Medicinrådet

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

The translation is based on the Danish document *"Medicinrådets procesvejledning for vurdering af nye lægemidler"* (Version 2.4). Please note: The translation is provided as a courtesy by the Danish Medicines Council for readers of English. In the event of any discrepancies between the two versions, the Danish version will prevail.

Version 2.2

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1. Introduction

The purpose of the process guide is to provide companies with information regarding the process involved when submitting an application for assessment of a new medicine or an extension of indication for an existing medicine by the Danish Medicines Council.

The guide outlines the Danish Medicines Council's processes for assessment of new medicines and extensions of indication. In the document, the term "new medicines" refers to both new medicines and extensions of indication. The method for assessment of new medicines, including requirements for applications to the Danish Medicines Council, is described in the Danish Medicines Council's methods guide for the assessment of new medicines. In combination, the process and methods guide form the basis of the Danish Medicines Council's working practices when assessing new medicines.

After January 12, 2025, new medicines may be subject to the EU Regulation on Health Technology Assessment (HTA) (Regulation (EU) 2021/2282). This process guide applies to all applications for the assessment of new medicines by the Danish Medicines Council, regardless of whether the medicines are subject to a common European clinical assessment. In applications for medicines undergoing a common European clinical assessment, the specific requirements for reporting clinical data are outlined in the Medicines Council’s application form. Further information about the HTA Regulation can be found on the Danish Medicines Council’s website.

In addition to this guide for the assessment of new medicines and extensions of indication, the Danish Medicines Council also has a process guide for placing medicines directly into treatment guidelines.

When conducting an assessment of new medicines, the Danish Medicines Council is guided by the Danish Parliament's seven general principles for prioritization of hospital medicines and the two principles of caution (forsigtighed) and severity (alvorlighed) of which the latter two principles are considered only in special cases. The Danish Parliament's seven principles as well as a description of how the Danish Medicines Council applies the principle of severity can be found on the Danish Medicines Council's website.

All documents referenced in this guide can be found on the Danish Medicines Council's website: www.medicinrådet.dk.

2. The Danish Medicines Council

The Danish Medicines Council was established on the 1st of January 2017 by the Danish Regions. The Danish Medicines Council prepares recommendations and guidelines 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's website.

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

2.1 Expert committees

When preparing recommendations regarding the use of medicines, the Danish Medicines Council is tasked with forming expert committees consisting predominantly of clinicians skilled in a medical speciality or sub-speciality pertaining to the disease areas covered by the Danish Medicines Council. The role of the expert committees is to provide advice in relation to diseases, treatments and medicines. They assess the clinical efficacy of the medicine for which an application has been submitted, the transferability of the study results presented in the application to the current clinical practice in Denmark as well as address the validity of any clinical assumptions utilised in the health economic model. The specific expert committee composition and tasks are described in detail in the terms of reference for expert committees. A list of all members of the expert committees and their specific terms of reference is available (in Danish) on the Danish Medicines Council's website. Expert committees convene as and when required. Members of expert committees are typically appointed for a period of service not exceeding two years, with possible renewal. Expert committee members are required to disclose any conflicts of interest in accordance with the Danish Medicines Council's policy regarding conflicts of interest.

An expert committee typically comprises the following members:

- A chairperson nominated by the Organisation of the Danish Medical Societies (LVS)
- Specialist doctors appointed by the regions in Denmark
- Patient representatives appointed by the Danish Patients' organisation
- Any other individuals with specific expertise or roles appointed by the medical societies, Danish Nursing Society, or invited by the chairperson or the Danish Medicines Council.

The chairperson appoints a vice chairperson among the members appointed by the regions.

The role of the patient representatives is to offer their experience-based knowledge and perspective regarding their condition and treatment and that of fellow patients where possible. See the Danish Medicines Council's website for more detailed information regarding patient involvement in expert committees.

