



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

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31 March 2026

To: Applicants for registration of pharmaceutical products and
certificate holders of registered pharmaceutical products

Dear Sirs/Madams,

**Revamping the Drug Registration Regime and
Implementation of Phase 1 of Primary Evaluation**

This letter serves to inform you that the Pharmacy and Poisons Board (the “Board”) has endorsed the revamping of drug registration regime and the publication of new and revised guidance notes for application for registration of pharmaceutical products, with a view to implementing **phase 1 of primary evaluation**^{Note 1}, which come into effect today on **31 March 2026**.

The Chief Executive announced in the 2023 Policy Address that to enhance the evaluation and approval mechanism for medical products, the Hong Kong Centre for Medical Products Regulation (“CMPR”) will be established with the objective of positioning it as an internationally renowned regulatory authority that registers medical products under the primary evaluation approach

Note 1 Primary evaluation is a regulatory process to approve applications for registration of new drugs which involves an independent assessment of primary data and information of all pre-clinical studies (i.e. animal testing), clinical studies, pharmacovigilance studies, manufacturing and quality control in order to fully evaluate their safety, efficacy and quality before and also after the drugs are placed on the market (i.e. throughout the product life-cycle).

On 26 June 2025, the Department of Health (the “DH”) announced the timetable for the establishment of CMPR by the end of 2026 and the roadmap towards adoption of primary evaluation in Hong Kong for pharmaceutical products. In accordance with the roadmap, the primary evaluation approach would be prudently implemented in four phases in the period between 2026 and 2030.^{Note 2}

Phase 1 of primary evaluation begins with products containing registered chemical entities with extended applications (e.g. new indications, new strengths, new posology, new dosage forms, etc.). For the purpose of conducting primary evaluation of applications for initial registration of pharmaceutical products, the Board has endorsed the revamp of the registration regime of pharmaceutical products, which includes the categorization of initial registration applications into six application categories (**Annex I**) and the formulation of three evaluation routes (**Annex II**).

New and Revised Guidance Notes

To reflect the revamped drug registration regime and requirements for primary evaluation of initial registration applications under the categories of New Drug Application (“NDA”)-2 and NDA-3 for products containing registered chemical entities, two new sets of guidance notes for products containing new chemical or biological entities and relevant applications, collectively referred to NDAs under the newly endorsed application categories, are published, and the existing guidance notes for advanced therapy products (“ATPs”) have been revised as follows:

- (i). *Guidance Notes on Registration of Pharmaceutical Products: New Drug Applications* ^{Note 3} (version 1.0);
- (ii). *Guidance Notes on Registration of Pharmaceutical Products: Specific Requirements for New Drug Applications of Chemical Entities via Primary Evaluation Route* (version 1.0); and
- (iii). *Guidance Notes on Registration of Pharmaceutical Products: Specific Requirements for New Drug Applications of Advanced Therapy Products via Abridged Evaluation or Verification Routes* (version 4.0).

^{Note 2} Details can be found in the website of the Preparatory Office for the CMPR at: www.dh.gov.hk/english/main/main_pocmpr/main_pocmpr.html

^{Note 3} *Guidance Notes on Registration of Pharmaceutical Products: New Drug Applications (version 1.0)* will replace *Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity as read with Guidance Notes on Registration of Pharmaceutical Products/Substances (version Nov 2022)*.

Subject to the establishment of the above two guidance notes (i) and (ii) for NDAs, the existing general guidance notes on registration below have also been updated to align the registration requirements for non-NDA applications with the current framework: ^{Notes 4, 5}

(iv). *Guidance Notes on Registration of Pharmaceutical Products/Substances*

Relevant guidance notes for the implementation of subsequent phases of primary evaluation (including new chemical or biological entities, registered biological entities, and ATPs), with associated updates for the other evaluation routes, will be promulgated at later stages.

Implementation of Phase 1 of Primary Evaluation

The aforementioned four new and revised guidance notes for phase 1 of primary evaluation take effective today on **31 March 2026**. For those applications which have been accepted for evaluation prior to the effective date of these new and revised sets of guidance notes (i.e. 31 March 2026), the existing guidance notes for registration of pharmaceutical products containing new chemical or biological entities and ATPs ^{Note 6} remain applicable for one year until **30 March 2027**.

The new and revised guidance notes have been uploaded to the websites of the Board (www.ppbhk.org.hk/eng) and the Drug Office of the DH (www.drugoffice.gov.hk). The Drug Office will soon organize online briefing sessions on the said implementation and details of the briefing can also be found in the website of the Drug Office.

