



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

**Your Ref. :**  
貴處檔號

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**Drug Office**

**Department of Health**

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衛生署藥物辦公室

31<sup>st</sup> 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 <sup>Note 1</sup>) as appropriate:

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<sup>Note 1</sup> 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](http://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

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