

Request for reassessment of the recommendation of <pharmaceutical> for <indication>

[Companies may request the Danish Medicines Council to reassess a recommendation by submitting this form. The request should be sent to the medicinraadet@medicinraadet.dk.

Based on the request the Danish Medicines Council will consider whether a reassessment will be initiated. The decision will be published on the Danish Medicines Council webpage, irrespective of whether a reassessment is initiated or rejected. A short summary of the basis for the decision will also be published on the webpage. The Danish Medicines Council will only grant a reassessment process if the new information demonstrates substantial changes regarding clinical efficacy and safety and/or changes in the results of the health economic analysis.

The company must complete the form and then submit it to the secretariat. Table 1, 2 and 3 must be completed for all cases. Table 4 should be completed for cases where the price is modified. Table 5 should be completed if the request includes new efficacy or safety data.

Companies must ensure that all confidential information is highlighted in yellow.

If the request contains a new price offer, negotiations with Amgros must be completed prior to submitting the request for reassessment to the Danish Medicines Council]

1. Contact information

Company

Name of the applicant

Name

e.g. Anders Andersen

Title

e.g. Medical director

Area of 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 can be found on the Danish Medicines Council's webpage)

Phone number/e-mail:

2. Information about the pharmaceutical and the existing recommendation

Pharmaceutical	<i>[Generic name]</i>
Indication	<i>[If multiple indications apply list only the one(s) that are relevant to the request for reassessment]</i>
The Danish Medicines Council's current recommendation	<i>[Insert the Danish Medicines Council's current recommendation for the relevant pharmaceutical and indication(s)]</i>
Subpopulations in the existing recommendation	<i>[If applicable, describe the subpopulations in the existing recommendation, including whether the pharmaceutical was recommended or not]</i>
Subpopulation(s) which is requested to be reassessed	<i>[If applicable, list the subpopulation(s) which is the focus of the request for reassessment]</i>
Publication date for the existing recommendation	<i>[Specify the publication date for the existing recommendation]</i>
Basis for request for reassessment	<input type="checkbox"/> New price offer <input type="checkbox"/> New data <input type="checkbox"/> New price and new data
Date of application to the DMC (for reassessments based on new data or new price and new data)	<i>[State the date (day-month-year) on which you plan to submit your application to the DMC (minimum 3 month after submitted request for reassessment). 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.]</i>

3. Basic preconditions for evaluation of the pharmaceutical

Clinical practice	<i>[Describe whether Danish clinical practice, as outlined in the existing assessment report, remains applicable and up-to-date. This includes information regarding whether the comparator specified in the assessment report remains the standard treatment in Denmark and whether previous lines of therapy remains unaltered, etc.]</i>
New data for the pharmaceutical (intervention)	<i>[Describe any new data pertaining to the pharmaceutical, e.g. documented by a systematic literature review]</i>
New data for the comparator	<i>[Describe any new data pertaining to the comparator, e.g. documented by a systematic literature review]</i>
Other considerations	<i>[If applicable, describe other relevant conditions or assumptions which have changed since the Danish Medicines Council published its existing recommendation]</i>

4. Applicable to requests associated with a new price offer

The price of the pharmaceutical at the latest DMC evaluation	<i>[State the discount percent of the AIP for all available pack sizes. The DMC will receive the confirmed prices from Amgros]</i>
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4. Applicable to requests associated with a new price offer

New price offer	<i>[State the discount percent of the AIP for all available pack sizes. The DMC will receive the confirmed prices from Amgros]</i>
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5. Applicable to requests containing new data

New data	<i>[Describe the new data in <u>comparison to</u> the corresponding results in the existing DMC assessment report]</i>
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Impact on cost-effectiveness	<i>[Provide argumentation regarding how the cost effectiveness of the pharmaceutical is expected to change, if the new data is included in the assessment of the pharmaceutical]</i>
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Consequence for the existing recommendation of the Danish Medicines Council	<i>[Provide argumentation for why the new data should lead to changes in the conclusion of the Danish Medicines Councils recommendation regarding the pharmaceutical]</i>
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References

[Insert a reference list. All published articles referenced in the request form must be attached as individual pdf-files]

Appendices

[If applicable list appendices, e.g. documentation of systematic literature reviews]

Version log

Version	Date	Change
1.0	2. June 2022	Form was made available on the DMC website.
1.1	3. August 2022	Added clarification on how to complete table 4. In the introduction it is specified how to mark confidential information.
1.2	13. januar 2023	Added that the decision will be published on the Danish Medicines Council webpage, irrespective of whether a reassessment is initiated or rejected.
1.3	1.marts 2024	Date of application to the DMC is added