

Issue for Discussion in the NtA Interlinking Meeting – EU Module 1 v1.2.1

Business Issues

Version	No.	Issue / Suggested Change	Notes	Conclusion
1.2.1	1	In the case of the DCP, the information submitted applies to all countries (as for the CP) but is effectively sent to one Member State (as for a NP). Therefore, which folders should be used to store the information? The folder "emea" would of course not be suitable, but should we use the folder of the particular Member State (e.g. "se" if sent to Sweden)? Or should the folder "common" be used? The use of folder 'common' is recommended for use in DCP in EU M1 v1.2.1.	Change Request submitted – common folder used in an example for v1.2.1, but mention is made of the use of this 'common' only as a footnote in the section on national applications – this is misleading.	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Write a new section to the specifications dedicated to the decentralised procedure, including a screenshot example using the common folder. ➤ Include the footnote on the use of the folder in this dedicated section instead of the section on national use of the eCTD. ➤ Discuss with the NtA how responses to questions should be handled within the DCP submissions. ➤ Change to v1.2.1

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1.2.1	2	Industry have asked the country codes for Bulgaria and Romania in both the EU M1 and the eAF, in preparation for next year' accession. The country codes were mentioned in EU m1 v1.1 in the specification only (not the DTD) and v1.2.1 in the EU M1 specification AND DTD, although a foot note is included here to indicate that the codes cannot be used until accession. A decision should be taken whether the codes should remain in v1.2.1.	Change Request submitted – codes now in the spec and DTD in v1.2.1. The EC is not in favour of introducing these new codes in advance of the countries entering the EU.	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Leave the BG and RO codes and reference in the DTD and specifications respectively, but ensure the new languages are not yet 'activated' in the eCTD (i.e. are not displayed in the style-sheet) ➤ Write an official communication to the EC explaining why this early inclusion of the languages is necessary (in order to allow applicants to prepare submissions). ➤ Change to v1.2.1
1.2.1	3	The resolution of discrepancies in CTD and eCTD guidance (v1.2.1) should be verified.	Change Request submitted and implemented	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Changes verified and agreed ➤ Change to v1.2.1
1.2.1	4	The removal of the restriction on submitting Word <u>and</u> PIM in 1.3.1 should be confirmed.	Change Request submitted and implemented	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Changes verified and agreed ➤ Change to v1.2.1
1.2.1	5	Verify correction of typos in file name examples in 1.8	Change Request submitted and implemented	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Changes verified and agreed ➤ Change to v1.2.1
1.2.1	6	Confirm correct reference to NtA is included in EU M1 v1.2.1	Change Request submitted and implemented	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Changes verified and agreed ➤ Change to v1.2.1

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1.2.1	7	Verify change to section names as displayed in the style-sheet in EU M1 v1.2.1 (in line with the post-TIGes meeting Change Request)	<p>Change Request submitted and implemented.</p> <p>However, it is felt that these changes alter the scope of v1.2.1 far beyond the scope agreed for this minor version, which is for release primarily to correct misalignment between CTC and eCTD guidance.</p> <p>The changes implemented introduce a high degree of change and complexity for applicants and tool vendors, and would have a large impact on the lifecycle of many products currently being handled in eCTD.</p> <p>It is recommended that the number of changes to element/folder/file names is greatly reduced to those which are absolutely necessary for clarity and interpretation of the section requirements and identification.</p>	<p><u>25/07/2006:</u></p> <ul style="list-style-type: none"> ➤ Introduce only the requested changes to section 1.5 and 1.7 (retain v1.1 original element, folder, file names for all other sections –roll back changes). ➤ Address general alignment of element, folder and file names in the next major version of the eCTD EU M1 spec, v1.3. ➤ Change to v1.2.1
1.2.1	8	Compared to v1.1, v1.2 refers only two times to a Decentralised procedure. The Decentralised procedure is no longer listed at p5 (Description envelope); p13 Row 8; p30 Appendix 2.1; p32 Appendix 3; p35 Appendix 4 and p38 Instructions for NP and MRP. Should the DCP be explicitly mentioned in these locations in order to emphasis that the specifications apply to this procedure also?	To be discussed – should this change be implemented in v1.2.1?	<p><u>25/07/2006:</u></p> <ul style="list-style-type: none"> ➤ Addressed by the introduction of a new section on the Decentralised procedure. ➤ Change to v1.2.1
1.2.1	9	The release notes define that 1.3.6 (Braille) is not country specific. The DTD, however, specifies that Language, Type and Country are required attributes for the entire pi-doc. Please clarify.	To be discussed – should this change be implemented in v1.2.1?	<p><u>25/07/2006:</u></p> <ul style="list-style-type: none"> ➤ Change request to be requested from the originator. Change to be considered for next version, v1.3. ➤ No change to v1.2.1.