2.2 The Secretariat

The Secretariat supports the Council's decision-making processes and, in collaboration with the expert committees, prepares the basis for the Council's decision by producing an assessment report. For each assessment, a project group from the Secretariat is assigned, typically consisting of a health sciences consultant and a health economist. The

project group contributes with expertise in health science methodology, biostatistics, and health economics and ensures that the assessment report is prepared according to the methodological, biostatistical, and health economic standards described in the Danish Medicines Council's methods guide for assessment of new medicines. The project group facilitates meetings with the expert committees and prepares the health economic analysis based on discussions with the expert committee. The Secretariat's biostatisticians and information specialists are involved in the assessment work when needed. The project group is responsible for contact with Amgros and the pharmaceutical company throughout the process.

2.3 The Council

The Council comprises the board of the Danish Medicines Council. The Council decides whether it is able to recommend new medicines and extensions of indication as possible standard treatments at Danish hospitals. The decision is based on comprehensive material presented to the Council by the expert committee and the Secretariat.

When the Danish Medicines Council recommends a medicine as a possible standard treatment, this means that the Council evaluates that the effect of the new medicine is proportionate to the cost as well as that the disadvantages linked to the use of the medicine. The responsibility for the implementation of the recommendations from the Danish Medicines Council lies with the regions.

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

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

Companies which have applied for market authorisation for a new medicine or extension of indication in Denmark may contact the Danish Medicines Council for an assessment of whether the Danish Medicines Council is able to recommend the medicine as a potential 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 which are only dispensed to hospitals.
- AP4BG: Medicines which are only dispensed to hospitals and dispensed only once for the same prescription.
- AP4NB: Medicines which are only dispensed to hospitals or prescribed by selected specialist physicians.
- NBS: Medicines which are only dispensed to hospitals or prescribed by hospital physicians and specified specialists. As a general rule, the Danish Medicines Council

only assesses medicines in this group if there is a possibility that the pharmaceutical will be dispensed free of charge to non-hospitalized patients.

The Danish Medicines Council may also decide to assess medicines and extensions of indication of their own accord, 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.

3. Request for assessment

A company wanting their medicine assessed by the Danish Medicines Council has to submit a request for assessment to the Danish Medicines Council Secretariat. The timing of the submission of a request depends on the timeline of the approval procedure at the European Medicines Agency (EMA).

A request for assessment can be sent at the earliest at day 120 in the assessment process for new medicines in the standard EMA approval procedure. For new medicines evaluated under EMA's accelerated approval procedure and for extensions of indication the request to the Danish Medicines Council can be sent at the earliest on day 1 of EMA's approval procedure. If the company wishes to submit a request at a later time point in the EMA process, the Danish Medicines Council urges that the request is sent as early as possible to avoid delays in the assessment process.

The Danish Medicines Council must receive the request at least 3 months before the time the company intends to submit its application.

The pharmaceutical company must use a request for assessment form which is available from the Danish Medicines Council's website. The request should be sent to the Danish Medicines Council's email address: ansogning@medicinraadet.dk.

The Danish Medicines Council's Secretariat uses the request to plan the assessment of the medicine, allocate resources for the assessment process, set an assigned application deadline and schedule expert committee meetings well in advance. If the medicine is subject to a common European clinical assessment, the information and timeline for the common European clinical assessment will also be incorporated into the planning of the Danish Medicines Council's assessment

In the request, the company must provide information covering:

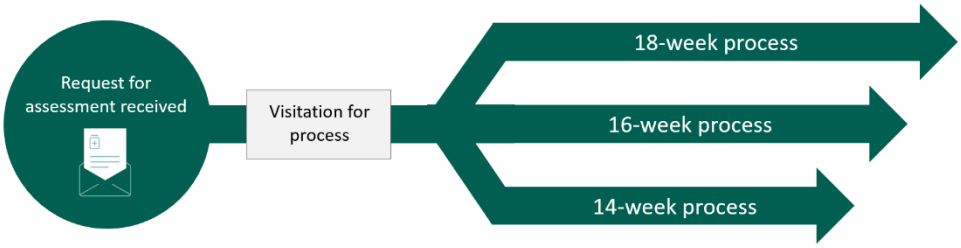
- Contact information
- The pharmaceutical company's preference for the process (18-, 16-, or 14-week process)
- A brief description of PICO (Population, Intervention, Comparator and Outcome)
- A brief description of the health economic model
- A request for a dialogue meeting

- The date (day, month, and year) the company intends to submit the application to the Danish Medicines Council (at least 3 months after submitting the request)

