

AUTO- EVALUATION CHECKLIST for CLOSING DOCUMENTS

At the closing department, we receive many documents that do not correspond to what is described in the guidelines, or are not in accordance with QRD, EDQM,...

By making corrections we lose a lot of time that could have been avoided, hence the creation of this document.

The aim of this document is to provide an overview to the industry on how to prepare the documents for administrative closing. This checklist refers to the sections that will be checked by the closing department and for which comments can be received. Therefore it is a form of "auto evaluation" by the industry before submitting the closing documents for administrative closing.

The checklist is drawn up per document. Only the documents concerned should be checked.

Please keep in mind: even when a variation is applicable to only one document, accordance between all documents should be maintained!

<u>Document</u>	<u>Section</u>	<u>Verification</u>
SPC		<p data-bbox="1171 966 1690 1031">For MRP/DCP check accordance with Final common SPC !</p> <p data-bbox="1276 1063 1585 1096">Check QRD template !</p> <p data-bbox="997 1101 1869 1198">http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580022c59</p>

SPC	1. NAME OF THE MEDICINAL PRODUCT <{(Invented) name strength pharmaceutical form}>	<p>Check accordance with other documents: MA, Pil, Labelling text, Mockup</p> <p>Check EC guideline “expression of strength” http://www.ema.europa.eu/htms/human/qrd/docs/70722909en.pdf</p> <p>Check EDQM standard term http://www.edqm.eu/StandardTerms/</p>
	2. QUALITATIVE AND QUANTITATIVE COMPOSITION <Excipient(s):>	<p>Check accordance with other documents: MA, Pil, Labelling text, Mockup</p> <p>Check with EC guideline “Excipients in the label and package leaflet of medicinal products for human use” http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000083.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580034cf8&jenabled=true</p>
	3. PHARMACEUTICAL FORM	<p>Check accordance with other documents: MA, Pil, Labelling text, Mockup</p> <p>Check EDQM standard term http://www.edqm.eu/StandardTerms/</p>
	4. CLINICAL PARTICULARS	<p>4.2 Posology and method of administration: Route of administration check EDQM standard term http://www.edqm.eu/StandardTerms/</p> <p>4.6 Pregnancy and lactation check with appendix I QRD template http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580022c59</p>

		<p>4.8 Undesirable effects check with appendix II QRD template http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580022c59</p>
5.	PHARMACOLOGICAL PROPERTIES	
6.1	List of excipients	Check accordance with MA document, PIL, Labelling text and Mock up
6.2	Incompatibilities	
6.3	Shelf life	Check accordance with MA (4pg) document
6.4	Special precautions for storage	<p>Check accordance with MA (4pg) document, PIL, Labeling and Mockup</p> <p>Check accordance with QRD template appendix III http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580022c59</p>
6.5	Nature and contents of container	<p>Check accordance with MA document and PIL</p> <p>Check with EDQM standard term http://www.edqm.eu/StandardTerms/</p>
6.6	Special precautions for disposal <and other handling>	

	7. MARKETING AUTHORISATION HOLDER	Check if MAH is in accordance with other documents: MA, Pil, Labelling text, Mockup
	8. MARKETING AUTHORISATION NUMBER(S)	Check if in accordance with other documents: MA, Pil, Labelling text, Mockup
	9. DATE OF FIRST AUTHORISATION /RENEWAL OF THE AUTHORISATION	
	10. DATE OF REVISION OF THE TEXT	
	<11. DOSIMETRY>	
	<12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS>	

Pil		<p style="text-align: center;"><u>Verification</u></p> <p style="text-align: center;">For MRP/DCP check accordance with harmonized Pil !</p> <p style="text-align: center;">Check QRD template !</p> <p style="text-align: center;">http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580022c59</p> <p style="text-align: center;">Check accordance with SPC !</p>
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	<p>PACKAGE LEAFLET PACKAGE LEAFLET: INFORMATION FOR THE USER (Invented) name strength pharmaceutical form} Active substance(s)</p>	<p>Check accordance with other documents: MA, SPC, Labelling text, Mockup</p> <p>Check EC guideline “expression of strength” http://www.ema.europa.eu/htms/human/qrd/docs/70722909en.pdf</p> <p>Check EDQM standard term http://www.edqm.eu/StandardTerms/</p>
	<p>1. WHAT X IS AND WHAT IT IS USED FOR</p>	
	<p>2. BEFORE YOU <TAKE> <USE> X</p>	
	<p>Important information about some of the ingredients of X</p>	<p>Check accordance with other documents: SPC, Labelling text, Mockup</p> <p>Check with EC guideline “Excipients in the label and package leaflet of medicinal products for human use” http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000083.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580034cf8&jsenabled=true</p>
	<p>3. HOW TO <TAKE> <USE> X</p>	
	<p>If you <take> <use> more X than you should</p>	<p>Check Blue box item: anti-poison center</p>
	<p>4. POSSIBLE SIDE EFFECTS</p>	

