Danish Regions' procedural framework for the Danish Health Technology Council

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Procedural framework for the Danish Health Technology Council

This document outlines the overall framework for the process in the Danish Health Technology Council. This is not the final description of the Council's process, but the framework within which the Council secretariat will prepare the full process description.

Target group

The final process description will be a guide for companies, regional governments and hospital administrators seeking to have a health technology or medical device assessed by the Danish Health Technology Council or to have a specific topic undergo a more comprehensive analysis by the Danish Health Technology Council. The process guide will also serve as a tool for the Danish Health Technology Council, including for council members, members of expert committees and the secretariat. Together with the final methodological guidelines, the process guide will constitute the foundation for the Council's work on assessing health technologies/medical devices as well as topics for more comprehensive analyses.

About the Danish Health Technology Council

This chapter briefly introduces the organisation of the Danish Health Technology Council.

The Danish Health Technology Council's expert committees

The expert committees carry out the actual evaluations and analyses, and prepare a decision basis for the Council. The expert committees are temporary and members are appointed in connection with the specific evaluation or analysis.

An expert committee consists of professionals with expert knowledge in the area relevant for the specific evaluation or analysis, and can comprise physicians, nurses, physiotherapists, engineers or other specialist groups with expert or practice-based knowledge. All five regions have the option of being represented in the expert committees. One or more patients with concrete experience with the technology under evaluation will also be included. Relevant patient associations appoint patients with relevant experience to the expert committees. Health economists and professionals with procurement knowledge, for example, can also be represented on the expert committees. Municipalities and general practice can take part if the technology is used across sectors. The secretariat will also take part by contributing relevant competencies and supporting progress in the evaluation process.

The Danish Health Technology Council secretariat

The Danish Health Technology Council secretariat is headed by a director. The secretariat prepares Council meetings and participates in evaluation and analysis work with the expert committees.

The secretariat is composed of staff with broad competencies, e.g. within the methods applied in evaluations and analyses, including experience with outcomes studies and similar, economic studies, systematic literature searches, statistics, and project management.

The Council

The Council constitutes the senior management of the Danish Health Technology Council and prepares advisory recommendations.

The Council consists of fifteen members and three observers. The specific distribution of representatives in the Council is shown below:

The chair (appointed by Danish Regions)

5 representatives from hospital management (health care professionals)

2 representatives appointed by the Organisation of Danish Medical Societies

1 representative appointed by the Danish Nursing Society (DASYS)

1 representative appointed by Danish Patients

1 representative appointed by the Disabled People's Organisations Denmark (DPOD)

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)

1. Structure of the process guide

This chapter outlines the structure of the process guide and the overall process in the Danish Health Technology Council

The process in the Danish Health Technology Council for assessing health technologies and medical devices, as well as topics selected for more comprehensive analyses, generally follows the steps below, and this process description has been structured according to these steps. Health technologies, medical devices as well as topics for more comprehensive analyses are referred to collectively as 'topics' or 'technologies'.

- Submission of topic proposal
- Dialogue with proposal submitter
- Application
- Categorising topics from applications
- Selection of topics

