Unofficial translation

Ministry of Social Affairs and Health, Pharmaceuticals Pricing Board
May 2011

Annex to the Decree of the Ministry of Social Affairs and Health on applications and price notifications made to the Pharmaceuticals Pricing Board (201/2009)

GUIDELINES FOR PREPARING A HEALTH ECONOMIC EVALUATION

1 General

The purpose of the health economic evaluation attached to the application for reimbursement status and reasonable wholesale price for a medicinal product is to provide, in support of the Board's decision-making, a comprehensive estimation of the costs and benefits of the use of the medicinal product that the application concerns compared to those of other alternative treatments.

The health economic evaluation should be prepared in accordance with these guidelines.

In these guidelines the parts of the health economic evaluation are dealt with in an order that can be followed when preparing the evaluation.

The health economic evaluation is a part of the application regarding reimbursement status and price. Matters that have been covered comprehensively elsewhere in the application need not be dealt with broadly in the health economic evaluation.

The evaluation must be reported logically, clearly and transparently. The initial data, calculations, phases of analysis and final results must be verifiable. The application must be accompanied by research reports and other source material on which the evaluation is based. The references to information sources should be made precisely and unambiguously. Grounds must be given for all the assumptions presented in the evaluation. Expert opinions should be reported clearly, too.

The evaluation can be prepared in Finnish, Swedish or English. The evaluation should always include a summary in Finnish or Swedish.

2 Therapeutic indication and target group of the evaluation

The health economic evaluation must apply to the therapeutic indication approved for the medicinal product for which reimbursement status is applied for or, if there are several of them, the most important one or ones of them.

3 Treatment comparators and clinical practice

In the health economic evaluation, the health effects (benefits and adverse effects) and costs of the use of the medicinal product that the application concerns are compared with treatment comparators. The therapies that the medicinal product is compared with are determined on the basis of which indications reimbursement status is applied for. If the medicinal product is meant to replace the use of a certain medicinal product or a certain treatment, the product should be compared to that medicinal product or treatment. The comparator should be therapeutically the most appropriate alternative. There can be several comparators. Reasons must be given for the choice of the comparator, and the choice must be based on Finnish clinical practice.

4 Time horizon

The time horizon for the evaluation is influenced by the indication of the medicinal product. The consequences of the therapies compared should be measured and evaluated using the same principles. The health effects and costs of the therapies must be presented for an equally long period of time. The time period should be long enough to enable taking into account all essential costs and health effects.

5 Method of analysis

The method of the health economic evaluation can be cost-utility analysis, cost-minimisation analysis, cost-effectiveness analysis or cost-benefit analysis. Reasons must always be given for the choice of the method.

6 Modelling

Modelling should be used for the analysis, if there is no other way to take into account all essential health benefits and adverse effects as well as costs. The evaluation must include a detailed account of the structure of the model used as well as the data and the calculation formulas used in the model.

7 Estimation of costs

The calculation of costs must include, irrespective of the payer, all direct health care and comparable social welfare costs related to the therapies that are being compared. An examination of the costs of medicinal products alone is not sufficient, except for situations where the cost of the medicinal products is the only difference between the treatments. If productivity losses are included in the cost calculation, the results must also be presented so that those are excluded. A detailed account must be presented of the resources used and unit costs, giving the grounds and source references. The health economic evaluation must be based on as up-to-date information on the costs in Finland as possible.

The doses used in the medicinal treatment, the frequency and the route of administration and possible dose titration with grounds and source references must be reported. An account must be given of both the medicinal product that the application concerns and comparator products and, as necessary, of other medicinal products used for the treatment of the disease concerned or of adverse effects, if it is justified to assume that there are differences between the therapies compared in this respect. The dosage of the products compared must be the same by which the health effects used in the evaluation have been achieved.

The costs of the medicinal treatment used as treatment comparator must be calculated mainly using a preparation available on the market that complies to the established clinical practice and is most affordable, or the average cost of comparator products weighted by sales according to user or unit. Reasons must be given for the method of calculation that has been chosen. Medicine wastage has to be included in the costs.

The costs of medicinal products are calculated using the retail price, excluding VAT. If a medicinal preparation is administered in the outpatient unit within public health care, from which it is also dispensed, the wholesale price has to be used.

8 Estimation of health effects

The estimations of health states used in the evaluation must be based on research. As the most reliable study design is in general considered controlled and blinded clinical trials in which the alternative therapies are directly compared with each other.

The health effects used in the evaluation must be based on all the relevant studies that have been carried out on the therapies compared. Systematic reviews and meta-analyses are often the best way of combining the results of different studies. The applicant must give reasons for why the studies used in the health economic evaluation have been chosen for it.

Effectiveness must be measured primarily in quality-adjusted life years (QALYs), which have been measured using a validated generic quality of life measure. Effectiveness can also be measured for instance by final endpoints, surrogate endpoints or disease-specific quality of life measures. Reasons must be given for the choices made.

9 Discounting

The health effects and costs occurring beyond one year shall be presented both discounted and undiscounted.

10 Results

The health effects and costs of both the medicinal product that the application concerns and the treatment comparators shall be presented both as total benefits and total costs and as incremental benefits and incremental costs in the form of a table. The main results should be compiled in a separate table.

11 Assessment of uncertainty and sensitivity analyses

The applicant shall assess the uncertainty related to the variables, the structure of the model used and the methods used in the evaluation. The evaluation must include a sensitivity analysis if the evaluation is based on assumptions or otherwise uncertain premises. Reasons must be given for the sensitivity analyses and the variables chosen for them. Attention should be paid to the most significant uncertainty factors in view of the final results.

12 Sources and appendices

The information and data sources on which the health economic evaluation is based shall be appended to the application documents.