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1.2.1	10	The attribute list on the eu-backbone specifies that the language is implied for "eu:eu-backbone". Since software vendors have different interpretations, it should be clarified what is mentioned here. Does it mean that for each leaf in the EU-M1 the xml:lang has to be specified or is it limited to the appropriate documents of Section 1.3 (pi-doc)?	To be discussed – should this change be implemented in v1.2.1?	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Change request to be requested from the originator. Change to be considered for next version, v1.3 ➤ No change to v1.2.1
1.2.1	11	There does not seem to be any tool that prompts the compiler of an eCTD for the Type of document for Section 1.3. Since tools do not offer this, it is too risky to adjust the xml file manually. What would happen when this attribute is not provided in actual eCTD submission?	To be discussed – should this change be implemented in v1.2.1?	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Change request to be requested from the originator. Change to be considered for next version, v1.3 ➤ No change to v1.2.1
1.2.1	12	The required attribute 'Country' for "1.3 pi-doc" should be implied for NP, DCP and MRP for 1.3.1, 1.3.2, 1.3.3, 1.3.5 and 1.3.6 only and not for 1.3.4 since this might be too general. Moreover, for the CP, the Country is only to be implied for the 1.3.2 and 1.3.3, because these concern country specific information, whereas the remainder in 1.3 concerns language specific information	Recommend that the attribute 'country' is not mandatory for 1.3.4 (consultation with patient groups) To be discussed – should this change be implemented in v1.2.1?	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Change request to be requested from the originator. Change to be considered for next version, v1.3 ➤ No change to v1.2.1
1.2.1	13	The required attribute Language for "1.3 pi-doc" should be implied for 1.3.1, 1.3.5 and 1.3.6 only and not for 1.3.4 since this might be too general. For a CP, 1.3.2 and 1.3.3 are country specific only and not specific to a language. "xml:lang" should therefore be allowed to remain empty. According to the current specs this would result in errors or warnings upon validation.	Recommend that the attribute 'xml:lang' is not mandatory for 1.3.2 (mock-ups) 1.3.3 (specimens) and 1.3.4 (consultation with patient groups) To be discussed – should this change be implemented in v1.2.1?	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Change request to be requested from the originator. Change to be considered for next version, v1.3 ➤ No change to v1.2.1
1.2.1	14	In the Introduction section the reference URL to find the full ICH eCTD specification is incorrect. It should refer to http://estri.ich.org/ectd .	Change agreed in Interlinking Group meeting – to be implemented.	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Change the URL ➤ Change to v1.2.1
1.2.1	15	Regional File Formats - Module 1 (Page 5): 'XML, image and archive formats are also accepted on ad hoc places.' This should read 'on an ad hoc basis' .	Change agreed in Interlinking Group meeting – to be implemented.	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Change the wording on p5. ➤ Change to v1.2.1

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1.2.1	16	<p>Incorrect Appendices: File naming conventions (page 7); reference for country codes should be to Appendix 2.1, not 2.2. Reference to document type codes is given as Appendix 2.1 - this should be Appendix 2.3 if it is the SPCDOC types codes that is being referred to. Appendix 2 : 1st page - codes : SPCDOC codes are explained in Appendix 2.3, not 2.2 Appendix 2 Entry 14 - file name for 131 SPCDOC, refers to 'Table 2.1', which doesn't exist, it's now Appendix 2.3.</p>	Change agreed in Interlinking Group meeting – to be implemented.	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Correct appendix references and numbers as specified ➤ Change to v1.2.1
1.2.1	17	<p>Appendix 1 - submission-description entry in the envelope table. 'This optional element can be used to describe the submission' But the submission-description is now mandatory and so 'should' rather than 'can' should be used as a more appropriate word.</p>	Change agreed in Interlinking Group meeting – to be implemented.	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Change wording as specified ➤ Change to v1.2.1
1.2.1	18	<p>Instructions to Migrate PI from Paper to PIM: reference to format of existing electronic files should be Word and PDF, not just PDF. All documents of any format need to be deleted at the same time the PIM file is submitted.</p>	Change agreed in Interlinking Group meeting – to be implemented.	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Change instructions as specified ➤ Change to v1.2.1
1.2.1	19	<p>Eu envelope.mod and eu-leaf.mod – is it necessary to change the version number as there is no other change apart from the version number?</p>	Agreed in Interlinking Group meeting that the version number should be changed to bring the envelope and leaf.mod files in line with the specification.	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Change envelope.mod and leaf.mod version numbers to be in line with the specification version. Include this change in the release notes. ➤ Change to v1.2.1
1.2.1	20	<p>Details (email address etc) of authors in the DTD, envelope.mod and leaf.mod should be deleted – not relevant. Retain the names but list the individuals as contributors.</p>	Change agreed in Interlinking Group meeting – to be implemented.	<u>25/07/2006:</u> <ul style="list-style-type: none"> ➤ Remove details of authors in envelope.mod, leaf.mod and DTD, but leave names as specified. ➤ Change to v1.2.1

