The Danish Health Technology Council's process guide

2021

Behandlingsrådet

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1 Introduction

This is a guide for companies, regional governments and hospital managements (in the following referred to as 'applicants') wanting to have a health technology assessed by the Danish Health Technology Council. Furthermore, the guide serves a working tool for the Danish Health Technology Council's council members, expert committee members and secretariat.

The method for evaluation of health technologies is described in the Danish Health Technology Council's methods guide. The process guide and the methods guide together comprise the foundation for the work of the Danish Health Technology Council.

The Danish Health Technology Council provides recommendations on the use of health technologies, including medical devices,[1] but also treatments, diagnostic devices, rehabilitation, prevention and types of organisation and collaboration in the provision of healthcare services. From now on, 'health technology' is used as an umbrella term for all these types of technology etc. The Danish Health Technology Council does not make recommendations concerning medicines and other products, the primary effect of which is exerted through a pharmacological, immunological or metabolic action.

The Danish Health Technology Council expects to prepare 15 to 25 evaluations and two to three more comprehensive analyses annually. Evaluations will be of one or more specific health technology(ies). Evaluations of single technologies will be of a single, specific technology, which will typically be compared to a single, relevant comparator.[2] In evaluations of product categories, several similar technologies will be compared to each other against a single, relevant comparator. The more comprehensive analyses will address more fundamental issues about treatment regimes, approaches to or organisation of treatments, for example how group-specific treatment is organised. Product categories can be the subject of an evaluation or a more comprehensive analysis. The Danish Health Technology Council will decide this on a case-by-case basis.

The process guide describes the process for the preparation of evaluations of either single technologies or product categories after the Council has health technologies for evaluation. As a general rule, the Danish Health Technology Council will apply the same evaluation process where new data about a technology previously evaluated enables evaluation of another, or of an extended, patient population than the one covered by the original recommendation (extensions of indication).

The process is different for preparing more comprehensive analyses. The Council will initiate the more comprehensive analyses based on analysis topics decided by the Board of Danish Regions. See section 7 for a more detailed description of the process for preparing more comprehensive analyses.

[1] In this context, the term 'medical devices' denotes apparatus, software and *in vitro* diagnostic devices/ materials used in diagnosing, prevention, monitoring, treatment or alleviation of diseases or injuries, for example, or used as assistive devices for injuries or disabilities. For a full definition, see Part 1 of the Medical Devices Executive Order (Bekendtgørelse om medicinsk udstyr no. 1263 of 15/12/2008). A new Executive Order entered into force on 26 May 2021 ((EU) 2017/745).

[2] See section 6.1 of the Danish Health Technology Council's methods guide for a more detailed definition of 'comparator.'

2 About the Danish Health Technology Council

The primary objective of the Danish Health Technology Council is to target Danish healthcare resources at the technologies and interventions that provide best value for money, across both physical and mental health services. This will help raise the quality of health services, ensure more equality in treatments, and reduce cost pressure in the healthcare system.

The Danish Health Technology Council works on the following principles decided by the Board of Danish Regions:

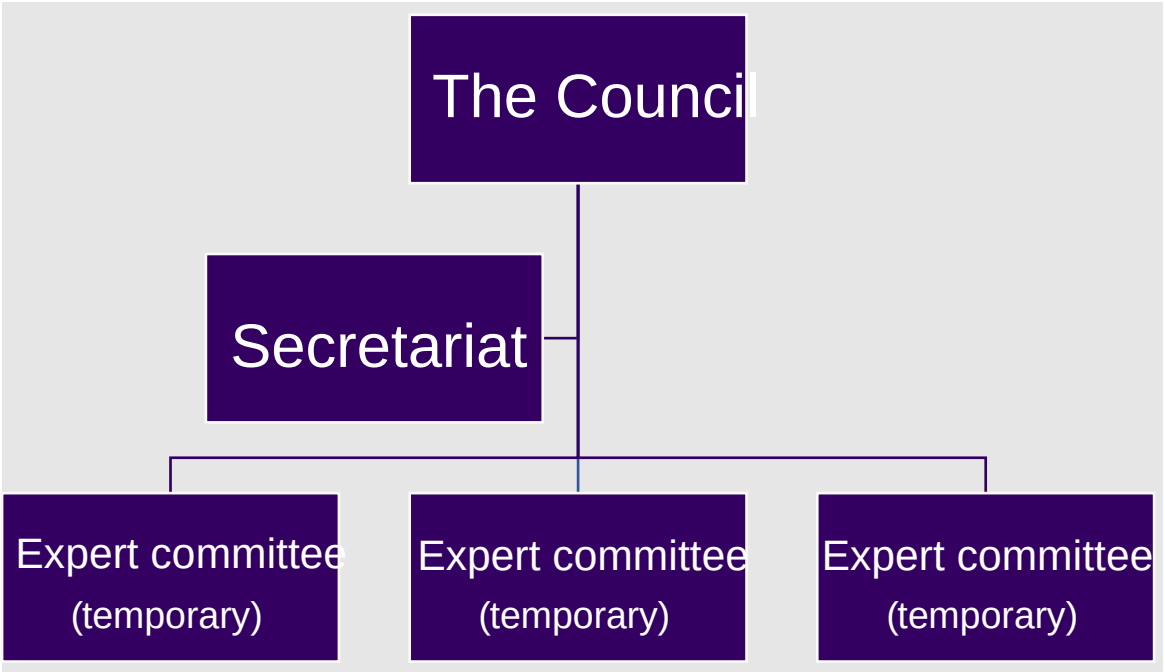
- More value for money
- Professionalism and independence from the political system
- Transparency
- Equity

The Danish Health Technology Council carries out evaluations as well as more comprehensive analyses for Danish regional governments, along with recommendations concerning the use of specific health technologies. Even if a process has been set in motion to start evaluation of a health technology, regional governments may still use the health technology in question during the process.

The terms of reference of the Danish Health Technology Council are available on the Council's website.

The Danish Health Technology Council consists of three units: The Council, the expert committees, and the secretariat. The Danish Health Technology Council is a collective term for the entire organisation, see the figure below.

Figure 1: Organisation of the Danish Health Technology Council



The Danish Health Technology Council will be evaluated after two years but will be continuously assessed and adjusted as required until then.

2.1 The Council

The Council constitutes the senior management of the Danish Health Technology Council and prepares advisory recommendations. The Council consists of 15 members and three observers:

- 1 chairperson appointed by Danish Regions
- 5 representatives from hospital management (healthcare professionals)
- 2 representatives appointed by the Organisation of Danish Medical Societies (LVS)
- 1 representative appointed by the Danish Nursing Society (DASYS)
- 1 representative appointed by Danish Patients
- 1 representative appointed by Disabled People's Organisations Denmark
- 2 health economists appointed by the Danish Health Technology Council
- 2 expert/specialist representatives appointed by the Danish Health Technology Council
- 1 member appointed by the Danish Health Authority (observer role)
- 1 member appointed by the Danish Medicines Agency (observer role)
- 1 member appointed by Life Science (observer role)

From 1 January 2024, when the Council will have been operating for three years, Council members will be replaced or reappointed such that one-third of the Council members are appointed each year.

