Guidance Notes on Registration of Pharmaceutical Products: New Drug Applications

VERSION 1.0

31 March 2026

Pharmacy and Poisons Board of Hong Kong

CONTENTS

1. Preface

1.1. These Guidance Notes outline the procedures and requirements for applications for initial registration of pharmaceutical products containing new chemical or biological entities, Advanced Therapy Products ("ATPs"), and related applications (**Table 1**), collectively referred to as new drug applications ("NDAs"). These Guidance Notes should be read in conjunction with the current laws governing pharmaceutical products in Hong Kong, which include the following Ordinances and their relevant subsidiary legislation:

- Pharmacy and Poisons Ordinance (Chapter 138);
- Antibiotics Ordinance (Chapter 137);
- Dangerous Drugs Ordinance (Chapter 134); and
- Undesirable Medical Advertisements Ordinance (Chapter 231).

1.2. If there is any inconsistency between these Guidance Notes and the legislation, the latter shall prevail.

1.3. This document serves as a general guide to the applicant regarding NDAs for initial registration of pharmaceutical products, and shall not be regarded as the complete registration requirements or authoritative statement of the relevant laws or the interpretation on any particular case. This document does not preclude requests by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee (the "Committee") or the Drug Office of the Department of Health for additional documents during screening or evaluation. Applicants are strongly encouraged to familiarize themselves with the content of these Guidance Notes before submitting their applications.

2. Pharmaceutical products subject to registration

2.1. Under the Pharmacy and Poisons Regulations, pharmaceutical products must be registered with the Pharmacy and Poisons Board of Hong Kong (the "Board") before they can be sold, offered for sale, distributed or possessed for the purposes of sale, distribution or other use. The Drug Office of the Department of Health is responsible for providing professional support to the Board in drug registration matters.

2.2. Pharmaceutical product —

(a) means a substance, or combination of substances that —

(i) is presented as having properties for treating or preventing disease in human beings or animals; or

(ii) may be used in or administered to human beings or animals with a view to –

(A) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or

(B) making a medical diagnosis; and

(b) includes an advanced therapy product.

2.3. In considering whether or not a product is a "pharmaceutical product", please refer to the <Guidance Notes on Classification of Products as "Pharmaceutical Products" under the Pharmacy and Poisons Ordinance (Cap. 138)> and <Guidance Notes on Registration of Pharmaceutical Products/Substances>.

3. Criteria for Registration

3.1. A pharmaceutical product will only be approved for registration if it meets the criteria of safety, efficacy and quality relevant to it.

4. Who should apply

4.1. If a pharmaceutical product is manufactured in Hong Kong, the person responsible for obtaining registration of the product is the licensed manufacturer, or the licensed wholesale dealer contracting with the licensed manufacturer.

4.2. If a pharmaceutical product is manufactured outside Hong Kong, the person responsible for obtaining registration is the licensed wholesale dealer who imported the pharmaceutical product, or the Hong Kong branch, subsidiary, representative, agent or distributor of the manufacturers outside Hong Kong.

5. How to apply

5.1. An NDA should be submitted via the online Pharmaceutical Registration System 2.0 ("PRS 2.0") of Drug Office of the Department of Health at www.drugoffice.gov.hk/prs2-ext/client_authentication.jsp together with the documents set out in pursuing sections. For submission on PRS 2.0, documents should be submitted in Portable Document Format ("PDF"), with table of contents, hypertext links and bookmarks provided to navigate through PDF documents. PDF files should be flattened (i.e. without layers) and text searchable. The PDF files should not be encrypted or password protected. Regarding the PRS2.0 account opening procedures and user guide, please refer to <Guidance Notes on New On-line User Account Registration for Pharmaceuticals Registration Systems 2.0 (PRS 2.0)> and the <Application User Manual>.

