

# Checklist for formal requirements in applications to the Danish Medicines Council

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## Purpose of the checklist

According to the Danish Medicines Council's (DMC) [methods guide](#), the Secretariat of the DMC conducts a technical validation of all received applications. The application must comply with all the formal requirements specified as part of the technical validation before the assessment process can commence (day 0).

This document contains a checklist of the formal requirements for the application. The purpose of the checklist is to enable the applicant in ensuring that all necessary fields are completed, all required attachments are provided, and that the health economic model complies with the requirements. The company will be notified within 10 working days whether the application meets all formal requirements of the technical validation (this timeline only applies if the application is submitted by the agreed application deadline).

If the application does not meet all formal requirements, the applicant will receive a brief explanation. The DMC will then initiate a dialogue with the applicant to determine a new application deadline. When the company submits an updated application, the Secretariat will perform a technical validation from the beginning.

After the application has been approved (i.e. the application fulfills the formal requirements), the DMC may request changes to the application or additional information if this is considered necessary to perform the assessment. Such requests can occur throughout the assessment process.

All the requirements listed below are included in the [application form](#) on [the Danish Medicines Council's website](#).

NB: If the application is to be assessed through a fast track-process or by updating an existing treatment guideline, the application should not include a health economic analysis. In that case, the last four formal requirements in the checklist are not relevant.

## Checklist for formal requirements

### 1. Application Content

The application must include the following documents:

- Application in Word format
- Application in PDF format
- The health economic model and budget impact analysis combined in one Excel file
- EPAR. Please provide a draft if the final version is not published at the time of application

NB: If the application is to be assessed through a fast track-process or by updating a treatment guideline, the application does not need to include a health economic analysis.

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### 2. Length of application

Ensure that the application (including cover page, contact information, table of contents and references - excluding appendices) does not exceed 100 pages.

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### 3. Format of application

Check that the formatting of the text itself has not been altered compared to the formatting used in the template.

The application template has the following formatting:

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

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### 4. Cross-references

Check for errors in cross-references (indicated as 'error' in the text when the document is updated or converted to PDF).

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### 5. Are all sections of the application answered?

Check that:

- No headings, tables, or sections have been deleted from the application template. This also applies to the appendices.
- All sections are filled, specify N/A if the section is not relevant.
- All tables are filled, specify with N/A if the table is not relevant.
- All figures are readable (corresponding to minimum Calibri 8 pt)
- All axes in graphic illustrations have titles

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### 6. Can the model be opened?

Check that the Excel file with the health economic model is not locked, to ensure that it can be opened outside your organization. The content should be viewable without requiring special permissions.

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### 7. Is the model certified?

The Excel file with the health economic model must be signed with a certificate if the model contains macros. The certification should be valid for minimum 1 year after application deadline. [Read about security requirements for applications here.](#)

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### 8. Is the "Key Figures Sheet" provided by the Danish Medicine Council included?

Check that the model uses relevant tabs from the sheet '[Key Figures including general mortality for the Danish population](#)'. Note that relevant tabs should be named exactly as in the results sheet of the DMC.

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### 9. Is the model dynamic?

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

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