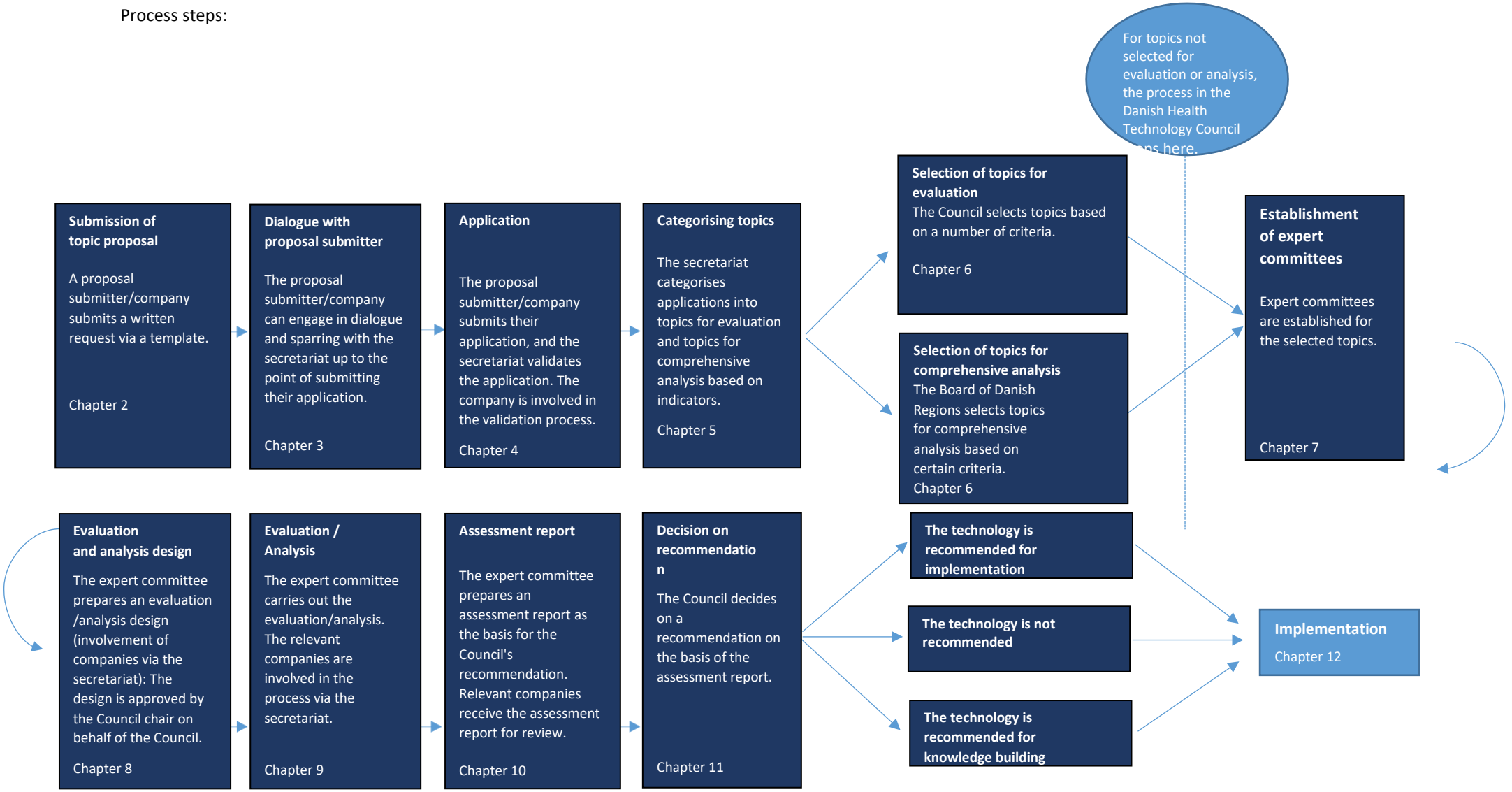
    - Topics for evaluation
    - Topics for more comprehensive analysis
- Establishment of expert committees
- Evaluation or analysis design
- Evaluation/analysis
- Assessment report
- Decision on recommendation
    - The technology is recommended for implementation
    - The technology is not recommended
    - The technology is recommended for knowledge building
- Implementation

An ordinary process for health technologies usually takes 5-8 months from the date of receipt of a complete application by the Danish Health Technology Council. An ordinary process for analysis topics usually takes up to 12 months from the date of receipt of a complete application by the Danish Health Technology Council.

Bearing the above in mind, note that the Council can evaluate both new technologies and technologies which are already widely used in the health care system. Evaluations by the Danish Health Technology Council are not a requirement for placing a new technology on the market.

The individual steps in the process for evaluations in the Danish Health Technology Council are shown in the figure below and described individually in chapters 2-13 of this guide.

Process steps:



Note: Dark blue boxes illustrate process steps in the Danish Health Technology Council, while blue boxes illustrate steps outside the Danish Health Technology Council.

2. Submission of topic proposal

This chapter contains information on the process for submission of proposals to the Danish Health Technology Council, including various options for proposal submission.

Stakeholders eligible to submit proposals to the Danish Health Technology Council include regional governments, hospital administrators and companies, and they all have various options for submission. Regional governments and hospital administrators can propose topics for evaluation *and* topics for more comprehensive analysis, e.g. complete treatment areas. Companies may submit proposals for topics for evaluation if they can substantiate that, in overall terms, the product does not lead to more costs for the health care system. 'Costs for the health care system' refers to the whole health care system and costs in a broad perspective, see the methodology guide.

If regional governments or hospital administrators submit a proposal to have a technology assessed, then the secretariat will enter into dialogue with the companies/manufacturers upon receipt of the proposal.

A proposal should include a description of the relevant technology. Furthermore, a proposal should substantiate that there is sufficient evidence of effectiveness, costs and organisational aspects for an evaluation or analysis to be carried out.

When the secretariat receives a proposal, it performs an initial assessment of the request to ensure that it falls within the remit of the Danish Health Technology Council.

