



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
衛生署藥物辦公室

31st December 2025

To: Certificate holders of registered pharmaceutical products

Dear Sir/Madam,

New Warnings for Oral Anticoagulants

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 anticoagulant-related nephropathy associated with the use of oral anticoagulants issued by the Therapeutic Goods Administration of Australia, as well as the related safety labelling information as approved by the drug regulatory authorities of Canada, the European Union, Singapore, the United Kingdom and the United States, and decided that the sales pack labels and/or package inserts of registered pharmaceutical products containing oral anticoagulants (including **warfarin, apixaban, dabigatran etexilate, edoxaban, rivaroxaban, etc.**) shall include 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.

(I) For warfarin:

“Special warnings and precautions for use

Anticoagulant-related nephropathy

There have been post-marketing reports of anticoagulant-related nephropathy (ARN) following anticoagulant use, presenting as acute kidney injury.

In patients with altered glomerular integrity or with a history of kidney disease, acute kidney injury may occur, possibly in relation to episodes of excessive anticoagulation and haematuria. A few cases have been reported in patients with no pre-existing kidney disease. Close monitoring including renal function evaluation is advised in patients with a supratherapeutic International Normalised Ratio (INR) and haematuria (including microscopic).

Undesirable effects

Renal and urinary disorders: Anticoagulant-related nephropathy.”

(II) For direct-acting oral anticoagulants (including apixaban, dabigatran etexilate, edoxaban, rivaroxaban, etc.):

“Undesirable effects

Anticoagulant-related nephropathy”

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 certain oral anticoagulants 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,

A handwritten signature in black ink, consisting of a stylized 'Y' followed by a dot.

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

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