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

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27 June 2024

To: Certificate holders of registered pharmaceutical products

Dear Sirs/Madams,

Incentive Measures for Applications for Registration of Pharmaceutical Products under "1+" Mechanism [Note 1]

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") for life-threatening or severely-debilitating diseases.

Apart from the recent enhancement measures for the processing of applications of NCE products submitted under the "1+" mechanism which has come into effect on 1 May 2024 [Note 2], the Pharmacy and Poisons Board of Hong Kong (the "Board"), with a view to facilitating patients' early access to new drugs which would be beneficial in

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Note 1 The "1+" mechanism refers to pathway for registration of NCE-containing products for life-threatening or severely-debilitating diseases to address the local unmet medical needs. For details, please refer to the Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity (the "Guidance Notes") 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

addressing the local unmet needs as well as paving the way for conducting primary evaluation of applications for registration of new drugs, endorsed at its recent meeting the following incentive measures for pharmaceutical companies to submit their new drug applications under the "1+" mechanism which will come into effect on **1 July 2024**: —

I. Initiating legislative amendment procedures upon receipt of an application for screening

For NCE products under application for registration via the "1+" mechanism, the legislative amendment procedures of the Pharmacy and Poisons Regulations, Cap. 138A, related to the new substances will be initiated during the screening stage of application when specific sales restriction is imposed in the reference country to a product under application as well as relevant information on the structure (chemical, amino acid sequence, etc.), proposed indications and safety profile could be provided by applicants in the application dossiers for consideration by the Board and its Poisons Committee and as required for the legislative amendment procedures of the Legislative Council.

In parallel, the measure will also be extended to other NCE products intended for life-threatening or severely-debilitating diseases that have been approved with orphan drug designation, breakthrough therapy designation, priority review designation, or equivalent, in any of the reference countries [Note 3] but submitted via other application pathways in order to expedite the introduction of new drugs for unmet medical needs. The Drug Office of the Department of Health, responsible for providing professional and executive support to the Board, shall assess whether the products under application are intended for life-threatening or severely-debilitating diseases and initiate the legislative amendment procedures upon receipt of an application for screening on its own merits.

II. Allowing use of electronic product information (collectively referred to as "ePI") as pilot run

To facilitate timely dissemination of latest product information while maintaining the continued supply of NCE products for life-threatening or severely-debilitating diseases, applicant for registration of NCE product under "1+" mechanism may opt for using ePI, as a pilot run, to replace a physical packaging insert served to provide product information intended only for healthcare professionals (generally known as Summary of Product Characteristics or "SmPC") as set out in Section 3.1.5 of the Guidance Notes. The

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[Note 3] The 36 reference countries include Australia, Austria, Belgium, Brazil*, Bulgaria, Canada, China*, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Holland, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Republic of Korea*, Romania, Singapore*, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the United Kingdom ("UK") and the United States ("US").
(*Brazil, China, Republic of Korea and Singapore were included as reference countries in November 2022.)

requirements for the use of ePI for healthcare professionals are provided in the **Appendix**.

In any circumstances, a patient information leaflet ("PIL") to be supplied to patients as required for the approval of the registration must be in physical form to be provided with the container or package of the product and will be approved as a package insert under the PPR, i.e. a registered particular. Should there be changes to be made to the ePI intended for healthcare professionals that also warrant changes to be made accordingly to the physical PIL, the certificate holder must ensure those changes should take effect only after any physical stock containing the previous PIL has been withdrawn from the market.

In addition, to facilitate the submission of an application under the "1+" mechanism, the Drug Office has prepared a template for assessment/evaluation report (as required under Section 4.2.2 of the Guidance Notes) to be compiled by the local expert engaged by the applicant. The template is available for download from the Drug Office's website at:

http://www.drugoffice.gov.hk/eps/do/en/popup_for_1+_mechanism_for_Reg_PP_contain_New_Chem_Bio_Entities_en.html

The Drug Office will soon organize online briefing sessions on the said incentive 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,

(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

Requirements for Use of Electronic Product Information ("ePI") Intended for Healthcare Professionals

(i) The content of ePI, when available for viewing online solely by healthcare professionals, has to be approved by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the "Registration Committee"));

(ii) The ePI should be kept on a platform maintained or caused to be maintained by the applicant; the applicant should provide the uniform resource locator ("URL") where the online information will be placed;

(iii) The ePI should be viewed by means of digital devices (such as computers and mobile phones) via the URL and/or a data matrix code diverting to the URL which should be printed on the product label or on a leaflet, notification or other documents supplied with the container or package;

(iv) The content of the ePI in text searchable Portable Document Format ("PDF") format and the layout of the ePI on the online platform as viewed by healthcare professionals should be provided with the application;

(v) The applicant should consult their own legal advisers and provide details on the verifiable means for not contravening the Undesirable Medical Advertisement Ordinance, Cap. 231, arising from the use or dissemination of any information or content pertaining to the URL, data matrix code and the online platform;

(vi) While the ePI will not be approved as a registered particular under the PPR, the URL when printed on the container or package and forming part of the product label, or on the leaflet, notification or other documents supplied with the container or package and forming part of the package insert, will be considered as registrable particular and once registered, any change to the URL will be subject to approval from the Registration Committee in accordance with regulation 36A of the PPR;

(vii) A condition should be imposed to the product registration certificate requiring the certificate holder to obtain prior approval by the Registration Committee for any changes in the ePI at initial registration;

(viii) In an event that the ePI of a product is not available at the time of application for registration, a condition should still be imposed to allow for subsequent variation when the ePI is available during the validity of the product registration. At any time when the ePI is made available during the course of registration, the condition will be amended as described at the above paragraph; and

(ix) When the Registration Committee decides that the label and/or package insert of an NCE product should include any new safety information in pursuance of the safety alert or update issued by other drug regulatory authorities, the decision shall be considered and followed when the certificate holder seeks to add the concerned safety information to the ePI, if any, within the required timeframe for approval by the Registration Committee.

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