The secretariat will further develop the process to include the more specific process for how to submit proposals and will prepare a template for submission of proposals.

3. Dialogue with proposal submitter

This chapter contains a description of the possibility for dialogue with the Danish Health Technology Council secretariat before submitting an application to the Danish Health Technology Council, including a description of the materials relevant for the dialogue.

After having submitted a proposal, a submitter can ask for a dialogue with the secretariat for advice on the application and the process. If the company (or companies) behind the technology did not submit the proposal, then the secretariat will invite these to take part in the dialogue.

Prior to the meeting, the proposal submitter will submit questions to the secretariat as well as relevant materials. These could include:

- Documentation for clinical effectiveness
- Dialogue on the scope of the analysis/evaluation
- Choice of comparator

The secretariat will elaborate further on the process for the dialogue with submitters of proposals. For example, the format and scope of the dialogue.

4. Application

This chapter describes the framework for submitting an application and the subsequent validation process for the application in the secretariat.

An application to the Danish Health Technology Council consists of a completed application form or template and various documentation, including any technical documents.

The Danish Health Technology Council secretariat will prepare an application form or template for companies to complete in connection with applications. The secretariat will also specify the requirements for documentation and for any technical documents to be included in an application.

When the Danish Health Technology Council receives an application, the secretariat will carry out a technical validation of the application materials. The validation process is to ensure that the application 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 knowledge available provides a sufficient basis for evaluation.

As part of the validation process, the secretariat will enter into dialogue with the proposal submitter/company about any deficiencies in the application, so that the application can be adjusted and supplemented as required. If the company (or companies) behind the technology did not submit the proposal, then the secretariat will also invite these companies to take part in the validation process.

5. Categorising topics

This chapter describes how the secretariat categorises applications.

The secretariat assesses and categorises the validated applications for either evaluation or comprehensive analysis.

The secretariat then prepares a long-list with an extended description of topics for evaluation and topics for more comprehensive analysis, respectively. In this process, the secretariat can draw on input from experts from the five regional governments. Descriptions of topics will be consistent and will be based on indicators for whether it is an analysis or an evaluation.

The secretariat will prepare concrete indicators for categorising topics for either broad analysis or more focussed evaluation.

6. Selecting topics

This chapter describes how applications are selected for processing in the Danish Health Technology Council, including the criteria for selection.

The Danish Health Technology Council has capacity to carry out approx. 15-25 evaluations a year, as

well as 2-3 more comprehensive analyses. Thus, a selection process will probably be necessary to select the applications to be processed by the Council.

The Council will select topics for evaluation based on the secretariat's detailed description of topics. For the technologies that are not selected for evaluation, the process in the Danish Health Technology Council stops here.

The Board of Danish Regions will select 2-3 analysis topics based on the secretariat's detailed description of topics for comprehensive analysis, and the topics selected will comprise the Council's annual programme for more comprehensive analyses. The analyses will subsequently be carried out in the Danish Health Technology Council. The Board of Danish Regions will select the topics for more comprehensive analysis once a year. For topics that are not selected, the process in the Danish Health Technology Council stops here.

The selection of topics for evaluation and for more comprehensive analysis is based on the criteria described below. The assessment of the relevance of a topic will be an overall assessment based on all criteria, e.g. so that the criterion 'patient group' can make a topic more relevant if a large patient group is affected. However, all selection criteria should be viewed together. This means that topics can be selected for evaluation even if they do not score highly on all criteria. And all criteria will be considered when selecting topics for evaluation/analysis.

In addition, the selection will consider other guidelines and recommendations in the field, including the national clinical guidelines from the Danish Health Authority and guidelines from pharmaceutical companies.

Criterion	Definition
Remit	Description of medical device or treatment
Patient group	Description of patient group, disease, scope, etc.
Impact	To what extent does the topic impact patient-related health and quality of life?
Safety (for devices)	Does the medical device meet safety requirements? What is the risk class of the medical device?
Population impact	How large a percentage of the patient population will benefit from the medical device/treatment?
Severity	What is the severity? Is the disease associated with high mortality and/or severe late complications? Etc.
Costs	How does a chosen medical device/treatment affect costs in the health care system? (Considerations concerning costs linked to acquisition, infrastructure, operation, associated spending, etc.)
Relevance	Is the health technology in wide clinical demand?

All topics selected for either analysis or evaluation are published on the Danish Health Technology Council website.

The secretariat can develop the criteria further with regard to how the relevance of a topic is to be assessed

7. Establishing expert committees

This chapter describes the overall framework for establishing expert committees.

