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 June 2024

Dear Sirs/Madams,

Enhancement of Screening Procedures
for Applications for Registration of Pharmaceutical Products/Substances

This letter serves to inform you that the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee ("the Committee") has endorsed the implementation of a Refuse-to-file ("RTF") mechanism for applications for initial registration of pharmaceutical products/substances at the screening stage which will come into effect on **1 July 2024**.

Under the Pharmacy and Poisons Ordinance (Cap. 138), pharmaceutical products must be registered with the Pharmacy and Poisons Board ("the Board") before they can be sold or supplied in Hong Kong. The Drug Office of the Department of Health is responsible for providing professional and executive support to the Board. Applicants should submit the applications for registration of pharmaceutical products via the online pharmaceutical Registration System 2.0 ("PRS 2.0") to the Drug Office. In order to ensure completeness of an application, Drug Office will first screen the submitted documents via PRS 2.0 before the application is accepted for subsequent evaluation. A deficiency letter will be issued to the applicant if there is outstanding information. Currently, there is no deadline for applicants to reply or provide outstanding information.

In order to enhance timeliness and efficiency in managing the review at the screening stage, the Committee agreed to implement the RTF mechanism with a 60-day timeframe for applicants to respond upon receiving the deficiency letter at the screening stage. The detailed arrangement is as follows:

(a). <u>For new applications submitted for screening on or after 1 July 2024:</u>

After screening of an application, a deficiency letter will remain to be issued if there is outstanding information for further review. If the applicant fails to reply and provide the outstanding information within 60 days in response to the letter, the application under screening will be automatically refused for filing in the PRS2.0 system.

(b). <u>For applications that are already in the screening pool before 1 July 2024:</u>

(i) If the latest deficiency letter is issued before 1 July 2024, the applicant is required to respond and provide the outstanding information on or before 1 September 2024. If the applicant fails to do so, the application under screening will be automatically refused for filing in the PRS2.0 system.

(ii) If the latest deficiency letter is issued on or after 1 July 2024, the applicant may reply and provide outstanding information within 60 days in response to the letter. If the applicant does not reply within 60 days, the application under screening will be automatically refused for filing in the PRS2.0 system.

Please note that under the RTF mechanism, if the applicant does not respond by providing the outstanding information during the screening stage within the prescribed timeframe, the application may be refused for filing. However, the refusal does not preclude the submission of a new application for registration. The applicant should ensure that the dossier is complete before submission or reply. Complete dossiers and timely responses to deficiency will avoid unnecessary delays to the registration process.

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 & Substances: Certification of Clinical Trial/ Medicinal Test) Committee

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