NCPE Pre-submission Meeting Guidance for Applicants

Version 1.2. (updated 18 September 2024)

Introduction

The NCPE hosts pre-submission meetings with Applicants once the Corporate Pharmaceutical Unit (CPU) has stated that a Health Technology Assessment (HTA) is required to inform a drug reimbursement decision.

What is the purpose of a pre-submission meeting?

The pre-submission meeting provides an opportunity for the Applicant to meet with the NCPE Review Group prior to finalising their HTA submission. The purpose is to outline the proposed approach to the clinical and cost-effectiveness modelling, and to obtain guidance from the NCPE on what may be the most appropriate approaches to adopt. The aim is to support the Applicant in submitting a HTA which is aligned with the needs of the decision maker and to avoid challenges later in the assessment process. Please note, the inclusion of videos or testimonials as part of the pre-submission meeting is not appropriate. Furthermore, the pre-submission meeting is not an opportunity to scope the possibility of circumventing the need to submit a HTA dossier. Once a HTA has been commissioned for a drug by the CPU, submission of a HTA dossier is required in order to progress through the reimbursement decision-making processes.

The parameters and methodology for the HTA submission will not be finalised until Applicants have submitted a dossier and the NCPE has reviewed the submission in the context of the full dossier. The NCPE may ask Applicants to change some of the parameters/methods that have been provisionally discussed at the meeting. Discussions are non-binding on either the NCPE or the Applicant.

The NCPE prohibits the photographing, filming or recording of pre-submission meetings.

What information do I need to provide prior to the pre-submission meeting?

Please provide the NCPE with the list of planned attendees prior to the meeting. Any PowerPoint slides to be used should be emailed to the NCPE FIVE working days in advance of the meeting.

Who should attend a pre-submission meeting?

It is suggested, for example, that the National Market Access Manager, a Medical Advisor, and the Statistician, Computer Programmer or Health Economist who was responsible for the development or adaption of the health-economic models should attend. Additionally, key individuals from the Consultancy commissioned to undertake the development and/or submission of the HTA should attend.

The attending NCPE group is expected to comprise a Senior Health Technology Assessor, a Health Technology Assessor, an Information Specialist and a Statistician.

What is the duration of a pre-submission meeting?

We allocate a maximum of one hour for the pre-submission meeting.

What facilities are available for pre-submission meetings?

NCPE facilitate video-conferencing for pre-submission meetings using Zoom. The NCPE will provide further instructions once the date for the pre-submission meeting is confirmed. The Applicant is requested to share the slides during the meeting.

What are the discussion points for a pre-submission meeting?

We recommend you consider the following points when preparing for the pre-submission meeting:

- Licensed indication.
- Summary of the pivotal trial(s) design and results which formed the basis for marketing authorisation from the EMA. **Note**: in the interests of time, it is not necessary to provide a detailed overview of the clinical trial programme, as this will have been provided as part of the Rapid Review. It is, however, beneficial to provide information on any changes since the Rapid Review was completed such as the availability of updated data cuts or any specific limitations of the clinical evidence highlighted in the Rapid Review report.
- Comparative effectiveness analysis, including evidence synthesis (if applicable).
- The decision problem
    - The population defined in the model; licensed indication/ patient population (including any subgroups) in which the reimbursement application is being sought
    - The intervention (e.g., dose, time on treatment)
    - The relevant comparator(s) (e.g., dose, time on treatment) considered in the economic evaluation.
- The clinical data used to inform model parameters (which trials are used, and/or any other data).
- Model outline/approach (how treatment effects are modelled over the time horizon of the model), structural assumptions, key drivers of the model.
- Key costs to be included and the source of costs.
- Type and source of quality of life data. Approach to modelling utilities.
- Approach to sensitivity analyses.
- Any limitations of the clinical or cost-effectiveness evidence.
- Budget impact analysis approach.

Is there a charge for pre-submission meetings?

Pre-submission meetings are provided to the Applicant free of charge.