Observers have access to the same information as the other Council members and may attend Council meetings on the same terms, but they do not have voting rights. Observers are subject to the same rules and guidelines as the Council members.

Information on upcoming Council meetings is available on the Danish Health Technology Council's website.

2.2 The Danish Health Technology Council's expert committees

The Danish Health Technology Council secretariat and the expert committees work together to carry out the actual evaluations and the more comprehensive analyses, and on this basis draw up an evaluation/analysis report for the Council. As a rule, the expert committees are temporary, and members are appointed to perform a specific evaluation or analysis. When, based on the evaluation/analysis report, the Council has produced its recommendation, the expert committee disband.

An expert committee may, however, in special circumstances, be reactivated after disbandment.[3] For example, this could be relevant if, within two-years after publishing the recommendation, important new data becomes available concerning clinical effectiveness, safety or health economic aspects. In these cases, the secretariat will carry out a first screening of the new data to assess whether the expert committee should be reactivated.

The composition and tasks of each expert committee are described in the committee's terms of reference, which are approved by the Council. A list of all current and former expert committees and their terms of reference is available on the Danish Health Technology Council's website.

[3] The expert committees are not standing committees and will only be reactivated when needed. Members of the expert committee are not required to submit declarations of impartiality on a regular basis, but when new data is assessed, members are required to complete a new declaration of impartiality.

The composition of expert committees takes account of the specific technology area to ensure that each committee has the necessary competencies to carry out the evaluation or analysis with which it has been tasked.

As a starting point, expert committees will always consist of:

- A chair – nominated by the Organization of Danish Medical Societies (LVS) or, in special cases, the Danish Nursing Society (DASYS), and appointed by the Council [4]
- Experts such as doctors, nurses, or physiotherapists, appointed by the regional governments
- Two patients/patient representatives, appointed by Danish Patients or by Disabled People's Organisations Denmark
- A representative of the regional governments' joint procurement function, appointed by the Regions Joint Procurement (RFI)

Depending on the specific case, it may be relevant to appoint further representatives with special competencies, for example within medical engineering and health technology. Such additional representatives can also be international experts if this is considered relevant for the specific evaluation.

If the technology is used across more sectors, it may also be relevant for the committee to include representatives from other organisations (local government, for example), or parts of a sector such as the general practice or specialist practice.

These expert committee members will be appointed by the chair of the expert committee upon agreement with the secretariat. A more detailed description of the work of the expert committee will be available on the Danish Health Technology Council's website.

The secretariat supports the work of the expert committee and provides competencies matching the topic of the evaluation/analysis.

2.3 The Danish Health Technology Council secretariat

The Danish Health Technology Council secretariat serves the Council and the expert committees. The secretariat is composed of staff with broad competencies, for example in the methods applied in evaluations and more comprehensive analyses, including experience of outcomes studies, economic studies, systematic literature searches, biostatistics, and project management.

The secretariat is responsible for assisting applicants in providing the Council with satisfactory evaluation proposals, based on which the Council will decide which evaluations to initiate. When the Council has decided which evaluations are to be carried out, the secretariat will be responsible for supporting the expert committee's work in this respect. For each evaluation, the secretariat will set up a project team to act as the key collaboration partner of the expert committee and the applicant. Furthermore, the project team will assist in facilitating the work/meetings of the expert committees and will prepare relevant materials, including draft assessment reports.

The secretariat is headed by the director of the Danish Health Technology Council, and the director reports to the chair of the Danish Health Technology Council.

[4] If deemed appropriate, the chair may come from another specialist group than doctors or nurses. For example, this could be relevant if the evaluation concerns rehabilitation, in which case a physiotherapist could chair the committee.

2.4 Impartiality

By default, members of the Council, the expert committees and the secretariat must comply with the Danish Health Technology Council's policy on impartiality.

The impartiality policy must be approved by the Council. When approved, the policy will be publicly available on the Danish Health Technology Council's website.

2.5 Remit of the Danish Health Technology Council

Regional governments, hospital managements, and companies can submit proposals for evaluations to the Danish Health Technology Council. Companies can propose that health technologies be evaluated if they can show that the health technology likely does not lead to higher costs but will be cost-neutral or cost-saving. Regional governments and hospital managements must account for costs associated with the proposed health technology; for these applicants, however, there is no requirement for the health technology to be cost-neutral or cost-saving.

'Costs for the healthcare system' refers to the whole healthcare system and costs in a broad perspective. The assessment of costs associated with the health technology should take a limited societal perspective. For a more detailed description of the scope of the assessment in terms of its perspective, and how costs should be estimated, see the Danish Health Technology Council's guidelines on cost statements.

The remit of the Danish Health Technology Council is broad and includes medical devices, but also treatments, diagnostic devices, rehabilitation, prevention and types of organisation and collaboration in the provision of healthcare services. The Danish Health Technology Council does not make recommendations concerning medicines and other products, the primary effect of which is exerted through a pharmacological, immunological, or metabolic action.

The Danish Health Technology Council can evaluate health technologies for use in hospitals, municipalities, and general practice. The aim is to always evaluate health technologies based on their assessed value, and technologies will be compared with the best existing, already implemented alternative in Danish practice. In cases in which there is no actual alternative, the comparator will for example be no active treatment or, as proxy for this, placebo and/or sham. The assessment of the value of a technology includes:

- clinical effectiveness[5] and safety
- patient perspective[6]
- organisation
- health economics

The Danish Health Technology Council can evaluate both new health technologies and health technologies already widely used in the healthcare system. However, a certain level of documentation for outcomes and costs is required in order for the Council to initiate an evaluation.

[5] The rules concerning medical devices and *in vitro* diagnostic medical devices include general requirements for safety and performance. Performance is the ability of the device to fulfil the declared purpose indicated by the manufacturer. From now on, the term 'clinical effectiveness' also covers performance, where relevant.

[6] The concept of 'patient' denotes a user of a health technology: a patient, a former patient, or a relative. Healthcare professionals/healthcare staff as users are therefore not part of the patient concept.

The Danish Health Technology Council cannot evaluate medicines, but it can evaluate products replacing medicines, for example where a technology to treat headaches can replace medicines used for the same purpose. Such cases will be handled in close coordination with the Danish Medicines Council. Conversely, a diagnostic test, such as a biomarker, conducted before use of a medicine will be assessed by the Danish Medicines Council.

3 Process for preparing evaluations

For evaluations, the process through the Danish Health Technology Council consists of three phases. These are:

1. The proposal phase
2. The evaluation phase
3. The follow-up phase

The three phases are briefly described below and illustrated in Figure 1. The individual elements of the three phases are described in more detail further down.