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1.2.1	21	As previously advised, the location of the EU Module 1 DTD and style-sheet is within the m1/eu/util subdirectory, rather than the root level util directory - this is the case throughout the specification and in the example submissions.	An agreement was made to use the EU M1 util folder only in the event of submission of PIM or eAF – otherwise use root util folder for DTD/style-sheet etc. Change specs and examples to use root util folder	<u>30/08/2006:</u> <ul style="list-style-type: none"> ➤ Move the EU M1 DTD and style-sheet from the util folder of EUM1 to the util folder of eCTD ➤ Keep the EU M1 util folder for other EU regional standards ➤ Add a note in the Specification and amend the examples ➤ Change to v1.2.1
1.2.1	22	The submission-description element is a mandatory element (it must appear once and only once in the envelope). The text in Appendix 1 (on page 11) that describes the element says that "This optional element can be used to describe the submission" though the constraint says that it is mandatory. Maybe the wording can be changed to "This element is used to describe the submission"	EFPIA change - agreed	<u>30/08/2006:</u> <ul style="list-style-type: none"> ➤ Align the text to state the field is mandatory ➤ Change to v1.2.1
1.2.1	23	Centralised Procedure Directory Structure - the example does 'depict' the submission of the PI as a PIM - all it shows is that 131-splabelpl folder is missing. The file itself doesn't show. I suggest that there are two alternative structures shown, firstly without PIM showing the full structure and secondly with PIM with the omitted folder	Agreed	<u>30/08/2006:</u> <ul style="list-style-type: none"> ➤ Provide 2 scenarios under CP: one with PIM and one with paper PI (PDF). Zoom the folder 1.3 to clearly show what it contains ➤ Change to v1.2.1
1.2.1	24	Decentralised Procedure Directory Structure - it is inappropriate to provide a structure as if a PIM file were being submitted as PIM is not applicable to the DCP. The structure should include a 131-splabelpl folder	Agreed	<u>30/08/2006</u> <ul style="list-style-type: none"> ➤ Amend the DCP example to use PDF/Word PI ➤ Change to v1.2.1

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1.2.1	25	In Section 2.7, elements <ul style="list-style-type: none"> - m1-5-3-data-market-exclusivity - m1-7-2-market-exclusivity need to be listed as these were changed between 1.2 and the first draft of 1.2.1 but have now been lost from the release notes	Agreed	<u>30/08/2006</u> <ul style="list-style-type: none"> ➤ Add the elements to the Release Notes ➤ Change to v1.2.1
1.2.1	26	Regional information: please delete "if required" after pharmacovigilance, as for a new initial submission this session will always have to contain document(s)	Agreed	<u>30/08/2006</u> <ul style="list-style-type: none"> ➤ Delete 'if required' ➤ Change to v1.2.1
1.2.1	27	It is not clear why readability testing (please note that the name should be changed to 'user consultation') and Orphan are mentioned as bullets under Product Information. Shouldn't these rather be considered as included under "other"?	Agreed	<u>30/08/2006</u> <ul style="list-style-type: none"> ➤ Remove the two last elements of Product Information as they do not belong to that category of information. ➤ Change to v1.2.1
1.2.1	28	For "1.3 product information", there is now also a "1.3 PIM" Do I understand it correctly that in case a normal word pi file is submitted, this will be called '1.3 product information', and in case of PIM submission '1.3 PIM'? That seems strange to me - shouldn't "1.3 product information" be used in both cases, in line with the paper CTD, independent from the underlying format?	1.3 is called Product Information in both cases. However, section 1.3.1 has different element names depending on the usage of PIM. This might be confusing, especially as EU M1 supports the submission of both paper PI and PIM. The XML structure is correct, but it might be required to enhance the rendering through a proper style-sheet	<u>30/08/2006</u> <ul style="list-style-type: none"> ➤ No change to v1.2.1 <u>19/09/2006 – Interlinking Meeting</u> <ul style="list-style-type: none"> ➤ No change in DTD but style-sheet amended to display PI in PDF and in PIM below the same heading 1.3.1 ➤ Added note in Specifications, page 16, about the submission of PI in PDF or PIM format ➤ Change to v1.2.1

