Notice of Application to Register a Trade Name Product (Notice No. MPI ACVM 51)

Notice is given under section 14(1) of the Agricultural Compounds and Veterinary Medicines Act 1997 ("Act"), of the following application to register a trade name product under section 9(1) of the Act:

Trade Name: Eurican C4

Registration Number: A012157

Active Ingredients and Concentrations:

Each 1mL dose contains:

Lyophilisate:	Minimum	Maximum
Attenuated canine parvovirus type 2, strain CAG2	104.9 CCID ₅₀	107.1 CCID ₅₀
Attenuated canine distemper virus, strain BA5	104.0 CCID ₅₀	106.0 CCID ₅₀
Attenuated canine adenovirus type 2, strain DK13	102.5 CCID ₅₀	106.3 CCID ₅₀
Attenuated canine parainfluenza virus type 2, strain CGF 2004/75	104.7 CCID ₅₀	107.1 CCID ₅₀

Formulation Type: Lyophilisate with aqueous diluent

Application method/ administration route: Subcutaneous injection.

Use Claim:

For active immunisation of dogs to:

- prevent mortality, clinical signs and viral excretion caused by canine parvovirus (CPV)*
- prevent mortality and clinical signs caused by canine distemper virus (CDV),
- prevent mortality and clinical signs caused by infectious canine hepatitis virus (CAV-1),
- reduce clinical signs and viral excretion caused by canine parainfluenza virus type 2 (CPiV) and canine adenovirus type 2 (CAV-2).

Onset of immunity: 2 weeks after the second injection of the primary vaccination course for all strains.

Duration of immunity: at least one year after the second injection of the primary vaccination course for all strains. Challenge and serology data obtained two years after primary vaccination and first annual booster, demonstrated persistent protection against parvovirus, distemper virus and adenovirus for at least two years.

*Protection has been demonstrated against canine parvovirus type 2a, 2b and 2c.

Any person may make a written submission to the director-general concerning this application.

Under sections 16 and 17 of the Act, a written submission:

- a. must state in full the reasons for making the submission; and
- b. may state any decision sought on that application; and
- c. must be received by the director-general no later than 30 working days after the date of this notice.

Each submission must state the trade name product(s) to which it relates. Under section 18 of the Act, a copy of every submission will be forwarded to the applicant.

The following address is:

- a. where submissions on this application are to be sent;
- b. where requests for copies of the public information relating to the application can be sent;
- c. where public information relating to the application can be viewed; and
- d. the director-general's address for service:

ACVM Team, Ministry for Primary Industries, Charles Fergusson Building, 38-42 Bowen Street, Pipitea, Wellington 6011. Postal Address: PO Box 2526, Wellington 6140. Email: <u>acvm.consultation@mpi.govt.nz</u>.

MPI encourages submission by email.

The applicant's address for service is: Boehringer Ingelheim Animal Health New Zealand Limited, Level 2, 3 Te Kehu Way, Mount Wellington, Auckland 1060. Postal Address: PO Box 76211, Manukau, Auckland 2241.

Dated at Wellington this 22nd day of November 2024.

NEW ZEALAND GAZETTE

SHALEEN NARAYAN, Manager Approvals, Ministry for Primary Industries (acting under delegated authority).

2024-go6048