The proposal phase is the initial contact between the applicant and the Danish Health Technology Council secretariat. In general, applicants are always welcome to contact the Danish Health Technology Council secretariat by phone or in writing. Applicants wishing to have a health technology evaluated by the Danish Health Technology Council can approach the Danish Health Technology Council secretariat at any time. Applicants should make their request by submitting information about the health technology via the Danish Health Technology Council's website. The secretariat will then contact the applicant to initiate the dialogue. After this, the applicant will have to prepare an evaluation proposal. The evaluation proposal will serve as the basis for the Council's decision on whether to initiate an evaluation. If the Council decides to initiate an evaluation based on the evaluation proposal, the applicant will move to phase 2, the evaluation phase.

In the evaluation phase, several elements are initiated at the same time: the establishment of an expert committee and the preparation of an evaluation design and of an application. The expert committee participates in determining the evaluation design, and the application cannot be finalised until the final evaluation design is available.

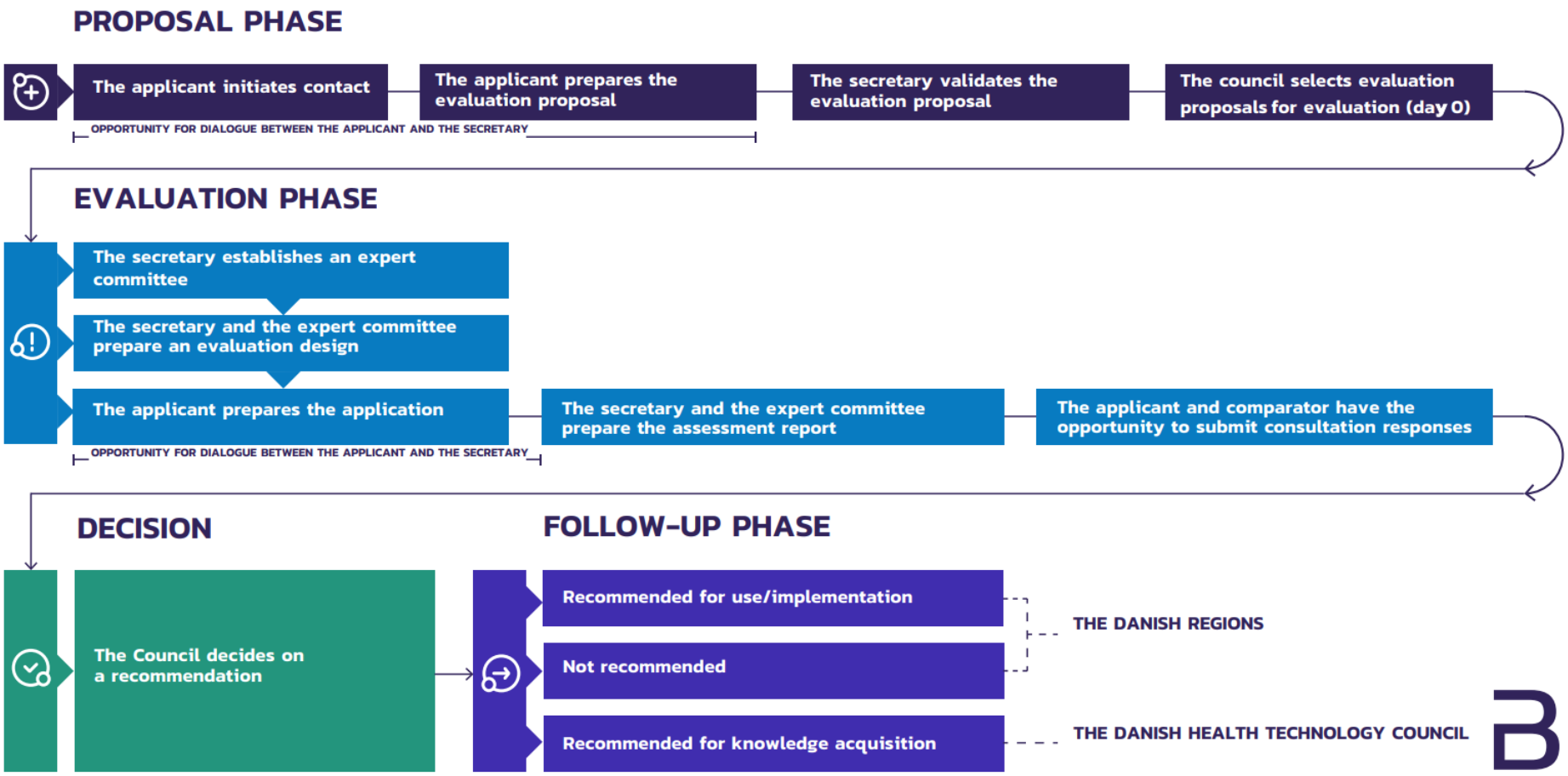
Work on the assessment report commences when the application has been submitted. When the assessment report has been completed, it is submitted for consultation with the applicant and the comparator[7] (if a single comparator/company has been appointed). After this, the Council makes its recommendation concerning the health technology in question.

The last phase is the follow-up phase, in which the Council either decides to recommend the health technology, to not recommend the health technology or to recommend it for knowledge acquisition. If the Council recommends the health technology for knowledge acquisition, the Danish Health Technology Council's work continues. If, on the other hand, the Council either recommends or does not recommend the health technology, then the regional governments will be responsible for implementing or phasing out the technology in their respective regions.

The Danish Health Technology Council's process for evaluating health technologies is illustrated below.

[7] The comparator is the company or companies with which the health technology under evaluation is compared.

Figure 2: Flow chart of the Danish Health Technology Council evaluation process



The table below shows the various elements and actions in the three process phases, including the participants responsible for the individual actions.

Table 1: Elements and actions in Danish Health Technology Council evaluations

Phase	Action	Participant responsible
Proposal phase	Possibility of dialogue meeting	Applicant and secretariat
	Preparation of evaluation proposals	Applicant
	Validation of evaluation proposals	Secretariat
	Selection of evaluation proposals	Council
Evaluation phase	Establishment of an expert committee	Secretariat
	Determination of the evaluation design	Expert committee
	Approval of the evaluation design	Council
	Preparation of the application	Applicant
	Validation of the application	Secretariat
	Preparation of the assessment report	Expert committee and secretariat
	Consultation on the assessment report	Applicant and comparator(s)
	Decision on a recommendation	Council
Follow-up phase	Implementation of the recommendation (The health technology is recommended or is not recommended for use/implementation)	Regional governments
	Knowledge acquisition	Regional governments and secretariat

The elements of the individual phases are described in more detail below. See section 7 for a more detailed description of the process in connection with comprehensive analyses.

