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Human Medicines Evaluation Division

User guide on how to generate PDF versions of the product information and other annexes - human

Product information

Since the product information consists of the combination of summary of product characteristics (Annex I), conditions of the marketing authorisation (Annex II), labelling (Annex IIIA), package leaflet (Annex IIIB) and conclusions on <marketing authorisation under exceptional circumstances> <conditional marketing authorisation> <similarity> <and> < derogation> <and> < the request for one-year <marketing protection> <data exclusivity> presented by the European Medicines Agency (Annex IV) if applicable, the PDF version of the product information requires bookmarks to identify the location of these different Annexes within the single file. File properties are also needed to correctly reference the product information.

The properties and bookmarks can be set in two ways:

1. directly in the PDF document each time after conversion (**method 1**, pages 1-5)

2. in the Word source document prior to conversion to PDF (**method 2**, pages 5-10).

Method 2 has the advantage that properties and bookmarks need only be defined once in the Word file for each language version; they will be maintained for each subsequent revision of the product information and are automatically carried over in the converted PDF files. The two methods are explained below.

Method 1: setting properties and bookmarks in the generated PDF files

1. Conversion of the Word source file into PDF

Before converting to PDF, accept all highlights (track changes) and comments from the Word source file.

Use any appropriate method and software to convert the Word source file into a PDF file.

2. Setting bookmarks and properties in the converted PDF file

1. **Open** the generated PDF file in Adobe Acrobat

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[*] User guide updated to align some requirements to e-CTD validation criteria. File naming convention revised.

2. Scroll through the document to check the quality of the conversion. In particular check that the PDF conversion from Word has not created extra blank pages to the original document. If blank pages are present in the PDF document, amend the page break corresponding to the blank pages in the Word source file and convert to PDF again.

3. Click on the **Bookmarks** tab (left)

4. Click on the **Select** icon from the main toolbar to initiate the bookmarking

5. Select the following text on the TITLE PAGE of Annex I:

<div align="center">

SUMMARY OF PRODUCT CHARACTERISTICS

</div>

6. Click **Ctrl+B** to create the new bookmark

7. Proceed in the same way to create bookmarks for the following HEADINGS text in Annex II (directly in the page/s that follow the cover page):

A. <MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND> MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

C. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

<E. SPECIFIC OBLIGATION TO COMPLETE POST-MARKETING AUJTPRISATION MEASURES FOR <THE CONDITIONSL MARKETING AUTHORISATION> <THE MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES>>

for the following text on TITLE PAGES of Annexes IIIA and IIIB:

A. LABELLING (on the Annex IIIA title page)

B. PACKAGE LEAFLET (on the Annex IIIB title page)

and for Annex IV, if applicable:

<div align="center">

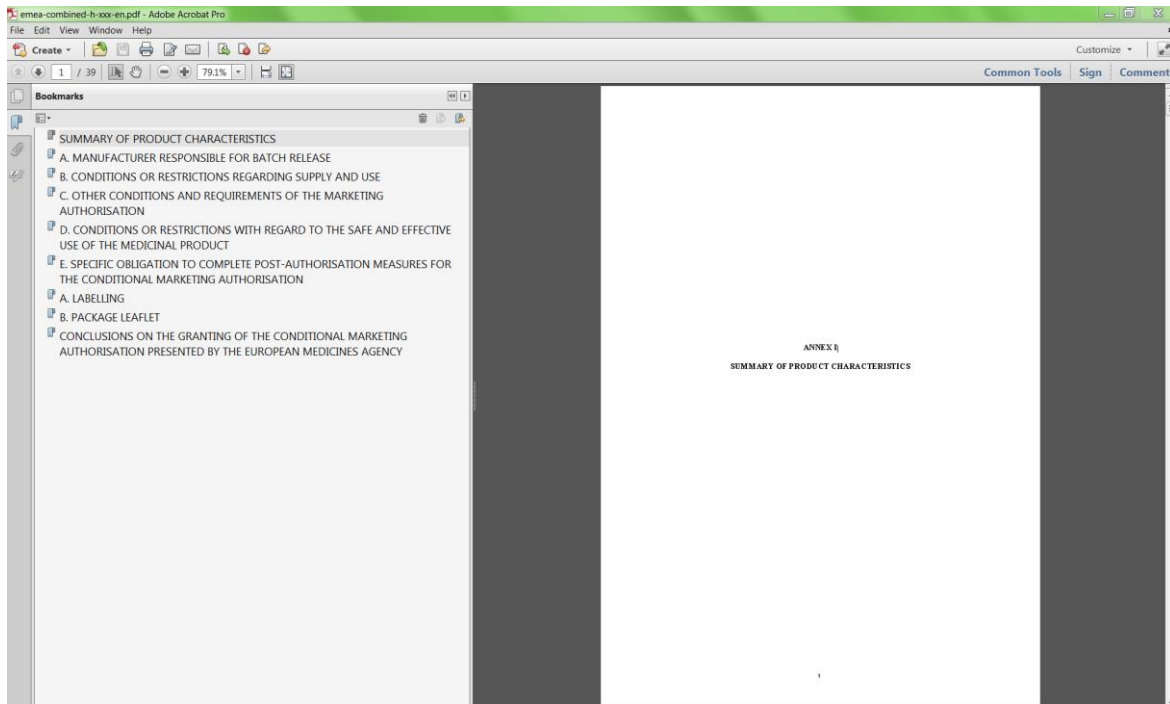**CONCLUSIONS ON <MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES> <CONDITIONAL MARKETING AUTHORISATION> <SIMILARITY> <AND> < DEROGATION> <AND> < THE REQUEST FOR ONE-YEAR <MARKETING PROTECTION> <DATA EXCLUSIVITY> PRESENTED BY THE EUROPEAN MEDICINES AGENCY**

