

Instructions for creating SPC files

Information content of the file

- The file must contain the information for the summary of product characteristics in both Finnish and Swedish.
- The Finnish version must be placed first.
- The Swedish version must begin on a new page.
- In common European processes, both the Finnish and the Swedish text must be a translation of the common SPC in English approved in the process.

Headings

- Begin a heading line with a number, not preceded by a space, tab or any other character.
- Separate the number from the following text with one or two spaces or one tab.
- Do not split a heading onto two lines using the Enter key; if the heading is too long for one line, allow Word to wrap it automatically.
- Headings must be left aligned.
- Headings must not be placed in tables.

Please note! When preparing an SPC, it is recommended to use the SPC template provided by Fimea, where all headings are prestyled and formatted.

Level 1 headings

- 1., 2., 3., etc.
- Mandatory level 1 headings according to Fimea administrative regulation 4/2019 are preset in the SPC template.
- Create level 1 headings using either the Heading1 style or the Normal style.
- Follow the number with a full stop (period).

Level 2 headings

- 4.1., 4.2., 5.1., etc.
- Mandatory level 2 headings according to Fimea administrative regulation 4/2019 are preset in the SPC template.
- Create level 2 headings using either the Heading2 style or the Normal style.

Body text

- Use the Normal style for body text. If you copy and paste text from another document, make sure that all of the body text in the final document is in the Normal style.
- Do not use smart tags in the document text.

Page headers and footers

- Do not use page headers and footers in the document.

Images

- Save images in JPG format and place them in their correct locations in body text or in a table.
- Do not create images in Word.
- If you need to place text and an image side by side, the image and text should be placed in a table. Even then, the images must be placed where they belong, i.e. next to the relevant text.

Tables

- Use the Tables function in Word to create tables. Each separate item of information must be contained in a separate cell.
- Tables must be sized so that they fit on a portrait-oriented A4 page.

Mathematical formulas

- It is recommended that you use the Tables function in Word to create mathematical formulas or else save them as images.

Special characters

- Use the Symbol function in Word to add special characters: Insert > Symbol. Select Normal as the style.

Logos

- Do not include logos.

Text emphasis

- The font colour must be black.
- Do not use colours or other special effects for emphasis in the document.

Format and file name

- If you use the SPC template to create the SPC document, i.e. if the document format is Document Template, you must save the file using Save As and change the document format to Word Document.
- Name the file as follows:

[name of medicinal product] [strength] [pharmaceutical form] SPC (OTC) [date when updated]. Example: Valmistex 250, 500 mg tabletti, SPC 2015-12-04.



- Add the OTC acronym to designate an over-the-counter version if both a prescription SPC and an OTC SPC have been approved for the medicinal product. If the product is only over the counter, omit the OTC acronym.

Other important points

- Do not include a cover sheet in the document.
- Do not use bold/italic/underline or any other emphasis in the name of the medicinal product.
- Do not include technical notes (footnotes/endnotes), customised field codes or macros. To keep styles and formatting technically consistent, disable the AutoFormat functions in Word.

Dates and version history

- The marketing authorisation holder must date the SPC.
- The SPC date must be given in the format dd.mm.yyyy.
- The same date must be given at the end of the Finnish and Swedish versions of the text. If the SPC is common for both Finland and Sweden, the date in Finland might differ from date in Sweden. It is not necessary to include the date in Sweden to the word-document that is sent to Fimea. If applicant so wishes, both dates can to be given at the end of the SPC in Swedish in format "i Finland: dd.mm.yyyy, i Sverige: dd.mm.yyyy".
- The date must not be in the future.
- The marketing authorisation holder must update the SPC date whenever a new version is released (because of corrections or proposed new text in a variation application) to both, the file name and end of the text.
- In case of a variation application, submit both the clean and tracked versions of the text to Fimea in Word format.