

Request for assessment of [pharmaceutical] for [indication]

[A company that wants to have a new pharmaceutical assessed by the Danish Medicines Council should contact the Secretariat using this form. The request for assessment is the company's indication that they expect to submit an application for assessment of a new pharmaceutical or an extension of indication of an existing pharmaceutical. A request for assessment should be sent to the main email address medicinraadet@medicinraadet.dk on or as soon as possible after day 120 in the assessment process at the European Medicines Agency (EMA) for new medicines in the normal approval procedure at the EMA or on day 1 for extensions of indication and new medicines in the accelerated approval procedure at the EMA.]

The Medicines Council's Secretariat uses the request for assessment to plan the assessment process, including to ensure that an expert committee has been established in the disease area. If the company wishes to request that the pharmaceutical be placed directly in a treatment guideline, Table 5 must be completed (see section 12 of the Danish Medicines Agency's methods guide).

Once the request for assessment has been submitted, the company can request a meeting with the Secretariat's project group for advice on the application and the process. If the company already knows that it wants a dialogue with the Secretariat about the application when requesting an assessment, the company can add the necessary information and any questions in Tables 6-9. If the company only later needs a dialogue with the Secretariat about the application, this information can be forwarded.]

Version 1.0

1. Contact information

Company	Name of the applicant company
Name	e.g. Anders Andersen
Title	e.g. medical director
Responsibility	e.g. clinical/medical, health economics or negotiation
Phone number	
E-mail	
External representation	Name/company:
(When using external representation, remember to enclose a power of attorney. A template is on the Danish Medicines Council's home page)	Phone number/e-mail:

2. Information about the pharmaceutical

Trade name

Generic name (active ingredient)

Marketing authorisation holder in Denmark

ATC code

Form of administration *E.g. tablet, subcutaneous injection*

Mode of action

Dosing

Expected (or approved) indication

Other approved indications for the pharmaceutical

Combination therapy and/or co-medication

Orphan drug-status by the EMA *State whether the EMA has granted an orphan drug designation*

Is the pharmaceutical being assessed in an accelerated process at the EMA?

3. Expected timeline for marketing authorisation

Expected date of CHMP Positive opinion *State the expected date of positive opinion from the EMA CHMP*

EC approval (date of marketing approval) *State the expected date of marketing approval by the European Commission*

Date the EPAR will be available *State when the EPAR is expected to be available for the Danish Medicines Council (will a draft version be made available for the Medicines Council before publication by the EMA?)*

Expected date of application to the Medicines Council *State the expected date of application to the Medicines Council (no earlier than at positive opinion)*

4. The disease and current treatment in Denmark

Briefly describe the pathophysiology of the disease and the clinical presentation/symptoms, incl. references. Describe the prognosis with current treatment options (or observation if there are no treatment options yet), incl. references. Describe the current standard treatment in Denmark, incl. references.

Specify the Danish patient population expected to be candidates for the treatment, including number (incidence, prevalence) and any subgroups/special mutations, etc., incl. references. If the new pharmaceutical is dosed in relation to body weight or surface

4. The disease and current treatment in Denmark

area, then state the average body weight or surface area for the patient group in question, incl. references. Describe when the new pharmaceutical is expected to be used in relation to current treatment.

5. Can the pharmaceutical be assessed via a treatment guideline?

Indicate whether there is a treatment guideline for the disease area from the Danish Medicines Agency. Explain whether the pharmaceutical is considered to be equivalent to one or more existing treatments and thus can be placed directly into a treatment guideline in accordance with section 12 of the Danish Medicines Council's process guide for evaluation of new medicines. Attach (e.g. as an appendix) direct or indirect comparison of the new pharmaceutical and relevant comparator on key outcomes.

6. Study characteristics for relevant clinical trials

Provide relevant information on available studies for efficacy and safety, e.g.

- Study name and NCT number
 - Purpose
 - Publications (alternatively expected date of publication) - title, author, journal, year
 - Study type and design
 - Follow-up time - If the study has not been completed, state the follow-up time for the data that is expected to be available for assessment at the Danish Medicines Agency and the expected / planned total follow-up time for the study
 - Population (inclusion and exclusion criteria, possibly from clinicaltrials.gov)
 - Intervention including dose and dosing interval as well as number of patients
 - Comparator including dose and dosing interval as well as number of patients
 - Primary, secondary and exploratory endpoints, including definition, measurement method and possibly time of measurement
 - Description of any subgroup analyses
-

7. Ongoing trials

Provide information on ongoing studies or completed studies where results have not yet been published. Please indicate the expected date of publication.

8. Expected health economic analysis

Enter information about the expected health economic analysis, e.g.

- The type of health economic analysis (cost-utility analysis or cost minimization analysis)
 - The patient population of the health economic analysis, including any subgroups
 - Intervention (incl. dose and dosing interval) for the current patient group
 - Suggestions for comparator (incl. dose and dosing interval) and justification for this
-

8. Expected health economic analysis

- *How quality-adjusted life years (QALY) are calculated*
 - *What costs are included in the analysis*
 - *What type of health economic model is used (e.g. Markov model, partitioned survival model or individual sampling model)*
 - *The time horizon for the health economic analysis*
 - *Include subsequent treatments*
 - *How uncertainties are handled (deterministic and probabilistic sensitivity analyses)*
-

9. Other relevant information

If there are any other matters that the Medicines Council's Secretariat and the expert committee should be aware of, these can be stated here. Indicate any specific questions or topics that you wish to discuss with the Secretariat before submission of the application.
