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Human Medicines Evaluation Division

User guide on how to generate PDF versions of the product information - veterinary

Introduction

Since the product information consists of the combination of summary of product characteristics (Annex I), labelling (Annex IIIA), package leaflet (Annex IIIB) and conditions of the marketing authorisation (Annex II), 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 1-4)
2. in the Word source document prior to conversion to PDF (**method 2**, pages 4-8).

Method 1 has the advantage that the bookmark will direct you to the top of the page instead of to the specific line in the text. It is also possible to select more than one full product name in one bookmark.

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 Writer.
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:

SUMMARY OF PRODUCT CHARACTERISTICS

6. Click **Ctrl+B** to create the new bookmark or alternatively mark the heading and select the icon "new bookmark" on the left-hand side column.
7. In case of product information with **more than one SPC** (i.e several products compiled in one set of annexes): steps 5 and 6 also need to be repeated for the text under section 1 in each SPC:

e.g.

Imaginary 10 mg/ml solution for injection for cattle and pigs

Imaginary 2 mg/ml oral suspension for dogs

In case more than one full product name is listed under section 1 all of them should be bookmarked:

e.g.

Imaginary 1 mg chewable tablets for dogs

Imaginary 3 mg chewable tablets for dogs

8. Repeat steps 5 and 6 to create bookmarks for the TITLE PAGE of Annex II:

ANNEX II

9. Repeat steps 5 and 6 to create bookmarks for the TITLE PAGE of Annex IIIA:

A. LABELLING (on the Annex IIIA title page)

In case of product information with **more than one SPC** (i.e several products compiled in one set of annexes): steps 5 and 6 need to be repeated for the text under labelling section 1 for each product and just for the outer carton label:

e.g.:

PARTICULARS TO APPEAR ON THE OUTER CARTON

Only bookmark the full product name under labelling section 1:

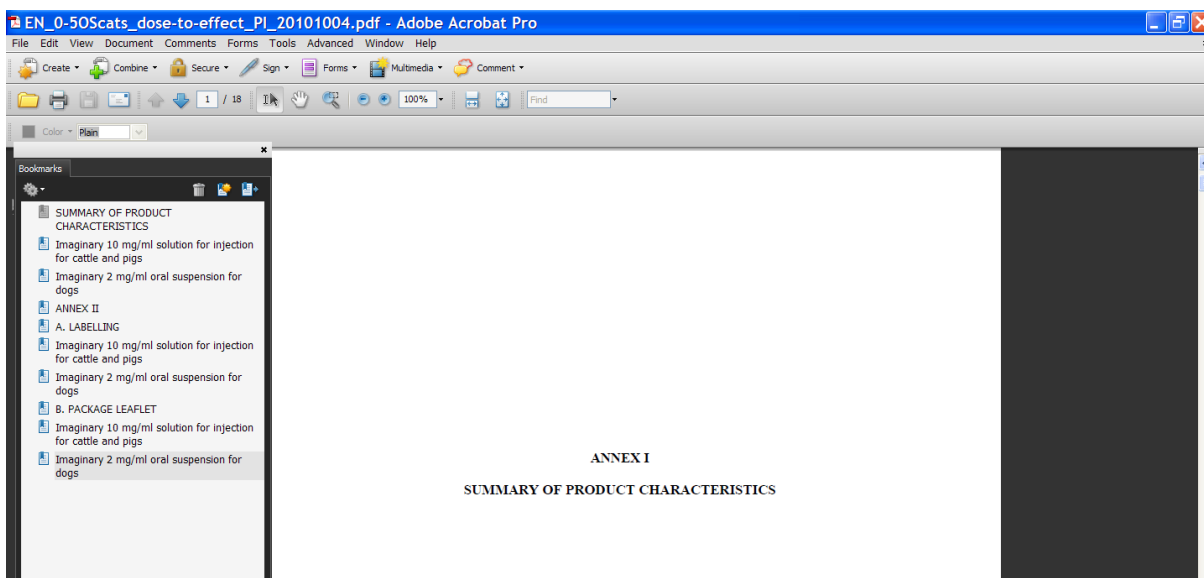
Imaginary 10 mg/ml solution for injection for cattle and pigs

10. Repeat steps 5 and 6 to create bookmarks for the TITLE PAGE of Annex IIIB:

B. PACKAGE LEAFLET (on the Annex IIIB title page)¹

¹ In case of product information with more than one package leaflet: steps 5 and 6 need to be repeated for the text under section 2 for each package leaflet.

