European Federation of Pharmaceutical Industries and Associations

20th April 2021
EFPIA Japan

EFPIA Recommendations on the Cost-Effective Assessment System in Japan

TOKYO – 20th April 2021 –Following the series of decision of the cost-effectiveness assessment results in the Central Social Insurance Medical Council (Chuikyo) by 14th April, 2021 for innovative new drugs marketed by EFPIA Japan member companies, which was the first case after the cost-effectiveness assessment system was formally introduced in April 2019, EFPIA Japan believes that we can have constructive discussions by sharing the issues that the member companies have experienced in the system, and would like to make the following recommendations and express our awareness of the issues. In addition to ensuring the scientific validity of the cost-effectiveness assessment system, we expect the system to mature by ensuring the transparency so that the system can be reviewed post-hoc by third parties through detailed records and information disclosure of the discussions held between the companies and the public analysis team, as well as the content of the evaluation by the Cost-Effectiveness Assessment Expert Panel.

1. **Inclusion of the clinical perspective**

   Recommendation:

   In the pre-analysis consultation between the company and the public analysis team, scientific evaluation must be ensured, taking into account the clinical characteristics of the items to be evaluated. To this end, we request that the clinical perspective, which is essential to reflect real world medical practice, be reflected in the framework of the cost-effectiveness analysis by actively utilizing the participation of clinical experts from both company and public analysis team.

   Issue:

   In the cost-effectiveness analysis for EFPIA member companies' cases, we had the impression that clinical perspectives, which are essential to reflect real world medical practice, were not sufficiently taken into account. In order to ensure the scientific validity of the cost-effectiveness analysis framework, we believe that it is necessary to reflect not only the health economics perspective, but also knowledge of clinical experts, such as defining the added usefulness of the product from a clinical point of view.

2. **Agreement on a realistic time frame for company analysis**

   Recommendation:

   We call for a reconsideration of the system whereby the time required for companies to submit their analysis results is agreed at the end of the pre-analysis consultation.

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Issue:
In the cases of the member companies, the predetermined time frame of nine months from the pre-analysis consultation to the submission of the analysis results does not reflect the actual process and workload required to conduct a cost-effectiveness analysis, as the time required for a company to conduct an analysis depends largely on what has been agreed at the pre-analysis consultation. We also call for consideration of a further extension, particularly when there is a significant difference from the analytical framework prepared in advance by the company (e.g. requiring additional data analysis beyond clinical trial data).

3. **Accurate records of pre-analysis consultations**

Recommendation:
We call for prompt provision of minutes of pre-analysis consultations between the company and the public analysis team immediately after the completion of each consultation, detailing the presentation of data necessary for the determination of the analytical framework and the background to the discussions that have taken place.

Issue:
Because the content of the records of the pre-analysis consultations was inadequate, the companies were not able to start the analysis work promptly based on the results of the consultations. Further, the records were not useful as reference information for post-analysis verification and system review. We believe that it is necessary to prepare detailed minutes of the meetings, rather than a summary (abstract).

4. **Disclosure of information including scientific evidence**

Recommendation:
In order to ensure the transparency of the cost-effectiveness assessment system and for third parties to conduct qualitative review of the pre-analysis consultation and the evaluation contents of analysis results, we request the public disclosure of "Expert Panel decisions" prepared by the Expert Panel.

Issue:
Based on these companies' cases, in addition to guaranteeing the quality of the cost-effectiveness assessment, it is necessary that information is disclosed in order to assess whether validity is maintained in all steps from the pre-analysis consultation to the end of the analysis by the expert panel. We believe that open qualitative review by experts will lead to future improvement of the system. EFPIA Japan welcomes the publication of the outline of the cost-effectiveness assessment results at Chuikyo and the publication of the cost-effectiveness assessment report by both the public analysis team and the company.

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Unless all issues in the current system, including but not limited to the aforementioned recommendations and issues, are examined and corrected, EFPIA Japan cannot accept discussions towards expanding the system, such as expanding the number of the products subject to cost-effectiveness assessment and using it to make decisions on the reimbursement of the products.

About EFPIA Japan (http://efpia.jp/)
Established in April 2002, EFPIA Japan represents 20 R&D-based European pharmaceutical companies operating in Japan. In 2019, combined sales from the member companies accounted for roughly 23% of the pharmaceutical market in Japan. The mission of EFPIA Japan is to "Contribute to healthcare and patients in Japan through the early introduction of innovative medicines and vaccines". EFPIA Japan aims to strengthen dialogue with decision-makers in order to improve Japanese healthcare for all.

About EFPIA (European Federation of Pharmaceutical Industries and Associations)
(http://www.efpia.eu)
EFPIA, EFPIA Japan's partner organisation, is headquartered in Brussels and represents the pharmaceutical industry operating in Europe. Through its direct membership of 36 national associations and 39 leading pharmaceutical companies, EFPIA provides the voice of companies committed to researching, developing and bringing new medicines to improve health and quality of life around the world.

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