3.1 Casework time

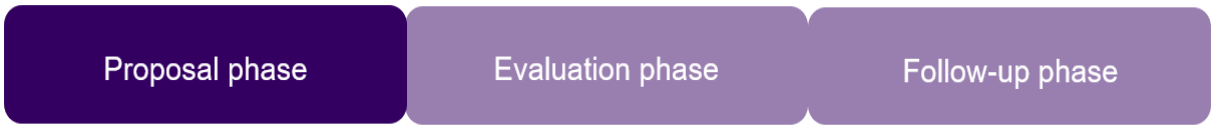
The Danish Health Technology Council has an expected casework time for evaluations of five to eight months. Casework times is calculated from the day on which the Council decides to initiate the evaluation (day 0) until the Council has produced a recommendation. This corresponds to the part of the process defined as the evaluation phase, see Figure 1.

As mentioned above, when the evaluation phase commences, several elements will be initiated simultaneously (Figure 2): Expert committees are established, the evaluation design is developed, and the application is prepared. The expert committee helps to determine the evaluation design, and the application cannot be completed until the final evaluation design has been determined. However, work on the application will commence as soon as the evaluation is initiated. Thus, the applicant and the secretariat will

engage in dialogue about the elements in the application that can be completed before the final evaluation design is available.
The estimated casework time includes a four-week-period for the applicant to finalise the application after the final evaluation design has been made available. If an applicant uses more than four weeks, this may prolong the total casework time beyond the five to eight months.

The process from the time of initiating a more comprehensive analysis and until a Council recommendation is available is expected to be between eight and 12 months.

4 Process for the proposal phase



The individual elements of the proposal phase are described below.

4.1 Initial contact/dialogue meeting

Applicants wishing to have a health technology evaluated by the Danish Health Technology Council can make a request to the Danish Health Technology Council secretariat at any time. This should be done by submitting information about the health technology via the Danish Health Technology Council's website to inform the subsequent dialogue. The secretariat will then contact the applicant to initiate the dialogue.

The following information must be submitted via the Danish Health Technology Council's website:

1. Name of applicant (company, hospital, region)
2. Name of contact person
3. Email address of contact person
4. Telephone number of contact person
5. Occupation of contact person
6. Name of health technology
7. Summary of the health technology and its area of application
8. Brief description of intended use/purpose[8] (including the core outcome: What is the main problem solved by the technology? For example, reduction in incontinence, reduction in mortality, increased quality of life)
9. Whether the technology bears the CE marking (only relevant for medical devices)
10. Summary of the existing/expected implemented alternative(s) to the health technology
11. Summary of the benefits of the health technology compared with existing practice

In cases where an applicant is represented by a consultancy firm, the request should always be accompanied by an authorization. A template for this is available on the Danish Health Technology Council's website.

After the Danish Health Technology Council secretariat has received a request concerning a new or existing technology, the applicant can ask for an initial dialogue meeting with the Danish Health Technology Council secretariat to help determine whether to submit an evaluation proposal to the Danish Health Technology Council. If the applicant requests further dialogue with the secretariat during the preparation of an evaluation proposal, a limited number of dialogue meetings may be held to discuss

[8] Intended use/purpose includes what the product does, how it achieves its outcome, as well as when and by whom the product will be used.

and provide feedback on the applicant's evaluation proposal.

During the initial dialogue the applicant should present:

- The mode of action and area of application of the health technology, including:
    - The expected Danish patient population
    - ○ Intended use/purpose
    - Existing alternative health technologies (where relevant)
- A summary of the clinical and health economic evidence collected as part of the health technology development programme
- A summary of existing evidence related to the patient and organisational perspective

During the initial dialogue the secretariat will go through:

- The Danish Health Technology Council's process and methodology for evaluating single technologies, including:
    - ○ Key procedural steps
    - ○ A description of the criteria for selecting health technologies for evaluation
    - ○ A preliminary timeline for the evaluation of health technologies
    - ○ Guidance on submitting evaluation proposals and applications
- Any questions regarding the Danish Health Technology Council's process for evaluations may also be addressed at the meeting.

4.2 Preparation of the evaluation proposal

After the initial dialogue with the secretariat, the applicant may choose to prepare an evaluation proposal. The submission of an evaluation proposal is the applicant's official indication of wanting to take part in the Danish Health Technology Council's evaluation process. The evaluation proposal should provide the Council with sufficient information to decide whether to initiate an evaluation of the health technology in question. The final application should not be prepared until after the Council has decided whether to carry out an evaluation.

The relevant areas to be described in the applicant's evaluation proposal are summarised below. Due to the broad remit of the Danish Health Technology Council, the secretariat and the applicant may need to engage in dialogue in connection with the preparation of an evaluation proposal.

The overall elements typically included in an evaluation proposal are listed below:

- Indication of the type of health technology, as well as a brief description and, for medical devices: risk class, intended use/purpose and documentation for CE marking
- A brief description of the clinical context in which the technology will be used
- Patient population for which the technology is expected to be used
- Existing, implemented alternatives to the technology
- Indication of the primary clinical outcomes (or other outcomes, for example performance) for the technology
- Indication of on-going or completed clinical studies as well as health technology evaluations
- Description of patients' experiences of the technology, including special considerations regarding accessibility and inequality for particular patient groups
- What are the likely organisational impacts of the technology and what organisational experiences have already been gained from use of the technology in practice?

- Indication of existing health economic analyses and overall description of costs.[9] The framework of the Danish Health Technology Council requires companies to provide documentation for the likelihood of cost neutrality/cost savings. For this purpose, applicants should use the outline of costs from the Danish Health Technology Council. Regional governments are not subject to the same cost neutrality/cost savings requirement, but they can use the outline of costs to illustrate the costs of the given technology
- Opportunity to mention and enclose publications and documents relevant to the health technology in question

When preparing the evaluation proposal, the applicant may assist in defining PICO[10] for the health technology to be evaluated. However, the individual expert committee will always be ultimately responsible for defining PICO in the evaluation design.

For a complete list of content to be included, see the evaluation proposal template on the Danish Health Technology Council's website.

For diagnostic technologies, there should be a brief description of the area of application (diagnostics, monitoring, screening, or prognostics), and for diagnostic tests, it should be indicated how the technology is expected to be included in the existing Danish diagnostic paradigm (for example, whether the test is intended to replace or supplement an existing diagnostic procedure).

Relevant published clinical and health economic evidence concerning the specific technology should be enclosed as appendices when submitting the evaluation proposal.

The evaluation proposal should be submitted via the Danish Health Technology Council's website. The evaluation proposal can be submitted in either Danish or English.

When the Danish Health Technology Council receives the final evaluation proposal, the secretariat will carry out a technical validation of the material in the evaluation proposal. The purpose of the validation process is to ensure that the proposal has been completed correctly and contains the required information and materials. The secretariat will also carry out an assessment of the extent to which the existing evidence provides a sufficient basis for evaluation.