When a decision has been made to carry out an evaluation or comprehensive analysis, the Council will establish an expert committee adapted specifically to the evaluation or analysis in question. The overall task of the expert committee is to prepare the expert evaluation or analysis that is to form the decision basis for the Council's recommendation.

Prior to establishing the expert committee, the Council will prepare the committee's mandate, detailing the committee's assignment. The mandate will also describe the competencies to be included in the committee and who will appoint the members. The chair of the committee is appointed by the Council on the recommendation of professional associations.

The secretariat handles the practicalities of establishing the expert committee and is responsible for ensuring that the right expert and specialist competencies are represented.

The secretariat staffs the expert committee in dialogue with relevant parties. To ensure clinical expertise, the secretariat will engage in dialogue with relevant professional associations, e.g. the Danish Nursing Society (DASYS) and the Organisation of Danish Medical Societies, who will be invited to appoint a representative. If there is no relevant professional association, the secretariat can also consult directly with a relevant expert. This could be experts with technical knowledge about the technology, such as engineers, people with knowledge about organisational or patient perspectives, or health economists. Furthermore, the five regional governments and companies can also be included in the dialogue on ensuring that all the right competencies are represented in the expert committee.

The secretariat will further develop the process for establishing expert committees, i.e. the more detailed process for selecting representatives, and for the dialogue on staffing with relevant parties.

Once the expert committee has been established, information about its composition will be published on the Danish Health Technology Council website, including information concerning impartiality and qualifications.

8. Determining the evaluation/analysis design

This chapter describes the process for how the expert committee determines the evaluation/analysis design, e.g. a plan for the committee's approach to the evaluation/analysis.

When the expert committee has been set up, the expert committee and the secretariat draw up an

overall evaluation/analysis design describing how they will approach the evaluation/analysis. The objective is to determine the review questions to be answered by the analysis or evaluation, so that the Council can decide on a recommendation.

As part of the evaluation/analysis design, the committee will also select relevant methods from the Danish ealth Technology Council methodological guidelines to be applied in answering the review questions.

The expert committee will include relevant parties in its preparation of the evaluation/analysis design, as required. Relevant companies will be involved in preparation of the design via the Danish Health Technology Council secretariat. In special cases, the secretariat and the chair of the expert committee may deem it appropriate for the chair of the expert committee or a member of the expert committee to participate in a meeting with the company.

Once the expert committee has prepared the evaluation/analysis design, the design will need to be approved by the chair of the Council before commencement of work on the evaluation or analysis.

The evaluation or analysis design will be published once it has been approved by the chair of the Council.

9. Preparing the evaluation/analysis

This chapter includes a description of the framework for preparation by the expert committee of the evaluation or analysis, including any price negotiations if one or more products needs to be priced.

The expert committee is responsible for carrying out the evaluation or analysis in accordance with the methods in the methodological guidelines. The following are fixed elements in evaluations/analyses: a description of effectiveness, costs and organisational aspects. Furthermore, actual patient experience with the technologies will be included on a systematic basis. Due to the nature of the field, a greater degree of uncertainty will be accepted than for medicines.

The expert committee will involve relevant stakeholders in its evaluation/analysis work as required, just as relevant companies will be involved in the work via the Danish Health Technology Council secretariat. In special cases, the secretariat and the chair of the expert committee may deem it appropriate for the chair of the expert committee or a member of the expert committee to participate in a meeting with the company.

As part of the evaluation/analysis process, there may be a need for price negotiations to determine a purchase price for use in the cost analysis and for the Council's assessment of cost-effectiveness and any implementation of the technology. For example, this can be in situations with a new product that has yet to be priced, or in situations where a number of products are compared which have not previously been subject to competition. Price negotiations take place in the context of the RFI (the five regional governments' joint procurement organisation) and are conducted by a representative with specialist knowledge about the product type under evaluation. The specific price negotiations will depend on whether there are alternatives to the product. If there are no competing products,

the representative from the RFI will conduct price negotiations with the relevant company. If there are several competing products on the market, or if the expert committee is evaluating an entire product category, the products will undergo a competitive tender procedure through a joint call for tenders in the context of the RFI.

10. The assessment report

This chapter briefly describes the process for the assessment report and for its presentation to the Council.

Once the expert committee has prepared the actual evaluation/analysis, it will draw up an assessment report. The assessment report contains the evaluation and a recommendation to the Council on one of the three categories of recommendation, i.e. the technology is recommended for implementation; the technology is not recommended; or the technology is recommended for knowledge building.