</div>

8. On the **View** menu, click **Navigation Panels and Bookmarks**. This displays the bookmarks on the left hand side of the document. Verify that the bookmarks appear according to the figure below.

9. On the **File** menu, click **Document Properties** (or click Ctrl+D). This opens the Properties.

10. Click on the **Description** tab and enter the following information, for example for a product with the invented name 'Imaginary' and with INN 'examplamin sodium':

- Title: Imaginary, INN-examplamin sodium
- Author: CHMP
- Subject: EPAR
- Keywords: Imaginary, INN-examplamin sodium
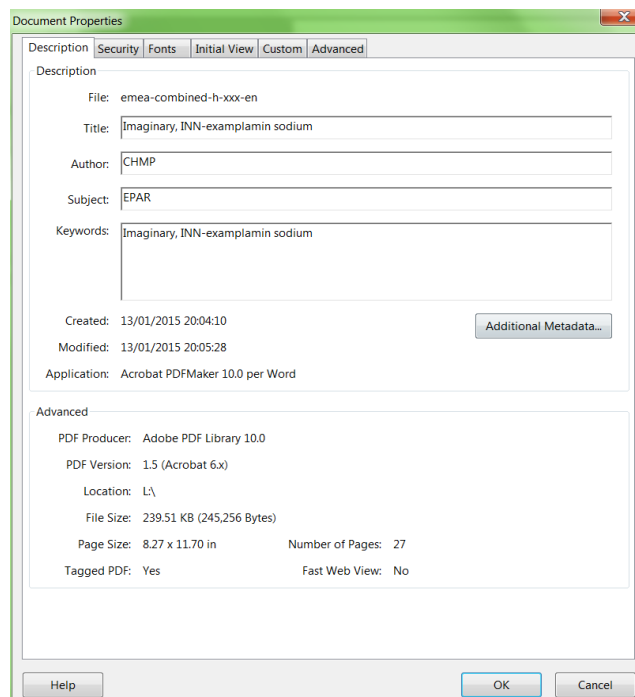
- Click on the **Initial View** tab and under **Navigation tab** select the option '**Bookmarks Panel and Page**' (this will ensure that readers see the bookmarks on opening the document). Set **Page layout** to **Default**.
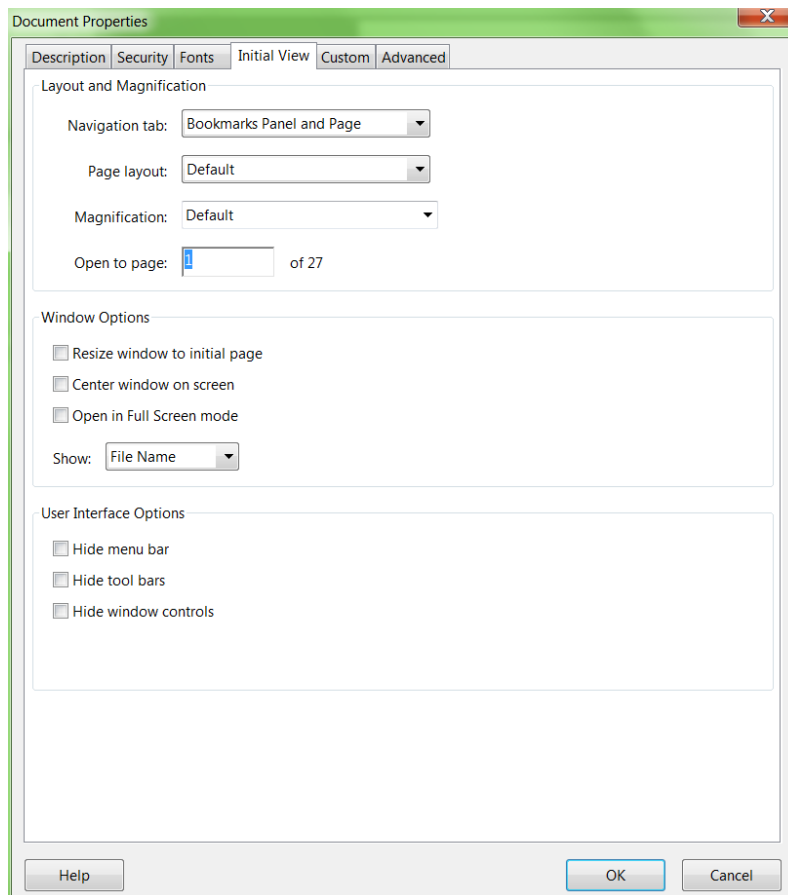
11. Click **OK** to close the Properties.

