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## **PRE-NEW DRUG APPLICATION MEETINGS**

### **for Initial Registration of Pharmaceutical Products under “1+” Mechanism**

**Pre-New Drug Application (“Pre-NDA”) Meetings** aim to enhance the efficiency and predictability of NDAs for initial registration of pharmaceutical products under the “1+” mechanism<sup>1</sup>. Companies who intend to submit NDAs under this mechanism may request for Pre-NDA Meetings with the Drug Office.

The Drug Office offers two types of Pre-NDA Meetings as follows:

- The **Company-focused Meetings** aim to introduce the requirements of NDAs under the “1+” mechanism to first-time applicants, as well as to facilitate the planning and streamlining of the submission process.
- The **Product-specific Meetings** aim to streamline the application process and to provide product-specific guidance for NDAs under the “1+” mechanism, as well as to establish an effective communication channel between the potential applicants and Drug Office. These meetings will also address any further questions related to specific products after company-focused meetings.

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

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<sup>1</sup> Starting from 31 March 2026, the “1+” mechanism falls under the abridged evaluation route for initial registration applications of pharmaceutical products. For details, please refer to Table 2 of [<Guidance Notes on Registration of Pharmaceutical Products: New Drug Applications>](#).

## 1. Eligibility

- 1.1. **First-time applicants** who intend to submit NDAs under the “1+” mechanism may request for **Company-focused Meetings**. The product(s) intended to be submitted for registration under the “1+” mechanism should have been approved or is/are under review by the drug regulatory authority of any of the reference countries/places<sup>2</sup> listed in Table 2 of the [Guidance Notes](#).
- 1.2. **Applicants** who intend to submit NDAs under the “1+” mechanism may request for **Product-specific Meetings**. In general, such meetings are applicable for potential NDA-1, i.e. initial applications for registration of pharmaceutical products containing new chemical or biological entities.

## 2. Meeting request

- 2.1. Before submitting a Pre-NDA meeting request, the applicant should attend a [briefing seminar\(s\) or view the briefing video](#) to gain sufficient understanding of the procedures and requirements for NDAs under the “1+” mechanism.
- 2.2. Complete the **Pre-NDA Meeting Request Form (FORM A)**, and lodge a meeting request via the Pharmaceutical Registration System (PRS 2.0). The meeting request should be made at least **SIX weeks** prior to the proposed meeting dates.
- 2.3. The meeting request should be accompanied with the following documents/materials (“**meeting package**”) uploaded onto the PRS 2.0:
  - 2.3.1. a completed **Pre-NDA Meeting Request Form (FORM A)**, in particular the questions proposed to be discussed in the meeting;
  - 2.3.2. a **meeting presentation slide deck** (limited to 30 slides);
  - 2.3.3. an **overview** of the product(s) intended to be applied for registration under the “1+” mechanism (Annex 1 of FORM A); and
  - 2.3.4. the proposed **Summary of Product Characteristics or package insert** of each product to be submitted for registration under the “1+” mechanism.
- 2.4. The requester 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.
- 2.5. Rescheduling of the date and time of a confirmed meeting is generally not accepted. Changes cannot be made to the meeting package once submitted.
- 2.6. 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.

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<sup>2</sup> The countries are Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chinese Mainland, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, the Netherlands, Hungary, Ireland, Italy, Japan, Republic of Korea, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the United Kingdom and the United States.

### 3. Meeting format and content

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

3.2. A **Company-focused Meeting** shall be arranged with a maximum duration of 45 minutes, structured as outlined below:

(a).	The Drug Office will give a brief introduction on the regulatory regime, the requirements and procedures for submitting NDAs under the “1+” mechanism.	(10 minutes)
(b).	The requester will give a presentation about their company and the product(s) concerned.	(10 minutes)
(c).	The Drug Office, which will chair the discussion, will discuss with the requester about requirements for submitting NDAs under “1+” mechanism and the questions listed in the meeting package.	(25 minutes)

3.3. A **Product-specific Meeting** shall be arranged with a maximum duration of 60 minutes, structured as outlined below:

(a).	The requester will give a presentation about their product(s) intended to be applied for registration under the “1+” mechanism.	(10 minutes)
(b).	The Drug Office, which will chair the discussion, will discuss with the requester on the requirements of the NDA and the dossier, and the questions listed in the meeting package.	(50 minutes)

3.4. 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.

3.5. A Pre-NDA Meeting aims to foster communication between the applicant and the Drug Office, ensuring common understanding of the products, NDA requirements and procedures, submission timelines and outstanding issues before NDA submission. The goal is to enhance the efficiency and predictability of NDA under the “1+” mechanism. Given the scope of the Company-focused Meetings, they are not designed to advise on developing data packages or studies required to support NDAs. For Product-specific Meetings, the Drug Office will offer advice to clarify any questions relating to the existing studies or the proposed data package. Nevertheless, questions that require evaluation of data or application dossier will only be addressed after NDA submission.

## 4. Meeting conduct

- 4.1. The Drug Office strives to accede to Pre-NDA Meeting requests. Nevertheless, to make the most efficient use of Drug Office resources, only (a) ONE Company-focused Meeting may be offered to each first-time applicant, and (b) ONE Product-specific Meeting may be arranged for each NDA-1 under the “1+” mechanism.
- 4.2. Audio or visual recording of discussions at meetings is strictly prohibited.
- 4.3. The Pre-NDA Meeting is reserved for regulatory and scientific discussions. The attendees should not promote its company or any products.
- 4.4. Minutes or notes of the meeting prepared by the requester is not required or acknowledged by the Drug Office.

## 5. Other important information

- 5.1. The requester 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](#).
- 5.2. 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 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.

For enquiries, please contact the Drug Office at telephone no. 3974 4175 or by email to [pharmgeneral@dh.gov.hk](mailto:pharmgeneral@dh.gov.hk).

## 6. Collection of personal data

- 6.1. 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:

Senior Pharmacist  
Drug Evaluation and Pharmacovigilance Division  
Drug Office, Department of Health  
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