



## agriculture, land reform & rural development

Department:  
Agriculture, Land Reform and Rural Development  
REPUBLIC OF SOUTH AFRICA

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**From:** The Registrar, Act 36 of 1947, Mr Jonathan Mudzungu. **Tel:** (012) 319-7303 • **Fax:** (012) 319-7179 • **e-mail:**  
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**16 April 2024**

**ATTN:**

Stock Remedy Registration Holders

Regulatory Managers, Technical Managers, and CEOs of Animal Health Companies

**RE: SALE AND USE OF DOG AND CAT VACCINES (REGISTERED AS STOCK REMEDIES  
IN TERMS OF ACT 36 OF 1947) AND RESTRICTED USE STATEMENT ON PACKAGE  
INSERT.**

**AS WELL AS PACKAGE INSERT AMENDMENTS TO VACCINATION SCHEDULE ON DOG  
AND CAT RABIES VACCINES.**

**A. SALE AND USE OF DOG AND CAT VACCINES**

To clarify the existing requirement for restricted use labeling of dog and cat vaccines (refer to Stock Remedy labeling regulations, 2006 as well as section 7 (2) (a) (i) of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947)):

**1. With immediate effect:**

**DOG AND CAT VACCINES MAY ONLY BE SOLD TO:**

- a) Veterinarians, veterinary nurses, and/or animal health technicians who are registered in terms of the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982).
- b) Welfare organisations that employ animal welfare assistants who are in possession of a valid authorisation letter issued by the South African Veterinary Council (SAVC) in terms of section 23(1)(c) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982).

- c) National and Provincial Government Veterinary Services.
- d) Pharmaceutical *Wholesalers* that are both licensed with the South African Health Products Regulatory Authority - SAHPRA as a wholesaler of medicines as well as registered with the South African Pharmacy Council as a wholesale pharmacy, that, in turn, may only sell directly to a) b) and c) above.

**2. With immediate effect:**

**DOG AND CAT VACCINES MAY ONLY BE USED BY:**

- a) Veterinarians, veterinary nurses, and animal health technicians who are registered in terms of the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982).
- b) Animal welfare assistants who are in possession of a valid authorisation letter issued by the SAVC in terms of section 23(1)(c) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982).

**B. RABIES VACCINES**

For **Rabies** vaccines, in addition to above, the dog and cat vaccination schedule must be aligned with the applicable regulations of the Animal Diseases Act, 1984 (Act No. 35 of 1984). And there must be a statement about Rabies being a controlled disease and reporting thereof. Refer to the required package insert statements below.

**C. REGISTRATION HOLDERS OF DOG AND CAT VACCINES HAVE A PERIOD OF 3 MONTHS FROM THE DATE OF THIS LETTER TO:**

Submit to the Registrar Act 36 of 1947 for approval, amended package inserts of dog and cat vaccines (including those approved additionally for use in other species) with the following statement inserted under the name and G number:

“Only for sale to:

- a) Veterinarians, veterinary nurses, and/or animal health technicians who are registered in terms of the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982).
- b) Welfare organisations that employ animal welfare assistants who are in possession of a valid authorisation letter issued by the South African Veterinary Council (SAVC) in

terms of section 23(1)(c) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982).

- c) National and Provincial Government Veterinary Services.
- d) Pharmaceutical Wholesalers that are both licensed with the South African Health Products Regulatory Authority - SAHPRA as a wholesaler of medicines as well as registered with the South African Pharmacy Council as a wholesale pharmacy, that, in turn, may only sell directly to a) b) and c) above.

Only for use by:

- a) Veterinarians, veterinary nurses, and animal health technicians who are registered in terms of the Veterinary and Para-Veterinary Professions Act, 1982 (Act No.19 of 1982)
- b) Animal welfare assistants who are in possession of a valid authorisation letter issued by the South African Veterinary Council in terms of section 23(1)(c) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982)."

In addition, for **Rabies** vaccines:

1. This statement must be inserted above the sale and use statements, and under the name and G number:

"Rabies is a controlled disease in terms of the Animal Diseases Act, 1984 (Act No. 35 of 1984) and any suspicion or confirmation of the disease must be reported to the responsible state veterinarian immediately."

2. Under "Dosage and Directions for use", replace existing dog and cat rabies vaccination schedule with:

"Dogs and cats in South Africa must be vaccinated at the age of three months followed by a second vaccination within 12 months, at least 30 days after the first vaccination and thereafter every three years.

Dogs and cats younger than three months may be vaccinated provided that they are again vaccinated at the age of three months, followed by a third vaccination within 12 months and thereafter every three years."

*If the above vaccination schedule (all parts) does not correlate with the current approved schedule for a particular rabies vaccine, the applicant must supply data in support thereof when they submit the label amendment application.*

There may be no additional amendments other than those indicated above.

The title of the amendment application cover letter must be preceded with the word "PRIORITY" (e.g. "PRIORITY package insert amendment including restricted sale and use statements for dog vaccine XYZ").

Fees are hereby waived for these amendment applications in terms of Part 1 point 7 (a) and (b) of the Regulations regarding Stock Remedies, No R956 of 29 September 2006.

**Failure to comply with the above restricted sale requirements and package insert amendments may result in criminal charges and/ or suspension of the particular vaccine's registration.**

Yours faithfully



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**Mr Maluta Jonathan Mudzunga**

**REGISTRAR: ACT NO. 36 OF 1947**