GUIDE FOR COMPANIES ON NEGOTIATING A CONFIDENTIAL PRICE FOR NEW, HIGH-COST MEDICINES FOR THE PRIMARY SECTOR

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Background

This guide is relevant for companies whose medicinal product has previously been rejected or is recommended for rejection for general or conditional reimbursement during the Danish Medicines Agency's reimbursement assessment. Companies may request to negotiate a confidential price with Amgros after receiving the Reimbursement Committee's recommendation for consultation. If a recent rejection has been given and the relevant case material is still valid, the company may contact Amgros directly to initiate negotiations.

Questions regarding the above and the reimbursement process in general can be directed to the Danish Medicines Agency at medicintilskud@dkma.dk.

Required documentation

To initiate negotiations with Amgros, the company must submit the following documentation:

1. Medical case presentation and price overview from the Danish Medicines Agency
2. Recommendation from the Reimbursement Committee
3. The company's own application for general or generally conditional reimbursement
4. Health economic analysis, as described below

Health economic analysis

To document the cost-effectiveness of the medicinal product, a health economic analysis must be submitted prior to negotiations. This may already have been submitted as part of the application for general or generally conditional reimbursement to the Danish Medicines Agency.

The health economic analysis should generally follow the Danish Medicines Agency's guidance:
Guidance on the preparation of health economic analyses of medicinal products

Please also use the Danish Medicines Council's methodological guidelines for inspiration.

The analysis should primarily compare two scenarios:

1. *The medicinal product is granted general or generally conditional reimbursement* based on the negotiated confidential price
2. *The medicinal product is not granted such reimbursement*, potentially resulting in higher or lower costs for single reimbursements

Examples of Content in the Health Economic Analysis

The cost-effectiveness of a medicinal product will be assessed based on various case-specific criteria. Companies should emphasize cost elements particularly relevant to the regions' overall budget impact. Municipal costs may also be included if relevant, such as expenses for home care or rehabilitation. Time spent by patients and relatives may also be considered.

The analysis should focus on drug-related expenses, including the regions' total additional costs if the product is granted reimbursement based on the negotiated confidential price. This includes an estimate of the patient population size. It should also compare derived drug-related savings, such as reduced costs for alternative treatments.

Expected drug-related costs may also include anticipated expenses for individual subsidies or other regional treatment-related costs if the product is not granted reimbursement.

Drug-related expenses should be compared to other treatment-related costs and savings for the regions, such as costs for general practitioners and specialists, especially if the reimbursement affects the number of consultations.

Other treatment-related costs may include hospital expenses associated with or resulting from the treatment. These may be reduced if the product is reimbursed, for example, through fewer acute treatments, hospitalizations, or outpatient visits.

Additional costs that may be included are medical examinations and diagnostic tests that the treatment may reduce the need for. If the product prevents disease progression or complications, it may reduce the need for expensive tests and services such as X-rays, MRIs, and blood tests. Potential savings from avoided surgical procedures should also be included.

Negotiation

Negotiations are based on the submitted material. They will generally focus on the reasons for previous rejection or recommendation for rejection, particularly if the price is deemed disproportionate to the therapeutic value. It may also be relevant to negotiate a maximum number of packages reimbursed by the regions, in cases where there is a risk of use outside the requested conditions.

Regional assessment of the negotiated Agreement

According to the *Act on Amendments to the Health Act (Introduction of a new pilot scheme for reimbursement based on a negotiated confidential price),* the regions assess whether an agreement between Amgros and the company can be made.

The regions are represented by a group of selected members tasked with evaluating whether the agreement is cost-effective for the regions if the product is granted reimbursement under the negotiated terms. The assessment is based on the negotiated elements and the health economic analysis. The confidential price is also presented as a consumer price, using a conversion formula from the pharmacy purchase price (AIP) to the consumer price (ESP), ensuring a common basis for both the regions and the Danish Medicines Agency.

Amgros prepares a proposal for the assessment group with a recommendation on whether an agreement should be made.

Final Decision on Reimbursement

Amgros and the company enter into a conditional agreement on a confidential price and other negotiated elements. If the regions assess that the result makes treatment with the product cost-effective under the agreed terms, the company may use the agreement to apply to the Danish Medicines Agency for reimbursement based on the negotiated confidential price. The Danish Medicines Agency then makes the final decision on reimbursement status. If the product is not granted reimbursement based on the negotiated price, the agreement will no longer apply unless the company wishes it to apply to single reimbursement.