Comment No.	***Comment or suggestion from SAPRAA members***	***Outcome of discussion from MCC workshop***
1.	The CTD guidelines allow applicants to submit more than one strength of the same dosage form in one dossier. • It should be allowed that applicants convert previously separate MFR1 or MBR1 dossiers into a combined dossier at the time of conversion. This will avoid unnecessary repetition of effort and reduce the overall volume of paper that MCC (and applicants) need to handle in the long run. *(Applicable to full MBR1/MRF1 → CTD conversions)*	Numbers are to be directly sequential A gap of even one is not allowed e.g. 42 001/2 + 42 004/5 not acceptable Module 1.2.1 per strength to be submitted
2.	The current ZA CTD roadmap Jun 10 v1 states that post-registration amendments Type A will not be accepted after 30 November 2010. • It is assumed that this refers to all new Type A changes only. (There could be a number of previously done Type A amendments, which were done in the MRF1 (or MBR1 format), which have just not been submitted to MCC yet, and which still need to be provided to MCC. • It is suggested that these guidelines be reconsidered once the amendment process has been agreed, since the nature of Type A & B amendments is to permit expeditious implementation of non-major changes. These cannot be delayed for administrative issues around dossier formats.	Refers to **all** type A at the time of submission of B or C in CTD format
3.	Is MCC sticking to the current roadmap dates?: • Post reg amendments Type C mandatory to be in CTD format from 1 Jan 2011? (voluntary from 1 Oct 2010) • Post-reg amendments Type B mandatory to be in CTD format from 1 Jan 2011? (voluntary from 1 Oct 2010) • The last date of acceptance of Type B and C amendments of 30 Nov 2010 seems to contradict the above-mentioned dates. • It is suggested that these guidelines be reconsidered once the amendment & dossier conversion processes have been agreed.	No 1 April 2011 1 April 2011 31 March 2011

Comment No.	***Comment or suggestion from SAPRAA members***	***Outcome of discussion from MCC workshop***
4.	According to the MCC's "post-registration amendments guideline Jun10 v4_2", page 14 of 42, applicants are required to provide MCC with pagination instructions in the amendment schedule table. • This would presuppose that an update of the table of contents of the dossier will be done. • However, at the CTD workshop it was mentioned by one MCC speaker that it would be possible to have a "hybrid dossier" (partly in CTD format and partly in MFR1 format, but not confirmed by another MCC official. It is unclear how applicants should handle the pagination instructions in the amendment schedule in these circumstances). • Can the Amendments Section deal with/accept a hybrid dossier? • We need clarification of MCC's document management requirements in order to plan an acceptable procedure for all future amendments.	PART 1B will change to Module 1.1 Indicate here what is in which format – i.e. MRF1 or CTD. **The TOC becomes a"transition status overview".** Yes
5.	• MCC should provide industry with a guideline describing the standard way to proceed when converting from the MFR1 (or MBR1) format to the CTD format. • Industry should adopt a common approach regarding to how to manage post-reg. amendments moving forward.	Separate document as discussed Agreed
6.	• When the conversions were done from MBR1 to MRF1 format, some applicants were asked to resubmit some of the preclinical and clinical information, whereas others were not. • MCC should provide clear guidance on this issue and apply it uniformly across the board.	Not required

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7.	The CTD format has additional headings in the table of contents for information which was not required to be included in the MBR1 or MRF1 format. • Will MCC require that this additional information be provided when converting to the CTD format, or would it be acceptable to simply leave these sections blank with a comment "NA – CTD conversion"? • It may be the case that some additional information needs to be obtained whereas other information can be left blank – MCC should provide guidance in this regard. • It may be the case that amendments cannot be compiled/submitted should MCC require fully completed CTD sections to be supplied, since additional information will have to sourced, that could significantly delay the ability of the Applicant to complete such amendments, with implementation ramifications at the manufacturing sites in the case of Type A & B amendments.	To convert from MRF1 to CTD you have to transcribe the approved info into the new format. This converted document is not submitted. Then update according to current requirements. If urgent don't do full conversion but only relevant parts
8.	Please could the post-registration unit provide a submission code for CTD conversions.	**This is not deemed necessary since conversions should only be submitted to MCC when there is an actual Type B or C amendment. Therefore**, the amendment codes as currently **used are still valid. (The applicant may perform the full conversion of the dossier in-house as a type A amendment, but submission to MCC should only occur with a subsequent amendment).**

Conversion:

All approved information from one format to another – no changes = reformat = transfer = transcribe = move

Inclusion of additional information as required by format = **update**

Amendment or variation to approved information = **update**