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1.2.1	29	<p>Several titles, which we discussed in the previous NTA interlinking meeting, have again been changed or shortened. In particular: application form, user consultation, approved pi, specific requirements.</p> <p>Particularly worrying is the Appendix 3 - example screenshot, where clearly all the abbreviated terms are used e.g. "specific" "consultation" "specific". Would it be possible to change them back into the originally agreed wording, or was there a particular reason to change this?</p>	Propose to release v1.2.1 with the element names as they stand, and to re-address all the element names, section names and file names, completely, in depth and formally, during the next update of EUM1.	<p><u>30/08/2006</u></p> <ul style="list-style-type: none"> ➤ No change to v1.2.1 <p>19/09/2006 – Interlinking Meeting</p> <ul style="list-style-type: none"> ➤ <u>No change in DTD but style-sheet amended to display CTD section names instead of element names</u> ➤ <u>Correction of the Specifications, page 16, regarding the CTD section name when submitting PI in PIM format</u> ➤ <u>Change to v1.2.1</u>
1.2.1	30	<p>At the start of the procedure (MRP and DCP) there will be one common (core) SmpC, PL and labelling in English which is valid for all member states (although some agencies also request for national translations at start of procedure). The common documents will be located in the common sub folder in m1\eu\13-pi\131-spclabelpl. There is no need to indicate the language and/or country.</p> <p>The text next to the image on page 35 ('...Files should be placed in the country directories inside the 'common' directory'...) should thus be changed (e.g. into '<i>...Files should be placed in the common folder. No country or language folder should be added....</i>'). <i>Any national translations should be treated similar to a national submission (files to be located in country folder and optional language sub folder). At the end of the procedure the applicant needs to submit the national translations of the common approved spc/pl/label. Similar to a national application, these documents should be located in the country specific folders and, if needed, in language specific sub-folders. For example: m1\eu\13-pi\131-spclabelpl\be\fr or m1\eu\13-pi\131-spclabelpl\be\nl'</i></p>	Agreed	<p><u>04/09/2006:</u></p> <p>Change text on p. 35 as indicated.</p> <ul style="list-style-type: none"> ➤ Change to v1.2.1

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1.2.1	31	On Page 40 the text states 'This example depicts national submissions containing information for several agencies in order to highlight the support of multiple languages and countries'. It is my understanding that it is not allowed to submit national applications in parallel, so the example would be valid for MRP or DCP only. The text for the procedure type in the xml file should be changed accordingly.	Agreed	<u>04/09/2006:</u> Change text on p. 40 as indicated. ➤ Change to v1.2.1
1.2.1	32	Page 34. Zoomed window : The example is incorrect. For SPCs etc we submit by language and not by country in the Centralised procedure. 'be' shouldn't be used as this is a country and not a language.	Agreed	<u>04/09/2006:</u> Change to language code. ➤ Change to v1.2.1
1.2.1	33	Page 37 still refers only to MRP. Should be 'and DCP'	Agreed	<u>04/09/2006:</u> Change text on p. 37 as indicated. ➤ Change to v1.2.1
1.2.1	34	Release notes - under 2.9, the DTD and .mod files have had the authorship removed. Also indicate that for the .mod files there has been no other change of content but the version number has changed to keep in synch with the spec.	Agreed	<u>04/09/2006:</u> Make change to release notes as indicated. ➤ Change to v1.2.1 release notes
1.2.1	35	In the specification, there are Example screenshots (cf. Appendix 3) which still show the "old" short titles and 1.3.1 PIM for instance. Perhaps it would be better to include updated screenshots?	Appendix 3 displays the directory structure, and not the output through the style-sheet. For instance, it is needed to differentiate PIM from paper PI, as one is done according to the DES (zip file with a certain naming convention) and the other follows the EU Module 1 rules.	<u>26/09/2006</u> Added a note in Appendix 3 to say that the screenshot represents directory structure and that the PIM file will display under section "1.3.1 SPC, Labelling and Package Leaflet"
1.2.1	36	For the example 1 (EMEA), it may be better to introduce the following changes to make the example more realistic: 1.3.5 and additional data; no documents need to be included, as these sections are not applicable to the EMEA. This may also apply to some other CP examples which I did not review individually.	Agreed	<u>26/09/2006</u> Examples 1 and 2 have been modified to remove 1.3.5 and additional data (both CP). The Example Coverage document has been modified accordingly.

