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

3 November 2025

To: Certificate holders of registered pharmaceutical products

Dear Sirs/Madams,

Refine the Requirements for Applications for Change of Registered Particulars Related to Indication, Dosage and Route of Administration

This letter serves to inform you that the Pharmacy and Poisons Board of Hong Kong (the "Board") has endorsed to refine the requirements for applications for change of registered particulars ("CORP") related to indication, dosage and route of administration of registered pharmaceutical products containing New Chemical or Biological Entities ("NCE products").

Under the Pharmacy and Poisons Regulation (Cap. 138A), the registerable particulars of a pharmaceutical product must correspond exactly with those registered with the Board, otherwise, the product will not be regarded as registered. The registrable particulars of a product shall include "its proposed indication, dosage and route of administration". The certificate holder of a product may apply to the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee (the "Committee") under the Board for approval to change the registered particulars of the product.

In accordance with the current "Guidance Notes on Change of Registered Particulars of Registered Pharmaceutical Products/Substances" ("CORP Guidance Notes") promulgated by the Board, for any proposed changes in indication, dosage and route of administration which have not been previously approved for products registered in Hong Kong, applicants are required to provide documentary proof for registration approval of the products issued by the drug regulatory authorities in two or more of the listed reference countries.

In order to further expedite access to expanded treatment options for patients, the Board has endorsed at its recent meeting to refine the requirements for CORP applications related to indication, dosage and route of administration of registered NCE products. The refined requirements are summarized as follows and will come into effect on **29 November 2025**.

Under the refined requirements, CORP applications for change of indication, dosage and route of administration for registered NCE products with documentary proof for registration approval in one of the listed reference countries (instead of two) may still be accepted for evaluation on a case-by-case basis, if the following criteria are fulfilled:

(i) the product is approved with orphan drug designation, breakthrough therapy designation, priority review designation, or equivalent[Note 1], and marketed in any of the reference countries; and

(ii) there are local clinical data (e.g. clinical studies, case reports, case series, real-world data, etc.) OR clinical data generated from Chinese and/or Asian populations[Note 2] related to the proposed indication(s) and posology of the product.

Applicants are required to provide documentary evidence showing that the product fulfils the above criteria and that the proposed and existing indications, dosage and route of administration are referenced from a single reference country, together with the assessment report by a local relevant expert and other additional documents specified in the CORP Guidance Notes. The Committee may approve such CORP application if the submitted information is satisfactory to support the efficacy and safety of the new indication, dosage and route of administration. The applicant shall commit to comply and include any requirements deemed necessary by the Committee in the local Risk Management Plan. Further, the Committee may vary the registration conditions of the product. In such case, a signature fee of $155 will be charged for re-issuing each Certificate of Drug/Product Registration.

The CORP Guidance Notes will be updated in a timely manner prior to the implementation of the refined requirements and uploaded to the website of the Board (www.ppbhk.org.hk) and Drug Office (www.drugoffice.gov.hk) of the Department of Health for reference.

Note 1 Including products indicated for treatment of any disease, with evidence demonstrating prominent clinical benefits, e.g. showing significant therapeutic effects and/or making improvements in patients' quality of life.

Note 2 Clinical data in Chinese and/or Asian patient population(s) representative of the local patient population(s) in Hong Kong should be gathered from clinical studies, in which the drug has been shown in accordance with ICH E5"Ethnic factors in the acceptability of foreign clinical data" to be ethnically insensitive and extrinsic factors (such as medical practice and conduct of clinical trials) in these region(s) are generally similar to those in Hong Kong.

If you have any queries on the above, please contact the Drug Office at tel. no. 3974 4175.

Yours faithfully,

(Y. F. YEUNG)
Secretary,
Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee

c.c. DH DO PRIE/7-15/3