PHARMACY AND POISONS BOARD
HONG KONG
香港藥劑業及毒藥管理局

Your Ref. **:**
貴處檔號

Our Ref. **:** DH DO PRIE/1-55/1
本局檔號

Tel. No. **:** **3974 4175**
電　話

Fax No. **:** **2803 4962**
圖文傳真

Drug Office
Department of Health
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong
香港九龍觀塘巧明街100號
Landmark East 友邦九龍大樓
20樓2002-05室
衞生署藥物辦公室

23rd October 2025

To: Certificate holders of registered pharmaceutical products

Dear Sir/Madam,

New Warnings for Isoxazoline

The Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee (the Committee) under the Pharmacy and Poisons Board has recently reviewed and considered the warnings regarding the risk of neurologic adverse events in dogs and cats associated with isoxazoline products issued by the Food and Drug Administration of the United States, as well as the related safety labelling information as approved by the drug regulatory authorities of Australia, Canada, the European Union and the United Kingdom, and decided that the sales pack labels and / or package inserts of registered pharmaceutical products containing isoxazoline for veterinary use (including **afoxolaner, fluralaner, lotilaner, sarolaner, etc.**) shall include one of the following new safety information (or equivalent [Note 1]) as appropriate:

[Note 1] Related safety information with other wording in accordance with reputable references and/or approved package inserts from drug regulatory authorities of reference countries may also be accepted on a case-by-case basis.

(1) <u>Applicable to all pharmaceutical products containing isoxazoline for veterinary use</u>

*"**Special warnings and precautions for use***

<Product name / Generic name> is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures. Seizures have been reported in <animal species> receiving isoxazoline class drugs, even in <animal species> without a history of seizures. Use with caution in <animal species> with a history of seizures or neurologic disorders."

or

(2) <u>Applicable to pharmaceutical products containing isoxazoline for oral use in dogs</u>

*"**Undesirable effects***

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):

Muscle tremor, Ataxia, Convulsion"

or

(3) <u>Applicable to pharmaceutical products containing isoxazoline as spot-on solution for use in cats</u>

*"**Undesirable effects***

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):

Neurological disorders (e.g., tremor, ataxia)"

You are therefore required to ensure the sales pack labels and / or package inserts of the concerned products registered by your company contain the above safety information to comply with the new requirements. Please submit application for the change of the registered particular(s) to the Drug Office via the online Pharmaceutical Registration System 2.0 (PRS 2.0) at www.drugoffice.gov.hk/prs2-ext/client_authentication.jsp for approval within 2 months from the date of this letter. Failing to comply with the above requirements may result in de-registration of the products or registration not being renewed by the Committee upon certificate expiry.

For further enquiries on the registration matters of pharmaceutical products, please contact the Drug Office at 3974 4175.

Yours faithfully,

(Y. F. YEUNG)
Secretary,
Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee

c.c. 7-15/3, Product Files