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1.2.1	37	In Example 5 (MRP), in the eu-envelope: It is not possible to have in one MR Procedure the numbers of two MS: ES and IT. There is only one number which defines the RMS – so either IT/123/456 or ES/123/456, but not both.	Application Number is a repeatable field, so no DTD change is needed. EU Module 1 has been developed so that it can contain different envelopes and have different behaviours depending on the submission procedure being employed.	<u>05/10/2006</u> The style-sheet has been updated to display repeated application numbers in comma-separated values. <u>19/10/2006</u> Amend the MRP examples so that: 1/ 1 envelope is provided for the RMS (with attribute country set to "common") 2/ Set the approved PI only for the RMS 3/ There is one and only one MRP number 4/ 1.5.1 and 1.5.2 seem mutual exclusive; this is covered by issues 42-to-45 per procedure 5/ 1.5.4 and 1.5.5 seem mutual exclusive; this is covered by issues 42-to-45 per procedure
1.2.1	38	In Example 5 (MRP), in m-1-3-pi: Even this is a procedure between ES and IT, the place for the product information in English is missing.	Agreed	<u>05/10/2006</u> Example has been modified to add English PI in a "common" folder
1.2.1	39	In Example 5 (MRP), general comment: The sequential arrangement of all documents in m1-3-1-spc-label-pl is fine as long we only have a small MRP (equally valid for DCP), but is difficult to navigate within large procedures. I generally miss a split in the beginning relating to a MS –but perhaps I have missed this discussion.	Agreed	<u>05/10/2006</u> Style-sheet has been amended to display paper PI in a table instead of a list. This is to address the concern about the clarity of information provided.

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1.2.1	40	In Example 5 (MRP), in m1-3-4-consultation: The patient consultation can be done in any language of the EEA, as long as the report about it is in English. Therefore no need to have a place for the patient consultation in ES, IT.	It is agreed that m1-3-4-consultation may contain information in the language of one Member States	<u>09/10/2006</u> Therefore, it is better to store such report per Member State, and if the same report applies to many (or all) Member States, the country "common" can be used. No action.
1.2.1	41	In Example 4 (MRP), in m-1-3-pim: Under the link PIM 'Submission 000a' you will see only a list of files which are in the file 131-pim-000-a.zip, but there is no link to the individual 'documents'.	That's the way PIM is used within the EU Module 1. To see the content of PIM, the ZIP file needs to be exploded first, before looking at documents.	<u>09/10/2006</u> No Action
1.2.1	42	Review of the examples: CP <ul style="list-style-type: none"> - No information for 1.3.3 (specimen) - Never information at the root of 1.4 (info about experts) - Never information at the root of 1.5 (specific requirements) - Elements 1.5.1 to 1.5.5 are all optional - No information for 1.5.2 (generic applications) - No information for 1.5.3 (data/market exclusivity) - Never information at the root of 1.6 (environmental risk assessment) - No information for responses to questions 1.5.1 and 1.5.2 are mutual exclusive 1.5.4 and 1.5.5 are mutual exclusive Questions & Answers <ul style="list-style-type: none"> - Approved PI do not apply to CP Correct - 1.5.1 and 1.5.2 are mutual exclusive Correct - 1.5.4 and 1.5.5 are mutual exclusive Correct - Additional data do not apply to CP Correct 	Mutual exclusion for 1.5.1-1.5.2: <ul style="list-style-type: none"> - or 1.5.1 is set - or 1.5.2 is set - or none Mutual exclusion for 1.5.4-1.5.5: <ul style="list-style-type: none"> - or 1.5.4 is set - or 1.5.5 is set - or none Mutual exclusion is not enforced by the DTD Assumption: the heading of section always displays even though it contains no information	<u>19/10/2006</u> Update examples Align specifications (Appendix 3, Appendix 4) Cf. Table of examples below

