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22 December 2025

To: Applicants for registration of pharmaceutical products and
certificate holders of registered pharmaceutical products

Dear Sirs/Madams,

Pre-New Drug Application Meetings for
Applications for Registration of Pharmaceutical Products containing
New Chemical or Biological Entities
under the “1+” Mechanism

This letter serves to inform you of the launch of pre-new drug application (“NDA”) meetings on 22 December 2025 for the registration of pharmaceutical products containing new chemical or biological entities (“NCE products”) with the Pharmacy and Poisons Board (the “Board”) under the “1+” mechanism^{Note 1}.

“The Chief Executive’s 2024 Policy Address” announced the introduction of a consultation service for NDAs under the “1+” mechanism to enhance the efficiency in processing relevant applications. The consultation service comprises three components, including briefing seminars, workshops and pre-NDA meetings^{Note 2}.

Since March of this year, the Drug Office of the Department of Health (“DH”), as the professional arm of the Board, has organized 7 briefing seminars and 3 workshops, which were attended by over 580 representatives from stakeholders including pharmaceutical companies, consultancy firms and research institutes in and outside of Hong Kong. As the trade gains a better understanding of the application process and requirements of the “1+” mechanism through the briefing seminars and workshops, the Drug Office will, upon request, organize pre-NDA meetings with potential applicants interested in registering new drugs in Hong Kong to provide one-on-one consultation, thereby bringing more treatment options for our patients.

***We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority***

The pre-NDA meetings aim to enhance the efficiency and predictability of applications for registration of NCE products under the "1+" mechanism. Companies who intend to submit applications under the "1+" mechanism may request for one or both of the following two types of Pre-NDA meetings with the Drug Office of the DH:

- **Company-focused Meetings** where the requirements for applications for registration of NCE products under the "1+" mechanism are introduced to first-time applicants in order to facilitate their submission planning and to streamline the submission process; and
- **Product-specific Meetings** where product-specific guidance is provided to potential applicants for registration of NCE products under the "1+" mechanism, aiming to assist them in streamlining their submission process and establishing an effective communication channel with the Drug Office regarding their applications.

The guidance notes on pre-NDA meetings, with details of the meeting arrangements and the Pre-NDA Meeting Request Form with a self-assessment checklist, have been uploaded to the website of the Drug Office (www.drugoffice.gov.hk). The Drug Office will soon organize online briefing sessions on the said pre-NDA meetings. You will be informed of the details of the briefing in due course.

To encourage the industry to experience the one-on-one pre-NDA meetings, no fees will be charged for this service at this stage. The DH will actively maintain communication with the industry to gather feedbacks and suggestions regarding the pre-NDA meetings.

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

Yours faithfully,



(Y. F. YEUNG)

for Assistant Director (Drug)

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

Note ¹ The “1+” mechanism refers to the pathway for registration of NCE-containing products under Special Considerations. For details, please refer to paragraph 4.1.2 of the Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity published by the Board:

www.ppbhk.org.hk/eng/files/Guidance_on_Reg_of_Pharm_Prod_Containing_New_Chem_or_Bio_Entity_en.pdf?v=5k52zd

Note ² Registration for future briefing seminars and workshops can be made via the thematic page on “1+” mechanism at the website of the Drug Office:

www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/onePlus_mechanism_for_Reg_PP_contain_New_Chem_Bio_Entities.html