What you need to know for **eCTD submissions in Australia**

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
Knowledge from experience

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
eRegulatory Affairs

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.

For further information, please contact: ectd@asphalion.com | info@extedo.com