21 February 2025

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Committees and Quality Assurance Department

Checklist for the submission of Type IA and Type IB (without linguistic review) product information annexes and Annex A (if applicable)

**Please be reminded that in accordance with Union data protection requirements, no personal data should be included in the annotated PIs. This applies to the English version and all the translations. Please submit annotated PIs in an anonymised format (i.e. names of the reviewers removed from the track-changes). If you do not wish to do so, please ensure that the individuals whose data is included consented to its sharing with EMA, the publication on the EMA website and its further sharing by EMA with third parties such as other marketing authorisation applicants, marketing authorisation holders and National Competent Authorities, as relevant.**

**EMA expressly disclaims any liability or accountability for the presence of unnecessary personal data in the annotated PI submitted by the marketing authorisation holder.**

| **For the submission of the full set of annexes, [i.e. Annex I (SmPC), Annex II, Annex IIIA (labelling), Annex IIIB (package leaflet) and Annex A (if applicable)] in all EEA languages, the applicant/MAH confirms that they have prepared the files in accordance with the following checklist:** | **Tick to confirm check** |
| --- | --- |
| The [QRD Convention](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/quality-review-documents-qrd-convention-be-followed-european-medicines-agency-qrd-templates_en.pdf) published on the Agency’s website was followed for the preparation of the Word source files |  |
| The [User guide on how to generate PDF versions of the product information and other annexes](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/user-guide-how-generate-pdf-versions-product-information-human_en.pdf) published on the Agency’s website was followed for the preparation of the PDF files |  |
| The PDF versions in all EEA languages are identical to the Word source files |  |
| Track changes and comments have been ‘accepted’ (not simply switched off) and coloured or highlighted text does not appear in the PDF versions (except for sections referring to Appendix V) |  |
| Changes from the latest approved procedure1 or parallel procedure(s) are included in the PI  1 Procedures **without** immediate Commission Decision (CD) are considered approved at the time of Opinion/Notification. Procedures **with** immediate CD are considered approved at the time of CD. |  |
| All EU numbers must be present in section 8 of the SmPC and in section 12 of Annex IIIA |  |
| The marketing authorisation Commission Decision dates of first authorisation (dates for different presentations to reflect the date of the first authorisation) and latest renewal Commission Decision date, if any, are correct and indicated in section 9 of the SmPC, as appropriate |  |
| Revision dates do not appear in section 10 (‘Date of revision of the text’) of the SmPC |  |
| Revision dates do not appear in section “This leaflet was last approved on” of the package leaflet |  |
| Pictures in the SmPC and package leaflet display correctly and do not overlap with the text. They appear in the correct order and references made to picture numbers in the text are correct. The entire text in pictures was translated into the respective EEA language |  |
| There are no blank pages or unexpected blank spaces (*note*: half empty pages are acceptable if they occur in connection with tables or pictures) |  |
| There is no text in the header of the pages |  |
| Only page numbers appear in the footer of the pages, starting with ‘1’ (bottom, centre) on the title page of Annex I. The font used is Arial, size 8 |  |
| If applicable, Annex IV from a previous procedure has been deleted |  |
|  |  |
| **Full set of annexes** is provided as an integrated document in Word (with tracked changes) in each EEA language in the 'Working document' folder, outside the eCTD structure.  The font used for the text is Times New Roman, size 11, and Arial, size 8, for the page number  **NEW**  The Word tracked changes files of the full set of annexes in all EEA languages should include the statement containing the procedure number(s) (Times New Roman 11, starting on page 1, row 1, left aligned and boxed) in the respective EU language, in accordance with the [Statement](https://www.ema.europa.eu/en/documents/template-form/tracked-product-information-annexes-statement-translation-cover-page_en.docx) translation.  The word “previous” in the statement means the previously authorised procedure and not the procedure for which you are preparing this checklist.  All language files **include document properties** under: File->Info->Properties->Title: **<Medicine name>: EPAR – Product information – tracked changes\***  \* Do not use any special characters, e.g. ‘&, $, [, ], {, }, %, (,)  The Word tracked changes files follow the naming convention **ema-combined-h–xxx-annotated-<language code>** and document properties are added. |  |
| **Full set of annexes** is provided in clean PDF format in each EEA language under Mod.1.3.1 |  |
| The PDF files follow the naming convention **ema-combined-h–xxx-<language code>**; bookmarks and document properties are added as per [guideline](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/user-guide-how-generate-pdf-versions-product-information-human_en.pdf) |  |
| **Annex A** table headings are in accordance with [the latest QRD template](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fdocuments%2Ftemplate-form%2Fqrd-annex-template_en.docx&wdOrigin=BROWSELINK) |  |
| **Annex A** is provided in Word (with tracked changes) in all EEA languages in the 'Working documents' folder, outside the eCTD structure |  |
| **Annex A** (if applicable) is provided as a separate document in clean PDF format in each EEA language (one document per language) under Mod.1.2.  The cover page ‘Annex A’ is removed, the font used is Verdana, size 9, for the text and Arial, size 8, for the page number |  |
| **Annex A**: The PDF files follow the naming convention and document properties are added as per [guideline](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/user-guide-how-generate-pdf-versions-product-information-human_en.pdf) |  |

# Confirmed by:

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_