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.

A request for assessment is sent to the DMC's main email address medicinraadet@medicinraadet.dk. The time for request depends on the European Medicines Agency (EMA) approval procedure and 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 proces.

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 request form should be used for the three different DMC process tracks: the standard process (cost utility assessments), the fast track process and the process regarding assessments by updating treatment guidelines.

Tables 1-4 are mandatory and must be completed for all process tracks before submission. Table 5 is only required for requests regarding assessment of a medicinal product by updating a treatment guideline (the economic analysis is not included). Table 6 is only required for assessment of a medicine in a fast track process (the economic analysis is not included).

If tables 5 and 6 are not required for a given application, 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 in order to clarify the questions prior to submittion of the application, these questions should be listed in section 7. The secretariat will based on these questions evaluate if a dialoque meeting is required.

Text marked in grey and [in brackets] is for example purposes only and must be deleted prior to submitting the request for assesment].

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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. EPAR or a draft version is required to 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.*

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3. Regulatory information on the pharmaceutical

Table 3, Regulatory information on the pharmaceutical	
Proprietary name	
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	
Orphan drug designation (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	

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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	
Dosage regiment and administration	
Choice of comparator incl. dosage regiment 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 population if applicable]
Clinical evidence	[State key references, trial names and NCT numbers relevant for the assesment]
Ongoing studies	[State references, trial names and NCT numbers, study phase and expected date when data will be made available]
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 analysis, including rationale for conducting these. Describe comparability between studies included in the analysis]
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, cost-effectiveness, cost-minimizing etc.), type of model (Markov model, partitioned survival model etc.) and endpoints included in the model]

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5. Assessment by updating a treatment guideline

Table 5, Assessment by updating a treatment guideline	
Treatment guidelines from the Danish Medicines Council	[Indicate the treatment guideline for the disease area from the DMC. 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. Describe if there are deviations from the PICOs in the treatment guideline. Please refer to the outcomes included in the current relevant DMC treatment guideline. Attach (e.g. as an appendix) direct or indirect comparison of the new medicine and relevant comparator on key outcomes.]
Expected follow up data (if the medicine is to be assessed by updating the treatment guideline)	[Indicate if data after a longer follow-up time from the relevant study/ies will be available, and if so when and, whether these data can be published in connection with the update of the DMC treatment guideline. The DMC cannot use confidential data in treatment guidelines.]

6. Assessment in a fast track process

Please indicate, which type of fast track is applicable for the specific medicine and provide the relevant information:

Table 6, Assessment in a fast track process	
PD-(L)1-inhibitors	
1. It is an extension of indication of an existing medicine, which is a PD-(L)1-inhibitor (ATC: L01FF) and has already been granted a marketing authorization for one or more other indications	[State other authorized indications]
2. The indication is for use as a monotherapy or in combination with non-patent-protected medicines	[Monotherapy] [Combination with non-patent-protected medicine – please state the dosage of the combination]

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Table 6, Assessment in a fast track process	
3. The PD-(L)1-inhibitor must be priced at the level of other recommended PD-(L)1-inhibitors at the time of request. The DMC assesses at the time of the request whether this condition is met based on current prices (SAIP) from Amgros	[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, differences in duration of treatment etc.]

Extension of indication from adults to younger age groups	
1. It is an extension of the indication within the same disease, but to a younger group	[State the original and new indication]
2. Efficacy and safety in the younger age group(s) is the same or better than in adults	[Key references, trial names and NCT numbers relevant for the assesment]
3. The medicine must be recommended by the DMC for adults	[Include link to the 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.]

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7. Other relevant information

[If there are any questions that the DMC 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.]

Version log		
Version	**Date**	**Change**
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.

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