During the process of preparing the evaluation proposal, the applicant may engage in dialogue with the secretariat about any shortcomings in the evaluation proposal. After receiving the evaluation proposal, the secretariat will always carry out a validation of the materials submitted. If the secretariat assesses that the evaluation proposal is incomplete, the applicant will have the opportunity to adjust or supplement the evaluation proposal. The evaluation proposal will be passed on to the Council once it has been finally validated by the secretariat. If the Council assesses that the evaluation proposal does not provide a sufficient basis for a decision, then the Council may require additional information from the applicant.

If the applicant is a regional government or a hospital, an evaluation proposal must be accompanied by a statement from the relevant company to the effect that the company wishes to participate in the

[9] To demonstrate cost neutrality and harmonise evaluation proposals, the applicant should use the outline of costs developed by the Danish Health Technology Council. For new health technologies not yet priced, this includes a binding maximum price, while for technologies already priced, the marketed price/price from existing contracts with regional governments will be used.

[10] PICO is a framework for identifying and answering clinical questions. See the Danish Health Technology Council's methodological guidelines for more detailed descriptions.

evaluation and will assist in the provision of necessary documentation and information. The secretariat is responsible for obtaining this statement. The reason is that the Council needs to know whether the company wishes to participate in the evaluation before it decides whether to initiate an evaluation of the health technology in question. A company cannot be forced to take part in an evaluation. The secretariat will notify the company behind the health technology if the Council decides to initiate an evaluation.

It is up to the applicant to decide how much time to spend on preparing the evaluation proposal. However, if the applicant wants its evaluation proposal to be considered at a specific Council meeting, the evaluation proposal must be validated at least three weeks before the Council meeting for it to be considered at the meeting. If the evaluation proposal is submitted close to this cut-off date, the applicant cannot expect the secretariat to have time to carry out its validation before the next Council meeting.

4.3 Selection of evaluation proposals for evaluation (day 0)

Based on the validated evaluation proposals, the Danish Health Technology Council selects technologies for evaluation. The selection will be based on the prioritization factors stated below (Table 2). The factors are not weighted relative to each other, and selection is based on an overall assessment.

Table 2: Information used by the Danish Health Technology Council to select technologies for evaluation

Prioritization factors	**Remit** – description of the technology and its area of application
	Patient population/target population – description of patient population/target population
	Safety/risk class – description of the technology risk class[11]
	Other aspects – Including whether the technology is expected to have any organisational and/or ethical implications, and whether the necessary evidence to carry out the evaluation is available
	Outcome – Has high priority if the technology is likely to have a significant positive impact on health and/or other relevant aspects related to patients
	Severity – Has high priority if the technology concerns treatment or diagnosis of diseases with excess mortality or severe morbidity
	Costs – Has high priority if it is considered likely that the technology will reduce costs
	General relevance – Has high priority if there is wide clinical demand for an evaluation of the technology and/or no national guidelines for using the technology exist, or if the technology has been implemented to a varying degree across Denmark

Based on the above information, which may be supported by dialogue with relevant experts from regional governments and/or applicant companies, the secretariat prepares a list of proposals to be presented to the Council. The Council will then select the technologies to be evaluated by the Danish Health Technology Council based on this list.

[11] Medical devices are classified as follows: I (Is, Im), IIa, IIb and III as well as active implantable medical devices (AIMD) and in vitro-diagnostic devices (IVD). The classification reflects the risk linked to use of the product, the vulnerability of the body parts on which the devices are to be used and how long the impact will last.

There may be health technologies among the submitted proposals that the Danish Health Technology Council deems to be best suited for a more comprehensive analysis of an entire technology area. For example, this may be the case if a single technology is predicted to have implications for a larger treatment or diagnostic paradigm, or if it is deemed most appropriate to compare several competing health technologies on the market (rather than comparing a single or a few health technologies to a relevant comparator). In these cases, the proposal may be included in the Board of Danish Regions' discussion of future analysis topics. Product categories can be the subject of an evaluation or a more comprehensive analysis. The Danish Health Technology Council will decide this on a case-by-case basis.

The Council can make its own proposals for evaluations, but this must be agreed unanimously. In such cases, the secretariat will prepare an evaluation proposal concerning the health technology, which will then be presented to the Council at an upcoming meeting where the proposal will be considered in the selection process on an equal footing with the other evaluation proposals. As is the case for evaluation proposals submitted by regional governments/hospital managements, the secretariat is responsible for obtaining a statement from the company behind the health technology stating whether the company wants to take part in the evaluation.

Once the Danish Health Technology Council has decided to initiate an evaluation, it will make the evaluation proposal publicly available. See section 9 on transparency and making information available to the public.

In the estimation of casework time, day 0 is the day when the Danish Health Technology Council decides to initiate an evaluation (see Figure 1). The respective processes to establish expert committees and to prepare the evaluation design and the application are initiated at the same time immediately after this. Based on its expert knowledge, the expert committee prepares the final evaluation design in collaboration with the secretariat. The expert committee's evaluation design is crucial to how the application should be designed and the materials for inclusion, which is why the applicant cannot complete the application until the evaluation design has been approved.

5 Process for the evaluation phase

The individual elements of the evaluation phase are described in more detail below.

5.1 Establishment of an expert committee

When the Danish Health Technology Council has decided to initiate an evaluation, the process of establishing an expert committee will commence. The secretariat handles the practicalities of establishing the expert committee and is responsible for ensuring that the right expert and specialist competencies are represented, possibly in consultation with the chair of the expert committee.

The chair of the expert committee is appointed by the Council on the recommendation of the Organization of Danish Medical Societies (LVS) or, in special cases, on the recommendation of the Danish Nursing Society (DASYS). In cases where LVS or DASYS cannot appoint a chair, the request will be passed on to the regional governments.

In some cases, the chair and the members of the expert committee may be appointed simultaneously. In other cases, however, the chair will have to be appointed first, so that the chair, in collaboration with the secretariat, can help to identify the different competencies to be represented in the expert committee for an evaluation to be made.

When establishing expert committees, the secretariat may seek advice from clinical experts, experts with technical knowledge about the health technology, for example engineers, people with knowledge about organisational and/or patient aspects, or health economists. Furthermore, the regional governments and companies can also be included in the dialogue on ensuring that all the right competencies are represented in the expert committee. When evaluating technologies that span sectors, the secretariat will ensure that the expert committee is composed of representatives from other relevant sectors.

The overall framework for work in the expert committee as well as the composition of the specific expert committee will be described on the basis of standard terms of reference. These are subject to approval by the Council and will be published on the Danish Health Technology Council's website along with the names of all members of the expert committee.

Prior to the first meeting of the expert committee, patients or patient representatives appointed to the committee will be given a general introduction to and guidance in the expert committee work. Furthermore, there will be an introduction to the specific expert committee work in which the patients or patient representatives will be involved. Similarly, the chair of the expert committee will be introduced to expert committee work, including the involvement of patients and patient representatives. The aim is to ensure the representation of both the overall patient perspective and the individual experienced-based perspective in expert committees.