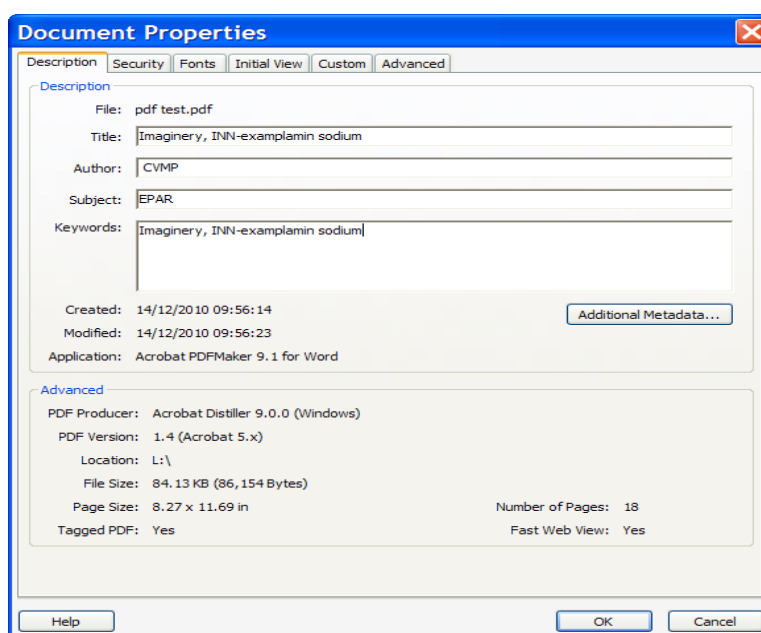
11. On the **View** menu, click **Navigation Panels and Bookmarks**. This displays the bookmarks on the left hand side of the document. Verify that the bookmarks appear according to the picture below.



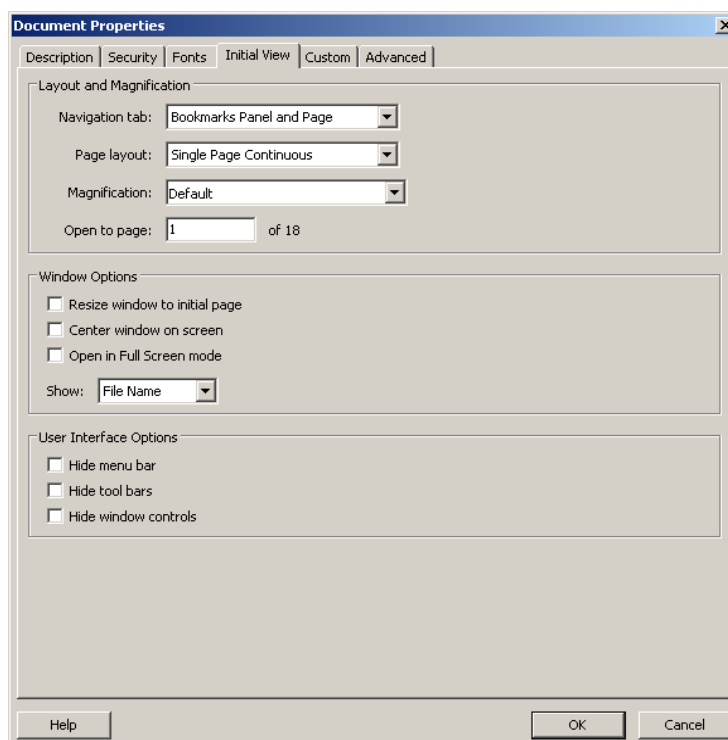
12. On the **File** menu, click **Document Properties** (or click Ctrl+D). This opens the Properties.

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

- Title: Imaginary, INN-exemplamin sodium
- Subject: EPAR
- Author: CVMP
- Keywords: Imaginary, INN-exemplamin sodium



- 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).



14. Click **OK** to close the Properties.

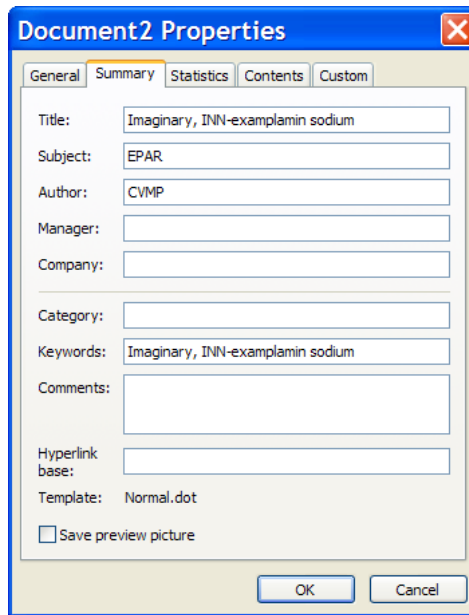
15. **Save** the generated PDF file using the file naming conventions described at the end of this guide.

