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

Your Ref. :
貴處檔號

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26 October 2023

To: Certificate holders of registered pharmaceutical products

Dear Sirs/Madams,

Update of Registration Requirements for Pharmaceutical Products containing New Chemical or Biological Entities

This letter serves to inform you that the Pharmacy and Poisons Board (the "Board") has endorsed a new mechanism (i.e. generally referred as "1+") for the registration of pharmaceutical products containing New Chemical or Biological Entities ("NCE products") for life-threatening or severely-debilitating diseases which will come into effect on **1 November 2023**.

Under the Pharmacy and Poisons Ordinance (Cap. 138), pharmaceutical products must satisfy the criteria of safety, efficacy and quality for registration with the Board before they can be sold or supplied in Hong Kong. In accordance with the "Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity" ("Guidance Notes"), applicants for registration of NCE products are required to provide, among others, documentary proof for registration approval of the products issued by the drug regulatory authorities in two or more of the reference countries.

Under the new mechanism of 1+, applications for registration of NCE products that cannot provide the official evidence of registration approval in two or more of the listed reference countries may still be accepted for evaluation on a case-by-case basis, provided that:-

(i) there is a local unmet medical need of the product for life-threatening or severely-debilitating disease(s);

(ii) 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

(iii) there are local clinical data (e.g. clinical studies, case reports, case series, real-world data, etc.) of the product related to the proposed indication(s) and posology.

The application together with additional information to be submitted which include supporting justification, document and expert report etc. may be accepted for evaluation by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee and the Expert Group on Drug Registration on a case-by-case basis and the NCE product may be conditionally registered once it satisfied the criteria of safety, efficacy and quality. Please refer to the Annex for details of additional information to be submitted for the registration of NCE products for life-threatening or severely-debilitating diseases under this new mechanism.

Accordingly, 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.

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

Annex

Additional information to be provided by the applicant for the registration of NCE products for life-threatening or severely-debilitating diseases under the new mechanism

- justifications for non-compliance with the registration requirement for approval in at least two reference countries and documentary evidence showing the product fulfils the requirements under the new mechanism;

- an assessment report prepared by a local expert with fellowship or equivalent qualification and has at least five years of experience in the field relevant to the product. The report should include a review of the following:

  - the global and local epidemiology of the disease(s);
  - international and local treatment paradigms of the disease(s);
  - local unmet medical need of the disease(s);
  - how the product could address the local unmet medical need; and
  - safety and efficacy of the product.

  The expert should also submit evaluation report(s) on the local clinical data of the product related to the proposed indication(s) and posology (e.g. clinical studies, case reports, case series, real-world data, etc.);

- assessment report(s), post-authorisation requirement(s), and/or licensing condition(s) issued and imposed by the drug regulatory authority which granted the approval of the product in the reference country;

- periodic safety update report(s), summary safety report(s), or equivalent, if available; and

- post-registration development plan (e.g. global regulatory planning of the product, planned and ongoing efficacy and safety studies, local clinical studies, real-world evidence studies).

Remarks:
An application which does not fulfill the requirements stated above may be refused to file under the new mechanism during screening. However, the refusal does not preclude an application for registration by submitting official evidence of registration approval in two or more of the listed reference countries.