

Request for assessment of [medicine] for [indication]

[The request for assessment is the company's formal declaration of their intention to initiate an assessment process with the Danish Medicines Council (DMC) and hence a declaration of the intent to submit an application to the DMC for assessment of a new medicinal product or assessment of an extension of indication of an existing medicine. The request for assessment is also required if a medicine will be assessed by updating an existing treatment guideline.

Requests for reassessment of current recommendations require a separate request form which can be found on the DMC's website: www.medicinraadet.dk.

A request for assessment is sent to the DMC's main email address medicinraadet@medicinraadet.dk. The timing of the submission of a request depends on the timeline of the approval procedure at the European Medicines Agency (EMA). A request for assessment can be sent at the earliest at day 120 in the assessment process for new medicines in the standard EMA approval procedure. For new medicines evaluated under EMA's accelerated approval procedure and for extensions of indication the request to the DMC can be sent at the earliest on day 1 of EMA's approval procedure. If the company wishes to submit a request at a later time point in the EMA process, the DMC urges that the request is sent as early as possible to avoid delays in the DMC's assessment process.

The request for assessment must be submitted no later than 3 months prior to the planned date for submission of the application.

The DMC Secretariat uses the request for assessment to plan the assessment process and to ensure that an expert committee has been established in the disease area.

The form should be used for requests for assessment by means of any of the three different DMC process tracks: the 18-week process (standard process including cost utility or cost minimization assessment), the 14-week process and assessment by updating a treatment guideline (16-week process).

Tables 1-4 are mandatory and must be completed for all process tracks. Table 5 is only required for requests regarding assessment of a medicinal product by updating a treatment guideline (no economic analysis is to be included). Table 6 is only required for assessment of a medicine in a 14-week process (no economic analysis is to be included). If tables 5 and 6 are not applicable to a given request, please refrain from deleting them, but simply mark the tables 'N/A'.

If the company has specific questions regarding the forthcoming application, which could necessitate a meeting with the Secretariat, these questions should be listed in section 7. Based on these questions the Secretariat will evaluate if a meeting is required.

Text in [brackets] is for example/instructional purposes only and must be deleted prior to submitting the request for assessment].

1. Contact information

Table 1. Contact information	
Name	[Name / Company]
Title	
Phone number	[Include country code]
E-mail	
Name (external representation)	[Name / Company]
Title	
Phone number	[Include country code]
E-mail	

[If a company wishes to use external representation in relation to the application for evaluation of a new pharmaceutical / extension of indications, the following [power of attorney](#) must be completed and sent to medicinraadet@medicinraadet.dk.]

2. Timeline

Table 2. Timeline	
Expected date of CHMP positive opinion	[State the expected date of positive opinion from the EMA CHMP]
Date the EPAR will be available	[State when the EPAR is expected to be available for the DMC. The final EPAR or a draft version must be submitted with the application.]
Date of application to the DMC	[State the date (day-month-year) on which you plan to submit your application to the DMC (no earlier than at positive opinion). Based on your stated date of submission, the DMC Secretariat plans the assessment process, and you will receive an agreed date of application. You need to submit your application no later than on the agreed date of submission, otherwise a new agreed date of application needs to be planned.]

3. Regulatory information on the pharmaceutical

Table 3. Regulatory information on the pharmaceutical	
Proprietary name	

Table 3. Regulatory information on the pharmaceutical

Generic name	
(Expected) Therapeutic indication as defined by EMA	[EMA indication]
Marketing authorization holder in Denmark	
(Expected) ATC code	
Combination therapy and/or co-medication	
(Expected) Date of EC approval	
Has the medicinal product received a conditional marketing authorization?	[If yes, state the specific obligations regarding post-authorization measures required for the conditional marketing authorization including due date]
Accelerated assessment in EMA	[Yes/no]
Orphan drug designation (include date)	[Yes/no, include date]
Other therapeutic indications approved by EMA	[In case of multiple indications please list them in bullets]
Other indications that have been evaluated by the DMC (yes/no)	[In case of multiple indications please list them in bullets]
Dispensing group	[BEGR/NBS]
Packaging – types, sizes/number of units and concentrations	

4. Key information summary

Table 4. Key information summary

Therapeutic indication relevant for the assessment	[Note if there are any deviations from the EMA indication and elaborate]
Mechanism of action	[Briefly describe the mechanism of action]
Dosage regimen and administration	