5.2. The application fee, currently at $1,100, to be paid via PRS 2.0 with credit card/PPS online payment services, or in person by cash or cheque along with the notification of payment at the following address:

Drug Evaluation and Pharmacovigilance Division,
Drug Office, Department of Health,
Suites 2002-05, 20/F,
AIA Kowloon Tower, Landmark East,
100 How Ming Street, Kwun Tong, Kowloon, Hong Kong.
(Enquiries: 3974 4175)

6. Categories of NDAs

6.1. NDAs for initial registration are divided into three categories as shown in **Table 1**.

Table 1. Categories of NDAs for initial registration

Category	Scope of initial registration applications
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[2] data to demonstrate its efficacy and safety.** ● NDA-2A: new salt / ester / ether / isomer / mixture of isomers / complexes / derivatives of registered chemical entity(ies) which potentially impacts its efficacy and / or safety[3] ● NDA-2B: new indication / dosage / patient population of registered entity(ies) ● NDA-2C: new strength of registered entity(ies) ● NDA-2D: new dose form of registered entity(ies) ● NDA-2E: new route of administration of registered entity(ies) ● NDA-2F: new composition or component of a registered product which potentially impacts efficacy and / or safety of the product (e.g. addition or change in adjuvant system of vaccine, change in composition that potentially affects release characteristics of modified release dose forms) ● NDA-2G: new container closure system / presentation of a registered product which potentially impacts the efficacy and/or safety of the product ● NDA-2H: new combination of registered entities as active ingredients ● NDA-2X: other types of line extension of a registered entity(ies) which potentially impacts its efficacy and/or safety, and need to be supported by non-clinical and / or clinical data

[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] For initial registration applications of pharmaceutical products containing registered entity(ies), of which a reference product has been registered in Hong Kong, and does not need to be supported by non-clinical or clinical (except bioequivalence study) data, please refer to the <Guidance Notes on Registration of Pharmaceutical Products/Substances>.

[3]The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance (i.e. contains the same active moiety as the registered entity) shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy, i.e. evidence that no change in the pharmacokinetics of the active moiety, pharmacodynamics and/or in toxicity which could change the safety/efficacy profile shall be demonstrated. Should this not be the case, the active substance shall generally be considered as an NDA-1.

Category	Scope of initial registration applications
NDA-3	**A subsequent initial registration application of a product registered as NDA-1 and NDA-2[4], which does not need to be supported by non-clinical or clinical data.** ● NDA-3A: new composition of excipients which does not impact the efficacy and/or safety of the product (e.g. new colourants) ● NDA-3B: new manufacturer on label ● NDA-3C: new container closure system (e.g. primary packaging and/or functional secondary packaging components), or new presentation (e.g. pack size which is the quantity of the dose form contained in its unit package)[5] ● NDA-3D: new component which does not contain an active ingredient or impact the efficacy and/or safety of the product (e.g. reconstitution diluent) ● NDA-3E: administrative changes for which a new product registration is required (e.g. different trade name) ● NDA-3X: other types of line extension of a registered product which does not need to be supported by non-clinical or clinical data

6.2. For initial registration applications of pharmaceutical products containing registered entity(ies), of which a reference product has been registered in Hong Kong, and non-clinical or clinical (except bioequivalence study) data is not required to support the application, please refer to the <Guidance Notes on Registration of Pharmaceutical Products/Substances>.

6.3. For initial registration applications 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, please refer to the <Guidance Notes on Registration of Pharmaceutical Products/Substances>.

6.4. For initial registration applications of biosimilar products, please refer to the <Guidance Notes on Registration of Biosimilar Products>.

6.5. The Drug Office would consider whether an application for initial registration of a pharmaceutical product is subject to the requirements specified on a case-by-case basis.

[4] Or products which have been registered as containing new chemical or biological entities before 31 March 2026.
[5] Regarding non-injectable products which differ only in package sizes, please refer to "Guidance Notes on Change of Registered Particulars of Registered Pharmaceutical Products/Substances" for the addition of package sizes.