^{Note 4} The Guidance Notes on Registration of Biosimilar Products remains effective.

^{Note 5} Please also refer to the letter dated 31 March 2026 issued by the Registration Committee on the “Implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)Q1 Guidelines on Stability”.

^{Note 6} Namely, *Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity (Version Nov 2024)* and *Guidance on Application of Certificate of Drug/ Product Registration – Advanced Therapy Products (Version 3.1)*.

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

Yours faithfully,

A handwritten signature in black ink, appearing to be 'Y. F. YEUNG', written in a cursive style.

(Y. F. YEUNG)

Secretary, Pharmacy and Poisons
(Registration of Pharmaceutical Products &
Substances) Committee

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

Categorization of initial registration applications

Application category	Scope of initial registration applications	
New Drug applications (NDAs)	NDA-1	An initial registration application of a pharmaceutical product containing a new chemical or biological entity(ies) ⁽¹⁾
	NDA-2	An initial registration application of a pharmaceutical product containing registered chemical or biological entity(ies) , which needs to be supported by non-clinical and/or clinical data to demonstrate the efficacy and safety of the product. <i>Examples of such applications are line extensions of registered entity(ies) with new indication(s), dosage, or patient population(s), and new combination(s) of registered entities.</i>
	NDA-3	A subsequent initial registration application of a product registered as NDA-1 and NDA-2 ⁽²⁾ , which does not need to be supported by non-clinical or clinical data . <i>Examples of such applications are line extensions of a registered product involving only quality-related (such as a new manufacturer on label) and/or administrative changes (such as different trade names).</i>
Other initial registration applications	Biosimilars ⁽⁵⁾	An initial registration application of a biosimilar pharmaceutical product of which a reference product ⁽³⁾ is/was registered in Hong Kong.
	Biologicals ⁽⁶⁾	An initial registration application of a pharmaceutical product containing registered biological entity(ies) , which does not differ significantly in properties with regard to safety and/or efficacy due to any differences in molecular structure, nature of the source material and/or manufacturing process. <i>Examples of such applications are human albumin, blood clotting factors, and human normal immunoglobulin.</i>
	Generics ⁽⁶⁾	An initial registration application of a pharmaceutical product containing registered chemical entity(ies) , of which a reference product ⁽³⁾ is/was registered in Hong Kong, and non-clinical or clinical data (except bioequivalence stud(ies) ⁽⁴⁾) is not required to support the application.

- (1) A new chemical or biological entity refers to an active ingredient contained in a pharmaceutical product which has not previously been registered in Hong Kong under some other name or description.
- (2) Or a product which has been registered as containing a new chemical or biological entity prior to the implementation of this new categorization approach.
- (3) A reference product refers to a product which has been registered under NDA-1/2/3 or as a product registered as containing a new chemical or biological entity prior to the implementation of this new categorization approach.
- (4) Such applications may need to be supported by bioequivalence study(ies) and/or quality data (e.g. ICH CTD modules 3: Quality).
- (5) Please refer to the *Guidance Notes on Registration of Biosimilar Products*.
- (6) Please refer to the *Guidance Notes on Registration of Pharmaceutical Products/Substances*.

Evaluation routes for initial registration applications for NDAs

Evaluation routes for NDAs			
Application category	Primary evaluation	Abridged evaluation	Verification
New Drug applications	NDA-1	A pharmaceutical product which is approved and is currently on the market in any of the reference countries/places. This is applicable to the "1+" mechanism ⁽⁴⁾ .	A pharmaceutical product which is approved in TWO or more of the reference countries/places, and is on the markets in any of those countries/places.
	NDA-2		
	NDA-3		

Phase 1 (for registered chemical entities) of Primary Evaluation

Notes:

- (1) To be implemented in Phases 3 and 4 of primary evaluation.
- (2) To be implemented in Phase 1 (for registered chemical entities) and Phase 2 (for registered biological entities) of primary evaluation.
- (3) To be implemented in the corresponding phases of primary evaluation of NDA-1/2 applications.
- (4) An assessment report, based on a complete independent scientific review, issued by the DRA of the reference country/place is required. Please refer to Table 2 of *Guidance Notes on Registration of Pharmaceutical Products: New Drug Applications (version 1.0)* for the eligibility criteria of abridged evaluation.