



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

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貴處檔號

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20樓2002-05室
衛生署藥物辦公室**

3rd March 2026

To: Certificate holders of registered pharmaceutical products

Dear Sir/Madam,

New Warnings for Warfarin and Tramadol

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 latest warnings about the risk of drug interactions when using warfarin with tramadol issued by the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK), as well as the related safety labelling information as approved by the drug regulatory authorities of Australia, Canada, the European Union, Singapore and the United States, and decided that the sales pack labels and/or package inserts of registered pharmaceutical products containing warfarin or tramadol shall include the following new safety information (or equivalent ^{Note 1}) as appropriate:

(I) For warfarin:

“Interaction with other medicinal products and other forms of interaction

Caution should be exercised during concomitant treatment with tramadol and warfarin due to reports of increased INR with major bleeding and ecchymoses in some patients.”

^{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.

(II) For tramadol:

“Interaction with other medicinal products and other forms of interaction

Caution should be exercised during concomitant treatment with tramadol and coumarin derivatives (e.g. warfarin) due to reports of increased INR with major bleeding and ecchymoses in some patients.”

You are 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.

In addition, please be reminded that the sales pack labels and/or package inserts of the registered pharmaceutical products containing warfarin or tramadol should contain the safety information previously endorsed by the Committee. For the list of previously endorsed safety information, please refer to the new “Search for Additional Safety Information” function in the online Pharmaceutical Registration System 2.0 (PRS 2.0) at www.drugoffice.gov.hk/prs2-ext/client_authentication.jsp.

Please review whether the concerned products registered by your company contain all required safety information on their sales pack labels and/or package inserts. If updates are required, please submit an application for the change of the registered particular(s) to the Drug Office via the abovementioned online PRS 2.0 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