12. On the bookmark panel under options, click **properties,** then click **edit** and under **Zoom** select the option '**Inherit Zoom'**
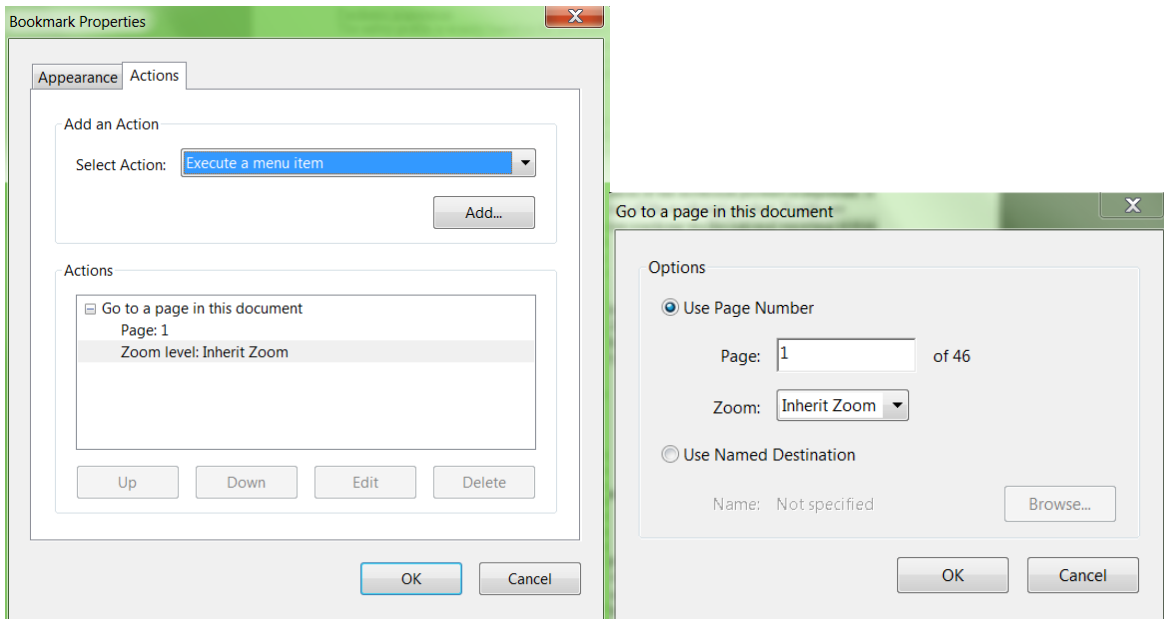
13. **Save** the generated PDF file using the file naming conventions described at the end of this guide.