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 (SPC), Annex II, Annex IIIA (Labelling) and Annex IIIB (Package Leaflet).
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: CVMP
 - 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.

1. Rename the style of the TITLE PAGES text shown below:

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

ANNEX II (on the Annex II title page)

A. LABELLING (on the Annex IIIA title page)

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

This can be done as follows:

- highlight the title page text
- click on menu **Format / Styles and formatting / New style**
- enter an appropriate name for that style (e. g. 'Title A') in the Name field
- click **OK**
- highlight the next title page text
- on menu **Format / Styles and formatting** click the just created 'Title A' to apply the style
- etc.

In case of product information with **more than one SPC** (i.e several products compiled in one set of annexes) the style for the full name of product text under SPC section 1, labelling section 1 and package leaflet section 2 also needs to be defined. This needs to be done for the text of each product in the set of annexes.

This can be done as follows:

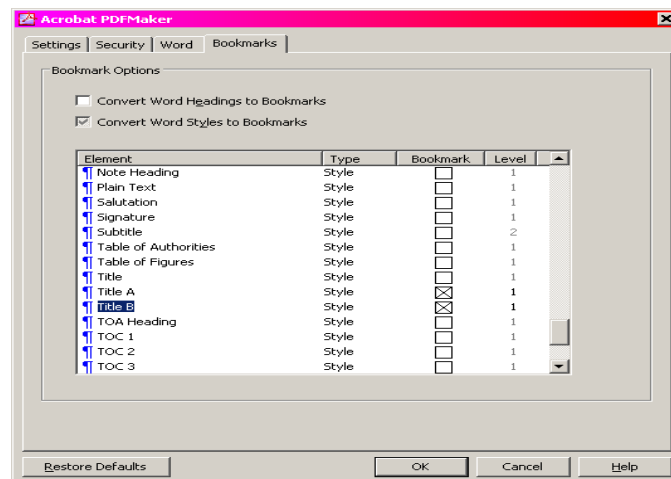
- highlight the appropriate full product name text
- click on menu **Format / Styles and formatting / New style**
- enter an appropriate name for that style (e. g. 'Title B') in the Name field
- click **OK**
- highlight the next text
- on menu **Format / Styles and formatting** click the just created 'Title B' to apply the style.
- etc.

2. **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.

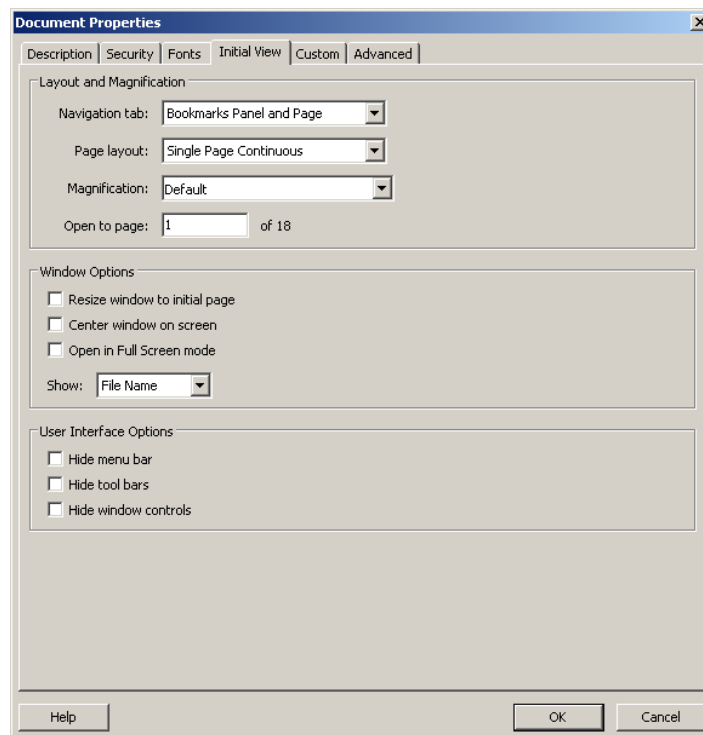
1. On the **Adobe PDF** menu in Word, click **Change Conversion Settings**.
2. On the **Settings tab**, make sure that only the following boxes are ticked:
 - Convert Document Information
 - Add bookmarks to Adobe PDF
 - Add links to Adobe PDF.
3. Go to **Advanced Settings** and under "Compatibility" 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 (e.g. Title A and Title B) for TITLE PAGES text and for the full product name 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.