7. Evaluation routes

7.1. NDAs for initial registration can be submitted via one of the three evaluation routes as shown in **Table 2**.

Table 2. Evaluation routes for initial registration of pharmaceutical products

Evaluation route	Eligibility criteria
Primary evaluation	The product has not been approved in any of the countries/places listed below.[6]
Abridged evaluation	(i) There is a local unmet medical need of the product for public health emergency [7], communicable diseases or matters of public health importance in the areas of tuberculosis, emerging and/or re-emerging infectious diseases (e.g. avian influenza, chicken pox, Ebola, COVID-19, etc.) and antimicrobial resistance; AND the product is promulgated by reputable international health agencies on human or veterinary medicines, including the World Health Organization (WHO), World Organisation for Animal Health, etc.; OR (ii) The product is approved with orphan drug designation, breakthrough therapy designation, priority review designation, or equivalent[8], and is currently on the market in any of the listed countries/places: Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chinese Mainland, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Republic of Korea, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the United Kingdom and the United States (U.S.); AND there are local clinical data (e.g. clinical studies, case reports, case series, real-world data, etc.) OR clinical data generated from Chinese and/or

[6]The primary evaluation route only applies to NDA-2 or NDA-3 of chemical entities during the phase 1 of the primary evaluation. Please refer to the phasic implementation of primary evaluation in <The Hong Kong Centre for Medical Products Regulation - Towards Primary Evaluation>.

[7] Public health emergency refers to the occasion as specified in section 8(5) of the Prevention and Control of disease Ordinance ("Cap. 599").

[8] Including products indicated for treatment of any disease, with evidence demonstrating prominent clinical benefits, e.g. showing significant therapeutic effects and/or making improvements in patients' quality of life.

Evaluation route	Eligibility criteria
	Asian populations[9] related to the proposed indication(s) and posology of the product (i.e. the "1+" Mechanism).
Verification	The product is approved in **two or more** of the above listed countries/places[10].

[9] Clinical data in Chinese and/or Asian patient population(s) representative of the local patient population(s) in Hong Kong should be gathered from clinical studies, in which the drug has been shown in accordance with ICH E5 "Ethnic factors in the acceptability of foreign clinical data" to be ethnically insensitive and extrinsic factors (such as medical practice and conduct of clinical trials) in these region(s) are generally similar to those in Hong Kong.

[10] For an advanced therapy product, approvals from the European Union countries must be issued from European Medicines Agency ("EMA").

8. General requirements for submission of NDAs

8.1. The application dossier should be organised in the Common Technical Document ("CTD") format promulgated by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH"). These organisation and format are described in ICH M4(R4), M4Q(R1), M4S(R2), and M4E(R2). The dossier should be complete and up-to-date. To ensure traceability, it is recommended to assign unique document and version numbers to each document.

8.2. CTD modules 2 to 5, where applicable (refer to sections 9.2, 11, and 12 for evaluation route-specific requirements), should be submitted in ONE DVD or blu-ray disc. Modules should be organised in folders and subfolders according to the chronology and titles specified in ICH M4(R4). To facilitate navigation through the dossier, bookmarks, a table of content (if appropriate), and reference hyperlinks to other documents should be included.[11]

8.3. Other requirements specific to NDAs to be submitted via each of the evaluation routes are outlined in sections 9.2 to 12, respectively.

8.4. For NDAs of ATPs, please also refer to the requirements in <Guidance Notes on Registration of Pharmaceutical Products: Specific Requirements for New Drug Applications of Advanced Therapy Products via Abridged Evaluation or Verification Routes>;

8.5. An NDA submitted on the PRS 2.0 will be screened for the completeness of the application dossier. An information request will be issued to the applicant if additional documents are required in the application dossier. The applicant is required to provide the required document(s) within 60 calendar days. If the dossier is incomplete and the outstanding documents are not provided within 60 calendar days, the NDA will be refused for filing. However, the refusal does not preclude the submission of a new application for registration. Notwithstanding, the acceptance of an NDA for evaluation does not denote the adequacy of the data for registration.

8.6. For non-injectable products which differ only in package size, only one application is required for various pack sizes. Separate application of registration is required for the following scenarios:

[11] In case supplementary information or revision is required during the application screening and evaluation phases, an updated DVD or blue-ray disc with complete CTD modules 2 to 5 (where applicable) should be submitted.

