Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Submitting data in the eCTD format

Steps to submit an eCTD sequence

Version 1.2, September 2023

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Contents

This information is for sponsors and manufacturers wanting to submit data in the electronic Common Technical Document (eCTD) format for a:

- prescription medicine;
- biological;
- over-the-counter medicine;
- registered complementary medicine;
- assessed listed medicine;
- listed medicine ingredient;
- master file.

This guidance is:

ü a step-by-step guide on submitting an eCTD sequence to the TGA.

This guidance does not cover:

û the application process

û what data is required within an eCTD sequence

Process Overview

You need to complete the following steps to submit your data in the eCTD format:

Step 1: Check that eCTD is an accepted format

Step 2: Ensure you have a Client ID

Step 3: Get an e-Identifier (e-ID)

Step 4: Compile and publish the sequence

Step 5: Validate the sequence

Step 6: Send the sequence to the eSubmissions team

Step 1: Check that eCTD is an accepted format

eCTD is recommended for all prescription medicine applications.

eCTD also can be used for:

- Biologicals;
- over-the counter medicines;
- registered complementary medicines;
- assessed listed medicines;
- ingredients for listed medicines;
- master files.

It may also be appropriate to submit your application in other formats.

To check the format requirements, refer to General Dossier Requirements – Part C: Formatting your dossier.

Once you have provided an eCTD sequence to us, all further sequences within that e-ID must also be provided in eCTD.

Step 2: Ensure you have a Client ID

Omit this step if you already have a Client ID.

To get a Client ID follow the instructions on:

- TGA Business services: getting started with the TGA

Your Client ID will be required in Step 4.

Client ID is a mandatory field within the XML envelope for each sequence. It is used to group all sequences from one sponsor (client) together.

Step 3: Get an e-Identifier

Omit this step if your medicine or biological already has an e-Identifier (e-ID).

If moving from Non eCTD electronic Submission (NeeS) to eCTD, a new number is not required: just change the ‘n’ to an ‘e’ in your e-ID. For example, n012345 to e012345. The e-ID for eCTD always starts with an ‘e’.

In general, an e-ID:

- is specific to a sponsor and active ingredient (or combination of active ingredients);
- includes all the dosage forms, strengths, trade names, and manufacturers.

If you need to deviate from this, contact the eSubmissions team using the contact box on the TGA electronic submissions page.

To get an e-Identifier

Email eSubmissions@health.gov.au with ‘Request for e-Identifier’ in the subject line. Your e-ID will be required in Step 4.

In your email, include:

- Company name (name associated with your Client ID);
- active ingredient(s) names (approved or proposed);
- proposed application type, for example ‘Type A - New Chemical Entity’ or ‘Drug Master File’.

Step 4: Compile and publish the sequence

Compile and publish your sequence with support from your eCTD software vendor or consultant.

Populating your XML envelope

In this step, you will need to populate your XML envelope. To do this you will need to know the:

- e-ID;
- Client-ID;
- approved name(s) of the active ingredients;
- trade name(s) (or proposed trade name(s)) – if no trade name is available, include the approved name in this field;
- submission or application number(s);
- sequence number;
- related sequence number;
- regulatory activity lead;
- sequence type;
- sequence description;
- submission mode – currently always ‘single’;
- contact email address;
- current ARTG number(s) , if applicable.

Compiling your sequence

To assist with compilation, we recommend you:

- become familiar with the eCTD specifications and validation criteria;
- ensure all information within the XML envelope is accurate and complete. Errors can lead to delays in processing your sequence;
- carefully consider the most appropriate sequence type and sequence description for your application.

Publishing your sequence

To assist with publishing, we recommend you:

- make no further changes to a sequence once it is published: ad hoc post publication changes can lead to modified file validation errors and delays in processing the sequence.

Data requirements for your sequence

Data requirements for sequences differ depending on the type of therapeutic good and the application type. Please refer to the relevant therapeutic area guidance for details:

- prescription medicines;
- biologicals;
- OTC medicines;
- registered complementary medicines and listed medicines ingredients;
- assessed listed medicines.

Determining what data is required within your sequence is NOT the focus of this guidance.

Step 5: Validate the sequence

We recommend that you validate your sequence prior to sending it to us.

Validation errors and warnings can result in delays in processing and evaluating your data.

Validation warnings

Eliminate validation warnings wherever possible. If you cannot eliminate them, justify them in your sequence cover letter.

Validation errors

Resolve validation errors before you upload the sequence to our system.

If you have concerns about the validation of a sequence, email the eSubmissions team at eSubmissions@health.gov.au before you submit the sequence.

Step 6: Send the sequence to the eSubmissions team

To ensure your sequence is uploaded in a timely manner, please send it to the eSubmissions team.

Submitting your sequence

Sequences must be provided as a single zipped file titled with the **e-ID** (e.g. e123456), containing a subfolder titled with the **sequence number** (e.g. 0001). You can submit your sequence through:

- email for submissions under 30MB uncompressed (the total uncompressed size of each document rather than the size of the file when it is unzipped). Please do not email sequences to individual evaluators.
- post in a USB or non-rewritable CD or DVD;
- the TGA Business Services (TBS) portal as an attachment to an application, if less than 100MB and the application form has this capability.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication No new regulatory requirements have been introduced	BSRR/PMAB/MRD	June 2020
V1.1	Minor edit for clarification between manufacturer and Australian sponsor name	BSRR/PMAB/MRD	March 2021
V1.2	Minor edit for clarification on naming convention of submission file.	BSRR/PMAB/MRD	September 2023

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