Instructions for expert opinions attached to an application

The Pharmaceuticals Pricing Board operates under the auspices of the Ministry of Social Affairs and Health. The task of the Board is to confirm the medicinal products covered by the medicines reimbursement system in Finland, their wholesale prices and reimbursement categories. The decisions regarding medicinal products subject to marketing authorisation are based on the application submitted by the marketing authorisation holder (pharmaceutical company). The applicants can attach written expert opinions to their applications.

The expert opinion attached to an application should describe e.g. the following:

- the present clinical practice regarding the disease, the treatment options available and access to treatment;
- an evaluation of the position of the medicinal product in clinical practice; does the medicinal product compensate for an existing treatment or medicinal product or does it reduce the need for other treatment/pharmacotherapy?
- clear benefits of the medicinal product compared to other treatments;
- possible uncertainty factors and drawbacks related to the medicinal product;
- particular monitoring, supportive treatment etc. related to the medicinal product;
- an estimate of the most commonly used daily dose of the medicinal product and typical length of the therapy;
- an estimate of the number of patients in Finland and how many of them use the medicinal product.

The studies on the basis of which the marketing authorisation has been granted and other studies regarding the medicinal product and indication concerned included in the application, as well as the existing Current Care Guidelines will be evaluated at the Pharmaceuticals Pricing Board. In general, these need not be dealt with in detail in the expert opinion. On the other hand, other national or international care recommendations that are generally observed in Finland can be beneficial in the evaluation of the medicinal product. Case reports on individual patients are not evaluated at the Board. If such are however presented, the party giving the opinion must see to it that individual patients are not recognisable. A description of the disease is necessary only if a rare dis-ease is concerned.

The Pharmaceuticals Pricing Board may confirm reimbursement for a medicinal product at the most to the extent specified in the summary of product characteristics confirmed by the marketing authorisation authority and the indications approved there. Reimbursement status can also be approved to apply to a more limited use than the approved indication (restricted reimbursement status).

Appeals by experts to grant reimbursement status are often useless in view of the evaluation of reimbursement status if no expert assessment or opinion is attached to them.

The party giving the opinion must clearly report any conflicts of interests related to the matter/application.