PRE-SUBMISSION MEETINGS MEDICINES

PRE-SUBMISSION MEETINGS

A pre-submission meeting is an essential aspect of the medicines assessment process. Pre-submission meetings provide an opportunity for advice and guidance prior to submission of a medicines dossier, as well as an opportunity for the applicant to meet the PQT medicines (PQTm) assessment team that will be involved with the assessment of their product. Pre-submission meetings can be especially helpful to applicants that have limited experience with PQTm, and are compulsory for all new applicants to PQTm. However, pre-submission meetings are also useful for applicants experienced with PQTm, to address issues specific to their intended dossier.

A pre-submission meeting allows the PQT medicines team to review an overview of the product and a) ensure that the applicant is on the right track, b) provide general guidance on how to proceed, and c) provide guidance on identified issues that should be dealt with prior to submission. At the same time, it is an opportunity for the applicant to, a) introduce and discuss the intended dossier, b) raise questions and gain valuable feedback and c) address issues prior to submission. The pre-submission meeting should enable an applicant to submit a medicines dossier that can proceed more quickly through the screening and subsequent stages of assessment.

QUALITY ASPECTS

The pre-submission meeting does not include a detailed review of data or full study reports. However, an essential aspect of the meeting is the submission (at least two weeks in advance of the pre-submission meeting) of a completed QOS-PD. During the meeting, feedback will be provided to the applicant identifying aspects of the QOS-PD (and associated modules 1 and 3 where appropriate) that should be expanded, corrected or clarified before submission of the dossier. Issues identified in the QOS-PD may be discussed during the meeting; for this reason, it is important that technical experts from the company be in attendance. Shortly after the meeting, a written document outlining the QOS-PD feedback will be provided to the applicant. This should be used as a reference document for aspects of the QOS-PD and modules 1/3 that should be expanded or corrected prior to submission of the dossier.

Issues relating to the API portion of dossier are also open for discussion at pre-submission meetings. This may include specific discussions on technical aspects of module 3.2.S, including reference monographs, treatment of impurities including residual solvents and metals, or stability data requirements. For attending FPP companies, where detailed technical discussions of API information may not be possible, advice can still be provided on the best method to provide required API information, or the timing of the API submission.

Note, API manufacturers themselves may also arrange for pre-submission meetings. Whether they are seeking to submit their APIMF in support of an FPP application, or seeking prequalification of the API itself.

BIOEQUIVALENCE ASPECTS

PQT medicines strongly encourages applicants to submit a final draft of a bioequivalence study protocol to PQTm for comment prior to undertaking the study. If this process has not taken place prior to the pre-submission meeting, the meeting provides an opportunity for discussions on the proposed bioequivalence study protocol and the timeline for completion of the study. If the protocol has been vetted by PQT medicines prior to the pre-submission meeting, the meeting provides an opportunity for applicants to update the assessment team on the status of study and if, for example, a pilot study has been conducted, discussion of any results that may be available. Protocols or other information to be discussed at the pre-submission meeting should be submitted at least two weeks in advance of the meeting.

The pre-submission meeting may also provide an opportunity to discuss completed studies.
For this, a completed Bioequivalence Trial Information Form (BTIF) needs to be submitted along with the QOS-PD. This will help identify issues, if any, with respect to the basic attributes of the study (e.g., acceptability of the comparator product, study design, etc.) and thereby help the applicant save time if there are serious issues and a new study needs to be conducted.

PREPARATION FOR A PRE-SUBMISSION MEETING WITH PQT MEDICINES:

1. Read Advice to Manufacturers:
   https://extranet.who.int/prequal/sites/default/files/documents/103%20Advice%20manufacturers_Oct2016.pdf

2. Fill out and submit the enclosed “Request for pre-submission meeting” form.

3. As soon as possible, commence filling out the QOS-PD and if applicable the BTIF, for the intended product. The QOS-PD and if applicable the BTIF should be fully completed and then submitted at least two weeks prior to the scheduled meeting, together with an agenda for the pre-submission meeting, and any additional briefing information.