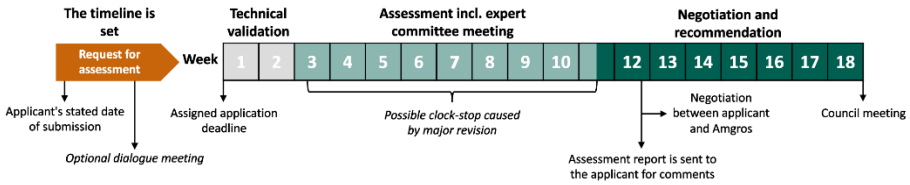
If the Danish Medicines Council determines that there is a need to establish a new expert committee to conduct the assessment, the secretariat will initiate this process upon receiving a request for assessment.

3.1 Visitation for process

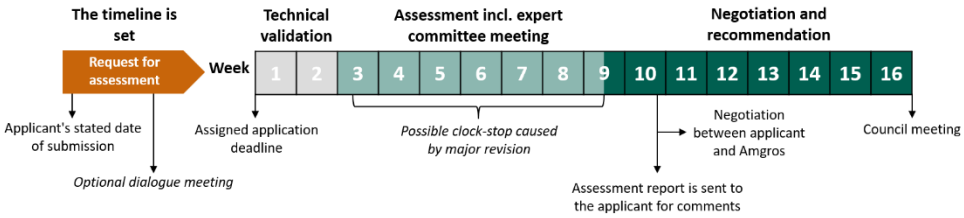
The Danish Medicines Council has three assessment processes for a new medicine: 18-week, 16-week, and 14-week process. The timeframe depends on the complexity of the assessment and whether a health economic analysis is included or not.



- **18-week process:** an assessment of a medicine following this process involves assessment of the clinical efficacy along with a health economic analysis, typically a cost-utility analysis (CUA) or a cost analysis (OMA). The politically determined goal for processing time is 18 weeks.

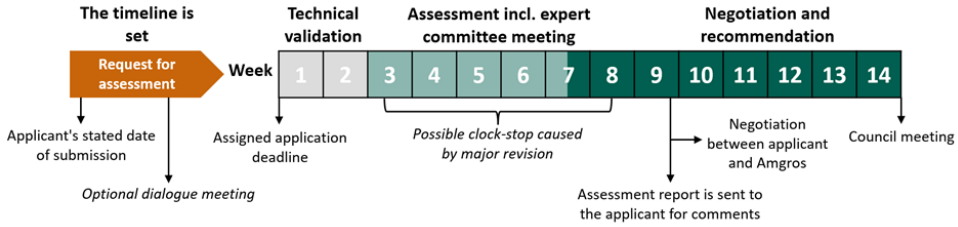


- **16-week process:** If a new medicine does not have higher efficacy and safety data compared to the medicine which is already included in a treatment guideline for the therapy area, the medicine can be assessed by updating the treatment guideline. The politically determined goal for processing time is 16 weeks.



- **14-week process:** An assessment of a medicine following this process focuses on assessment of the clinical efficacy. The assessment does not include a health

economic analysis. The process applies to extensions of indication of PD-(L)1 inhibitors and extensions of indication from adults to children. The politically determined goal for processing time is 14 weeks.



3.2 Assigned application deadline

To ensure predictable and robust processes for the assessment of new medicines, the secretariat assigns a deadline by which the application must be received.

The secretariat determines the application deadline based on:

- Applicant's desired date for submission
- Scheduled Council meetings
- Availability of expert committee meetings
- For medicines subject to a common European clinical assessment: expected time of publication of the report on the common clinical assessment.

The Secretariat assigns an application deadline upon receiving a request for assessment of a new medicine, based on the date indicated by the applicant in the request form and the availability of the expert committee and Council meetings. The pharmaceutical company's desired application deadline should be a realistic date (day, month and year) when the company is able to submit a comprehensive application to the Danish Medicines Council. There should typically be at least 3 months between the submitted request and the applicant's desired application deadline.

The assigned application deadline is set with the aim of initiating the processing at the earliest possible date. This assigned application deadline is binding. If the application is not submitted on time, a new application deadline will be arranged based on subsequently available expert committee meetings and upcoming Council meetings.

