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**
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圖文傳真

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Landmark East 友邦九龍大樓
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衞生署藥物辦公室

9th July 2024

To: Certificate holders of registered pharmaceutical products

Dear Sir/Madam,

New Warnings for Ophthalmic Preparation containing Atropine

On 4th July 2024, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) decided that the sales pack labels and / or package inserts of all ophthalmic/ocular pharmaceutical products containing atropine not approved with the indication of slowing the progression of myopia should include the following new safety information as appropriate:

(I) *"The container is designed to maintain the quality of this product, to prevent microbial contamination and the risk of infections, this product is not to be diluted. 本產品的容器設計旨在維持產品品質，為了預防微生物污染及感染風險，本產品不得稀釋。"*

(II) *"This product is not intended for slowing the progression of myopia. 本產品不擬用於減緩近視加深。"*

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 our 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 our 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