MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

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ZA CTD and ZA eCTD IMPLEMENTATION

In June 2010 the Medicines Control Council (MCC) announced the intention to implement the South African Common Technical Document (ZA CTD) format which will replace the current MRF1 and any applications still in MBR1 format.

The major milestones of the implementation strategy are as follows:

ZA CTD	**Voluntary / recommended**	**Implementation date**
New product applications for registration	1 July 2010	1 June 2011
Post-registration amendments Type A, B and C	1 October 2010	1 June 2011
ZA eCTD	**Date**	
Pilot phase - new applications for registration		
Step 1: Identify applicants and applications	*1 March – 31 May 2013*	
Step 2: Run pilot phase	*1st June 2013 –31 Dec 2016*	
Maintenance phase		
Step 3: Start maintenance phase	*6 October 2014*	
Start Operational Phase		
Step 4(a): eCTD process open to entire industry for new applications for registration of NCEs	*01 April 2016*	
Step 4(b): eCTD process open to entire industry for new applications for registration of generics	*02 January 2017*	
Step 5: All other application types – paper to eCTD	*To be advised*	
MRF1 format	**Last date for acceptance**	
New product application for registration	31 May 2011	
Clinical evaluations	31 May 2011	
Post-registration amendments Type A, B and C	31 May 2011	

MRF1 format	Last date for acceptance
Post-registration amendments Type A, B and C *are not acceptable in MBR1 format*[*]	
Conversion of all other MBR1 and MRF1 dossiers	01 June 2016

Pre-registration responses and the submission of post-registration follow-up stability data should comply with the Amendment guideline sections 1 and 6 and may be submitted in the format of the application for registration if still MRF1.

DR JC GOUWS
REGISTRAR OF MEDICINES

[*] In exceptional cases, contact the Secretariate for guidance

Project Plan eCTD implementation at MCC