

MOH MEDICINE'S FORMULARY (MOHMF) PRE-SUBMISSION MEETING REQUEST

There are two types of pre-submission meeting pertaining to submission of dossiers for listing of medicines into the MOHMF that can be requested from the MOHMF Secretariat, which are **Standard Pre-Submission Meeting** and **Early Pre-Submission Meeting**.

1) Standard Pre-Submission Meeting [after the issuance of Letter of Acceptance (LOA)]

Applicant may request for **Standard Pre-Submission Meeting** with the MOHMF Secretariat for pending submissions to be filled within 6 months (after issuance of LOA by secretariat). The meeting is intended to offer an opportunity for applicants to seek clarification **on matters pertaining to submission requirements only**.

A decision to accept the applicant's request for a pre-submission meeting will be made by the MOHMF Secretariat on a case-by-case basis.

The **Standard Pre-Submission Meeting** is scheduled for a maximum of one hour and applicants are limited to one meeting per pending drug submission. The meeting is meant to facilitate filling of dossier and preparation of the supporting documents. A maximum of three (3) representatives from the applicant's company are allowed in each session.

To request for **Standard Pre-Submission Meeting**, applicants are required to complete Ministry of Health Medicines Formulary (MOHMF) Pre-submission Meeting Request Form (Please fill in Section 1 and 2). The filled form should be attached to the official request for pre-submission meeting to the MOHMF Secretariat (sekretariatfukkm@moh.gov.my). The request should be sent at least seven (7) days prior to the suggested meeting date.

The suggested pre-submission meeting date and time and the questions/ matters for clarification should be stated in the said form. Kindly ensure that item to discuss is reasonable for the meeting duration (1 hour).

2) Early Pre-Submission Meeting [before sending Letter of Intent (LOI)]

Applicant may request for **Early Pre-Submission Meeting** with the MOHMF Secretariat (before sending LOI) up to 12 months in advance of filling of dossier with at least one of the following characteristics:

1. The drug is indicated for a relatively small patient population.
2. Clinical data are limited to surrogate end points.
3. The natural history of the disease is poorly characterized.
4. There are limited numbers of clinical trials and they have small sample sizes.
5. Treatment has a high cost relative to appropriate comparators.
6. The applicant has questions regarding the appropriate type of economic analysis to submit.

Applicants are advised to send MOHMF Secretariat supporting information for points aforementioned. Decision to accept the applicant's request for an **Early Pre-Submission Meeting** will be made by the MOHMF Secretariat on a case-by-case basis.

The **Early Pre Submission Meeting** is scheduled for a maximum of one hour and applicants are limited to one meeting per pending drug submission. The meeting is not meant to be consultative in nature. A maximum of three (3) representatives from the applicant's company are allowed in each session.

To request for **Early Pre-Submission Meeting**, the applicants are required to complete a *Ministry of Health Medicines Formulary (MOHMF) Pre-submission Meeting Request Form* **(Please fill in all Section 1, 2 and 3)** and submit it to the MOHMF Secretariat (sekretariatfukkm@moh.gov.my).