOCALLY REGISTERED PRODUCT**

**6. OWNER’S INFORMED CONSENT**

1. **PREVIOUS APPROVAL NUMBER (repeat) and six months progress report: (attach progress report form)**

**8. NAME OF VETERINARIAN/COMPANY REPRESENTATIVE:**

 **SIGNATURE:**

 **DATE:**

***NB:*** The following accompanying documents must be attached the application

1. A clear proof of payment
2. Proof of registration in the country of origin
3. Package insert and label of the product (English language)
4. Public assessment report/any documentation to support quality, safety, and efficacy of the product
5. Proof of GMP positive status of the manufacturing facility
6. ADRs experienced in the last 5 years (if any)

**9. For official use: Administrative screening outcome**

Complies: Yes No

Comments if “No”:

**Screener Signature:**  **Date:**

**10. Complex applications only**

Comments:

**Unit Manager/ MRO’s Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_