**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\_v4 Guidelines on Access to Unregistered Veterinary Medicines on the SAHPRA website.

1. **APPLICANT DETAILS**
2. Name:
3. Postal/ Street address:

1. Telephone number/ Cell phone:
2. Fax number:
3. E-mail address:
4. Designation:
5. Qualification:
6. SAVC Registration number:
7. **PATIENT DETAILS**
8. Owner name:
9. Street address:

1. **Patient Identity (Name, Age, Sex, Breed):**
2. **Diagnosis:**
3. **Current treatment regimen:**
4. **DRUG/ PRODUCT INFORMATION**
5. Trade name:
6. Active substance:
7. Indication:
8. **Total quantity required for 6m:**
9. Dose, route, frequency and duration of administration:

1. Concomitant medication:

1. Has the product been approved for use in other countries?
2. If approved, specify countries and conditions of authorisation:

1. If so, specify major side effects of this product:

1. **ADDITIONAL INFORMATION FOR USE OF VACCINES (if applicable)**
2. **Admission date:**
3. **Discharge date:**
4. **Presenting Complaint:**
5. **Date of sample submission:**
6. **Date of positive sample:**
7. **Serotyping:**
8. **Surveillance data:**
9. **Interventions implemented:**
10. **Organism identified:**
11. **Mode of transmission:**
12. **Environmental persistence:**
13. **Carrier status:**
14. **Biosecurity measures in place:**
15. **MOTIVATION FOR USE OF THE UNREGISTERED PRODUCT:**

1. **REASON FOR NOT USING A SIMILAR REGISTERED PRODUCT OR CURRENT TREATMENT REGIMEN:**

1. **OWNER’S INFORMED CONSENT AND PROCEDURE (YES/ NO)**

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

1. **VETERINARIAN DETAILS:**

 **Name:**

 **Signature:**

 **Date:**

1. **FOR OFFICIAL USE: Administrative screening outcome**

Complies: Yes No

Comments if “No”:

 **Screener Signature: Date:**

1. **COMPLEX APPLICATIONS ONLY**

Comments:

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