Medicinrådet

The Danish Medicines Council's process guide for assessing new pharmaceuticals

This translation is based on the Danish document "Medicinrådets procesvejledning for vurdering af nye lægemidler" (Version 1.1). Please note: The translation is provided as a service by the Danish Medicines Council to English-language readers. In the event of discrepancies, the Danish version prevails.

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Introduction

The aim of this process guide is to help pharmaceutical companies that want to have a new medicine, or an extension of indication for an existing medicine, assessed by the Danish Medicines Council. The process guide also serves as a tool for the Danish Medicines Council, including council members and members of expert committees. Furthermore, the process guide may provide other stakeholders with insight into the Danish Medicines Council's process for assessing new medicines and extensions of indication. In this document, the term "new medicine" refers to both new medicines and extensions of indication. The methods for assessing new medicines, including specification of requirements for applications to the Danish Medicines Council, are described in the Danish Medicines Council's methods guide on assessing new medicines. The two guides form the basis for how the Danish Medicines Council assesses new medicines.

A recommendation for a medicine by the Danish Medicines Council is based on an assessment of whether the effect (measured as quality-adjusted life-years (QALY)) and safety of a medicine is reasonably proportionate to the cost of bringing the medicine into use. Assessment of a new medicine is within the political framework of the Danish Parliament's seven overarching principles for prioritising hospital medicines and the two principles of economic cautiousness and severity that the Danish Medicines Council can consider in exceptional circumstances. The seven principles of the Danish Parliament and a description of how the Danish Medicines Council applies the severity principle are available (in Danish) on the Danish Medicines Council website: www.medicinraadet.dk

About the Danish Medicines Council

The Danish Medicines Council was established on 1 January 2017 by Danish Regions. The Danish Medicines Council prepares recommendations and guides for the Regions on the use of medicines. The terms of reference, rules of procedure etc. are available (in Danish) on the Danish Medicines Council website.

The Danish Medicines Council consists of three units: expert committees, the Secretariat and the Council, and these are further described below.

Expert committees under the Danish Medicines Council

When the Danish Medicines Council prepares recommendations regarding the use of medicines, the Danish Medicines Council establishes an expert committee consisting of members with specific knowledge about the relevant disease, including physicians, nurses, pharmacists, patients, etc. The expert committees assist the Danish Medicines Council with medical, pharmaceutical and patient-oriented assessments. The composition and tasks of each expert committee are described in the terms of reference for the expert committee, and these are approved by the Council. A list of all the specialist committees and their terms of reference is available (in Danish) on the Danish Medicines Council website. Expert committees are standing committees convened as required. Members of expert committees are appointed for a period of two years with the possibility of reappointment. Members of expert committees have to submit declarations of interests, i.e. direct and indirect interests, in accordance with the Danish Medicines Council's impartiality policy.

An expert committee typically consists of the following members:

- A chair nominated by the Organisation of Danish Medical Societies (LVS) and appointed by the Council.
- Members appointed by the regions.
- Members appointed by relevant scientific societies, including the Danish Society for Clinical Pharmacology, the Danish Society for Hospital Pharmacy Management and the relevant scientific societies for the relevant disease area.
- One-two nursing staff appointed by the Danish Nursing Society (DASYS).
- One-two patients/patient representatives appointed by Danish Patients.

Furthermore, the chair of an expert committee can appoint members with special qualifications or knowledge necessary for the work of the expert committee, e.g. a physiotherapist, a dietician, etc.

Patients/patient representatives contribute experience-based knowledge from their own disease pathway and, where possible, other patients' experience of the disease and the medicines used in treatment. See the Danish Medicines Council website for more information about involving patients in expert committees.

The Danish Medicines Council Secretariat

The Secretariat supports the Council and the expert committees. A project group from the Secretariat is assigned to each assessment. The project group is responsible for the process and methods for the assessment and it consists of health sciences consultants and health economists. The project group ensures that applications and analyses from companies meet the standards described in the Danish Medicines Council's methods guide, and it ensures that the assessment process follows this guide. The project group facilitates the work of the expert committees and it prepares materials for meetings, including draft assessment reports. Biostatisticians and information specialists from the Secretariat are involved in the assessment as needed. The project group is responsible for contact with Amgros and the company during the process.