- products with the same description and composition, but different in strengths, e.g. “ABC Tablets 100mg” and “ABC Tablets 50mg”;
- products presented in different dose forms, e.g. injection, tablet and capsule;
- products with more than one presentation for the same pack size, unless otherwise justified;
- injectable products with different container volumes, e.g. “ABC Solution for Injection 10mg/5ml” and “ABC Solution for Injection 20mg/10ml”.

9. Document requirements applicable to NDAs to be submitted via any evaluation route

9.1. The following documents and information, including selected sections from the CTD modules should be electronically submitted via the PRS 2.0.[12]

9.1.1. The business registration certificate of the applicant;

9.1.2. A letter of authorization* signed by the authorized representative of the marketing authorization holder (or manufacturer, if applicable), who is also the owner of the product and its application dossier, and stamped with company chop (if applicable), to authorize the applicant to apply for registration and be the holder of Certificate of Drug/Product Registration in Hong Kong for their product; the official email address of marketing authorization holder (or the manufacturer) should be provided for verification of authenticity;

9.1.3. A letter of authorization signed by the applicant (sole-proprietor, managing partner, or director) and stamped with the applicant's company chop (if applicable), to authorize a person or a company to be the regulatory contact point for this application;

9.1.4. A letter of undertaking, signed by the applicant, agreeing to provide, at any stage of registration, any information and / or documents relating to the product upon request within the prescribed timeframe. The contact details for both the regulatory and pharmacovigilance contact points should be stated;

9.1.5. A cover letter that includes, a description of the CTD, justifications if any of the required modules are not included in the CTD, and whether the application relates to other registered product(s) or product(s) under application(s), with similarities and differences highlighted;

9.1.6. A declaration letter, signed by marketing authorization holder, to confirm that the product name(s), if different, mentioned in the application dossier are identical in all aspects of quality, safety and efficacy, except for the product name;

9.1.7. Official evidence of registration approval[13] of the product (e.g. Certificate of a Pharmaceutical Product)* in–

[12] Some of the subsections in CTD modules 2 to 5 should be uploaded in module 1 on PRS for administrative purposes.
[13] At least one of the Certificates of a Pharmaceutical Product should indicate that the product is currently on the market within the jurisdiction of the certifying authority.

- two or more of the countries / places listed in **Table 2** for NDAs via the verification route; or

- any of the countries / places listed in **Table 2** for NDAs via the abridged evaluation route;

9.1.8. A summary of the worldwide marketing approval status of the product, including the trade name(s), date(s) of first approval, type(s) of approval and designation(s) granted by the drug regulatory authority(ies), approved indication(s), post-approval condition(s) and / or post-market requirement(s)/commitments, legal classification(s), and the marketing status of the product in the country(ies) / places. If the marketing authorisations or applications of the product have been refused, suspended, revoked, withdrawn, approved via appeal process, or pending deferral in any countries / places, the assessments issued by the drug regulatory authority(ies) and the relevant correspondence should be provided;

9.1.9. The name, address, and responsibility of each manufacturer (including any outsourced manufacturer under contract), and each proposed production site or facility involved in manufacturing of the dose form, packaging, testing, batch release, and other production activities (if applicable) of the drug product (Module 3.2.P.3.1);

- In general, only one manufacturer will be allowed for each manufacturing step, except for quality control including stability testing. For products with more than one manufacturer involved in the same production step (i.e. alternative manufacturing pathway), a separate application is required for each pathway;

- For biological products, please refer to the "Supplementary Notes for Application for Registration of Biological Products Involving Alternative / Back Up Manufacturer(s) for Manufacturing Steps";

9.1.10. Good Manufacturing Practices ("GMP") certificate(s)* of the manufacturer(s) of the product, with evidence of compliance to the Pharmaceutical Inspection Co-operation Scheme ("PIC/S") GMP standards. The inspection scope of the GMP certificate should cover the product categories and operations relevant to the product. Please refer to the <Questions and Answers on PIC/S GMP Requirements for Registration of Imported Pharmaceutical Products>;

9.1.11. The manufacturer(s)' licence(s)* issued by the drug regulatory authority where the manufacturer(s) is located, if the GMP certificate(s) is not issued by that authority;