See section 2.2. for more on the composition of the Danish Health Technology Council's expert committees, including the appointment of members to the committees.

5.2 Preparation of evaluation design

Once established, the expert committee prepares an evaluation design in collaboration with the secretariat. The purpose is to determine the review questions that the evaluation is to answer so that the Council can decide on a recommendation.

Furthermore, the evaluation design will serve as a protocol for how applicants should prepare their application, including for example which comparator to use and how to perform the health economic analysis. The evaluation design will follow the Danish Health Technology Council's methods guide.

In general, the evaluation design should include the following:

- Background information about the health technology's area of application, including an estimate by the expert committee of the size of the patient or target population
- A search strategy for searching for relevant published research literature, including search results, which the applicant should use when identifying evidence to be included in the application
- One or more clinical questions and associated descriptions of the population, intervention, comparator, and outcomes that will be used to examine the clinical effectiveness of the technology
- A description of how the patient perspective should be examined, including special considerations about accessibility and inequality for particular patient groups
- The specification of requirements for the description of the organisational and implementation/phase-out implications
- Specifications for the design of the health economic analysis

Once the expert committee has developed the evaluation design, the Council must approve it before the evaluation is started. The evaluation design will be published once it has been approved by the Council. When the final evaluation design has been approved, the applicant can prepare the final application.

If a final application has not been submitted one year after publication of the evaluation design, the design will be reassessed by the expert committee. The expert committee may then change the evaluation design to ensure that it reflects current clinical practice and the most recent evidence.

If the evaluation design designates a single specific product/brand as the comparator, then the secretariat will contact the company who markets the comparator and inform them that the evaluation is being initiated. If the comparator is not a specific product but instead comprises a number of technological and possibly non-technological components, for example a conventional surgical procedure, the secretariat will not contact the companies marketing the relevant individual components. If the evaluation concerns a product category, and if specific products are being compared, it may be relevant to contact all the companies marketing the relevant products. With regard to product categories, the evaluation design determines whether or not a health technology is to be evaluated as part of a product category, and this cannot be changed later on in the process.

If the evaluation of a product category compares relatively few technologies, then the applicant will usually be responsible for preparing the application materials. However, if the product category includes a large number of technologies, the secretariat will be responsible for providing information

and will assist in preparing the application. A decision on this will be made on a case-by-case basis to ensure the most appropriate division of responsibilities between the applicant and the secretariat.

5.3 Preparation and validation of application

The application must be prepared by the applicant and should follow the specifications described by the expert committee in the evaluation design. The applicant may seek advice from the Danish Health Technology Council secretariat to support this work.

The application should be structured using the template available on the Danish Health Technology Council's website.

The application should include:

- Basic information on the specific technology and its area of application
- The applicant's summary of the most important clinical and health economic findings
- A review of the study data applied (including study and population characteristics at study level)
- A reply to the clinical question(s) in the evaluation design, including appropriate comparative statistics
- The applicant's summary of existing evidence regarding patient/user preferences for the health technology examined
- The applicant's considerations regarding the organisational and implementation prerequisites and implications of using the health technology examined
- A health economic analysis in line with the specifications presented in the evaluation design

The Danish Health Technology Council's methods guide (section 6) explains the elements described above in more detail.

If the applicant is not able to provide all the analyses/results/information requested in the evaluation design, the best possible alternative(s) should be submitted along with a brief explanation of why the requested information cannot be submitted. For example, the evaluation design may request data on a given outcome produced after a one-year follow-up. If the applicant does not possess, or have access to, such data, data must be submitted which, in terms of follow-up period, is as close as possible to what the expert committee has defined.

If important requested information cannot be provided, the applicant must notify the secretariat before submitting the application. The applicant and the secretariat will then enter a dialogue to ensure progress of the continued process.

The application may be submitted in either Danish or in English.

Just as with the preparation of the evaluation proposal, if required, the applicant and the secretariat may engage in dialogue in conjunction with the preparation of the 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 aim of the validation is to check whether:

1. The application template has been used and filled out appropriately
2. The application is in line with the evaluation design and complies with the methods guide
3. The screening of literature is adequate and has been clearly described
4. The analyses used are appropriate and have been adequately described

5. Relevant results are clearly stated

As soon as possible after the technical validation, the applicant will receive notification of whether the application is considered satisfactory and can be approved. If the application is not approved, a brief explanation will be attached to the notification indicating the shortcomings in the application. To facilitate the planning of the expert committee and the secretariat, the applicant should notify the secretariat as soon as possible of when it expects to submit a revised application. When the applicant submits a revised application, the secretariat will carry out a new technical validation. The time spent on preparing and approving a revised application is not included in the calculation of the overall casework time.

5.3.1 Withdrawal of application

An applicant may, at any time in the process, withdraw an application by notifying the secretariat in writing. However, since the Danish Health Technology Council may take up a case at its own initiative, the Council may decide to continue the evaluation of the health technology. The Danish Health Technology Council may allow documents already submitted by the applicant to be included in the further process and may publish information from these documents in the same way as if the application had not been withdrawn. The company behind the health technology as well as any comparator will retain their right to comment on the assessment report before it is presented to the Council.

5.4 Preparation of the assessment report

The expert committee prepares the evaluation in accordance with the methods guide with assistance from the secretariat. When needed, the expert committee will involve relevant players in the evaluation work, and the company may present its views to the expert committee during the evaluation work, provided that the expert committee sees a need for this. Similarly, the applicant and the secretariat may engage in dialogue during the preparation of the evaluation, if deemed relevant.

The assessment report will contain descriptions of the following elements:

- clinical effectiveness and safety
- patient perspective
- organisation
- health economics

The expert committee will summarise the key conclusions for the four perspectives and will make a statement to the Council.

The assessment report will be presented to the Council at a meeting, where it will usually be presented by the chair of the expert committee, a patient representative, and a representative of the secretariat's project team.

5.4.1 Consultation on the assessment report

The applicant and the comparator company (if a single comparator/company has been specified) will review the assessment report for factual errors before it is presented to the Council. In addition, the applicant and the relevant comparator company have the option to submit a two-page memo to accompany the assessment report for the Council's consideration of the case. The memo may not

contain new data that has not been used in the application. The applicant and the relevant companies involved have 10 days to submit any comments and the memo.

The assessment report and the memo will be published with any confidential information redacted. The secretariat and the company will jointly assess confidentiality.

5.5 Decision by the Council

Based on the expert committee's assessment report and the presentation of the report, the Council will make its recommendation. Only the Council can decide on a recommendation. The Council operates with three categories of recommendation:

- The health technology is recommended for use or implementation
- The health technology is recommended for knowledge acquisition
- The health technology is not recommended

The recommendation is based on the four perspectives described in the assessment report. All recommendations must be specific and include a description of the target group for the health technology as well as the use and implementation of the technology.

