

# The Danish Medicines Council's Methodological Guideline for the Assessment of New Drugs



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# 1. Introduction

The Danish Medicines Council's methodological guideline is intended to support applicants seeking an assessment by the Danish Medicines Council of a new drug or an indication extension of an existing drug. The guideline also serves as a working tool for the Danish Medicines Council's three bodies: the Council, the expert committees, and the Secretariat. In addition, the methodological guideline provide other stakeholders with insight into the Danish Medicines Council's methodology for the assessment of new drugs and indication extensions. In this guideline, the term "new drug" refers to both new drugs and indication extensions that are not directly included in one of the Danish Medicines Council's treatment guidelines. The term also includes potential combination therapies involving two or more drugs.

The methodological guideline consists of the present document and a series of supplementary guidelines providing more detailed guidance on specific topics. These documents are to be used in the preparation of a comprehensive submission.

The process for the assessment of new drugs is described separately in the Danish Medicines Council's process guideline for the assessment of new drugs. Together, the methodological guideline and the process guideline form the basis for the Danish Medicines Council's work in assessing new drugs.

The assessment of new drugs takes place within the political framework of the Danish Parliament's seven overarching principles for the prioritisation of hospital drugs, as well as the two principles of caution and severity, which the Danish Medicines Council may apply in certain cases. The seven principles and a description of how the Danish Medicines Council applies the caution and severity principle are available on the Danish Medicines Council's website: <https://medicinraadet.dk/>.

## **Deviations from the Danish Medicines Council's methodological standards**

All submissions to the Danish Medicines Council must comply with the standards set out in the methodological guideline. In cases where data are limited, for example in the context of rare diseases, the applicant must present the available evidence in accordance with the current methodological guideline, including a description of any data limitations. The applicant must also prepare a health economic analysis in which the limitations and underlying assumptions are thoroughly described and evaluated. Any deviations from the Danish Medicines Council's methodological standards must be justified and clearly stated in the submission.

## **Use of Experts**

In general, it is preferable that applicants use international data and/or Danish expert sources as references where Danish data are not available. When expert sources are used, applicants must engage experts other than members of the Danish Medicines Council's expert committees. As a general principle, it would be contrary to the Danish Medicines Council's conflict of interest policy for a member of an expert committee to participate in advisory activities with applicants with interests within the committee's



area of expertise. For further details, see the Danish Medicines Council's conflict of interest policy.

## 2. Patient Population, Intervention, Comparator(s), and Outcomes (PICO)

The applicant must describe the intervention and the patient population expected to be eligible for treatment in Danish clinical practice, including its placement within the existing treatment algorithm.

The drug must be compared with one or more comparators that constitute the current standard of care for the relevant patient population in Danish clinical practice. Survival, health-related quality of life, and safety must always be included in the comparison between intervention and comparator(s). The primary endpoint(s) of the study or studies on which the regulatory approval is based must always be included in the submission.

Documentation related to the PICO must follow the instructions provided in the Danish Medicines Council's submission dossier. The Danish Medicines Council's guideline on PICO should be used as a supporting document when preparing a comprehensive submission.

## 3. Analyses of Effect and Safety

The applicant must describe the study design, patient characteristics, and the results for all studies used to document efficacy and safety for both the intervention and comparator(s).

The Medicines Council prefers that differences in efficacy between the intervention and the comparator(s) are demonstrated through a study that directly compares the two treatments (head-to-head) with follow-up of sufficient duration to capture all relevant differences in effects. When indirect comparisons (e.g., network meta-analysis or matching-adjusted indirect comparison) are required, or when real-world evidence is used to estimate differences in efficacy, the applicant must provide a detailed description of the statistical methods applied and all underlying assumptions. The applicant must also present sensitivity analyses assessing the robustness of the results.

The applicant must justify which endpoints measures from the clinical studies are included in the health economic analysis and which are excluded. For all intermediate endpoints, including surrogate endpoints, the applicant must describe the evidence supporting the relationship between the patient-relevant endpoint and the intermediate endpoint.



Regardless of the chosen type of analysis, the applicant must present the key uncertainties and assess the impact of any prognostic or effect-modifying variables.

Documentation related to efficacy and safety must follow the instructions set out in the Danish Medicines Council's submission dossier. The Danish Medicines Council's guideline on effect and safety and on real world evidence should be used as supporting documents when preparing a comprehensive submission.

## 4. Health Economic Analysis and Extrapolation

The Danish Medicines Council's recommendation regarding a new drug is based on an assessment of whether the drug's effect, measured in quality-adjusted life years (QALYs), and safety are reasonably balanced against the costs associated with introducing the drug compared with the current standard of care in Danish clinical practice. The assessment is based, among other considerations, on a health economic analysis.

The health economic analysis takes the form of a cost-utility analysis, in which differences in QALYs and costs between the intervention and comparator(s) are expressed as an incremental cost-effectiveness ratio (ICER).