The Council

The Council constitutes the board of the Danish Medicines Council. The Council decides whether it can recommend new medicines and extensions of indication as possible standard treatment at Danish hospitals on the basis of decision groundwork submitted by the expert committee, the Secretariat and Amgros.

A recommendation from the Danish Medicines Council for a medicine to be a possible standard treatment means that the Council has assessed that the overall effect of the medicine is proportionate to the cost and disadvantages linked to the use of the medicine. Implementation of recommendations from the Danish Medicines Council is the responsibility of the regions.

The Council's terms of reference and composition, as well as information about previous and upcoming Council meetings are available (in Danish) on the Danish Medicines Council website.

The Danish Medicines Council prepares recommendations for medicines restricted to use at hospitals

Companies that have applied for authorisation to market a new medicine or extension of indication in Denmark can contact the Danish Medicines Council for an assessment of whether the Danish Medicines Council can recommend the medicine as a possible standard treatment in Denmark. The Danish Medicines Council assesses medicines that are, or are expected to be, included in one of the following dispensing groups:

- BEGR: Medicines only to be dispensed to hospitals.

- AP4BG: Medicines only to be dispensed to hospitals and dispensed only once on the same prescription.
- AP4NB: Medicines only to be dispensed to hospitals or prescribed by selected specialist physicians.
- NBS: Medicines only to be dispensed to hospitals or prescribed by specialist physicians as determined by the Danish Health Authority on a case by case basis. As a general rule, the Danish Medicines Council only assesses medicines in this group that may only be distributed to hospitals.

The Danish Medicines Council may also decide to assess medicines and extensions of indication at its own initiative, e.g. on the basis of a request from one or more regions. This may be medicines covered by the above dispensing groups or other medicines.

1. Structure of the process guide

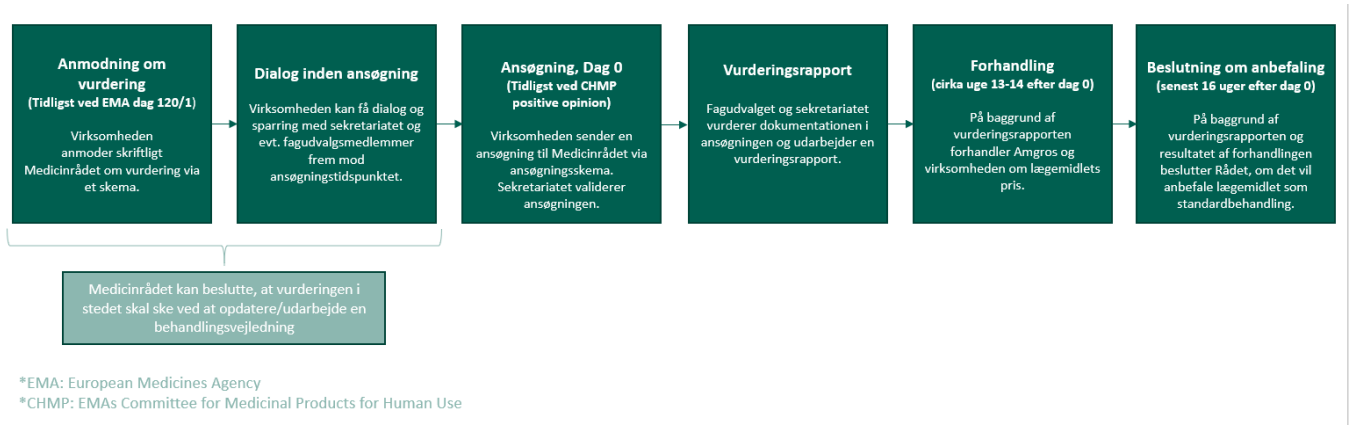
The Danish Medicines Council's process for assessing new medicines and extensions of indication generally follows the following steps.

- Request for assessment
- Dialogue before application
- Application
- Assessment report
- Negotiation
- Decision regarding recommendation.

