



15 November 2018  
EMA/801564/2018  
Veterinary Medicines Division

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

For the submission of the full set of annexes, [i.e. Annex I (SPC), 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 <a href="#">ORD Convention</a> published on the Agency's website was followed for the preparation of the Word source files	<input type="checkbox"/>
The <a href="#">User guide on how to generate PDF versions of the product information</a> published on the Agency's website was followed for the preparation of the PDF files	<input type="checkbox"/>
The PDF versions in all EEA languages are identical to the Word source files	<input type="checkbox"/>
Tracked 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)	<input type="checkbox"/>
Changes from the latest approved procedure <sup>1</sup> or parallel procedure(s) are included in the PI <sup>1</sup> Procedures <b>without</b> immediate Commission Decision (CD) are considered approved at the time of Opinion/Notification. Procedures <b>with</b> immediate CD are considered approved at the time of CD.	<input type="checkbox"/>
All EU numbers must be present in section 8 of the SPC and in section 12 of Annex IIIA	<input type="checkbox"/>
The marketing authorisation dates of first authorisation (dates for different presentations to reflect the date of the first authorisation) and latest renewal, if any, are correct and indicated in section 9 of the SPC, as appropriate	<input type="checkbox"/>
Revision dates do not appear in section 10 ('Date of revision of the text') of the SPC	<input type="checkbox"/>
Revision dates do not appear in section "This leaflet was last approved on" of the package leaflet	<input type="checkbox"/>
Pictures in the SPC 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	<input type="checkbox"/>



For the submission of the full set of annexes, [i.e. Annex I (SPC), 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
There are no blank pages or unexpected blank spaces ( <b>note</b> : half empty pages are acceptable if they occur in connection with tables or pictures)	<input type="checkbox"/>
There is no text in the header of the pages	<input type="checkbox"/>
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	<input type="checkbox"/>
If applicable, Annex IV from a previous procedure has been deleted	<input type="checkbox"/>
<p><b>Full set of annexes</b> is provided as an integrated document in Word (with tracked changes) in each EEA language in the 'Add-info' folder, in the VNeS structure.</p> <p>The font used for the text is Times New Roman, size 11, and Arial, size 8, for the page number</p>	<input type="checkbox"/>
<b>Full set of annexes</b> is provided in clean PDF format in each EEA language in Part 1b	<input type="checkbox"/>
The PDF files follow the naming convention <b>ema-combined-v-xxx-&lt;language code&gt;</b> ; bookmarks and document properties are added as per <a href="#">guidance</a>	<input type="checkbox"/>
<b>Annex A</b> table headings are in accordance with <a href="#">the latest ORD template</a>	<input type="checkbox"/>
<b>Annex A</b> is provided in Word (with tracked changes) in EN only in the 'Add-info' folder, in the VNeS structure	<input type="checkbox"/>
<p><b>Annex A</b> (if applicable) is provided as a separate document in clean PDF format in each EEA language (one document per language) in Part 1a</p> <p>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</p>	<input type="checkbox"/>
The PDF files follow the naming convention <b>v-xxx-AA-&lt;language code&gt;</b> ; document properties are added as per <a href="#">guidance</a>	<input type="checkbox"/>

## Confirmed by:

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