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

Our Ref. **:** DH DO PRIE/1-55/1
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衞生署藥物辦公室

31st December 2025

To: Certificate holders of registered pharmaceutical products

Dear Sir/Madam,

New Warnings for Levetiracetam and Clobazam

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 risk of drug reaction with eosinophilia and systemic symptoms (DRESS) related to the use of levetiracetam and clobazam issued by the Food and Drug Administration of the United States, as well as the related safety labelling information as approved by the drug regulatory authorities of Australia, Canada, the European Union and the United Kingdom, and decided that the sales pack labels and / or package inserts of registered pharmaceutical products containing levetiracetam or clobazam 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.

*"**Special warnings and precautions for use***

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multiorgan hypersensitivity, has been reported in patients taking antiepileptic drugs, including <Product name / Generic name>. These events can be fatal or life-threatening, particularly if diagnosis and treatment do not occur as early as possible. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling, in association with other organ system involvement, such as hepatitis, nephritis, hematological abnormalities, myocarditis, or myositis, sometimes resembling an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its expression, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately. <Product name / Generic name> should be discontinued if an alternative etiology for the signs or symptoms cannot be established.

Undesirable effects

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan Hypersensitivity"

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 levetiracetam or clobazam 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

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