9.1.12. One set of prototype sales pack (e.g. outer carton, container label, and other component(s) comprising the sales pack) for each of the pack sizes of the product under application. All prototypes must be clear and legible in printed format. Please refer to the <Guidelines on the Labelling of Pharmaceutical Products>;

9.1.13. Proposed package insert[14], which should include prescribing information for local healthcare professionals, for each of the pack sizes of the product under application. Please refer to the <Guidelines onthe Labelling of Pharmaceutical Products>;

9.1.14. Colour photos of the product clearly showing the complete content of the prototype sales pack and its component(s), primary and secondary packaging components (i.e. the container closure system), and the unit dose form of the product sample (e.g. the colour and engraving / printing of a tablet/capsule; the colour of liquid or semi-solid dosage forms; the colour and shape of suppositories/pessaries);

9.1.15. Information of pre-registration importation of the product (e.g. for the purpose of treatment of a particular patient or a clinical trial) in Hong Kong. If a clinical trial has been/will be conducted locally, information regarding the clinical trial certificate number, trial site, principal investigator, locally reported serious adverse drug reactions, etc., should be provided;

9.1.16. Proposed Risk Management Plan ("RMP") and/or Risk Evaluation and Mitigation Strategy ("REMS") to be implemented in Hong Kong, taking into account the identified and potential risks, and missing information of the product;

- For NDAs via the abridged evaluation and verification routes, the proposed RMP and/or REMS should take reference to that currently approved by the drug regulatory authorities of the countries/places listed in **Table 2**;

9.1.17. Periodic benefit-risk evaluation report(s) ("PBRER"), or equivalent, if applicable;

9.1.18. Quality overall summary (Modules 2.3.S, 2.3.P, 2.3.A, and 2.3.R, if applicable), nonclinical overview (Module 2.4), clinical overview (Module 2.5), nonclinical

[14] A common package insert should be used for different strengths or dosage forms of a product, unless there are significant differences in the indications, posology, and/or methods of administration.

summary (Module 2.6, if applicable), clinical summary (Modules 2.7.1, 2.7.2, 2.7.3, and 2.7.4, if applicable), and their addendums (if applicable). Please refer to the evaluation route-specific requirements in sections 10, 11, and 12;

9.1.19. Information about the quality expert, the nonclinical expert, and the clinical expert, each including a signed declaration and a curriculum vitae;

9.1.20. Quality information of the drug substance (Module 3.2.S);

9.1.21. Description and composition of the drug product (Module 3.2.P.1);

9.1.22. Descriptions of the manufacturing process and process controls of the drug substance (Module 3.2.S.2.2) and the drug product (Module 3.2.P.3.3);

9.1.23. Specifications of the drug product (Module 3.2.P.5.1) and justification of specification (Module 3.2.P.5.6) in accordance to relevant ICH guidelines and the <Requirement of Microbiological Quality of Registered Pharmaceutical Products in Non-sterile Dosage Forms>;

9.1.24. Analytical procedures of the drug product (Module 3.2.P.5.2);

9.1.25. Batch analysis (Module 3.2.P.5.4) and certificate of analysis of a representative batch of the finished product issued by the manufacturer or the company performing the analysis. The certificate of analysis should include all tests listed in the release specification of the drug product, and the representative batch should be manufactured by using the manufacturing process and process controls in Module 3.2.P.3.3;

9.1.26. Batch release certificate issued by Official Medicines Control Laboratory ("OMCL") or laboratory designated for the purpose of official batch release (applicable for vaccines and products derived from human blood or human plasma only);

9.1.27. Characterisation of impurities in drug product (Module 3.2.P.5.5), including a risk assessment of elemental impurities in accordance with ICH Q3D(R2);

9.1.28. Container closure system of drug product (Module 3.2.P.7);

9.1.29. Stability test data of drug substance and drug product (Modules 3.2.S.7 and 3.2.P.8), and in-use stability data (if applicable), in accordance with ICH Q1A(R2), Q1B, Q1C, Q1D, and Q1E;