An ordinary process takes up to 16 weeks from the date of receipt of a complete application by the Secretariat (Day 0) to a final recommendation by the Danish Medicines Council.

The individual steps are shown in the figure below and described individually in sections 2-7 of this guide.

Process line



*EMA: European Medicines Agency
*CHMP: EMAs Committee for Medicinal Products for Human Use

Translation of figure

Request for assessment (earliest EMA day 120/1)	**Dialogue before application**	**Application day 0 (earliest after positive opinion from CHMP)**	**Assessment report**	**Negotiation (approx. 13-14 weeks after day 0)**	**Decision on recommendation (latest 16 weeks after day 0)**
The company submits a written request to have a pharmaceutical assessed by the Danish Medicines Council using a form	The company may enter into dialogue and request advice from the Secretariat and possibly members of the expert committee before submitting an application	The company sends an application to the Danish Medicines Council via an application form. The Secretariat validates the application	The expert committee and the Secretariat assesses the documentation in the application and prepares an assessment report	On the basis of the assessment report, Amgros and the company negotiate the price of the medicine.	On the basis of the assessment report and the results of the negotiation, the Council decides whether it will recommend the

					medicine as a standard treatment

The Danish Medicines Council may decide that the assessment can happen while updating or preparing a treatment guideline.

Sections 8-11 describe guidelines for the Danish Medicines Councils processing time , the use of clock-stops, companies' ability to withdraw their application, the process for reassessing a recommendation, as well as the information and documents published by the Danish Medicines Council and when they are published. In some cases, the Danish Medicines Council assesses new medicines or extensions of indication by updating treatment guidelines or preparing new ones. This applies if the effect and safety profile of the medicine is comparable with the existing treatment options, and the Danish Medicines Council therefore expects to assess the medicine as equivalent to existing medicines. This is described in section 12. Entry into force of this guide is described in section 13.

2. Request for assessment

A company wanting a medicine assessed by the Danish Medicines Council has to submit a request for assessment to the Danish Medicines Council Secretariat by no earlier than day 120 in the assessment process at the European Medicines Agency (EMA) for new medicines in the normal approval procedure at the EMA and no earlier than day 1 for extensions of indication and new medicines in the accelerated approval procedure at the EMA.

A form is necessary, and this can be downloaded from the Danish Medicines Council website and sent to the Danish Medicines Council's main email: medicinraadet@medicinraadet.dk.

The request signifies that the pharmaceutical company wants the medicine to be assessed by the Danish Medicines Council. The Danish Medicines Council Secretariat will use the request to enter into a dialogue with the company about the content of its application and to plan the assessment process, including ensuring that an expert committee is set up.

The company has to include the following information in the form:

- Name of company
- Contact person and possibly power of attorney, if the company uses an external representative.
- Information about the medicine (incl. ATC code, form of administration, dose)

- Expected timeline for issuing marketing authorisation and for the final application to the Danish Medicines Council
- Brief account of the disease and existing treatment in Denmark
- The new medicine
- Any relationship with existing treatment guidelines
- Any further information described in section 3. Dialogue before application.

If there is a need to set up a new expert committee to carry out the assessment, the Secretariat will start establishing the expert committee upon receipt of a request for assessment.

When the Danish Medicines Council receives a request for assessment from a company, the Danish Medicines Council will make public the name of the company, the generic name of the medicine and its indication. A process indicator for the assessment is set up on the Danish Medicines Council website. The process indicator is updated regularly and it indicates how far the Danish Medicines Council has come in its assessment of the medicine, as well as when it is expected that the Council will decide on its recommendation. See also section 11 on transparency and publication.

3. Dialogue before application

When a company has submitted a request for assessment, it can request a meeting with the Secretariat's project group for advice on the application and process. Prior to the meeting, the company should submit any questions and relevant material so that the Secretariat can prepare for the meeting and, if necessary, confer with members of the expert committee on any issues relating to the disease, treatment and Danish clinical practice. This may be information on:

- Study characteristics for relevant clinical studies
- Results of clinical studies
- Expected health economic analysis
- Ongoing studies
- Other relevant information.

