Frequently Asked Questions

Q1: What is “1+” mechanism?

A: The "1+" mechanism that came into effect on 1 November 2023 targeted for new drugs used for treatment of life-threatening or severely debilitating diseases. After meeting the requirement of local clinical data and the scope of application was recognised by local relevant expert, an applicant was only required to submit evidence of approval from the drug regulatory authority of one of the reference countries (instead of two in the past) for application for registration in Hong Kong.

Q2: What is the difference between the extended "1+" mechanism and the previous one?

A: Starting from 1 November 2024, apart from the above-mentioned situation, the “1+” mechanism will extend to all new drugs, including vaccines and advanced therapy products. Generally speaking, these new drugs refer to pharmaceutical products which have never been registered in Hong Kong, and with evidence demonstrating prominent clinical benefit (e.g. showing significant therapeutic effects and/or making improvements in patients’ quality of life) on treating diseases (e.g. diabetes mellitus) .

Q3: What are the differences in documentary requirements for application of registration between the extended "1+" mechanism and the previous one?

A: The extended “1+” mechanism is applicable for all new drugs indicating for any diseases. Applicants are required to provide documentary evidence (e.g. the product is approved with orphan drug designation, breakthrough therapy designation, priority review designation, or equivalent) to substantiate the new drugs under application of registration have prominent clinical benefit and are marketed in any of the reference countries; as well as 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 related to the proposed indication(s) and posology of the product.

For details, please refer to the section 4.1.2 of the “Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity” issued by the Pharmacy and Poisons Board of Hong Kong:

www.ppbhk.org.hk/eng/files/Guidance_on_Reg_of_Pharm_Prod_Containing_New_Chem_or_Bio_Entity_en.pdf

Q4: How long does it take for an application submitted under the "1" mechanism to be evaluated?

A target timeline for the review process of application for registration of NCE products under the "1+" mechanism with a "stop-clock" mechanism has been set for the evaluation of applications for registration of pharmaceutical products since 1 May 2024.

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 under the "1+" mechanism is 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.

For details, please refer to the letter to trade "Enhancement of Evaluation Procedures for Applications for Registration of Pharmaceutical Products under "1+" Mechanism": www.drugoffice.gov.hk/eps/upload/eps_news/53112/EN/1/PRC%20Letter%20to%20Trade_1+%20Enhancement_2024.03.25.pdf

Q5: Who can prepare the assessment report on the safety and efficacy of the product to be applied for registration under the "1+" mechanism? What have to be included in the assessment report?

The assessment report on the safety and efficacy of the product should be prepared by a local expert with fellowship or equivalent qualification and he/she has at least 5 years of experience in the field relevant to the product.

The assessment report should include an evaluation on the clinical data of the product as required under "1+ mechanism", a review of the global and local epidemiology of the disease(s), international and local treatment paradigms of the disease(s), and safety and efficacy of the product.

A suggested template of the assessment report can be found at:
www.drugoffice.gov.hk/eps/do/en/doc/Local_expert_assessment_eval_rpt.pdf