9.1.30. Information on the materials of animal and human origin (e.g. biological fluids, tissues, organs, cell lines) used in the production, including a description of the source and starting material and raw materials of biological origin used in the manufacture of the drug substance (Module 3.2.S.2.3), information regarding the excipients of human or animal origin (Module 3.2.P.4.5), and adventitious agents safety evaluation (Module 3.2.A.2). Information should include the source of the animals, the nature of the animal tissues used in the production processes, and should show compliance with one or more of the safety measures taken to minimize the risk of potential contamination with adventitious agents, including but not limited to Transmissible Spongiform Encephalopathy;

9.1.31. Site master file(s), or equivalent, of the manufacturer(s) outside Hong Kong, providing detailed information regarding their production and quality control facilities and technical personnel, etc; and

9.1.32. Plasma master file ("PMF") for the product derived from human blood or plasma, or if such materials are used in the manufacturing process (e.g. culture media). The PMF should include information on the collection and control of the source materials. A PMF Certificate issued by the EMA, or equivalent document issued by regulatory authority, for each of the source materials derived from human blood or plasma should be provided (if applicable).

9.2. The originals[15] or certified true copies of the documents marked with "*" (9.1.2, 9.1.7, 9.1.10 and 9.1.11), together with a cover letter specifying the application number(s) should be submitted to:

Drug Evaluation and Pharmacovigilance Division,
Drug Office, Department of Health,
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong
(enquiries: 3974 4175).

If it is necessary to submit the certified true copies of the documents, the electronic

[15] An electronic copy of the certificate may be sufficient if it is issued electronically with a valid and verifiable electronic signature by an authorized person of the issuing regulatory authority, and its authenticity could be verified on the designated official website.

documents uploaded to the PRS 2.0 should include those pages related to certification. A certified true copy certifies that the photocopy presented is a true and accurate copy of the original document. Documents can be certified by a Hong Kong solicitor, a notary public, the original issuing authority of the document, or an Embassy / Consulate.

9.3. If there is any doubt that any of the submitted scanned documents is not an accurate reflection of the original document, the applicant may also be requested to submit the original or certified true copy of the scanned document.

10. Additional requirements for NDAs via the verification route

10.1. Applicants are also required to provide the following documents for NDAs via the verification route:

10.1.1. For NDAs of chemical and biological entities, CTD Modules 2, 3 and 5 (and Module 4 may also be required if appropriate);

10.1.2. A comparison of the therapeutic indications, dosage, warnings / precautions, contraindications, and adverse effects in the package inserts authorized in other countries/places, with justifications for any differences; and

10.1.3. Package insert(s) of the product currently approved by the drug regulatory authority of at least one of the countries / places listed in **Table 2**, to substantiate the content of proposed package insert.[16]

11. Additional requirements for NDAs via the abridged evaluation route

11.1. Applicants are also required to provide the following documents for NDAs via the abridged evaluation route:

11.1.1. A cover letter indicating the intention to submit an NDA via the abridged evaluation route, with documentary evidence showing that the product fulfils the criteria stated in **Table 2**;

11.1.2. An assessment report on safety and efficacy of the product to 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;

11.1.3. A comparison of the therapeutic indications, dosage, warnings / precautions, contraindications, and adverse effects in the package inserts authorized in other countries/places, with justifications for any differences; and

11.1.4. Package insert(s) of the product currently approved by the drug regulatory authority of at least one of the countries / places listed in **Table 2**, to substantiate the content of proposed package insert.

[16] If the reference document is not in English or Chinese, a certified translation provided by a professional translator is required. Cross-referencing to documents should be made by referring to the page number of the reference documents and the relevant parts of the reference documents should be highlighted clearly.

11.2. For NDAs under the "**1+" Mechanism,** the following documents are **also** required:

11.2.1. The assessment report by the local expert (paragraph 11.1.2) should also include an evaluation on the clinical data of the product as required in **Table 2**, 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;

11.2.2. An assessment report(s) [17], post-authorization requirement(s), and licensing condition(s) issued and imposed by the drug regulatory authority(ies) which granted the approval of the product in the countries/places listed in **Table 2**; and

11.2.3. A 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).

11.3. An application which does not fulfil the eligibility criteria for the abridged evaluation route (**Table 2**) may be refused for filing during screening. However, the refusal does not preclude submission of an NDA via the verification route.