If the company already knows it wants a dialogue with the Secretariat about the application when it submits the request for assessment, the company may add the necessary information and any questions to the form to request an assessment.

In some cases, the Secretariat and the chair of the expert committee may deem it appropriate for the chair of the expert committee or a member of the expert committee to participate in the meeting with the company. For example, this may be in situations where there is only sparse knowledge about the disease and/or treatment in Denmark.

The company can receive general advice at the meeting. The Secretariat cannot say anything binding about the specific case. The content and choices in the application are always the responsibility of the company.

In addition to the meeting, the company can always contact the project group in the Secretariat with any further questions.

4. Application

The company can submit an application to the Danish Medicines Council when the EMA's Committee for Medicinal Products for Human Use (CHMP) has given a positive opinion. The application form is on the Danish Medicines Council website, and specifications of requirements for applications are described in the methods guide.

An application to the Danish Medicines Council will consist of a completed application form, a health economic analysis and a budget impact analysis. The health economic analysis and budget impact analysis must be submitted in Excel format.
The application materials should be sent to the Danish Medicines Council's main email address (medicinraadet@medicinraadet.dk).

The Secretariat will plan the assessment process according to the date of submission of the application that the company has stated in the request previously submitted. If the application is not submitted on the date the company has agreed with the Secretariat, this may cause longer case processing time, and the Council decision on the recommendation may be postponed to a later meeting. See section 8 on case-processing times and clock-stop.

4.1 Validation of application

The Secretariat carries out a technical validation of the application by reviewing the application materials to ensure that all the specifications of requirements have been met. The validation includes checking whether the application form has been completed correctly with relevant information and source references, and whether the health economic analysis has been submitted in Excel format with the possibility to change relevant parameters. All inputs in the model must be fully editable, and in the event of changes, the model must automatically update all the results, sensitivity analyses etc.

The company will be notified on whether the application can be approved and considered as satisfactory as soon as possible, and by no later than within 10 business days, provided the application was submitted at the agreed time. If the application is not approved, a brief explanation will be attached to the notification. As soon as possible, the company must state when it expects to submit a new/ updated application to help

planning by the Secretariat and the expert committee. When the company submits an amended application, the Secretariat will start a new validation.

Day 0 is the day when the Danish Medicines Council receives an application that is assessed as complete in the validation.

4.2 Additional data after day 0

If, following day 0, the company gains access to additional data not included in the original application, and which changes the analysis significantly, this must be sent to the Secretariat as an annex to the original application with an updated health economic analysis. New data submitted after day 0 may lead to the need for a new assessment by the expert committee and for amendments to the assessment report. If supplementary data is submitted after day 0, this may cause longer case processing, and the Council decision on the recommendation may be postponed to a later meeting.

5. Assessment report

The Secretariat and the expert committee work together on reviewing and assessing the application material from the company. The assessment report includes a description and assessment of the clinical studies, the effect and safety of the medicine against comparator(s), and a description and assessment of the health economic analysis from the company. The results of the clinical studies and from the health economic analysis, as well as the most important uncertainties are presented in the report. Clinical assessments by the expert committee and their comments on the estimated results and most important uncertainties will also be stated in the report.

The expert committee will assess the results and quality of the clinical studies and assess whether study populations and comparator(s) correspond to Danish clinical practice. The Secretariat's project group is responsible for the technical review of the methods used in the clinical analysis and health economic analysis. The Secretariat will identify the parts of the health economic analysis and budget impact analysis that the expert committee is to assess, in order to ensure that they correctly reflect Danish clinical conditions.

The expert committee and the project group will meet and draw up an assessment report at one, and possibly more, expert committee meeting(s).

If, during the process, the expert committee or the Secretariat discovers errors, requires changes in the application, lacks important data, or has questions for the company, these will be compiled in a communication to the company. See more in section 8 on case-processing times and clock-stop.

When the expert committee and the Secretariat have completed the assessment report, it will be sent to the company and to Amgros. This will usually be 12 weeks after day 0.