A pharmaceutical company is always able to submit their application before the assigned application deadline. Applications received before the assigned application deadline will be placed in a queue, and if possible, the assessment process can be initiated earlier (for example, if another assessment is delayed due to clock-stop or missed application deadline).

In case of any unforeseen changes which prevent the pharmaceutical company from submitting the application by the assigned deadline, the applicant should contact the Secretariat as soon as possible. The Secretariat will then update the planned assessment

process, convene new expert committee meetings, and set a new assigned application deadline.

3.3 Dialogue before application

In the request for assessment form, the pharmaceutical company may request a dialogue meeting with the Secretariat to clarify specific questions regarding the application. The company must specify these questions in the request form. The Secretariat and the expert committee chairperson may deem it appropriate for an expert committee member to participate in the meeting with the company. This may occur, for example, in cases where knowledge about the disease and/or treatment in Denmark is limited.

The project group will be available for dialogue with the pharmaceutical company as and when needed in order to quickly address any specific questions the pharmaceutical company may have regarding the application.

The Secretariat is unable to provide any binding statements regarding the assessment of the medicine. The content and choices made in the application are, at all times, at the discretion and the responsibility of the pharmaceutical company.

4. Application

The pharmaceutical company should use an application form which is available from the Danish Medicines Council's website. All applications should be emailed to the Danish Medicines Council's mailbox: ansogning@medicinraadet.dk.

The requirements for applications are outlined in the Danish Medicines Council's methods guide as well as in the supplementary guidance for health economic analyses (*Supplerende vejledninger til sundhedsøkonomiske analyser* – in Danish), which can be found on the Danish Medicines Council's website.

An application to the Danish Medicines Council includes a completed application form. For medicines assessed for an 18-week process, the application also includes a health economic analysis and a budget impact analysis. The health economic analysis and the budget impact analysis should be submitted in Excel format. For medicines that are subject to a common European clinical assessment, the applicant must assess which parts of the application are covered by the common European assessment report (JCA report) and refer to it.

The pharmaceutical company should submit the application no later than the assigned application deadline (see section 3.2).

4.1 Technical validation

The Secretariat conducts a technical validation of the application by reviewing the application material to ensure that all formal requirements are met. A checklist for the formal requirements is available on the Danish Medicines Council's website.

The company will be notified as to whether or not the application fulfills the Danish Medicines Council's formal requirements as soon as possible and no later than within 10 working days if the application is submitted at the assigned application deadline. If the application meets the formal requirements, the processing time is calculated from the date of the assigned application deadline.

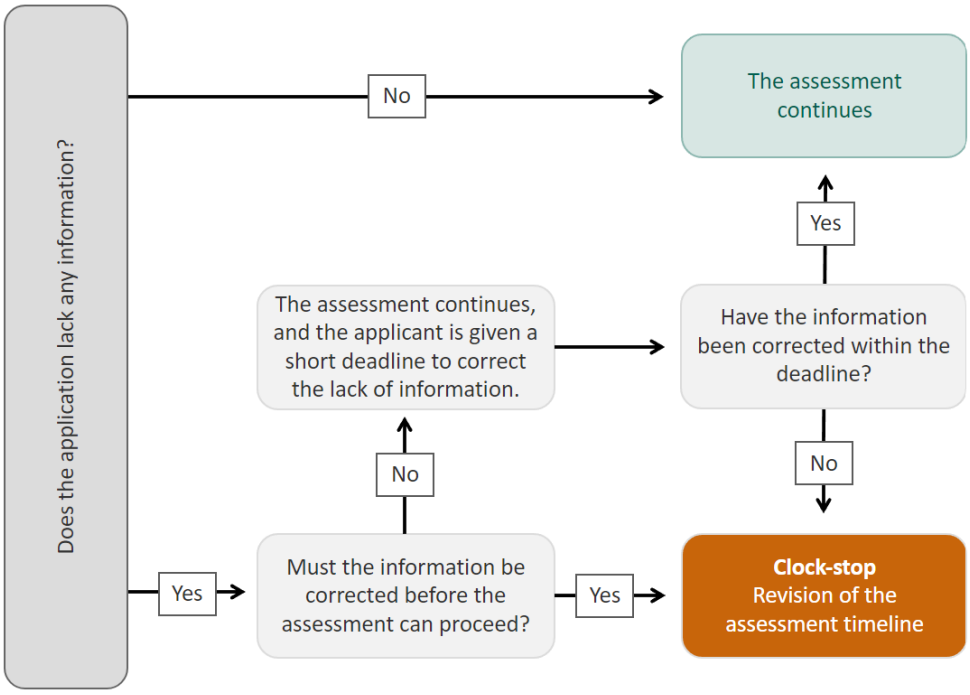
If the application does not fulfill the formal requirements, the company will receive a brief explanation and a new application deadline will be assigned based on subsequent available dates for expert committee meetings and upcoming Council meetings.

