



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 April 2011
EMA/62470/2007 rev. 8
Patient Health Protection

QRD convention to be followed for the EMA-QRD templates

BRACKETING CONVENTION USED IN THE TEMPLATES:

{text}	Information to be filled in, i.e. normal text.
<text>	Text to be selected or deleted as appropriate.
[Green text]	Guidance and explanatory notes only. To be deleted when using the templates.

PAGE SET-UP: Orientation: Portrait

PAGE LAYOUT: Section breaks must be avoided. Line breaks or page breaks should only be used if necessary.

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

FONT:

- Font: Times New Roman
- Size: 11
- Font style: Regular
- Character spacing: Normal
- Font colour: Black (i.e. the text throughout the annexes should be presented in black font, including figures, tables, pictograms, etc.).

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.

TEXT ALIGNMENT: Left alignment, except for title pages where the text is centred.

LINE SPACING:

- Paragraph: single-line spacing (one line before and one line after must not be used).
- Between paragraphs: one additional single-line spacing.
- Between headings and text: see information on headings below.



CHARACTER SPACING:	To avoid separation in the text and between figures and units use: - Non-breaking space (Ctrl + Shift + space): e.g. 10 mg - Non-breaking hyphen (Ctrl + Shift + hyphen): e.g. 100–200
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.
TITLE PAGES:	Centred, line 24 (BOLD, CAPITAL LETTERS). Keep title page as per template, e.g. “ A. LABELLING ”
HEADINGS:	1. HEADINGS (BOLD, CAPITAL LETTERS) (2 single lines before and 1 single line after)
SUBHEADINGS: (SmPC only)	1.1 Subheadings (bold, normal letters) (1 single line before and 1 single line after)
SUBHEADINGS: (package leaflet only)	Subheadings (no numbering, bold, normal letters) (1 single line before and 1 single line after)
ADDITIONAL SUBHEADINGS:	In the SmPC, do not use bold or additional numbering, instead use underline or italics or both and be consistent throughout the document, e.g.: Additional subheading <u>Additional subheading</u> <i>Additional subheading</i> <u><i>Additional subheading</i></u>
HEADINGS NUMBERING:	Must respect the current template. No additional numbering should be created. Do not use automatic numbering insertion.
BOXED HEADINGS:	1. HEADING Boxed headings in Annex 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. Boxed headings should be created by using “outside borders” and not by inserting a table. <u>Boxed headings should always be kept, even when not applicable.</u>
SCIENTIFIC SYMBOLS:	Insert from the symbol window (normal text), e.g. μ , α , $\frac{1}{2}$, $\leq$, $\pm$, etc. Do not use AutoCorrect to automatically insert symbols that are included in the built-in list to ensure that the symbols are always readable.
TABLES:	Font: in case the table is too big to fit in the page, a slightly smaller font size may be accepted on a case by case basis, as long as readability is maintained. Borders: single line style, colour automatic, width 1/2 pt. Do not use background or shading.
CROSS-REFERENCE:	When cross-referring in the SmPC, do not mention the section heading but only the section number and be consistent throughout the text. • Examples: ... (see section 5.1) ... (see sections 5.1 and 5.3)

SHADED TEXT:

Shaded text can be used by applicants to highlight text which will not be printed in the actual SmPC, PL or label. Its use should be limited.

- Example in SmPC:

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {group}, ATC code: {code} Not yet assigned

- Example in labelling:

12. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/001 28 tablets
EU/0/00/000/002 56 tablets
EU/0/00/000/003 100 tablets

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted