



CONVENTION TO BE FOLLOWED FOR EMEA-QRD TEMPLATES

This convention must be followed exactly in order to ensure absolute consistency between templates, to avoid discrepancies between language versions and formatting problem when compiling and merging documents.

SOFTWARE:	We recommend the use of WORD 9.0 (Office 2000) or later versions
FONT:	Font: Times New Roman Size: 11 Font style: Regular Character spacing: normal
LANGUAGE:	Use the relevant language settings, i.e. European standard spelling and grammar when editing the text, e.g. English (UK); French (France); Portuguese (Portugal); Spanish (Spain-Modern sort); etc.
SCIENTIFIC SYMBOLS:	Insert from the symbol window (normal text), e.g. μ , α , $\frac{1}{2}$, \leq , \pm , etc.
MARGINS:	From top of page: 2.0 cm From bottom of page: 2.0 cm From left of page: 2.5 cm From right of page: 2.5 cm Gutter: 0 cm Header: 1.3 Footer: 1.3 cm
TEXT ALIGNMENT:	Left alignment, except for title pages where the text is centred.
LINE SPACING:	Single-line spacing. (0 pt before and after paragraph)
CHARACTER SPACING:	Normal. Between figures and units use non-breaking space (Ctrl + Shift + space): e.g. 10 mg; use also non-breaking hyphen to avoid separation (Ctrl + Shift + -).
INDENTS:	1.0 cm from the left-hand margin for the first indent.
BULLET POINTS:	Left alignment. Text indentation: 1.0 cm from the left-hand margin
PAGE LAYOUT:	Section breaks must be avoided where possible. Do not use line breaks.
TITLE PAGES:	Centred; horizontal position: line 24 (BOLD, CAPITAL LETTERS) Keep title page as per template, e.g. "A. LABELLING"
HEADINGS:	1. HEADINGS (BOLD, CAPITAL LETTERS) (2 lines before and 1 line after the heading)
SUBHEADINGS: (SPC only)	1.1 Subheadings(bold, normal letters) (1 line before and 1 line after the heading)
SUBHEADINGS: (Package leaflet only)	Subheadings (no numbering, bold, normal letters) (1 line before and 1 line after the heading)

ADDITIONAL
SUBHEADINGS:

Do not use bold or additional numbering in the SPC, instead use underline or Italics or both and be consistent throughout the text, e.g.:

Additional subheading:

Additional subheading

Additional subheading

Additional subheading

NUMBERING:
(of headings)

Must respect the current template
No additional numbering should be created .

BOXED HEADING:

1. HEADING

Boxed headings in Annexes III A (labelling) provide a structure to facilitate the work of applicants, assessors and reviewers etc.; they must remain in the annexes during the whole evaluation procedure. However, they must NOT appear in the final printed packaging materials (e.g. actual carton, container label) or on the mock-ups and specimens.

BRACKETING
CONVENTION:

{text} Information to be filled in, normal text;
<text> Text to be selected or deleted as appropriate;

[Green Italic text]

Guidance and explanatory notes in annotated English template version (PDF) only.

[Shaded text]

Shaded text can be used by applicant to highlight certain text parts which will not be printed in the actual SPC or label;
Its use should be limited.

- Example in SPC:

Applicants may present, during evaluation, a combined SPC for different strengths, clearly indicating with a grey-shaded text the strength or presentation to which alternative text elements refer.

- Example in SPC:

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {group}, ATC code: {code} [proposed:
under application]

- Example in labelling:

7. OTHER SPECIAL WARNING(S), IF NECESSARY

[None] *[alternatively leave blank]*

Cross-reference:

When cross-referring in the SPC do not mention the section heading but only the section number and be consistent throughout the text

- Example:(see section 5.1)