Method 2: setting properties and bookmarks in the Word files and conversion to PDF

1. Preparation of the Word source files

The following steps should be performed to appropriately set up the Word source files to ensure that properties and bookmarks are automatically carried over to PDF files that are generated from the Word source files.

1. **Open** the Word source file of the product information composed of Annex I (SmPC), Annex II, Annex IIIA (labelling), Annex IIIB (package leaflet) and Annex IV (if applicable)

2. On the **File** menu, click **Properties**. This opens the file properties.

3. Click on the **Summary** tab and enter the following information, for example for a product with the invented name 'Imaginary' and with INN 'examplamin sodium':

- Title: Imaginary, INN-examplamin sodium
- Subject: EPAR
- Author: CHMP
- Keywords: Imaginary, INN-examplamin sodium
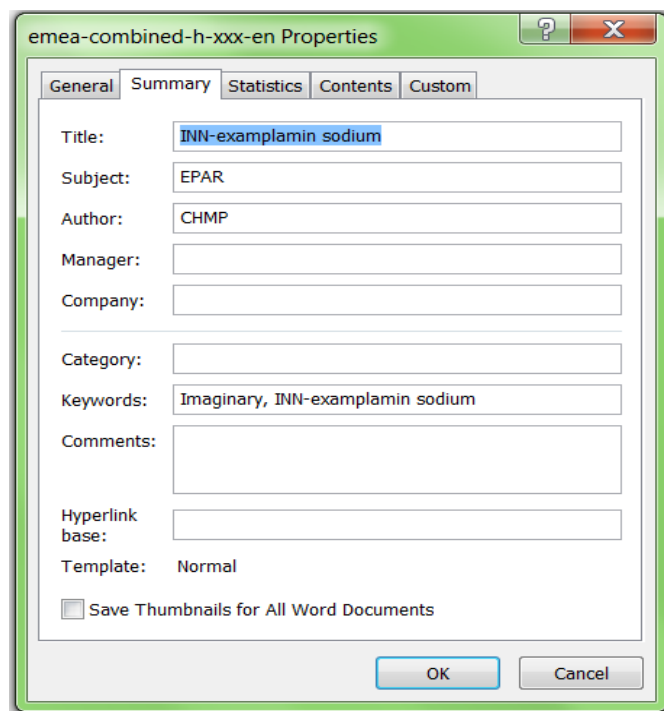
4. Click **OK** and save the file to commit the changes.

5. To automatically set bookmarks based on styles in Word, the styles for the text to be bookmarked need to be renamed. Rename the style of the TITLE PAGES text shown below:

SUMMARY OF PRODUCT CHARACTERISTICS (on the Annex I title page)

A. LABELLING (on the Annex IIIA title page)

B. PACKAGE LEAFLET (on the Annex IIIB title page)

(CONCLUSIONS ON <MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES> <CONDITIONAL MARKETING AUTHORISATION> <SIMILARITY> <AND> < DEROGATION> <AND> < THE REQUEST FOR ONE- YEAR <MARKETING PROTECTION> <DATA EXCLUSIVITY> PRESENTED BY THE EUROPEAN MEDICINES AGENCY) (on the Annex IV title page, if applicable)

This can be done as follows:

- highlight the text of all three title pages at once as shown above

- click on menu **Styles / New style**

- enter an appropriate name (e.g. 'Title A') in the Name field

- click **OK**

- leave the text selected/highlighted and under "Pick formatting to apply" pick the 'Title A' formatting style.

6. Untick the highlighted text and without closing the "Style" screen, proceed in the same way as above in order to define an appropriate name (e.g. 'Title B') for the style of the Annex II HEADINGS (directly in the page/s that follows the cover page) as shown below:

A. <MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND> MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

C. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

<E. SPECIFIC OBLIGATION TO COMPLETE POST-MARKETING AUJTPRISATION MEASURES FOR <THE CONDITIONSL MARKETING AUTHORISATION> <THE MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES>>

7. **Save** the file to commit the changes.

2. Conversion of the Word source file into PDF

The following steps should be performed to correctly convert an appropriately set Word source file into the final PDF file. Adobe Acrobat Writer must be properly installed on the same computer so that the Adobe PDF appears in Word. Before converting to PDF, accept all highlights (track changes) and comments from the Word source file.

1. On the **Adobe PDF** menu in Word, click **Preferences**.

2. On the **Settings** tab, make sure that <u>only</u> the following boxes are ticked:

   - Convert Document Information

   - Create bookmarks

   - Add links

3. Go to Advanced Settings and under "Compatibility" select Acrobat 5.0 from the dropping list and click OK.

4. On the Bookmarks tab, make sure that only the boxes corresponding to the two styles defined in the previous steps for TITLE PAGES text and Annex II HEADINGS (e.g. styles named 'Title A' and 'Title B') are ticked.
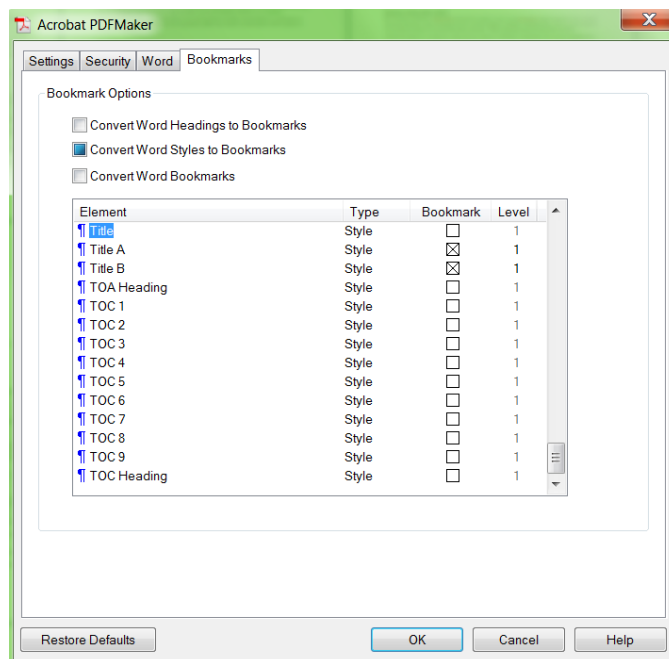
5. Click OK to accept changes and to close the Conversion Settings. Save the changes.

6. On the Adobe PDF menu, click Convert to Adobe PDF.

   Note: A warning may pop up, in which case it is recommended to select take off tagging for a faster conversion to PDF.

7. Save the generated PDF file using the file naming conventions described at the end of this guide.

8. Open the generated PDF.

9. On the File menu, click Document Properties (or click Ctrl+D). This opens the Properties.

10. Click on the Initial View tab and under **Navigation tab** select '**Bookmarks Panel and Page'** (this will ensure that readers see the bookmarks on opening the document). Set **Page layout** to **Default.**

11. Save the file and close.
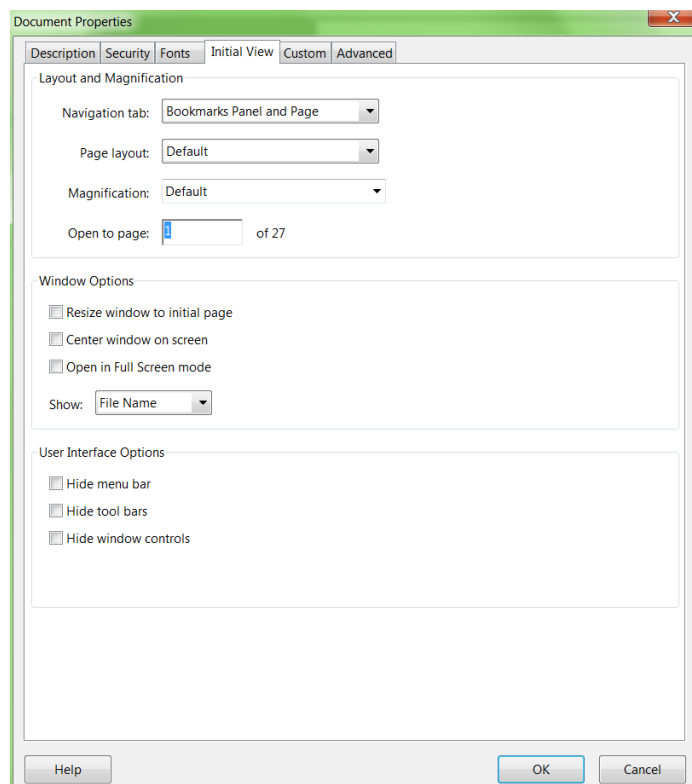
3. Verification of the generated PDF file

Perform the following check to ensure that the PDF file has been properly generated:

1. Open the generated file with Adobe Acrobat Reader.

2. Verify that upon opening the bookmarks appear according to the figure below (in the event of extra bookmarks being created, delete those not relevant).
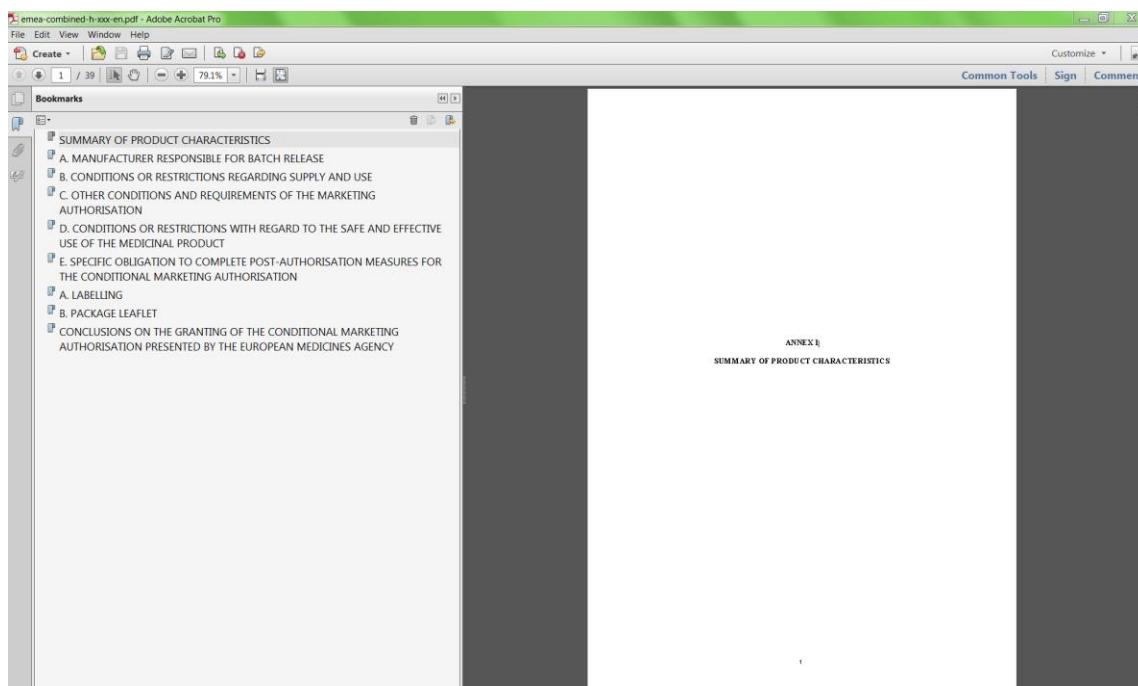
3. On the **File** menu, click **Document Properties (or Ctrl+D)**. This opens the Properties.
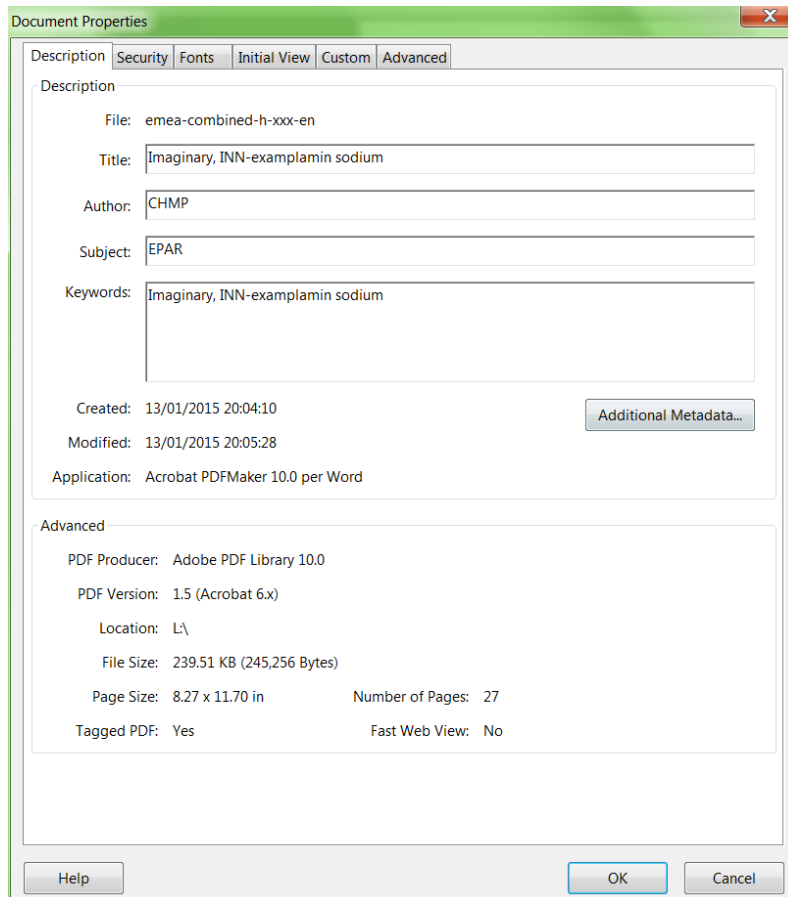
4. Click on the **Description** tab. Verify that the information for Title, Author, Subject and Keywords are correct.