5.1 Feedback from the company on the assessment report

The company will be asked to review the draft assessment report for factual errors and verify that all information they consider as confidential has been marked in the report. The company also has the option to write a two-page note to accompany the assessment report when the Council examines the matter. The company can include additional information in the note which they want the Council to be aware of. The note may not contain new data that has not been used in the company's application. The note will be published with any confidential information blocked out. The company has 10 days to submit any comments and remarks.

6. Negotiation

On the basis of the assessment report, Amgros will negotiate the price of the medicine with the company. Negotiations with Amgros take place at the same time as the company has the draft assessment report for review. An employee from the Secretariat may participate as an observer in negotiations between Amgros and companies.

When negotiations have been completed, Amgros will send a negotiation note to the Secretariat with the negotiated prices.

The Secretariat updates the assessment report on the basis of the agreed prices from Amgros.

In the event of any delay in the negotiations due to circumstances at the company, Amgros can notify the Secretariat that a clock-stop is to be triggered. The Council decision on the recommendation will then be postponed to a later Council meeting. See section 8 on case-processing times and clock-stop.

For further information about the negotiation process, the Danish Medicines Council refers the reader to Amgros.

7. Decision on recommendation

The Secretariat prepares the basis for decision for the Council based on the assessment report and the negotiation note from Amgros.

The expert committee and the project group will present the assessment report to the Council. The focus of the presentation is on the results of the clinical studies and the health economic analysis, as well as the most important uncertainties that the Council should be aware of. The Council may subsequently ask questions to representatives from the expert committee and the Secretariat. Amgros will present the negotiation note and

answer any questions from the Council. Only the Council can decide the recommendation.

When the Council is to decide whether the medicine is to be recommended as a possible standard treatment, it will assess whether the effect and safety of a product are proportionate to the cost of putting the medicine into use. This assessment will be based on the Danish Parliament's (the Folketing) seven overall principles for prioritising hospital medicines, as well as the principles of caution (*forsigtighed)* and severity (*alvorlighed)*. In assessing whether the uncertainties are acceptable, the Council may consider the size of the patient group and whether more or better data on the effect of the medicine could reasonably be expected. The seven principles of the Danish Parliament and a description of how the Danish Medicines Council applies the severity principle are available (in Danish) on the Danish Medicines Council website: www.medicinraadet.dk.

In connection with the recommendation, the Council may call for further data collection, e.g. about the effect of the medicine on Danish patients within a defined period of time, in order to reassess the recommendation when sufficient new data is available. This could be in assessments for which the data available is associated with significant uncertainty, or where the Council wants to see data on adverse effects after a period of time.

The Council will formulate its recommendation, and the Danish Medicines Council will publish the recommendation immediately thereafter.

8. Case-processing times and clock-stop

A final recommendation by the Danish Medicines Council for new medicines usually takes 16 weeks from the date of receipt of a complete application by the Secretariat (day 0).
If delays from the company's side arise during the process, e.g. if the company submits an application later than agreed, or if there are delays in the negotiations with Amgros as a result of factors at the company, these will not be included in the case processing time.

If, during the process, the Secretariat, the expert committee or the Council lacks information, requests changes in the applications, or has questions for the company, these will be compiled in a communication to the company. The company will have three working days to reply to the questions. If the company needs more than three days to provide the required information, the assessment process will be temporarily suspended (clock-stop) until the Secretariat has received the information. To help in further planning, the company must notify the Secretariat as soon as possible about when it expects to submit a reply.

The Danish Medicines Council has an option to implement an extended clock stop in exceptional cases in which unforeseeable technical problems arise in connection with the Council's assessment of a medicine. In these cases, the Council may have to collect new information or verify data further in order to assess the case. With an extended clock-stop, among other things, the Danish Medicines Council will be able to have a more in-depth dialogue with an expert committee or discuss a matter at a further Council meeting. An extended clock-stop will mean a delay in the process.

9. Withdrawal of an application

A company may, at any time in the process, withdraw its application by notifying the Secretariat in writing. Since the Danish Medicines Council may take up a case at its own initiative, the Council may decide to continue processing the withdrawn application. The Danish Medicines Council may have documents already submitted by the company included in the further processing. The Danish Medicines Council may publish documents on the website to the same extent as if the application had not been withdrawn. For more on management of confidential information, see section 11.