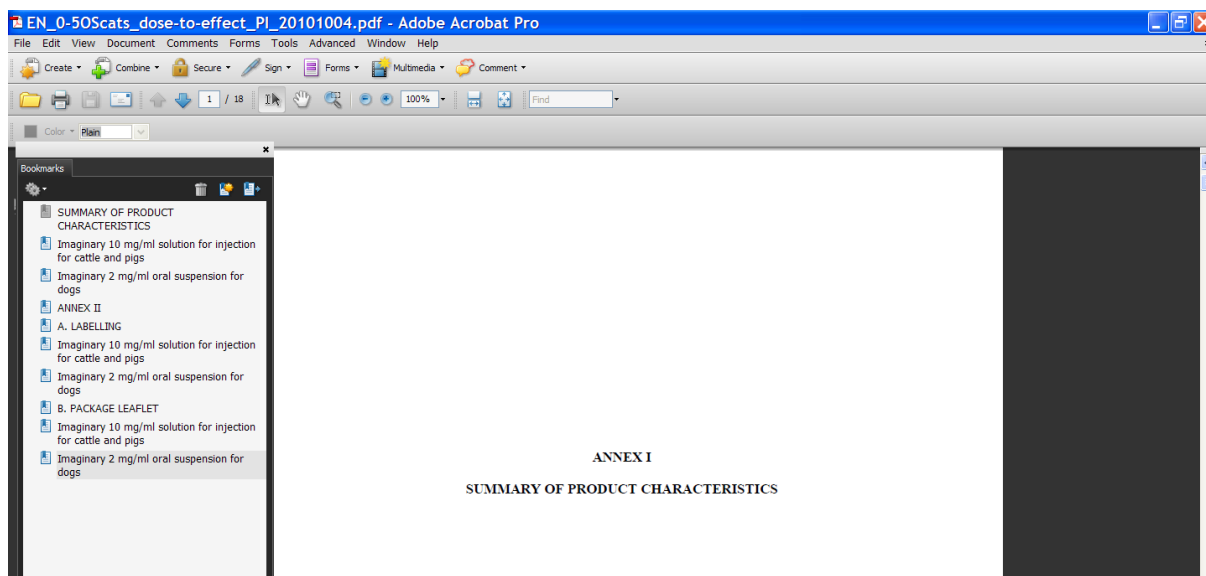
7. Save the generated PDF file using the file naming conventions described at the end of this guide.
8. Open the generated PDF.
9. On the File menu, click Document Properties (or click Ctrl+D). This opens the Properties.
10. Click on the Initial View tab and under Navigation tab select 'Bookmarks Panel and Page' (this will ensure that readers see the bookmarks on opening the document).
11. Save the file and close.



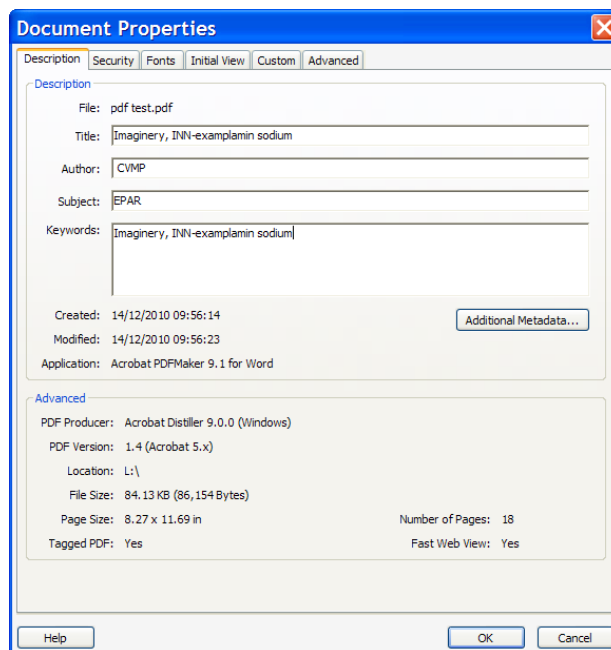
3. Verification of the generated PDF file

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 picture 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

Before converting to PDF, accept all highlights (track changes) from the Word source files and remove the title 'Annex A'.

Set document properties as described above. 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/V/C/**0205**/II/25.

For the PDF filename, remove any zero that might appear in front of the EMA product number, and organise the filename as:

ema-combined-v-[EMA product number]-[procedure number]-[2 letter language code]

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

ema-combined-v-205-II-25-bg for Bulgarian,

ema-combined-v-205-II-25-cs for Czech, etc.

Language codes to be used

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

All the PDF translations have to be zipped in one file. The title of the zip file must include name of the product and procedure number.