	<p>5. HOW TO STORE X</p>	<p>Check accordance with SPC, labeling, mock up and MA (4pg) document</p> <p>Check accordance with QRD template appendix III http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580022c59</p>
	<p>6. FURTHER INFORMATION What X contains - The active substance(s) is (are)... - The other ingredient(s) is (are)...</p>	<p>Check accordance with SPC, MA document, mock up and labellingtext</p>
	<p>What X looks like and contents of the pack</p>	<p>Check accordance with MA document and SPC</p> <p>Check with EDQM standard term http://www.edqm.eu/StandardTerms/</p>
	<p>Marketing Authorisation Holder and Manufacturer</p>	<p>Check accordance MAH with other documents: MA, SPC, Labelling text, Mockup</p> <p>Check if Manufacturer is in accordance with batchrelaeser on MA document</p>
	<p>This medicinal product is authorised in the Member States of the EEA under the following names:></p>	<p>Check ISO landcode abbreviations</p>
	<p>Blue box : delivery mode and BE number</p>	<p>Delivery mode : check accordance with MA, labeling and mockup BEnumber: check accordance with other documents: MA, SPC, Labelling text, Mockup</p>

		http://www.fagg-afmps.be/nl/binaries/FAQ%20administratief%20afsluiten%20finale%20versie-2010-08_tcm290-106575.pdf
	Additional information	
	This leaflet was last approved in {MM/YYYY}.	

Labelling text		<p style="text-align: center;"><u>Verification</u></p> <p style="text-align: center;">For MRP/DCP check accordance with harmonised labelling!</p> <p style="text-align: center;">Check QRD template !</p> <p style="text-align: center;">http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580022c59</p> <p style="text-align: center;">Check with document “etiquetage/etikettering” on FAGG website !</p> <p>NL : http://www.fagg-afmps.be/nl/binaries/verpakking-%20finaal-2010-08_tcm290-106539.pdf</p> <p>FR: http://www.fagg-afmps.be/fr/binaries/verpakking-finaal%20fr-2010-08_tcm291106539.pdf</p> <p style="text-align: center;">Check accordance with SPC !</p>
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	<p>1. NAME OF THE MEDICINAL PRODUCT (Invented) name strength pharmaceutical form {Active substance(s)}</p>	<p>Check if name is in accordance with other documents: MA, SPC, Pil, Mockup</p> <p>Check EC guideline “expression of strength” http://www.ema.europa.eu/htms/human/qrd/docs/70722909en.pdf</p> <p>Check EDQM standard term http://www.edqm.eu/StandardTerms/</p>
	<p>2. STATEMENT OF ACTIVE SUBSTANCE(S)</p>	<p>Check accordance with SPC/PIL and MA document</p>
	<p>3. LIST OF EXCIPIENTS</p>	<p>Check accordance with SPC/PIL and MA document and mockup</p> <p>Check with EC guideline “Excipients in the label and package leaflet of medicinal products for human use” http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000083.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580034cf8&jsenabled=true</p>
	<p>4. PHARMACEUTICAL FORM AND CONTENTS</p>	<p>Check accordance with SPC/PIL, mockup and MA document</p> <p>Check EDQM standard term http://www.edqm.eu/StandardTerms/</p>
	<p>5. METHOD AND ROUTE(S) OF ADMINISTRATION</p>	<p>Check accordance with SPC/PIL, MA (4pg) document and mockup</p> <p>Check EDQM standard term http://www.edqm.eu/StandardTerms/</p>

	6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN	Check QRD template
	7. OTHER SPECIAL WARNING(S), IF NECESSARY	Check accordance with SPC document, Pil and mockup
	8. EXPIRY DATE	
	9. SPECIAL STORAGE CONDITIONS	Check accordance with SPC, PIL and MA (4pg) document and mockup Check accordance with QRD template appendix III http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580022c59
	10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE	Check accordance with SPC document
	11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER	Check accordance with other documents: MA, SPC, Pil, Mockup
	12. MARKETING AUTHORISATION NUMBER(S)	Check accordance with other documents: MA, SPC, Pil Mockup

	13. BATCH NUMBER	
	14. GENERAL CLASSIFICATION FOR SUPPLY	<p>Check accordance with PIL, MA document and mockup</p> <p>http://www.fagg-afmps.be/nl/binaries/FAQ%20administratief%20afsluiten%20finale%20versie-2010-08_tcm290-106575.pdf</p>
	15. INSTRUCTIONS ON USE	Check accordance with SPC/PIL document and mockup
	16. INFORMATION IN BRAILLE	Name and dosage is mandatory (pharmaceutical form is optional)
	OTHER	<p>Check if needed :</p> <ul style="list-style-type: none"> • Blue box for narcotics (code/red lines) • Blue box external use (orange rectangle/triangle), • Radiopharmaceuticals • ...

Mockup		<p style="text-align: center;"><u>Verification</u></p> <p style="text-align: center;">Accordance with labelling text (= exact reproduction)!</p> <p style="text-align: center;">Check with document “etiquetage/etikettering” on FAGG website (for more information about lay-out, readability, logo’s and pictograms)</p> <p>NL : http://www.fagg-afmps.be/nl/binaries/verpakking-%20finaal-2010-08_tcm290-106539.pdf</p> <p>FR: http://www.fagg-afmps.be/fr/binaries/verpakking-finaal%20fr-2010-08_tcm291-106539.pdf</p>
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