**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
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**20樓2002-05室**
**衞生署藥物辦公室**

23rd October 2025

To: Certificate holders of registered pharmaceutical products

Dear Sir/Madam,

## New Warnings for Third Generation Aromatase Inhibitors

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 tendon disorders related to the use of third generation aromatase inhibitors issued by the 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 third generation aromatase inhibitors (including **anastrozole, exemestane, letrozole, etc.**) shall include the following new safety information (or equivalent [Note 1]) as appropriate:

> *"**Special warnings and precautions for use***
>
> *Tendon disorders: The use of third generation aromatase inhibitors, including <Product name / Generic name>, was found to be associated with tendonitis and tenosynovitis as reported in randomized controlled trials. Tendon rupture was found to be a potential risk. Tendonitis and tenosynovitis were estimated to be of uncommon occurrence, and tendon*

[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.

*rupture of rare occurrence. Treating physicians should monitor patients for these adverse drug reactions.*

***Undesirable effects***

*Musculoskeletal and connective tissue disorders: Tendonitis and tendon rupture"*

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