Table 4. Key information summary

Choice of comparator incl. dosage regimen and administration	[Describe the choice of comparator and the alignment with Danish medical practice]
Prognosis with current treatment (comparator)	[Briefly describe the expected course of the disease (progressive or stable disease). Does it lead to decreased life expectancy and / or decreased health-related quality of life? State median survival or survival rate from the Danish patient population if applicable]
Clinical evidence	[State key references, trial names and NCT numbers for studies relevant for the assessment]
Ongoing studies	[State references, trial names and NCT numbers, study phase and expected date when data will be made available (applies to ongoing studies relevant to the specific indication)]
Population	[Describe the study population and deviations from patients in Danish medical practice]
Type of comparative analysis for the clinical evaluation	[Head-to-head study or indirect comparison (ITC, NMA, MAIC, other). Describe relevant subgroup analyses if applicable, including rationales for conducting these. Describe comparability between studies included in the analysis if applicable]
Most important efficacy endpoints that will be included in the application	[E.g. OS, PFS, HRQoL]
Subsequent treatment (if relevant)	[Briefly describe what constitutes subsequent treatment following the intervention as well as the comparator in Danish medical practice.]
Expected type of economic analysis	[State the type of health economic analysis (cost-utility or cost-minimization), type of model (Markov model, partitioned survival model etc.) and endpoints included in the model]

5. Assessment by updating a treatment guideline (16-week process)

Table 5. Assessment by updating a treatment guideline

Treatment guideline from the Danish Medicines Council	<p>[Indicate the treatment guideline for the disease area from the DMC.</p> <p>Explain whether the medicine is considered to be equivalent to one or more existing treatments recommended as first choice treatments in the guideline or whether the medicine should be applied in subsequent lines of treatment. Please refer to DMC's information about treatment guidelines on the DMC's website: www.medicinraadet.dk.</p> <p>Describe if there are deviations from the PICO's in the treatment guideline. Please refer to the outcomes included in the current relevant DMC treatment guideline.</p> <p>Attach (e.g. as an appendix) direct or indirect comparison of the new medicine and relevant comparator on key outcomes.]</p>
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Table 5. Assessment by updating a treatment guideline

Expected follow up data (if the medicine is to be assessed by updating the treatment guideline)

[Indicate if data with a longer follow-up time from the relevant study/studies will be available, and if so when. Describe whether these data can be published within the update of the DMC treatment guideline. The DMC cannot use confidential data in treatment guidelines.]

6. Assessment in a 14-week process

Please indicate, which criteria is applicable for the specific medicine and provide the relevant information:

Table 6. Assessment in a 14-week process

PD-(L)1-inhibitors

Criteria:

1. The request concerns an extension of indication for a PD-(L)1-inhibitor (ATC: L01FF)?

Yes
 No

2. The indication is for use as a monotherapy or in combination with non-patent-protected medicines?

Yes
 No

3. The PD-(L)1-inhibitor must be priced at the level of other recommended PD-(L)1-inhibitors. The DMC assesses whether this condition is met when receiving the request based on prices (SAIP) from Amgros.

[Please state if there are any concerns regarding prices that the DMC and Amgros should be aware of; e.g. other package sizes or formulations, more frequent hospital visits, differences in duration of treatment etc.]

4. The extension of indication must not involve unusually prolonged treatment compared to indications for PD-(L)1 inhibitors that the Danish Medicines Council has previously assessed.

[Briefly describe treatment duration as observed in the pivotal study, including mean and median duration of treatment as well as key stopping rules (if applicable)]

Extensions of indication from adults to younger age groups

Criteria:

1. It is an extension of the indication within the same disease, but to a younger patient group.

[State the original and new indication]

Table 6. Assessment in a 14-week process

2. Efficacy and safety in the younger age group(s) is the same or better than in adults.	[To support this assertion, include key references and trial IDs relevant for the assessment]
3. The medicine must be recommended by the DMC for adults.	[Include a link to the DMC recommendation for adults]
4. The medicinal costs for treating the younger age group(s) must be at the same level as the costs for treating adults.	[The DMC Secretariat receives the prices from Amgros. Please state if there are any concerns regarding prices that the DMC and Amgros should be aware of; e.g. other package sizes, more frequent hospital visits, treatment duration beyond 2 years etc.]

7. Other relevant information

[If there are any questions that the DMC Secretariat and potentially 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.]

Version log

Version	Date	Change
2.2	2 April 2024	Revised text about on process names.
2.1	8 February 2024	Revised text about date of application to the DMC.
2.0	1 December 2023	Revised version of the request assessment form made available on the website of the Danish Medicines Council.
1.1	1 November 2021	Clarification of the introduction, including instructions on how to complete the form.
1.0	27 November 2020	Request for assessment form made available on the website of the Danish Medicines Council.