In connection with preparation of a recommendation, on a case-by-case basis, the Danish Health Technology Council may decide whether special circumstances justify setting a fixed date for reassessment or expiry of the recommendation. The Council's recommendations will be published immediately after they have been decided.

The regional governments are then responsible for ensuring uniform implementation throughout Denmark.

The three categories of recommendations are described below.

5.5.1 The health technology is recommended for use or implementation

The Council may recommend implementation or continued use of the health technology. The recommendation will be accompanied by a description of areas requiring special attention when using the technology.[12] There will also be a description of the conditions potentially influencing the implementation of the technology.[13]

When deciding on a recommendation on use or implementation of health technologies, the subsequent implementation period will depend on whether other contractual aspects influence the ability of regional governments to immediately implement the health technology.

[12] The Danish Health Authority's guidelines on the introduction of new treatments in the healthcare system ("*Vejledning om indførelse af nye behandlinger i Sundhedsvæsenet*") and the guidelines on doctors' and dentists' use of implants ("*Vejledning om lægers og tandlægers anvendelse af implantater*") will also be considered.

[13] As of 26 May 2021, a new Regulation on medical devices entered into force. This could influence products/medical devices with CE marking under the current Directive. Transitional provisions will apply to the implementation of the Regulation so that the certificates will remain valid until May 2024. The same applies to in-vitro diagnostic devices for which a new Regulation will enter into force in May 2022.

Recommendations by the Danish Health Technology Council to implement a technology are forwarded to Danish Regions and to each of the five regional governments. The recommendations by the Danish Health Technology Council will also be forwarded to the Organization of Danish Medical Societies, who will brief the relevant professional association in the field so that the recommendation can be incorporated into relevant clinical guidelines. In cases where the recommendation also concerns matters in municipalities and/or general practice, the recommendation will be forwarded to Local Government Denmark and to the Danish College of General Practitioners. This is to ensure uniform implementation.

5.5.2 The health technology is recommended for knowledge acquisition

In cases where the Council assesses that the evidence base is insufficient to make a recommendation on whether or not to implement the technology, but the results available are promising, the Council may choose to recommend the health technology for knowledge acquisition. Knowledge acquisition means that the health technology will be used at one or a few selected hospitals and, concurrently with this use, more knowledge will be compiled in areas in which it has so far been insufficient. For health technologies that have already been implemented, there is generally no limitation in the use of the technologies during the knowledge-acquisition period.

When a technology is recommended for knowledge acquisition, the expert committee together with the Danish Health Technology secretariat will prepare a number of review questions in dialogue with the company. These questions need to be answered for the Council to be able to decide whether the technology can be recommended for use/implementation or phasing out.

Once the review questions have been prepared, the health directors of the five regional governments will select one or a few lead hospitals to be in charge of the knowledge acquisition.

As a rule, when the Council recommends health technologies for knowledge acquisition, the company will cover the costs associated with this. If the company does not want to cover the costs of knowledge acquisition, then knowledge acquisition cannot usually be carried out. However, in special cases, the Council may recommend that the five regional governments cover the costs. For example, this could be the case when the company is a small start-up, and the health technology has great potential. If a regional government/hospital proposes a health technology for evaluation, and the technology is subsequently recommended for knowledge acquisition, then the regional government/hospital will usually cover the costs associated with this.

When the knowledge acquisition has been completed, the secretariat will update the assessment report and, when needed, the expert committee will convene again. The Council will then make a final decision on whether or not to recommend the health technology for implementation.

Knowledge acquisition will be described in more detail after further discussions between the Council and the regional governments.

5.5.3 The health technology is not recommended

When the Council has decided not to recommend a technology, the recommendation and the assessment report will be sent to the relevant players. Once the Council has issued its recommendation, its work with the specific technology ends. The regional governments will then take over the task of

implementing the recommendation, including ensuring that already implemented health technologies are phased out.

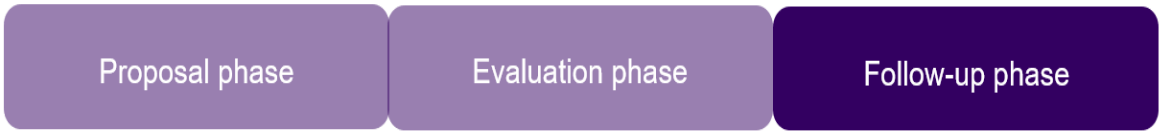
5.6 The role of the Danish Health Technology Council after a recommendation

For all evaluations and the more comprehensive analyses, the Council will conclude the process either by recommending the relevant health technology for use/implementation, not recommending the health technology or by recommending the technology for knowledge acquisition. When the Council has made its recommendation, it will be sent to the relevant players, including the individual regional governments, Danish Regions, and relevant medical associations. If the technology could also be relevant for municipalities and general practice, the decision and the assessment report will also be forwarded to Local Government Denmark and to the Danish College of General Practitioners (DSAM).

After this, the Council's work is complete. The only two exceptions are when the Council is to resume processing of an evaluation or a more comprehensive analysis because:

- The Council itself has stipulated a time for reassessment or expiry of the recommendation
- The Council resumes processing after a knowledge acquisition process

6 Process for the follow-up phase



A brief description of the follow-up phase follows below.

6.1 Implementation

The regional governments are responsible for implementation of the recommendations from the Danish Health Technology Council.

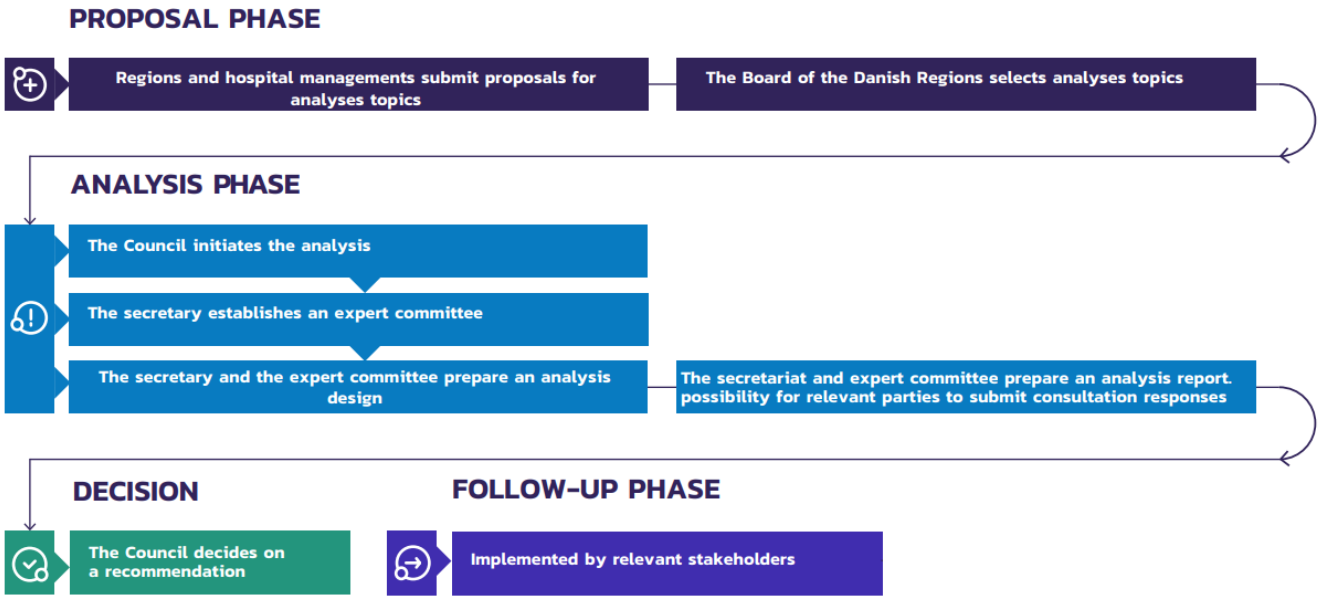
It is important both for the Danish Health Technology Council and for the regional government that the time between the Council making its recommendation and the recommendation being implemented is as short as possible. Recommendations by the Council are not legally binding for the regional governments, but they are expected to follow them unless they have special reasons to deviate from them.