[17] Assessment reports issued by the drug regulatory authorities that granted the approval (and if any, designation) should be complete and unredacted. The report should be translated to English or Chinese, if applicable. In case an unredacted assessment report is not available, clarifications on the redacted information and other supporting documents relevant to the product's safety, efficacy or quality should be provided, which may include, but not limited to, the assessment or correspondence on questions and answers between the applicant in the reference country and the concerned authority during the authority's evaluation and/or at the meetings.

12. Additional requirements for NDAs via the primary evaluation route

12.1. Prior to submission of an NDA via the primary evaluation route, the applicant must request for a pre-NDA meeting.

12.2. The requirements of CTD Modules 2 to 5 for NDAs of chemical entities via the primary evaluation route are set out in <Guidance Notes on Registration of Pharmaceutical Products: Specific Requirements for New Drug Applications of Chemical Entities via the Primary Evaluation Route>. An application with an incomplete CTD may be refused for filing during screening stage. However, the refusal does not preclude an NDA under the abridged evaluation or verification routes.

12.3. Applicant may be requested to submit samples of drug product.

13. Pharmaceutical products for veterinary use

13.1. Guidelines promulgated by International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products apply to the registration of NDA for animal use. Other ICH guidelines may also be applicable on a case-by-case basis.

14. Pharmacovigilance and post-registration requirements

14.1. After submission of a NDA and during the application process, the applicant is required to report:

14.1.1. any regulatory actions taken by health authorities outside Hong Kong, including but not limited to withdrawal or refusal of applications, suspension or revocation of marketing authorisations or distribution, clinical holds, safety alerts, restriction of indications, product recalls, etc., within 72 hours; and

14.1.2. result of new information that may lead to a significant change to the benefit/risk profile, e.g. study suspension or termination.

14.2. The applicant will be required to comply with the following requirements upon registration of the pharmaceutical product:

14.2.1. report all serious[18] adverse drug reactions of the product occurring in Hong Kong; any actions taken by health authorities outside Hong Kong, any changes of the manufacturer or manufacturing process, and any product recalls to Drug Office within a prescribed time frame;

14.2.2. document any product defect;

14.2.3. implement the proposed RMP[19];

14.2.4. submit all final reports of all planned, on-going or future clinical studies of the product for reassessment at the same time when the reports are submitted to the relevant drug regulatory authorities.[20] A summary of the conclusion of the clinical studies and the proposed follow-up actions should also be provided. Inform the Drug Office of any regulatory actions taken by the relevant drug regulatory authorities in

[18]For NDAs via the primary or abridged evaluation routes, the applicant will also be required to report all unexpected adverse drug reactions of the product occurring in Hong Kong, and any actions taken by health authorities outside Hong Kong, including withdrawal or refusal of applications.

[19]For NDAs via the abridged evaluation route, the applicant will be required to update the proposed RMP in accordance with the global RMP when the latter is modified and implemented in the relevant country(ies)/places. For NDAs via the primary evaluation route, the applicant will be required to update the RMP at the request of the Committee or whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

[20] For NDAs via the primary evaluation route, the applicant will be required to submit study protocols and reports of all planned studies of the product requested by the Committee or detailed in the agreed RMP; and inform the Drug Office of any regulatory actions taken by drug regulatory authorities outside Hong Kong in view of the result of the studies of the product as soon as possible, and in any event no later than 72 hours after the actions have been taken.

view of the result of the clinical studies of the product as soon as possible, and in any event no later than 72 hours after the actions have been taken;

14.2.5. submit PBRER, or their equivalents, of the product every 6 months for the first 2 years, and then annually for the following 3 years after the registration is approved,[21] or at a frequency as specified by the Drug Office; and

14.2.6. any additional requirements the Committee thinks fit to impose.

[21] For NDAs via the primary or abridged evaluation routes, PBRER, or equivalent, should be submitted every 6 months.

15. Imposing sales control on NDAs

15.1. In general, when an NDA is approved by the Committee, the product can be registered once appropriate sales control has been imposed by the enactment of legislative amendment to the Pharmacy and Poisons Regulations, subject to any conditions the Committee thinks fit to impose. The certificate of registration will then be issued subject to payment of registration fee.