If an application is received before the assigned application deadline, the Secretariat will conduct the technical validation. However, the processing time is counted from the date of the assigned application deadline. In cases where the Secretariat is able to start the assessment before the assigned application deadline, the processing time is counted from this date.

5. Assessment report

After the technical validation, the Secretariat reviews the application for substantial lack of information. This review can result in three different scenarios:

- **Scenario A**: The application is complete or has minor deficiencies which are not significant for the assessment. The assessment continues as planned.
- **Scenario B**: The application needs clarification or corrections by the applicant within a short deadline but the Secretariat continues to work on the assessment concurrently. If the applicant exceeds the deadline the case processing is paused (clock-stop).
- **Scenario C**: The application has significant substantive deficiencies which need to be addressed by the applicant before the Secretariat is able to proceed with the assessment. The assessment is paused (clock-stop).



In connection with the assessment of the medicine, for example at the expert committee meeting, questions may arise regarding the application material or requests for additional information in the application material. The Secretariat assesses whether the deficiencies are so significant for the assessment that a clock-stop is required (scenario C), or if the assessment can continue while the questions are being clarified (scenario B).

5.1 Supplementary data after submission of the application

In case the company obtains access to additional data which were not included in the originally submitted application, and which significantly alter the analysis, the company may request that the Danish Medicines Council include this data in the assessment. If the Danish Medicines Council also regards the data as relevant to the analysis, it should be submitted to the secretariat as an appendix to the original application, along with the updated health economic analysis. The secretariat will assess whether this results in a clock-stop.

5.2 Setting a new timeline during clock-stop

Clock-stop would continue until the assessment of the medicine can be resumed when the new necessary information has been submitted. Subsequently, the assessment process is adjusted to align with available dates for expert committee meetings and upcoming Council meetings. When an assessment is clock-stopped, the Secretariat needs additional 10 working days before the processing time can be resumed as the application material needs to be reviewed again.

The Danish Medicines Council prioritizes the assessment of medicines that are in progress over assessments which have been clock-stopped. Therefore, there may be cases where a clock-stop lasts longer than the time between two Council meetings. This typically occurs if the expert committee is not available due to meetings scheduled for other assessments. The clock-stop would then last until the assessment phase may be resumed with available dates for expert committee meetings and upcoming Council meetings.

The pharmaceutical company would be informed of the deadline by which the Secretariat should receive the updated application in order to be able to resume the assessment of the medicine.

A pharmaceutical company may always submit the updated application before the specified deadline. In that case, the Secretariat would resume the assessment ahead of time if possible (e.g., if another assessment is delayed due to clock-stop or does not meet the assigned application deadline).

In exceptional cases, an assessment may enter into clock-stop if there is a delay in price negotiation with Amgros. In this case, the company should inform the Secretariat if they wish the assessment to be paused. The Danish Medicines Council would determine whether there is a basis for clock-stop and for how long.

The Council has the option to enter an assessment into the clock-stop process if it considers that there is a particular need to gather further information or further qualify data in order to make a decision on recommendation. The clock-stop would last until the assessment may be resumed and aligned with subsequent available dates for expert committee meetings and upcoming Council meetings.

6. Conclusion and recommendation

6.1 The company's feedback on the assessment report

When the expert committee and the Secretariat have completed a draft version of the assessment report, it is emailed to the pharmaceutical company and Amgros.

