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PRE-NEW DRUG APPLICATION MEETINGS

for

Initial Registration of Pharmaceutical Products under Primary Evaluation Route

Primary evaluation¹ is the regulatory process to approve applications for initial registration of new drugs which involves the 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).

Pre-New Drug Application (“Pre-NDA”) Meetings aim to enhance the efficiency and predictability of NDAs for applicants who wish to apply for initial registration of pharmaceutical products via this route.

The relevant procedures and requirements for submitting NDAs are stipulated in the [<Guidance Notes on Registration of Pharmaceutical Products: New Drug Applications>](#) and other relevant guidance documents.

¹ The primary evaluation route only applies to NDA-2 or NDA-3 of chemical entities during the phase 1 of the primary evaluation. For details, please refer to [<The Hong Kong Centre for Medical Products Regulation - Towards Primary Evaluation>](#) and the [<Guidance Notes on Registration of Pharmaceutical Products: New Drug Applications>](#).

1. Meeting objectives

- 1.1. A Pre-NDA meeting held according to this set of notes is intended for an applicant who wishes to apply for initial registration of a pharmaceutical product via the **primary evaluation** route.
- 1.2. The Pre-NDA meeting aims to streamline the application process, by discussing the format and content of the anticipated NDA, and projecting the NDA submission date.

2. Eligibility

- 2.1. Prior to submission of an NDA via the primary evaluation route, the applicant must request for a Pre-NDA Meeting with the Drug Office.

3. Meeting request

- 3.1. Before submitting a Pre-NDA meeting request, the applicant should attend a [briefing seminar or view the briefing video](#) to gain sufficient understanding of the procedures and requirements for submission of NDAs via the primary evaluation route.
- 3.2. The applicant should complete the [Pre-NDA Meeting Request Form \(Form B\)](#), and lodge a meeting request via the Pharmaceutical Registration System (PRS 2.0). The meeting request should be made at least **EIGHT weeks** prior to the proposed meeting dates.
- 3.3. The meeting request should be accompanied with the following documents/materials (“**meeting package**”) uploaded onto the PRS 2.0:
 - 3.3.1. a completed [Pre-NDA Meeting Request Form \(FORM B\)](#), in particular the questions proposed to be discussed in the meeting;
 - 3.3.2. a **meeting presentation slide deck** (limited to 30 slides);
 - 3.3.3. an **overview** of the NDA(s) intended to be submitted (**Annex 1 of the Form B**);
 - 3.3.4. overviews of the technical information to be submitted in the NDA, including the **tabular listings** of all non-clinical and clinical studies, a **brief summary of results** of the pivotal and supportive trials;
 - 3.3.5. a **draft index** of the Common Technical Dossier (“**CTD**”); and
 - 3.3.6. the proposed **package insert**. The applicant will receive a response from the Drug Office via PRS 2.0 within **FOUR weeks**. If required, the Drug Office may request for additional documents.
- 3.4. Rescheduling of the date and time of a confirmed meeting is generally not accepted. Changes cannot be made to the meeting package once submitted.
- 3.5. If the submitted meeting package does not include sufficient information for the meeting, the Drug Office may decline the meeting request. Nonetheless, a new meeting request can be submitted.

4. Meeting format and content

4.1. The meeting will be held in English and/or Chinese.

4.2. A Pre-NDA Meeting shall be arranged with a maximum duration of **90 minutes**, structured as outlined below:

(a).	The applicant will give a presentation about their product(s) intended to be applied for registration under the primary evaluation route, and a brief introduction of the format and content of the CTD and the data package.	(15 minutes)
(b).	The Drug Office, which will chair the discussion, will discuss with the applicant on the NDA requirements via the primary evaluation route, the proposed format and content of the CTD, and the questions listed in the meeting package.	(75 minutes)

4.3. The meeting will focus on information and questions provided in the meeting package. Any new material which is not included in the meeting package will not be discussed in the meeting.

4.4. A Pre-NDA Meeting aims to foster communication between the applicant and the Drug Office, ensuring common understanding of the products and submission package, NDA requirements and procedures, submission timelines and outstanding issues before NDA submission. The goal is to enhance the efficiency and predictability of NDA. The Drug Office will offer advice to clarify any questions relating to the proposed CTD. Nevertheless, questions that require evaluation of data will only be addressed after NDA submission.

5. Meeting conduct

- 5.1. The Drug Office strives to accede to Pre-NDA Meeting requests. Nevertheless, to make the most efficient use of Drug Office resources, only ONE Pre-NDA Meeting may be arranged for each product to be submitted.
- 5.2. Audio or visual recording of discussions at meetings is strictly prohibited.
- 5.3. The Pre-NDA Meeting is reserved for regulatory and scientific discussions. The attendees should not promote its company or any products.
- 5.4. Minutes or notes of the meeting prepared by the applicant is not required or acknowledged by the Drug Office.

6. Other important information

- 6.1. The applicant is advised to take note of the drug regulatory system in Hong Kong and the relevant provisions in the Laws of Hong Kong. Depending on the nature of business, relevant trader's licences may be required. Relevant information can be found on the websites of the [Drug Office](#) and the [Department of Justice](#).
- 6.2. The applicant 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 organisations (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 organisations.
- 6.3. For enquiries, please contact the Drug Office at telephone no. 3974 4175 or by email to pharmgeneral@dh.gov.hk.

7. Collection of personal data

- 7.1. Regarding the collection of personal data, please refer to "Statement of Purposes" at Appendix for more information.

Statement of Purposes

Purpose Collection

This personal data is provided by applicants for the purposes of application for registration under the Pharmacy and Poisons Ordinance requesting for Pre-New Drug Application (“Pre-NDA”) Meetings. The personal data provided will be used by Department of Health for the following purposes:

- (a) Proof of eligibility
- (b) Processing of requests for Pre-NDA Meetings

2. The provision of personal data is voluntary. If you do not provide sufficient information, we may not be able to prove your eligibility for requesting a Pre-NDA Meeting.

Classes of Transferees

3. The personal data you provide are mainly for use within the Department of Health and the Pharmacy and Poisons Board. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

Access to Personal Data

4. You have a right of access and correction with respect to the personal data as provided in sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

Enquiries

5. Enquiries concerning the personal data provided, including the making of access and corrections should be addressed to:

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