The affected company (or companies), including companies behind the comparator, will be asked to review the assessment report for factual errors and to verify that all information they consider as confidential has been marked in the report. The company (or companies) also has the option to submit a two-page memo to accompany the assessment report when the Council examines the matter. The company can include additional information in the memo which they want the Council to be aware of. The memo may not contain new data that has not been used in the company's application. The memo and the assessment report will be published with any confidential information blocked out.

The assessment report will be presented to the Council at a meeting, where it will be presented by the chair of the expert committee, a health economist and a patient representative.

11. Decision on recommendation

This chapter describes how the Council prepares its recommendations and what a recommendation contains.

On the basis of the assessment report and presentation by the expert committee, the Council members decide on a recommendation. The Council can make one of three categories of recommendation:

- The technology is recommended for use or implementation
- The technology is recommended for knowledge building
- The technology is not recommended

A recommendation will include a description of the target group for the health technology. This includes whether the technology is relevant for a specific group of patients, age group, or similar.

The recommendations will be specific and will contain a description of aspects such as the organisational changes needed to achieve the desired effects of a technology recommended for implementation.

In connection with preparation of a recommendation, on a case-to-case basis, the Danish Health Technology Council may decide whether special circumstances justify setting a fixed date for reassessment or expiry of the recommendation.

If there is insufficient basis for the Danish Health Technology Council to assess whether or not a technology is to be recommended for implementation, then the Council can choose to recommend the technology for knowledge building. Knowledge building means that the technology can be used at one or a few selected hospitals if, concurrently with this use, more knowledge is compiled on the effectiveness and costs of the technology. The process for knowledge building is described in more

detail in Chapter 12.

Only the Council can decide on the recommendation, and the recommendations are published soon after they have been prepared.

12. Implementation

This chapter briefly describes the processes instigated once the Council has published a recommendation. The implementation process generally lies outside the Council's remit.

Recommendations by the Council are not binding, but the five regional governments are expected to follow them unless they have special reasons to deviate from them.

Where a technology is 'recommended for implementation' or where a technology is 'not recommended', information about the recommendation will be sent to relevant stakeholders, for information or for possible implementation. The overall implementation process is the same for these two categories of recommendation and is described in chapter 12.2. The process for technologies 'recommended for knowledge building' is different and is described in chapter 12.1.

12.1 Knowledge building

That a technology is recommended for knowledge building means that the technology is recommended for use at one or more hospitals while more knowledge is generated about its effectiveness and costs.

When a technology has been recommended for knowledge building, the expert committee 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 on whether or not the technology can be recommended.

Once the review questions have been prepared, the health directors of the five regional governments will select a lead hospital to be in charge of the knowledge building. The company is also included in efforts to answer the review questions.

When the Council recommends technologies for knowledge building, there will often be costs involved with the knowledge building. A company that did not itself request an evaluation, cannot be required to finance such knowledge building. In special cases, the Council may recommend that the five regional governments bear the costs. For example, if the company is a small start-up company or the company did not itself propose the technology for evaluation, and the technology has great potential. There may also be cases in which more knowledge is needed in the field, and the technology is not a single product from a single company but several products or product types, which must be reviewed together.

Once the knowledge building has been completed, the expert committee and the secretariat will update the original assessment material. Then the Council will make a final decision on whether or not to recommend the technology for implementation, based on the updated material.

12.2 The implementation process for 'recommended for implementation' and 'recommended for phase-out'

Recommendations by the Danish Health Technology Council to implement a technology or to phase out a technology (the technology is not recommended) will be forwarded to Danish Regions and to the five regional governments, including to relevant planning and procurement managers in the five regional governments. The Board of Danish Regions will moreover receive quarterly status

briefings on the recommendations by the Danish Health Technology Council. The recommendations by the Danish Health Technology Council will also be forwarded to the Organisation 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.

In cases of recommendations to phase out a technology already widely used, the Danish Health Technology Council supports the 'choosing wisely' initiative, which makes similar recommendations for the phase-out of treatments.

In addition to this, Danish Regions will set up a 'Cross-regional forum for the coordination of recommendations from the Danish Health Technology Council'.
The forum will discuss the implementation of all of the Council's recommendations concerning technologies, i.e. the recommendations stemming from the Council's evaluations. The cross-regional forum will be tasked with sharing experiences and following up on any necessary changes to work procedures and other organisational aspects, etc.

The implementation process for the more comprehensive analyses will be anchored with the health directors of the five regional governments, who can choose to establish a 'treatment community' to support the implementation process.