5. **Close** the Properties.

6. Click on the "Pages" tab and scroll through the document to check the quality of the conversion. In particular check that the PDF conversion from Word has not created extra blank pages to the original document. If blank pages are present in the PDF document, amend the page break corresponding to the blank pages in the Word source file and convert to PDF again.

Annex A and Annex 127a

Before converting to PDF, accept all highlights (track changes) and remove the comments from the Word source files. For Annex A remove cover page 'Annex A'. For Annex 127a remove from the title page '127a' where applicable.

Set document properties as described above in point 2.9 using method 1 or point 1.2 using method 2. Document properties for the product information and Annex A should be identical.

File naming convention to be used for the generated PDF files

The EMA product number is the unique product identifier appearing in the EMA procedure number as for instance: EMEA/H/C/000205/II/0025. All 6 digits in bold/underlined or perhaps better in a different colour. The next action is to ignore all leading zero. Alternatively, you may set only the relevant digits in bold (but not the zero).

For the PDF filename, remove any zero that might appear in front of the EMA product number, and organise the filename in accordance with following file naming convention.

Document codes to be used are defined as:

combined	Combined' means presented as one document: SmPC + Annex 2 + labelling + package leaflet (+ Annex IV, if applicable)
other	Any annex in combination with a tag of 'aa' (Annex A) or 'conditions' (Art. 127a) in the variable part

For PI: **ema**-**combined**-**h-**[EMA product number]-[2 letter language code]

For Annex A: **ema-other-h-**[EMA product number]-**aa**-[2 letter language code]

For Annex 127a: **ema-other**-**h-**[EMA product number]-**a127a**-[2 letter language code]

Use only lower case characters and hyphens as separators, as shown in the following examples of correct filenames:

ema-combined-h-205-bg for Bulgarian,
ema-combined-h-205-cs for Czech,
ema-combined-h-205-da for Danish, etc.

Language codes to be used

bg	Bulgarian	**es**	Spanish	**it**	Italian	**pl**	Polish
cs	Czech	**et**	Estonian	**lt**	Lithuanian	**pt**	Portuguese
da	Danish	**fi**	Finnish	**lv**	Latvian	**ro**	Romanian
de	German	**fr**	French	**mt**	Maltese	**sk**	Slovak
el	Greek	**hu**	Hungarian	**nl**	Dutch	**sl**	Slovenian
en	English	**hr**	Croatian	**no**	Norwegian	**sv**	Swedish
is	Icelandic						

Highlighted (i.e. with track changes) product information documents prepared following linguistic comments at the end of the procedure need to be provided separately as Word files.

In cases where the translations as PDF files are submitted to the Agency outside of an eCTD submission, all the PDF translations have to be zipped in one container. The title of the zip container must include the name of the product and procedure number.