The company is afforded the opportunity to review the draft assessment report for factual errors and to ensure that all information which they consider confidential is highlighted in the report. Additionally, the company is afforded the opportunity to submit a two-page note which should be attached to the assessment report when the Council considers the case. The note should not contain new data which were not included in the company's original application. The note will be published after the Danish Medicines Council has made a recommendation. If there are confidential details

in the note, the company should submit a version of the note where the confidential information is blinded for publication.

More information regarding blinding of confidential information is available in section 9 and on the Danish Medicines Council's website.

The company is afforded ten business days to comment on the assessment report and send a possible note.

6.2 Negotiation

Based on the assessment report, Amgros negotiates the price of the medicine with the company. Price negotiations with Amgros occur concurrently with the company's review of the draft assessment report. A representative from the Secretariat may participate as an observer in Amgros' price negotiations with the company.

Once the price negotiations have been concluded, Amgros emails a price memo to the Secretariat with the negotiated prices.

The Secretariat updates the assessment report based on the prices provided by Amgros.

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

6.3 Decision on recommendation

The basis for decision-making, including the assessment report, is presented to the Council by representatives from the expert committee and the project group. The presentation focuses on the results of the primary clinical studies, the health economic analysis and the most significant uncertainties which the Council should be aware of. Subsequently, the Council may put forward questions to the representatives from the expert committee and the Secretariat. It is solely the Council that makes the decision on recommendation.

The Council formulates its recommendation and the Danish Medicines Council generally publishes the recommendation the day after the Council meeting.

When a medicine is assessed by updating a treatment guideline, it is only recommended after publishing a recommendation that includes the particular medicine (see the Danish Medicines Council's process guide for the assessment of new medicines in a treatment guideline on the Danish Medicine Council's website).

7. Withdrawal of application

A company may withdraw its application at any time during the process by notifying the Secretariat in writing. Since the Danish Medicines Council may initiate assessments of medicines of its own accord, the Council may choose to continue processing the withdrawn application. In such an event, the Danish Medicines Council may include documents already submitted by the company in the further processing and the Danish Medicines Council may publish documents on the website to the same extent as if the application had not been withdrawn. See section 9 for further details on handling confidential information.

8. Process for re-assessment of a recommendation

Pharmaceutical companies can request the Danish Medicines Council to reassess a recommendation based on a new price and/or new data. All reassessments of recommendations must follow our current methods. This means that if a company wants reassessment of a recommendation, which was conducted using previous methods, e.g. assessments from before the transition to cost-utility analysis methods in 2021, the company must submit a new application and a new health economic model that complies with the current methods guide.

After receiving a request for reassessment, the Danish Medicines Council's chairpersons assess whether there is a basis for reassessing the existing recommendation. It depends on whether the new data or the new price is expected to lead the Council to make a different decision regarding the recommendation of the medicine in question. If this is not likely, the Danish Medicines Council will refuse to reassess the medicine. The applicant will be informed in writing of the decision.

If the Danish Medicines Council decides to initiate a reassessment, a reassessment can follow two main types of processes: reassessment based on new data and reassessment based on a new price.

Reassessment based on new data:
Reassessment of a medicinal product based on new data requires a reassessment of the clinical effect as well as possibly an update of the health economic analysis. The process corresponds to the process for the assessment of a new medicine, as described earlier in this process guide. This includes setting a new agreed application deadline, the applicant submitting an updated application, including a health economic model with an opportunity for new price negotiations.

If the fundamental assumptions of the original assessment have changed, a new application is generally required, and the reassessment will be classified as a

reassessment based on new data. This may, for example, involve changes in the population or comparator.

The reassessment is assigned for an 18-, 16- or 14-week process based on the same criteria as for a new medicine.

Reassessment based on new price:
A reassessment based solely on a new price is only possible if the fundamental assumptions of the original assessment still apply, e.g., that the comparator in the original assessment continues to reflect the Danish practice, and that no new significant data has become available for the new medicine and/or comparator.

Reassessment of a medicinal product solely based on a new price only requires an update and recalculation of the health economic analysis, meaning that submitting a new application is generally not necessary. The new price is included in the reassessment request form.

The processing time for a reassessment based on a new price begins on the date the Danish Medicines Council's chairpersons decide to carry out a reassessment, and there is no need to set a new agreed application deadline.
The Danish Medicines Council obtains the new price from Amgros, and there is no opportunity for further price negotiations during the assessment process. The politically determined goal for processing time is 16 weeks.

