Preliminary Consultation in Cost-Effectiveness Evaluation of Medicines and Medical Devices

National Institute of Public Health
Center for Outcomes Research and Economic Evaluation for Health (C2H)

1. Timing and Contents

In principle, in the process of cost-effectiveness evaluation of medicines and medical devices, preliminary consultations between the manufacturer and the National Institute of Public Health will be held between 2 and 4 times.

The National Institute of Public Health will prepare minutes of the contents of consultations and send them to the manufacturer. If any questions arise about the contents of the minutes, the manufacturer will submit a query to the National Institute of Public Health within 3 business days. The contents of minutes may be reported to Expert Committee of Cost-Effectiveness Evaluation if necessary.

(1) First preliminary consultation

In principle, the first preliminary consultation will be held within a period of 2 weeks after the product is designated by the Chuikyo General Assembly. The manufacturer will enter the necessary items on the form in Attachment 1 and send it to the National Institute of Public Health by 3 business days before the date of the consultation. At the first preliminary consultation, there will be an explanation by the manufacturer about the following items. The consultation will include question-and-answer sessions, in principle last no more than 75 minutes, with about 10 to 15 minutes spent on each item. The manufacturer will print and distribute handouts.

i Overview of the target disease and product (for example, an overview of the indication, epidemiological information, the current standard therapy, the effect of the target product, the dosage and administration method and the mechanism)
ii An overview of the pivotal clinical trials and their results
iii An overview of evaluation by overseas Health Technology Assessment Agencies
iv The proposed framework of analysis for cost-effectiveness evaluation
v Other items for consultation

(2) Second preliminary consultation

In principle, the second preliminary consultation will be held within a period of 11 weeks after the product is designated by the Chuikyo General Assembly (about 9 weeks after the first preliminary consultation). In the second preliminary consultation, in response to the debate at the first preliminary consultation, the manufacturer may propose a new framework of analysis. The National Institute of Public Health will present its opinion on the framework of cost-effectiveness evaluation proposed by the manufacturer at the first preliminary consultation and hold a question-and-answer session. The opinion of the National Institute of Public Health will be sent to the manufacturer by 5 business days before the date of consultation. With the agreement of both parties, relevant clinical specialists may also participate. In principle, the consultation will last no more than 60 minutes.

(3) Third and later preliminary consultations

If the manufacturer and National Institute of Public Health do not reach agreement on a framework of analysis at the second preliminary consultation, a third preliminary consultation will be held after the second preliminary consultation, in principle within 2 weeks. With the agreement of both parties, relevant clinical specialists may also participate.

If agreement is not reached at the third preliminary consultation, a fourth preliminary consultation will be held, in principle within 2 weeks. With the agreement of both parties, relevant clinical specialists may also participate.

If agreement cannot be reached by the fourth preliminary consultation, in principle, the points of disagreement about analysis will be summarized and submitted to an Expert Committee of Cost-Effectiveness Evaluation.

2. Participants

In principle, the manufacturer (and company contracted by the manufacturer) and the National Institute of Public Health will participate. Academic analysis groups will not participate, but the contents of consultations will be shared with them as necessary.

From the second preliminary consultation onwards, with the agreement of both parties, relevant clinical specialists may also participate. However, the

participating experts have to disclose any conflicts of interests involving the relevant manufacturer at the preliminary consultation. The participating experts and their conflicts of interest will also be reported by the Expert Committee of Cost-Effectiveness Evaluation.

So that the preliminary consultation proceeds smoothly, in principle, the participants from the manufacturer will include at least one representative with specialist knowledge of cost-effectiveness evaluation (preferably with at least a master's degree in a field related to cost-effectiveness evaluation).

If necessary, representatives of the relevant section of the Ministry of Health, Labour and Welfare may also participate in the preliminary consultation.

3. Application method

Applications for the first preliminary consultation will be made to the contact address specified separately and will include a preferred date and time. In principle, preliminary consultations will be held each Friday (excluding the New Year holiday period and other weeks determined by the National Institute of Public Health) at the following times: (1) 11:15-12:30, (2) 13:30-14:45, (3) 15:00-16:15 and (4) 16:30-17:45. The timing of the second and subsequent preliminary consultations will be arranged as necessary, for example at the first preliminary consultation.

The location of consultations will be specified in a separate document, but at present it is expected to be in the vicinity of Kasumigaseki or at the National Institute of Public Health.

4. Pre-selection consultation

In the case of products with a high probability of being selected as target products for cost-effectiveness evaluation, consultation prior to the first preliminary consultation (pre-selection consultation) may be held if the manufacturer wishes, and if the National Institute of Public Health confirms that this is necessary.

Manufacturers who wish to request this should apply to the contact address using Attachment 2.

The main purpose of the pre-selection consultation is to provide explanations of the matters that should be considered in future preliminary consultations, such as the analysis guidelines and how to analyze the National Claims Database. The

discussions in this consultation do not restrict what can be discussed in subsequent preliminary consultations.

5. Joint analysis of the National Claims Database

If the manufacturer investigates the methods for analyzing the National Claims Database jointly with the National Institute of Public Health and wishes to be provided the results of analysis performed by the National Institute of Public Health (joint analysis), in principle, the manufacturer will request this at the first preliminary consultation. In this case, the manufacturer will present the proposed method of analysis to the National Institute of Public Health, in principle at the first or second preliminary consultation.

In principle, an investigation of whether the proposed method of analysis is appropriate should be performed in advance using data such as actual claims data. If the National Institute of Public Health judges that the proposed method of analysis is not feasible due to being insufficiently appropriate from a scientific viewpoint, it may refuse or suspend joint analysis.