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Danish Health Technology Council principles for use of unpublished data

1 Introduction

This memorandum describes how and when the Danish Health Technology Council uses unpublished and possibly confidential data in relation to evaluations of new and existing health technology. The purpose of the memorandum is to define the practice of the Danish Health Technology Council with regard to data included in the analysis of clinical effectiveness and safety[1]. For the three other perspectives in evaluations by the Danish Health Technology Council (the patient perspective, organisational implications and health economics), it has been judged that there will usually not be any peer-reviewed, published literature, and therefore this memorandum does not apply to these.

This memorandum is based on the Danish Medicines Council's principles paper for the use of unpublished data [1], but it has been revised to cover the broader remit[2] and more varied evidence base that is likely to apply for evaluations by the Danish Health Technology Council. The Danish Health Technology Council has a confidentiality policy (link) and the use and redaction of confidential data must be in line with this. This principles paper should be considered in the context of the confidentiality policy.

[1] In this memorandum, 'safety' refers to, for example, the risk of adverse reactions, harm and/or adverse events that the patient may experience in connection with correct use of a given health technology. This could include nausea in connection with treatment with virtual reality equipment or perforations in connection with endoscopic procedures. It does not refer to indirect risks or safety specifications for the actual product.

[2] The Danish Health Technology Council evaluates health technology, including medical devices, but also other types diagnostic devices, as well as treatments, rehabilitation, prevention, and types of organisation and collaboration in the provision of healthcare services. In the following, 'health technology' is used as an umbrella term for all of these.
In this context, the term 'medical devices' denotes apparatus, software and *in vitro* diagnostic devices/materials used for diagnosing, preventing, monitoring, treating or alleviating diseases, for example, or used as assistive devices for injuries or disabilities. For a full definition, see Part 1 of the Medical Devices Executive Order (*Bekendtgørelseom medicinsk udstyr* nr. 1263 af 15/12/2008).

2 Definitions

2.1 Data that is published and peer-reviewed

Data from full-text articles that *have been* published in scientific, peer-reviewed journals. Furthermore, the Danish Health Technology Council considers data from internationally recognised HTA agencies (e.g. NICE, MSAC, CADTH, etc.), documentation from notified bodies, as well as documentation from the authorities (e.g. the Food and Drug Administration) as of a quality corresponding to peer-reviewed publications.

2.2 Data that is published, but not peer-reviewed

This could be data reported in the ClinicalTrials.gov database or data that is published in abstract or poster format, but that has *not been* peer-reviewed. When this type of data is submitted to the Danish Health Technology Council, it will often not be enough to refer to the relevant poster or abstract. When submitting such data, companies should comply with the Danish Health Technology Council's guidelines for reporting, which are described in this principles paper (sections 4 and 5).

2.3 Data that has neither been published nor peer-reviewed and that is often confidential

This could be data from companies (data-on-file) or data from data collection in clinical practice (real-world data). The Danish Health Technology Council expects that data from the former category will often constitute confidential information and therefore it will often *not* be possible to publish it directly in the assessment report. When submitting such data, companies should comply with the Danish Health Technology Council's guidelines for reporting, which are described in this principles paper (sections 4 and 5).

3 Unpublished data - professionalism and transparency

In order to ensure a high level of professionalism and transparent evaluations, the Danish Health Technology Council will accept data on clinical effectiveness and safety from the following sources, listed in order of priority:

1. Published and peer-reviewed data (see definition in section 2.1) can always be included in evaluations from the Danish Health Technology Council.

2. Published but not peer-reviewed data (see definition in section 2.2) can generally be included in evaluations from the Danish Health Technology Council.
   Applicants should report sufficient information on how the data has been obtained and the expert committee will conduct a more rigorous assessment of the quality and the validity of the data submitted. A prerequisite for using such data is that there is no published, peer-reviewed data that can be used as a completely acceptable alternative (e.g. data from the same study that shows a similar picture, but with shorter follow-up).

3. Data that has neither been published nor peer-reviewed and that is often confidential (see

definition in section 2.3) may be used in evaluations from the Danish Health Technology Council under certain circumstances.
Applicants should report sufficient information on how the data has been obtained and the expert committee will conduct a more rigorous assessment of the quality and the validity of the data submitted. A prerequisite for using such data is that there is no published data that can be used as a completely acceptable alternative (e.g. data from the same study that shows a similar picture, but with shorter follow-up). If unpublished and confidential data concerning clinical effectiveness and safety is used in an evaluation, the Danish Health Technology Council will generally publish this by no later than 12 months after publication of the recommendation (see section 4, point 6).

In many cases, it will be academically relevant for the applicant to submit unpublished data (data-on-file) to the Danish Health Technology Council. The Danish Health Technology Council and its expert committee may also request specific data and analyses that the company has not included in the evaluation proposal and/or the application, and that are not available in the published evidence material. It is likely that applicants will often consider unpublished data as confidential, e.g. if an applicant intends to publish the relevant data in a journal at a later date.