Reassessments – Council's own initiative
The Danish Medicines Council can also initiate a reassessment on its own. This may be due to inquiries from medical societies with new information about the medicine or the disease area, or if the price of a medicine has changed.

The Council may, in connection with a recommendation, decide to reassess the recommendation within a specified time interval, during which additional data on the effect or side effects is collected. This could happen, for example, in the case of recommending a medicinal product where the available data is subject to significant uncertainty, or where the Council wishes to review side effect data after a certain period of time.

9. Transparency and publication

To ensure transparency in the process of assessment of new medicines and extensions of indication, the Danish Medicines Council continuously publishes relevant information describing the stages of the assessment process.

On the Danish Medicines Council's website, a timeline is continuously updated for each medicine under assessment, indicating the progress of the assessment - from the Danish

Medicines Council receives the company's request for assessment until the Council makes a decision on recommendation.

The Danish Medicines Council publishes the following information:

- Company’s name, generic and trade name of the medicine, ATC code, disease area, specific disease and expert committee. The specific indication (use) is only disclosed when receiving the application.
- Process for the assessment of a medicine (18-, 16-, 14-week process or whether the medicine is assessed in the Nordic collaboration Joint Nordic HTA-bodies (JNHB)).
- Date of assigned application deadline.
- Expected date of the Council's decision on recommendation.
- Date when the assessment report is sent to Amgros and the company.
- Date when Amgros sends the negotiation outcome to the Secretariat.
- Date of the Danish Medicines Council's decision on recommendation.
- Any clock-stops and the new timeline for the assessment of the medicine.
- If the medicine is subject to a common European clinical assessment, this will be indicated with a link to the JCA report.

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

- Danish Medicines Council’s recommendation and assessment
- Appendices to the Danish Medicines Council’s recommendation and assessment, where confidential information is blinded, including:
    - Company's note to the Council
    - Company's application
    - Amgros' negotiation note
    - Any other relevant documents.

As described in the Danish Medicines Council's confidentiality policy – in Danish, companies may request that the Danish Medicines Council keeps information that is shared with the Council confidential. The company should indicate this when submitting documents to the Danish Medicines Council by clearly highlighting what information should be considered confidential. See more information about blinding of confidential information below.

The data which supports the assessment of the new medicine or extension of indication are generally published on the Danish Medicines Council's website when the Danish Medicines Council publishes the assessment report. However, according to the Danish

Medicines Council's principles for the use of unpublished data, there may be cases where data may only be published after 1 year.

Blinding of confidential information
The pharmaceutical companies should ensure that the blinding is sufficient so that the confidential information cannot be read when the document is edited.

The company should therefore ensure that confidential information is sufficiently blinded in relation to publication on the Danish Medicine Council's website. This may be done, for example, by covering the text / information that is to be blinded in black highlighting and at the same time replacing the underlying text with **crosses** (”XXX”), so that the text / information may not be read in connection with editing the document.

Read more about blinding of confidential information here on the Danish Medicine Council’s website.

10. Version log

Version log		
Version	**Date**	**Change**
2.2	April 1, 2025	Addition in sections 1, 3, 4 and 9: reference to common European clinical assessments has been added. Addition in section 5.1 regarding supplementary data. Addition in section 8 regarding changes in the fundamental assumptions for an assessment. New e-mail address ansogning@medicinraadet.dk has been added.
2.1	November 8, 2024	Chapter 8 regarding the process for reassessments has been elaborated.
2.0	August 29, 2024	Significant changes related to the implementation of new processes. More detailed information on blinding of confidential information.
1.3	November 1, 2022	Danish Regions have approved a change in section 12.
1.2	May 11, 2021	Change in sections 2 and 11: Specified the information to be disclosed when the Danish Medicines Council receives a request for assessment.
1.1	February 17, 2021	Change in section 1.1: The criterion paper regarding the use of unpublished data has been replaced by the Danish Medicines Council's principles for the use of unpublished data.
1.0	November 19, 2020 October 28, 2020 August 19, 2020	Approved by the Board of Danish Regions Version for the Board of Danish Regions Version for consultation