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1.2.1	43	<p>Review of the examples: NP</p> <ul style="list-style-type: none"> - Information for 1.3.3 (specimen) needs to be checked with NtA Chapter 7 <ul style="list-style-type: none"> o NtA Chapter 7 describes CP with details, not NP o Specimen are provided only before launch (i.e. after authorisation); as the example is an initial MA, there should be no information o A footnote states that the procedure is being reworked - Never information at the root of 1.4 (info about experts) - Never information at the root of 1.5 (specific requirements) - No information for 1.5.3 ((extended) data/market exclusivity) - No information for 1.5.5 (conditional marketing authorisation) - Never information at the root of 1.6 (environmental risk assessment) - No information for 1.6.2 (GMO) - No information for 1.7.1 (similarity) - No information for 1.7.2 (market exclusivity) - No information for responses to questions <p>Questions & Answers</p> <ul style="list-style-type: none"> - Approved PI do not apply to NP Correct - 1.5.1 and 1.5.2 are mutual exclusive Correct - 1.5.4 and 1.5.5 are mutual exclusive not applicable - Additional data are applicable to NP Correct 	<p>Mutual exclusion for 1.5.1-1.5.2:</p> <ul style="list-style-type: none"> - or 1.5.1 is set - or 1.5.2 is set - or none <p>For 1.5.4-1.5.5:</p> <ul style="list-style-type: none"> - 1.5.4 and 1.5.5 are not applicable to National Procedure <p>Mutual exclusion is not enforced by the DTD</p> <p>Assumption: the heading of section always displays even though it contains no information</p>	<p><u>19/10/2006</u></p> <p>Update examples</p> <p>Align specifications (Appendix 3, Appendix 4)</p> <p>Cf. Table of examples below</p>

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1.2.1	44	<p>Review of examples: DCP</p> <ul style="list-style-type: none"> – Information for 1.3.1 (SPC, labelling and package leaflet) is in PDF, not in PIM – Never information at the root of 1.4 (info about experts) – Never information at the root of 1.5 (specific requirements) – No information for 1.5.3 ((extended) data/market exclusivity) – No information for 1.5.4 (exceptional circumstances) – No information for 1.5.5 (conditional marketing authorisation) – Never information at the root of 1.6 (environmental risk assessment) – No information for 1.6.1 (Non-GMO) – No information for responses to questions <p>Questions & Answers</p> <ul style="list-style-type: none"> – Approved PI do not apply to DCP Correct – 1.5.1 and 1.5.2 are mutual exclusive Correct – 1.5.5 Not possible – Additional data are applicable to DCP Correct 	<p>Mutual exclusion for 1.5.1-1.5.2:</p> <ul style="list-style-type: none"> – or 1.5.1 is set – or 1.5.2 is set – or none <p>For 1.5.4-1.5.5:</p> <ul style="list-style-type: none"> – 1.5.4 and 1.5.5 are not applicable to Decentralised Procedure <p>Mutual exclusion is not enforced by the DTD</p> <p>Assumption: the heading of section always displays even though it contains no information</p> <p>As 1.5.5 is not possible for DCP, the header of section 1.5.5 will NEVER display for that procedure (style-sheet update)</p>	<p><u>19/10/2006</u></p> <p>Update examples</p> <p>Align specifications (Appendix 3, Appendix 4)</p> <p>Cf. Table of examples below</p>

Version	No.	Issue / Suggested Change	Notes	Conclusion
1.2.1	45	<p>Review of examples: MRP</p> <ul style="list-style-type: none"> - Remove IT information for the envelope - Remove IT information for 1.0 (cover letter) - Remove IT information for 1.2 (application form) - Remove ES, IT & FR information from 1.3.1; leave COMMON - Only 1 document in COMMON for 1.3.2 - Remove IT information for 1.3.3 - Collect both documents under COMMON for 1.3.4 - Keep only IT information for 1.3.5 - Never information at the root of 1.4 (info about experts) - Never information at the root of 1.5 (specific requirements) - Never information at the root of 1.6 (environmental risk assessment) - No information for 1.6.1 (Non-GMO) - No information for 1.7.1 (similarity) - No information for 1.7.2 (market exclusivity) - No information for responses to questions - Keep ES & FR information for additional data <p>Questions & Answers</p> <ul style="list-style-type: none"> - Keep flexibility of multiple envelopes Yes - Differentiate information for CMS from RMS Yes - Provide PI for all participating MS <ul style="list-style-type: none"> o No for first submissions o Yes for subsequent submissions - Approved PI applies to MRP Yes 	<p>Assumption: the heading of section always displays even though it contains no information</p> <p>Potential issue</p> <ul style="list-style-type: none"> - Is there a need to define which MS is the RMS from which are the CMSs (e.g. in the envelope)? 	<p><u>19/10/2006</u></p> <p>Update examples</p> <p>Align specifications (Appendix 3, Appendix 4)</p> <p>Cf. Table of examples below</p>