15.2. To facilitate timely registration of pharmaceutical products containing NCEs, the Pharmacy and Poisons Board determined that with effect from June 2018, once an NDA of the concerned product is submitted and accepted for evaluation[22], or is listed in public medical assistance programme, the legislative amendment procedures to impose appropriate sales control would be commenced unless it is necessary to seek advice (e.g. if the sale control is subject to the indications or dosage of the product to be approved) from the Committee in advance.

16. Registration fee

16.1. When an application is approved, the applicant will be required to pay a registration fee of $1,370 per product. A notification for collection of the Certificate of Drug/Product Registration will be issued to the applicant after the payment. Payment should be made by post, via the PRS 2.0 with credit card/PPS online payment services, or in person by cash or cheque at the address specified in paragraph 19.1. Cheque should be made payable to "The Government of the Hong Kong Special Administrative Region" and crossed.

16.2. Hours of Shroff office: Monday to Friday 9:00 am – 1:00 pm and 2:00 pm – 5:30 pm (open until 5:45 pm on Monday).

17. Public assessment summary

17.1. Upon approval of an NDA via primary evaluation, the Committee may release a summary of the safety, efficacy and quality of the approved product and the Committee's benefit-risk assessment for the approval for public's viewing.

[22] The legislative amendment procedures may be commenced, on a case-by-case basis, when NDAs of the concerned products approved with orphan drug designation, breakthrough therapy designation, priority review designation, or equivalent, in any of the listed countries in **Table 2** are first submitted.

18. Infringement on patent right

18.1. Please note that the Pharmacy and Poisons Board does not take into consideration of the factor of "patent right" while deciding on an application for registration of a pharmaceutical product/ substance. Nevertheless, an applicant shall not overlook the issue of infringement of patent right. Doing the following acts in Hong Kong without the consent of the patent proprietor may be liable for infringement of a patent registered in Hong Kong:

18.1.1. making, putting on the market, using or importing a patented product; or

18.1.2. stocking the patented product whether for the purpose of putting it on the market (in Hong Kong or elsewhere) or otherwise.

18.2. An applicant should ensure that their product does not infringe any patent right. Please see sections 73 to 75 of the Patents Ordinance (Cap. 514) for further details. The applicant should always seek legal advice if there is any doubts on this issue.

19. Enquires on the progress of NDAs

19.1. At any stage of the application process, the regulatory contact point may direct enquiries to regarding the progress of the application to the Drug Registration Unit. Please quote the application number when making an enquiry.

20. Disclaimers

20.1. These Guidance Notes serve as a general guide to the applicant of new product/ substance registration and shall not be regarded as the complete registration requirements or authoritative statement of the relevant laws or its interpretation on any particular case. Copies of the Pharmacy and Poisons Ordinance and its subsidiary legislations shall be referred, which can be purchased by calling the Publications Sales Section of Information Services Department at 2537 1910, by placing an order at the Online Government Bookstore at www.bookstore.gov.hk, or by email at puborder@isd.gov.hk. Contents of the relevant legislation can also be found at the Department of Justice's website at https://www.elegislation.gov.hk/.

20.2. The Drug Office would consider whether an application for registration of pharmaceutical product is subject to the requirements specified in these Guidance Notes on a case-by-case basis.

20.3. These Guidance Notes list out the documents which are generally required to demonstrate the quality, efficacy and safety of the products. The Pharmacy and Poisons Board reserves the right to revise these Guidance Notes at any time without giving prior notice. Applicants are responsible for making their own assessments of these Guidance Notes.

21. Compliance with the Prevention of Bribery Ordinance

21.1. Applicants and their employees or agents must not offer an advantage as defined in the Prevention of Bribery Ordinance (Cap. 201) to any government officer or Members of statutory organizations (including but not limited to the Pharmacy and Poisons Board and its Committees) in connection with their applications or while having dealings of any kind with government departments or statutory organizations.

22. Change history

Version	Date	Description of Change
1.0	31 March 2026	New document.