10. Process for reassessment of a recommendation

Companies may request the Danish Medicines Council to reassess a recommendation. The Danish Medicines Council will generally regard this positively, if there is new information which shows a significant change in the clinical effect and safety and/or in the results of the health economic analysis.

The company will have to update the application with the new information and submit the application again, with clear indication of the changes compared with the original version. In light of the new information, the Secretariat will inform the Council that there is new information that changes the results in the assessment report. On this basis, the Council will decide whether the recommendations should be reassessed. In this process, the Danish Medicines Council has the option to reassess all the elements of the application.

The Danish Medicines Council may also reassess a recommendation if the company wants to reduce the price of the medicine substantially. In this case, the Secretariat will receive notification from Amgros that the price has been substantially changed and it will update the health economic analysis with the new price. On the basis of the new price

and an updated analysis, the Council will consider whether the recommendation should be reassessed. In this process too, the Danish Medicines Council has the option to reassess all the elements of the application.

The Danish Medicines Council may, at its own initiative, e.g. following inquiries from medical societies about new information about the medicine or the disease area, decide to reassess a recommendation.

11. Transparency and publication

In order to ensure transparency in the process of assessing new medicines and extensions of indication, the Danish Medicines Council regularly publishes relevant information.
A process indicator is regularly updated on the Danish Medicines Council website. The indicator runs from when the Danish Medicines Council receives a request for assessment from a company to when the Council has decided whether it will recommend the medicine as a possible standard treatment.

The Danish Medicines Council publishes the following information on the process indicator:

- Company name and generic name and indication of the medicine. The Danish Medicines Council publishes this information when the company submits a request for assessment, i.e. no earlier than EMA day 120 for new medicines in the normal approval procedure at the EMA, and no earlier than day 1 for extensions of indication and new medicines in the accelerated approval procedure at the EMA. The Danish Medicines Council does not publish requests for assessment from companies.
- Date of day 0. The Danish Medicines Council publishes the date on which the application is approved.
- Date on which the assessment report is submitted to Amgros and the company.
- Date on which Amgros submits the results of the negotiations to the Secretariat.
- Date of the decision by the Danish Medicines Council on a recommendation.
- Clock stops, if relevant.

The Danish Medicines Council publishes the following documents in connection with the Danish Medicines Council's recommendation:

- Recommendation by the Danish Medicines Council
- Assessment report by the Danish Medicines Council
- Application from the company and, if relevant, the two-page note to the Council

- (The Danish Medicines Council will not publish the health-economic model submitted in Excel, and any accompanying technical documents)
- Negotiation note from Amgros (confidential information blocked out).

As described in the Danish Medicines Council's confidentiality policy, companies can request that the Danish Medicines Council keep confidential the information they share with the Danish Medicines Council. The company should indicate this when it forwards documents to the Danish Medicines Council by clearly marking which information is confidential. Since the Danish Medicines Council's recommendations are based on transparency, the data used as the basis for the assessment of new medicines or extensions of indication will generally be published on the Danish Medicines Council website when the Danish Medicines Council publishes the assessment report. However, according to the Danish Medicines Council paper of principles regarding unpublished data, there may be cases where the data cannot be published until after one year.

12. Assessment of new medicines via treatment guidelines

In some cases, the Danish Medicines Council can assess new medicines, extensions of indication or new formulas of well-known medicines by updating existing treatment guidelines prepared in accordance with the Danish Medicines Council's methods or by drawing up new treatment guidelines. This applies if the effect and safety profile of the medicine is comparable with the existing treatment options, and the Danish Medicines Council therefore expects to be able to assess the medicine as equivalent with existing treatment options.

12.1 Treatment guidelines by the Danish Medicines Council

The Danish Medicines Council draws up common regional treatment guidelines as described in the *Process and methods guide – how the Danish Medicines Council assesses several medicines within the same therapeutic area*. In treatment guidelines, the Danish Medicines Council has assessed several medicines within the same disease area. If two or more medicines are assessed to have comparable effect and safety for a patient group, the Danish Medicines Council can decide that they are equivalent. If medicines are equivalent, the Danish Medicines Council expects that the majority of patients will experience the same effect from the treatment, irrespective of which of the equivalent medicines they receive.