It is to be expected that most of the Council's recommendations on use or implementation of a health technology will involve procurement of such technology. The regional governments' procurement organisations and the Regions Joint Procurement (RFI) will be responsible for the procurement and tendering procedures. Note that tendering and procurement conditions may influence the pace of implementation

7 Process for preparing more comprehensive analyses

The Danish Health Technology Council's process for preparing more comprehensive analyses is illustrated below.

Figure 3: Flow chart of the Danish Health Technology Council's process for comprehensive analyses



As mentioned in the introduction, in addition to the 15 to 25 annual evaluations, the Danish Health Technology Council is also expected to carry out two to three more comprehensive analyses per year. The difference between an evaluation and an analysis is that an evaluation is based on a product in the form of one or more health technologies. Product categories can be the subject of an evaluation or a more comprehensive analysis. The Danish Health Technology Council will decide this on a case-by-case basis. An analysis addresses more fundamental issues about treatment regimes, approaches to or organisation of treatments, across both physical and mental health services. For example, an analysis could address how treatment has been organised for a specific patient group. The process from the time of initiating a more comprehensive analysis and until a Council recommendation is available is expected to be between eight and 12 months.

Hospital managements and regions, including the regional councils, may propose topics for more comprehensive analyses. The Danish Health Technology Council may also propose topics for analyses at its own initiative. The Board of Danish Regions will select two to three analysis topics from the topics recommended for analysis, and these will comprise the Council's annual programme for more comprehensive analyses. The topics will be selected once every year at a meeting of the Board of Danish Regions. Based on the selected topics, the Council will specify and launch the individual analyses. The start dates for the analyses will be staggered over the year to avoid several comprehensive analyses being launched at the same time.

The process of preparing more comprehensive analyses is similar to the process of preparing evaluations. When it has been decided to launch an analysis, an expert committee will be established, and an analysis design will be prepared. The Council approves the expert committee's terms of reference and analysis design in the same way as for evaluations. Unlike for the evaluations, however, the analysis process does not involve an application. Therefore, the Danish Health Technology Council secretariat and the expert committees are the ones to perform the literature search, data extraction and analyses. The secretariat also prepares the economic analyses. The Danish Health Technology Council may involve relevant stakeholders during the process and may ask for supplementary information and contributions on specific issues.
When the analysis has been completed, relevant stakeholders will have the opportunity to provide consultation responses to the report in the same way as for evaluations.

8 Process for the reassessment of a recommendation

For up to two years after a recommendation, applicants may ask the Danish Health Technology Council to reassess the recommendation. As a rule, the Danish Health Technology Council will be willing to conduct a reassessment if new data is available that shows significant changes in the clinical effectiveness and safety and/or in the results of the economic analysis, typically as a consequence of a new price.

The first screening of new data is performed collaboratively between the applicant and the secretariat. If the new data relates to clinical effectiveness, the reassessment will be carried out in collaboration with the expert committee. On this basis, the expert committee will make a statement to the Council, and this will be presented to the Council together with the existing recommendation. Subsequently, the Council will assess whether to launch a reassessment of the recommendation resulting in a new evaluation. This will be part of a selection process along with other evaluation proposals.

If the Council decides that the recommendation is to be reassessed, a new evaluation process will be initiated, including relevant aspects such as reappointment of an expert committee. The expert committee will therefore also have to prepare a new assessment report. The Council will then decide whether to change its recommendation on the basis of the new report.

In this process, the Danish Health Technology Council has the option to reassess all other relevant elements of the application. The Danish Health Technology Council may also reassess a recommendation if the company wants to significantly reduce the price of the health technology assessed. When submitting a new price, the applicant must also submit an updated economic analysis. Based on this analysis, the secretariat will then carry out the first screening and assess whether there is reason to reactivate the expert committee with the purpose of making a statement to the Council. In this process, the Danish Health Technology Council also has the option to reassess all other relevant elements of the application, if the Council decides to reassess the recommendation.

The Danish Health Technology Council may, at its own initiative, for example on the basis of new information from specialist companies about the health technology or the disease area, decide to reassess a recommendation. In such cases, the secretariat will notify the applicant of this.

9 Transparency and public information

To ensure transparency in the process of assessing new health technologies, the Danish Health Technology Council regularly publishes relevant documents. Generally, the Danish Health Technology Council will publish the following documents:

- Evaluation proposals
- Evaluation designs
- Applications
- The expert committee's assessment report and, if relevant, the two-page(s) memo to the Council from the applicant and the comparator
- Recommendation from the Danish Health Technology Council

The status of evaluations will be updated regularly on the Danish Health Technology Council's website, from initiation of the evaluation to the final recommendation.

Applicants may request that sensitive information (such as prices) shared with the Danish Health Technology Council be kept confidential. In this case, the applicant should indicate this when forwarding documents to the Danish Health Technology Council by clearly marking which information is confidential. In practice, the applicant should submit two versions of the same document: one version in which the confidential information has been redacted, and one version where the confidential information is not marked. The applicant also has the opportunity to redact any confidential information in connection with the consultation process for the assessment report. The assessment of confidentiality will be undertaken in dialogue with the secretariat.

Generally, because the Danish Health Technology Council's recommendations are based on transparency, the data used as the basis for the assessment of the new health technology will be published on the Danish Health Technology Council's website when the Danish Health Technology Council publishes the assessment report. However, according to the Danish Health Technology Council's criteria document on unpublished data, there may be cases in which some data cannot be published until after one year.

10 Version log

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	03-06-2021	Approved by the Danish Health Technology Council
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