

## **Updates**

The Therapeutic Goods Administration (TGA) has started a staged transition to Electronic Common Technical Document-only (eCTD-only) for all regulatory submissions in Australia.

## 1 November 2021 - eCTD-Only Stage 1:

- New Chemical Entity Medicine (Type A)
- New Biological Entity Medicine (Type A)
- New Biosimilar Medicine (Type A)
- New Combination Medicine (Type B)

## 1 June 2022 - eCTD-Only Stage 2:

- Extension of Indications Medicine (Type C)
- Major Variation Medicine (Type F)
- New Generic Product (Type D)

## 1 November 2022 - eCTD-Only Stage 3:

All remaining prescription medicine data including master files

eCTD format is now the accepted format for all prescription medicine applications.

TGA highly recommends to use a baseline when converting to eCTD from another format. However, you can choose to not baseline and submit a new application without resubmitting any previous documents.

The submissions of the sequences are via email, post or via TBS portal.



Asphalion can give you support in the following areas:

- eCTD compilation and publishing for TGA submissions
- Document formatting
- Non-eCTD compilation and publishing
- Transition from non-eCTD to the mandatory eCTD format
- Submission to the agency according to the latest version of TGA validation rules



EXTEDO's Regulatory Solutions for Australia:

- eCTDmanager: eCTD compilation and publishing for Australian submissions.
- eSUBmanager: Viewing and reviewing of archived and in-progress electronic submissions.
- eDOCSmanager: Manage all your regulatory documents in a secure document management system.