The Danish Medicines Council prepares cost analyses for equivalent medicines, and these form the basis for a tendering procedure in Amgros. On the basis of the results of this tendering procedure and the cost analyses, the Danish Medicines Council prepares a medicine recommendation such that the medicine with the lowest total costs for the

regions is recommended as first choice. Treatment guidelines can thereby generate increased competition if several medicines with the same clinical effect are made available on the market.

In contrast to the process for assessing new medicines and extensions of indication described in sections 4-7, the Secretariat and expert committees, and *not* the companies, carry out literature search, data extraction and analyses. The Secretariat also prepares the cost analyses. The Danish Medicines Council may involve the companies during the process, and may ask for supplementary information and contributions on specific issues.

12.2 Process for assessing a new medicine in a treatment guideline

Companies may request the Danish Medicines Council to assess a new medicine directly in a treatment guideline, if the company considers the effect and safety of the medicine to be no better or worse than existing medicines. A company can state this in its request for assessment, as described in section 2.

If the expert committee and the Council agree that the Danish Medicines Council should assess the medicine in a treatment guideline, the company needs not follow the standard process described in sections 4-7. The objective of assessing the medicine directly in a treatment guideline is to have the new medicine included more quickly in the appropriate treatment guideline and medicine recommendation. Updating the treatment guidelines from the Danish Medicines Council should be possible within 16 weeks. If the Danish Medicines Council assesses that the treatment guideline cannot be updated within approximately 16 weeks, the Danish Medicines Council can decide to assess the medicine under a standard process for assessing new medicines.

Assessment of new medicines and extensions of indication in connection with a treatment guideline follows the following process:

1. The company states in its request for assessment that it is possible that the new medicine or extension of indication could be equivalent with existing medicines, and that the company would like the Danish Medicines Council to assess the medicine by preparing or updating a treatment guideline. The request must include appropriate documentation that the medicines have the same effect and safety in the form of a comparison between the new medicine and relevant comparators on important effect and safety parameters within the disease area.
2. On the basis of the request from the company, the expert committee assesses whether they agree with the company that the medicine seems to be equivalent to existing medicines. If this is the case, the expert committee and the Secretariat recommends to the Council that the Danish Medicines Council assess the medicine by preparing or updating a treatment guideline.
3. The Danish Medicines Council prepares a treatment guideline or updates existing treatment guidelines. After this, the Council approves the treatment guideline.

4. The Danish Medicines Council prepares or updates the cost analysis. After this, the Council approves the basis of comparison.
5. Amgros informs the Secretariat about the new prices. Amgros obtains new prices, either through negotiation or through a tendering procedure.
6. The Secretariat updates or prepares the medicine recommendation, and this is subsequently approved by the Council.

If the expert committee and the Council find that the medicine is equivalent with existing treatments, the Council may decide that the medicine is to be assessed under this process, even if the company has not requested this.

13. Entry into force of the process guide

This process guide and the Danish Medicines Council's methods guide for assessing new medicines replaces the previous *Process and methods guide – how the Danish Medicines Council develops joint regional assessments of the added clinical value of new medicines and new indications*. This guide is applicable for all applications to the Danish Medicines Council in which a request for assessment is submitted to the Danish Medicines Council from 1 January 2021. Cases for which a provisional application in line with the Danish Medicines Council's previous process was submitted before 1 January 2021 will generally be finalised according to the process and methods described in the *Process and methods guide – how the Danish Medicines Council develops joint regional assessments of the added clinical value of new medicines and new indications*.

14. Changes in processes

The Danish Medicines Council will publish changes in the processes described in this guide on the Danish Medicines Council website and update this guide (see version log). The Secretariat will inform companies about any changes in connection with an application process.

15. Version log

Version log		
Version	**Date**	**Change**
1.1	17 February 2021	Amendment of section 1.1: Criteria paper regarding the use of unpublished data has been replaced by the Danish Medicines Agency's principles for the use of unpublished data.
1.0	19 November 2020	Danish version approved by the board of Danish Regions