Version	No.	Issue / Suggested Change	Notes	Conclusion
1.2.1	46	<p>Consequences of the review of all examples:</p> <ul style="list-style-type: none"> – Information can NEVER be attached to root level 1.4 – Information can NEVER be attached to root level 1.5 – Information can NEVER be attached to root level 1.6 – In the case of DCP, section 1.5.5 never displays (i.e. no section header) as it is not possible for this procedure 	<p>Therefore, placeholder for such information can be removed from the DTD</p> <p>Amend the style-sheet so that heading of section 1.5.5 does not display for DCP</p>	<p><u>19/10/2006</u></p> <p>DTD Update (remove leaf / node-extension from elements m1-4-expert, m1-5-specific and m1-6-environrisk)</p> <p>Style-sheet Update (no display of heading 1.5.5 for DCP)</p> <p>Align specifications (Appendix 2, Appendix 3, Appendix 4, Appendix 5)</p>

Table of Examples (v1.2.1)

ID	Heading	Example 1 CP, PIM	Example 2 NP	Example 3 DCP	Example 4 MRP (RMS=IT)
	Envelope	EMEA	CC	COMMON	COMMON Not RMS
1.0	Cover Letter	EMEA	CC	COMMON	CCs Not RMS
1.2	Application Form	EMEA	CC	COMMON	CCs Not RMS
1.3	Product Information	-	-	-	-
1.3.1	SPC, Labelling and Package Leaflet	PIM	CC – LL	COMMON – LL	COMMON – LL
1.3.2	Mock-up	EMEA	CC	COMMON	COMMON
1.3.3	Specimen	-	-	COMMON	CCs Not RMS
1.3.4	Consultation with Target Patient Groups	EMEA	CC	COMMON	COMMON
1.3.5	Product Information already approved in the Member States	-	-	-	RMS
1.3.6	Braille	File	File	File	File
1.4	Information about the Experts	-	-	-	-
1.4.1	Quality	File	File	File	File
1.4.2	Non-Clinical	File	File	File	File
1.4.3	Clinical	File	File	File	File
1.5	Specific Requirements for Different Types of Applications	-	-	-	-
1.5.1	Information for Bibliographical Applications	-	-	File	-
1.5.2	Information for Generic, 'Hybrid' or Bio-similar Applications	-	File	-	File
1.5.3	(Extended) Data/Market Exclusivity	-	-	-	File

ID	Heading	Example 1 CP, PIM	Example 2 NP	Example 3 DCP	Example 4 MRP (RMS=IT)
1.5.4	Exceptional Circumstances	File	-	-	-
1.5.5	Conditional Marketing Authorisation	-	-	-	-
1.6	Environmental Risk Assessment	-	-	-	-
1.6.1	Non-GMO	File	-	-	-
1.6.2	GMO	-	-	-	-
1.7	Information relating to Orphan Market Exclusivity	-	-	-	-
1.7.1	Similarity	File	-	File	-
1.7.2	Market Exclusivity	File	-	File	-
1.8	Information relating to Pharmacovigilance	-	-	-	-
1.8.1	Pharmacovigilance System	File	File	File	File
1.8.2	Risk-management System	File	File	File	File
1.9	Information relating to Clinical Trials	File	File	File	File
	Responses to Questions	-	-	-	-
	Additional Data	-	CC	COMMON	CCs Not RMS

Legend

- - No file is provided
- File File is provided with no attachment to any country
- EMEA File is provided for country "EMEA"
- CC File is provided for a country indicated by the 2-letter ISO code
- CCs File is provided for more than one country indicated by the 2-letter ISO code
- LL File is provided for a language indicated by the 2-letter ISO code
- Not RMS No file is provided for the Reference Member State