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

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圖文傳真

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31st December 2025

To: Certificate holders of registered pharmaceutical products

Dear Sir/Madam,

New Warnings for Ezetimibe

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 regarding the risks of drug-induced liver injury and severe cutaneous adverse reactions issued by Health Canada, as well as the related safety labelling information as approved by the drug regulatory authorities of Australia, Singapore, the United Kingdom and the United States, and decided that the sales pack labels and / or package inserts of registered pharmaceutical products containing ezetimibe shall include the following new safety information (or equivalent [Note 1]) as appropriate:

*"**Special Warnings and Precautions for Use***

Liver enzymes
When <Product name / Generic name> is administered alone or with a statin, liver function tests should be performed at initiation of therapy and as indicated or according to the recommendations of the statin.

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.

Adverse Effects (Undesirable Effects)

Post-marketing Experience

The following adverse reactions have been reported in post-marketing experience, regardless of causality assessment:

Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS); hepatitis."

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