PHARMACY AND POISONS BOARD
HONG KONG
香港藥劑業及毒藥管理局

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25 October 2024

To: Certificate holders of registered pharmaceutical products

Dear Sirs/Madams,

Extending the "1+" Mechanism [Note 1] for Applications for Registration of Pharmaceutical Products containing New Chemical or Biological Entities

I refer to the letter issued on 26 October 2023 regarding the "1+" mechanism which has come into operation on 1 November 2023 for the registration of pharmaceutical products containing New Chemical or Biological Entities ("NCE products").

Apart from the recent enhancement and incentive measures for the processing of applications of registration of NCE products submitted under the "1+" mechanism which have come into effect on 1 May 2024 [Note 2] and 1 July 2024 [Note 3] respectively, the Pharmacy and Poisons Board of Hong Kong (the "Board"), with a view to facilitating good drugs for use in Hong Kong, endorsed at its recent meeting to extend the scope of the "1+"

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 Please refer to the letter issued on 25 March 2024 for the details about the enhancement measures: www.drugoffice.gov.hk/eps/upload/eps_news/53112/EN/1/PRC%20Letter%20to%20Trade_1+%20Enhancement_2024.03.25.pdf

Note 3 Please refer to the letter issued on 27 June 2024 for the details about the incentive measures: www.drugoffice.gov.hk/eps/upload/eps_news/53697/EN/1/PRC%20Letter%20to%20Trade_1+%20Incentive.pdf

mechanism to all NCE products, including vaccines and advanced therapy products. The extension measure will come into effect on **1 November 2024.**

Under the current "1+" mechanism, NCE products for treatment of life-threatening or severely debilitating diseases that are supported with local clinical data and scope of application recognised by local relevant expert are required to submit approval from one reference drug regulatory authority (instead of two) for application for registration in Hong Kong. With effect from 1 November, all the applications for registration of NCE products, including vaccines and advanced therapy products, may also be accepted for evaluation on a case-by-case basis and processed within a defined timeframe, if the following criteria are fulfilled:

(i) the product is approved with orphan drug designation, breakthrough therapy designation, priority review designation, or equivalent, 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 4] related to the proposed indication(s) and posology of the product.

Applicants are required to provide a cover letter indicating their intention to submit applications under the "1+" mechanism with documentary evidence showing that the product fulfils the above criteria, together with the assessment report by a local relevant expert and other additional documents specified in the "Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity" ("Guidance Notes"). The Guidance Notes have been updated and uploaded to the website of the Board (www.ppbhk.org.hk) and Drug Office (www.drugoffice.gov.hk) of the Department of Health.

In connection with the extension of the "1+" mechanism, the composition of the Expert Group for Drug Registration ("Expert Group") [Note 5] and the Core Team under the Expert Group will be expanded to cope with the increased number, variety and complexity of applications under the "1+" mechanism.

[Note 4] 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.

[Note 5] The Expert Group is established under the Board for providing expert opinion on safety, efficacy and quality of data submitted by applicants for registration of NCE products and giving advice on associated risk management for the consideration of the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee. Composition of the Expert Group can be found at the website of the Board: www.ppbhk.org.hk/eng/organization/expert_group.html

The Drug Office of the Department of Health, as the professional and executive arm of the Board, will soon organize online briefing sessions on the said extension measures. You will be informed of the details of the briefing in due course.

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

Yours faithfully,

(Julianna LI)
for Secretary, Pharmacy and Poisons
(Registration of Pharmaceutical Products & Substances: Certification of Clinical Trial/ Medicinal Test) Committee

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