

MEDICINES CONTROL COUNCIL



Implementation Guidance of South African eCTD Module 1 specification v2.1 and Validation Criteria v2.1

This document is intended to provide clarity on the implementation timelines for applications for the registration of medicines in eCTD format.

First publication	October 2016
Update v1.1	November 2016
Update v1.2	April 2017

DR JC GOUWS
REGISTRAR OF MEDICINES

TABLE OF CONTENTS

	Page
1 Introduction.....	3
2 Timelines for Implementation	3
3 Update History	3

1 Introduction

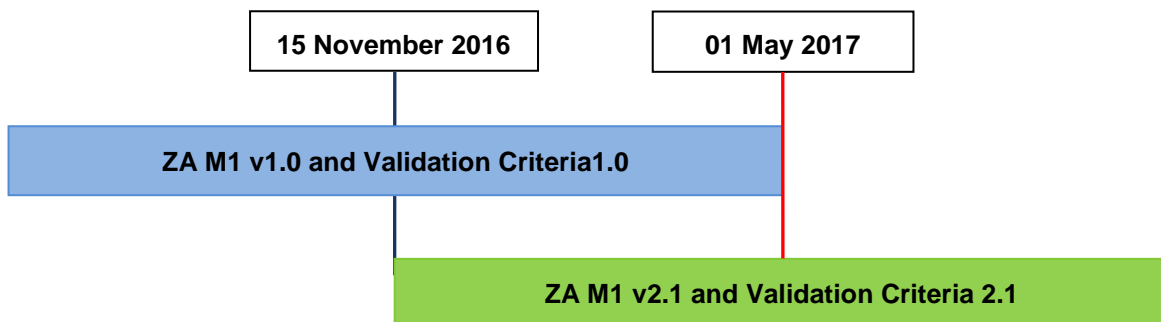
This document provides guidance to applicants and tool vendors regarding the timelines for implementation of the South African Module 1 eCTD Specification v2.1 and Validation Criteria v2.1.

2 Timelines for Implementation

The eCTD Specification of the South African Module 1 and the new South African validation criteria v2.0 contain several changes from experience of the pilot phase and was published in October 2016. The validation criteria were also aligned to the EU validation criteria v6.1. A track-change version of all changes to the previous version of each document has been published on the MCC website. Due to technical reasons the MCC module 1 specification v2.0 will not be implemented and submissions of this type will be not accepted. Furthermore, a correction has been effected in the text in the file naming convention of the validation criteria. An updated version of the M1 specification v2.1 is provided and should be used together with the modified validation criteria v2.1.

The timeline for implementation is as follows:

- 2.1 On 15 November 2016 the new South African Module 1 Specification for eCTD v2.1 will be implemented. Both versions of the South African Module 1 Specification for eCTD – v1.0 and the v2.1 - will be valid for a period from 15 November 2016 to 30 April 2017.
- 2.2 As from 01 May 2017 the South African Module 1 Specification for eCTD v2.1 and the Validation Criteria v2.1 must be used for all eCTD submissions. Any eCTD submission provided from this date using a former version of the South African Module 1 Specification for eCTD undergo a rejection.
- 2.3 All eCTD submissions with sequences submitted before 01 May 2017 have to upgrade to the new South African Module 1 specification v2.1 for a submission after 01 May 2017. Please note that previously submitted sequences for existing applications don't need to be updated to the South African Module 1 v2.1 and resubmitted. Lifecycle between sequences with old and new South African Module 1 specification has to be possible for publishing and reviewing tools.



3 Update History

Date	Reason for update	Version & publication
Sept 2016	First publication	v1 October 2016
Sept 2016	Update according to M1 specification v2.1	v1.1 November 2016
Sept 2016	Update due to correction of validation criteria v2.1	v1.2 April 2017