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

18th December 2024

To: Certificate holders of registered pharmaceutical products

Dear Sir/Madam,

New Warnings for Vitamin B6

The Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) under the Pharmacy and Poisons Board has considered, in its meeting on 13th December 2024, the latest warnings regarding the risk of peripheral neuropathy associated with the use of vitamin B6 by the drug regulatory authorities of Australia and Singapore, and decided that the sales pack labels and / or package inserts of registered products containing daily doses over 10mg of vitamin B6 (including pyridoxine and pyridoxal) shall include the following new safety information (or equivalent [Note 1]) as appropriate:

> *"WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6]."*

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

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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.

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: Certification of Clinical Trial/Medicinal Test) Committee

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