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

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25 March 2024

To: Certificate holders of registered pharmaceutical products

Dear Sirs/Madams,

Enhancement of Evaluation Procedures 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.

At a recent meeting, the Pharmacy and Poisons Board of Hong Kong (the "Board"), with a view to being on a par with the international regulatory practices and paving the way for conducting primary evaluation of applications for registration of new drugs, endorsed the following enhancement measures for the processing of applications of NCE products submitted under the "1+" mechanism which will come into effect on **1 May 2024**: —

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

I. Refuse-to-file Mechanism

In order to facilitate the registration of drugs for life-threatening or severely-debilitating diseases with local unmet medical needs and to avoid unnecessary delay in handling ineligible applications, a "refuse-to-file" mechanism for applications at the screening stage will be introduced. An application which does not fulfill the criteria for submission under the "1+" mechanism set forth in Section 4.1.2 of the Guidance Notes or which could not demonstrate or address the local unmet medical needs will be refused to file (i.e. the application could not be processed under the "1+" mechanism). However, the refusal does not preclude the submission of applications for registration under the normal pathway as per the requirements stated in Section 3 of the Guidance Notes.

II. Expansion of Expert Group for Drug Registration ("Expert Group")

Currently, 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 (the "Committee"). To pave way for building the capacity within the local regulatory framework in carrying out primary evaluation of applications for registration of NCE products, composition [Note 2] of the Expert Group will be expanded that will comprise additional local and international experts. A Core Team will also be formed under the Expert Group to provide expert advice or comments to the Committee for applications under 1+ mechanism. When deemed necessary by the Core Team during the evaluation stage of an application, advice and comments by other Member(s) of the relevant specialty(ies) and/or international expert(s) in the Expert Group may also be sought.

III. Stop-clock Mechanism with a target processing time

A target timeline for the review process of application for registration of NCE products under the "1+" mechanism with a "stop-clock" mechanism will be set as a pilot phase for the evaluation of applications for registration of pharmaceutical products. This serves to better manage the processing of new drug applications in terms of timeliness, predictability, consistency, transparency, clarity, and efficiency.

[Note 2] Updated composition of the Expert Group can be found at the website of the Board: www.ppbhk.org.hk/eng/organization/expert_group.html

Taking reference to the timeline for processing registration evaluation adopted by overseas regulatory authorities, the target processing time (i.e. the time period between the acceptance of an application upon payment of the prescribed fee and the decision made by the Committee) of an application for registration of an NCE product under the "1+" mechanism will be set at **150 working days**. Under the target processing timeline, the "stop-clock" will be paused as evaluation of the application is paused upon request for written response sent to the applicant for supplementary documentary evidence. The "stop-clock" and evaluation of the application will be resumed upon receipt of a response from the applicant.

Meanwhile, the "stop-clock" will also apply to the applicant in that it starts when the applicant is requested for supplementary evidence and pauses when the applicant submits a response accordingly. The "stop-clock period" for the applicant ends if complete and satisfactory supporting evidence has been provided or the total response time exceeds **120 calendar days**.

Please refer to the **Annex** for an illustration of the "stop-clock" mechanism during the pilot phase.

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 enhancement measures. You will be informed of the particulars of the briefing in due course.

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

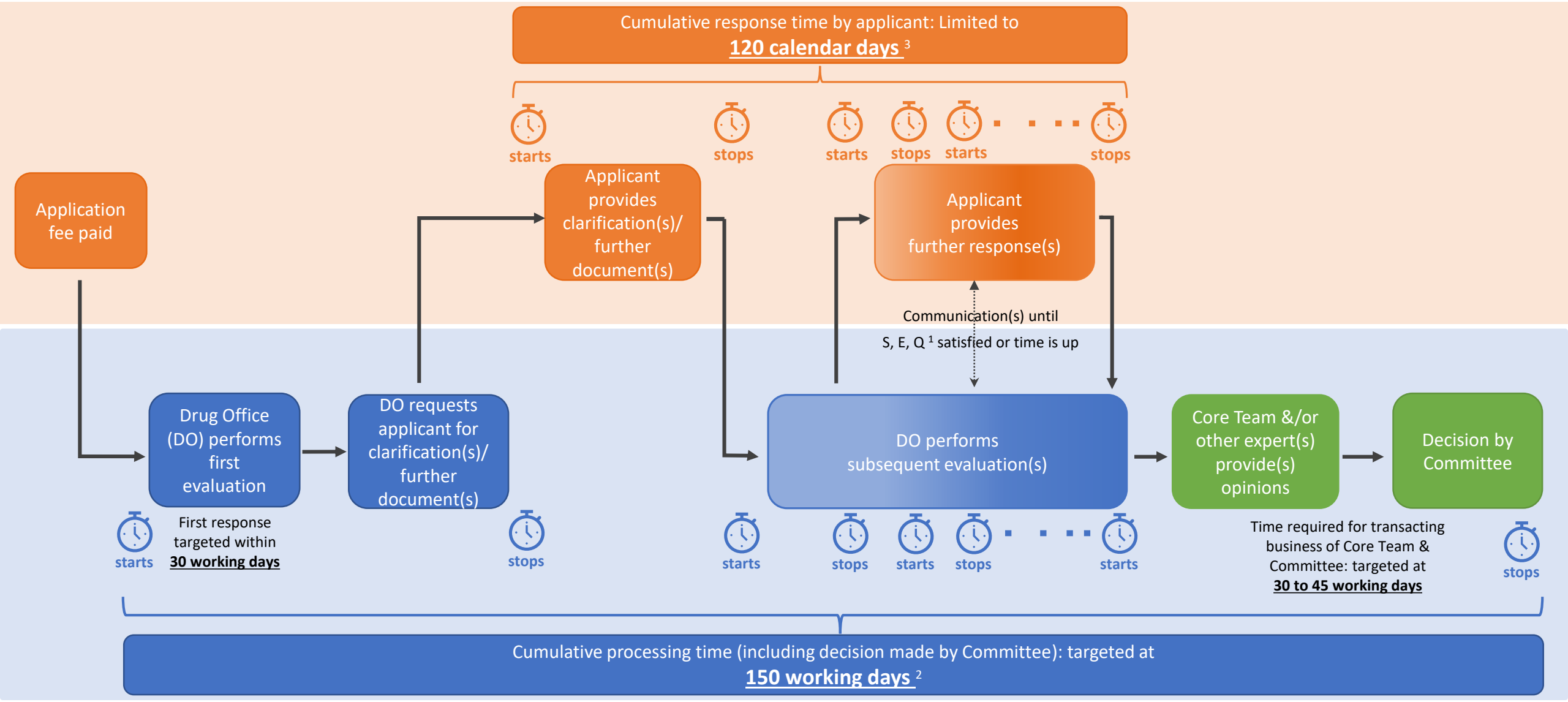
Yours faithfully,

(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

Pilot phase for "stop-clock" mechanism for evaluation of initial applications for registration of NCE products

Annex



1. E, Efficacy ; Q, Quality; S, Safety
2. Target cumulative evaluation time (**150 working days**) excludes the applicant's response time (limited to **120 calendar days**).
3. Application will be passed to the Committee for decision once the cumulative response time (excluded from the processing time) has reached the maximum of **120 calendar days**.