The Danish Health Technology Council assesses health technology in accordance with the principles 'more cost-effective health care solutions (value for money)', 'transparency', 'equality', 'professionalism' and 'independence from the political system'. With regard to confidential data, it is often necessary to balance the need for the highest quality of the evaluation against a desire for transparency in the evaluation process. Therefore, there could be professional reasons for including unpublished and confidential data in the evaluation process, and these should be balanced against the likelihood that unpublished, confidential data will often not be published by the Danish Health Technology Council in connection with the recommendation.

In order to ensure the greatest possible adherence to the principles of professionalism and transparency, the Danish Health Technology Council has drawn up the following principles for how the applicant should act when submitting unpublished data (section 4), as well as principles for how the Danish Health Technology Council will manage such data (section 5).

4 Principles for submission of unpublished and possibly confidential data

When applicants submit unpublished data, the Danish Health Technology Council will prioritise compliance with the following criteria:

1. The applicant should (e.g. in the evaluation proposal or application) make it clear that there is unpublished data and give reasons for including this, given that any published data basis is essential for the evaluation.
2. The applicant should provide sufficient information about the study design and performance so that the Danish Health Technology Council can make a critical assessment of the risk of bias. See the CONSORT and STROBE guidelines for randomized and observational studies, respectively. If data stems from later cut-off or follow-up studies, for example, the (published) main study in which the patients were originally included should be clearly stated.
3. In connection with the economic analysis, applicants should conduct sensitivity analyses of the significance of inclusion and exclusion of the unpublished data, as far as this is possible and relevant.
4. The applicant should comply with any requests from the Danish Health Technology Council for further data or analyses during the assessment. If it is not possible to meet a request, the applicant should provide reasons.
5. The applicant should indicate confidential data clearly, e.g. in the evaluation proposal, the

application, an annex, etc. In connection with the consultation on the assessment report, the applicant should also clearly mark data which the applicant considers to be confidential.

6. The applicant should state whether confidential data is expected to be published by the applicant at a later date, and if so, when it is expected to be published. As a general rule, the Danish Health Technology Council expects that it will be possible to publish all information in applications (except confidential prices and the actual health economic model, etc.) 12 months after the Danish Health Technology Council's recommendation. If the applicant submits confidential data, the Danish Health Technology Council will usually request reasons for why the applicant considers that data is confidential, so that the Danish Health Technology Council can carry out its assessment of whether the information is covered by the rules on confidentiality. For more about this, see the Danish Health Technology Council's confidentiality policy (link to follow).

If the applicant expects the evaluation proposal or application to include unpublished data that is essential for the evaluation, then the company should inform the secretariat at the earliest opportunity. This will allow ongoing dialogue concerning the possible use and management of confidential information.

5 Principles for management of unpublished and possibly confidential data by the Danish Health Technology Council

The Danish Health Technology Council will manage unpublished and possibly confidential data on the basis of the following principles:

1. As a general rule, the Danish Health Technology Council may include unpublished and possibly confidential data in cases where the Council or its expert committee has requested specific statements, analyses, or data that do not exist in the published material.
2. The expert committee and the secretariat will ensure that the applicant has provided sufficient information on data and the underlying studies and statistical analyses that can support an informed recommendation. The expert committee and the secretariat will also assess whether, given any published data basis, the unpublished data is essential for the evaluation.
3. The expert committee and the secretariat will make a critical assessment of the data validity. When relevant, these assessments will be described in the assessment report by the expert committee.
4. If points 2 or 3 have *not been* met (i.e. there is a lack of information about how data has been obtained or there are concerns regarding data validity), the expert committee may decide to disregard unpublished data in its assessment report, possibly after consulting the Danish Health Technology Council.
5. The importance of including and excluding unpublished data in economic analyses will be covered and described in the assessment report, if relevant and possible.
6. It is always up to the Danish Health Technology Council to assess whether, and, if so, to what extent, unpublished and possibly confidential data should have an influence on the overall assessment of the technology and the decision on the recommendation.
7. The assessment report will state when unpublished data has been used.
8. Where it is not possible for the Danish Health Technology Council to publish the unpublished data, as far as possible the significance of the unpublished data will be described, although with respect for any confidentiality issues.

Twelve months after the Danish Health Technology Council has published a recommendation that has involved unpublished and confidential data in the analysis of clinical effectiveness and safety, the Danish Health Technology Council secretariat will review the case documents with a view to publishing the data that has not previously been published. The company will be consulted in this process, so that the Danish Health

Technology Council can make an assessment of the data concerned in accordance with the rules (legislation) on confidentiality and ensure that any right of confidentiality continues to be respected.

Note that members of the Danish Health Technology Council and its expert committees, as well as employees in the secretariat are subject to the Danish Health Technology Council's eligibility and confidentiality policy (link to follow).

6 Version log

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1.0	6 July 2021	Published
	3 June 2021	Approved of the Danish Health Technology Council

7 References

1. Danish Medicines Council, Medicinrådets principper for anvendelse af upublicerede data, (2021). https://medicinraadet.dk/media/louf5ufc/medicinrådets_principper_for_anvendelse_af_upublicerede_ data_godkendt_270121_adlegacy.pdf (accessed May 17, 2021).