

Checklist of Formal Requirements for Submissions to the Danish Medicines Council

Purpose of the Checklist

The Secretariat of the Danish Medicines Council performs a technical validation of all submissions. The submission must comply with all requirements in this checklist before the assessment process can begin (day 0).

The purpose of this checklist is to assist the applicant in verifying that all formal requirements set out in the submission dossier have been fulfilled, that all necessary appendices have been attached, and that the health economic model complies with the applicable requirements. The applicant will be informed whether the submission meets all formal requirements within 10 working days, provided that it has been submitted no later than the agreed submission deadline.

If the submission does not meet all formal requirements, the applicant will receive a brief explanation. The Danish Medicines Council will then initiate a dialogue regarding a new submission deadline. When the applicant submits an updated submission, the Secretariat's review of the formal requirements will restart.

After the formal requirements have been approved, the Danish Medicines Council may, during the assessment process, request changes or additions to the submission of a more content-related nature.

If the submission is to be assessed through the fast-track process or through direct placement in a treatment guideline, the submission must not include a health economic analysis. In that case, the last four formal requirements in the checklist below are not relevant.

Checklist of formal requirements

1. Submission content

The submission must include the following documents:

- the submission in Word format
- the submission in PDF format
- the health economic model and the budget impact analysis combined in one Excel file
- the EPAR. A draft version must be submitted if the final version has not been published at the time of submission.

Note: If the submission is to be assessed through a fast-track process or through direct placement in a treatment guideline, it must not include a health economic analysis.

2. Submission length

Check that the submission (excluding the title page, instructions for the applicant, contact information, table of contents, references, and appendices) does not exceed 100 pages.

3. Submission format

Check that the formatting of the main text has not been changed from the template.

The submission form uses the following formatting:

- Font: Calibri
- Font size for body text: minimum 10 pt
- Line spacing: minimum 14 pt
- Margins (minimum): top 3.6; bottom 2.9; left 4.8; right 3.4.

4. Cross-references

Check that there are no errors in cross-references (these appear as "Error" in the text when the document is updated or converted to PDF).

5. Has the entire submission been completed?

Check that:

- no headings, tables, or sections have been deleted from the submission or appendices.
- all sections have been completed, or marked as N/A if the section is not relevant.
- all tables have been completed, or marked as N/A if the table is not relevant.

6. Are justifications for confidential information provided?

Check that the appendix concerning justification of confidential information has been completed with specific and detailed justifications explaining why each item of information must be kept confidential. This includes, among other things:

- unpublished study data
 - estimated health gains (life years and QALYs)
 - utility values
 - treatment duration
 - expected patient numbers
 - use of non-confidential data for extrapolation of patient transitions
 - the name, job title, and workplace of clinical experts.
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Checklist of formal requirements

7. Can the health economic model be opened?

Check that the Excel file containing the health economic model is not locked, so it can be opened outside your organisation. The contents must be viewable without requiring special permissions.

8. Is the health economic model certified?

Check that the Excel file containing the health economic model is signed with a valid certificate if the model contains macros. The certificate must be issued by one of the certificate providers listed in the security requirements for submissions. See the security requirements [here](#).

9. Are the Danish Medicines Council's standard sheets (excel) used?

Check that the health economic model uses the Danish Medicines Council's standard sheets, and that the names of the sheets have not been changed.

10. Is the health economic model dynamic?

Check that the results update automatically when changes are made to the health economic model.