A cost-utility analysis may be reduced to a cost-minimisation analysis, in which only differences in costs between the intervention and the comparator(s) are considered, if the new treatment and the current standard of care are equivalent across all relevant endpoints, including health-related quality of life, and safety. Equivalence will always be based on an overall assessment that the intervention is neither superior nor inferior to the comparator(s), based on the available evidence and clinical experience.

The health economic analysis must be conducted from a limited societal perspective. This means that only treatment-related effects and costs are to be included. The time horizon of the health economic analysis must be sufficiently long to capture all important differences in treatment-related effects and costs between the intervention and the comparator(s).

The health economic model is based on a series of assumptions regarding the patients' disease and treatment pathway in Danish clinical practice, as well as a range of inputs in the form of study data, external sources, and other assumptions. The result of the health economic analysis is therefore an estimate that relies on extrapolation of several inputs both during and beyond the observation period of the clinical studies. Regardless of whether extrapolated time-to-event data derived from parametric extrapolation models, fixed transition probabilities, or clinical expert opinion are used to estimate effects or resource use over time, such extrapolation is inherently based on estimates and assumptions that are subject to varying degrees of uncertainty.



The health economic analysis must be based on a health economic model, which is a quantitative tool that enables synthesis of the available evidence for the intervention and comparator(s). All inputs to the health economic model must be thoroughly described based on the available evidence.

Documentation related to the health economic analysis must follow the instructions set out in the Danish Medicines Council's submission dossier. The Danish Medicines Council's guideline on health economic analysis and extrapolation should be used as a supporting document when preparing a comprehensive submission.

## 5. Health-related Quality of Life

The Danish Medicines Council assesses health-related quality of life both as an independent endpoint and as a basis for estimating utility values used to calculate QALYs in the health economic analysis.

To ensure consistency in the assessment of health-related quality of life and QALY effects across the Danish Medicines Council's recommendations, all submissions must include data on health-related quality of life measured using the generic instrument EQ-5D-5L. Utility values must likewise be derived from EQ-5D-5L with Danish preference weights.

If EQ-5D-5L data have not been collected in the clinical study or studies documenting clinical efficacy and safety, or such data are very limited, it may be necessary to report health-related quality of life measured with other instruments, apply mapping algorithms, or use external sources.

In cost-minimisation analyses, the drugs must also be equivalent in terms of health-related quality of life. Such equivalence must preferably be documented using the EQ-5D-5L instrument and, if relevant, supplemented with other generic and/or disease-specific instruments.

Documentation relating to health-related quality of life must follow the instructions in the Danish Medicines Council's submission dossier. The Danish Medicines Council's guideline on health-related quality of life should be used as a supporting document when preparing a comprehensive submission.

## 6. Costs

To compare the costs associated with the drugs included in the health economic analysis, it is necessary to identify, quantify, and value the resource use for the intervention and the comparator(s). As a general rule, cost estimation must be based on resource use in Danish clinical practice and current Danish unit costs.



Treatment-related costs include drug costs, hospital costs, and costs related to patients' resource use in terms of time and transportation. In certain cases, it may also be relevant to include other costs covered by the public health insurance or municipal budgets.

The estimation of costs must follow the instructions in the Danish Medicines Council's submission dossier. The Danish Medicines Council's guideline on cost calculations should be used as a supporting document when preparing a comprehensive submission.

## 7. Presentation of Results and Uncertainty

The results of the health economic analysis must be presented in tables in both the submission dossier and the health economic model. The applicant must systematically identify, describe, and analyse the key uncertainties associated with the results.

Documentation must follow the instructions set out in the Danish Medicines Council's submission dossier. The Danish Medicines Council's guideline on uncertainty and sensitivity analyses should be used as a supporting document when preparing a comprehensive submission.

## 8. Budget Impact Analysis

To inform the Danish Medicines Council of the regional budget implications associated with the introduction of a new drug, the applicant must calculate the total regional budget impact for the relevant patient population. The budget impact analysis must estimate the magnitude of any additional costs associated with the introduction of the new drug compared with the existing standard of care.

Documentation must follow the instructions set out in the Danish Medicines Council's submission dossier. The Danish Medicines Council's guideline on budget impact analysis should be used as a supporting document when preparing a comprehensive submission.

## 9. Literature

Where relevant, the applicant must conduct literature searches to identify and select relevant documentation on clinical efficacy and safety, health-related quality of life, and other key inputs to the health economic analysis. The objective is to ensure that all sources potentially relevant to the assessment are considered.

Literature searches and study selection must be conducted according with internationally recognised principles that ensure a systematic and transparent approach.



For all key data, the applicant must describe how the data were identified and selected to ensure that the selection process can be validated and reproduced.

Documentation must follow the instructions set out in the Danish Medicines Council's submission dossier. The Danish Medicines Council's guideline on literature should be used as a supporting document when preparing a comprehensive submission.



## 10. Version log

Version	Date	Revision
2.0	March 6 2026	Approved and published.
1.0	November 19 2020	Approved by the Board of the Danish Regions.

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