

eCTD IMPLEMENTATION ROADMAP COMMUNICATION

12 October 2021

This document is intended to provide communication to applicants regarding the eCTD implementation roadmap. This will be a “living document” and will be updated.

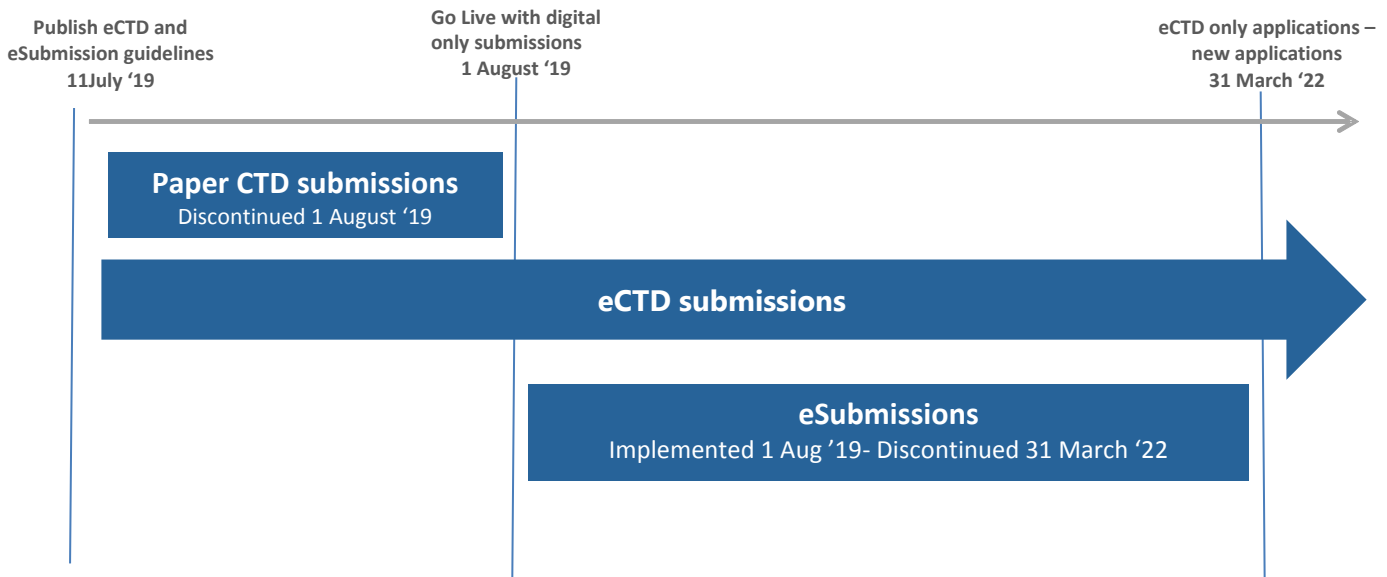
Document History

First Publication – Version 1	June 2021
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The purpose of this document is to provide an update to all applicants regarding the eCTD implementation roadmap and the revised deadline.

Reference is made to a SAHPRA-ITG working group meeting, held on the 06th of August 2021, where the eCTD Implementation Roadmap was further discussed and an extension to take us through to 31 March 2022, was communicated.



SAHPRA will engage individually with the 13 applicants identified from the 2021 submission data set (5 of which are already submitting in eCTD format as well) -- to discuss their implementation plan and the intended efforts to comply and meet the deadline that will take effect at the end of March 2022, as the rest of the applicants have now fully converted to eCTD format.

Further communication will be shared for the plans to implement then submission format change for **variations** submissions as well once we have completed the handful of system corrections on the DVP portal.

SAHPRA will then engage with stakeholder and align on a roadmap to transition these variation submissions also to single format in the near future and would encourage all applicants to bear this in mind from a planning perspective.

CHIEF EXECUTIVE OFFICER