Australian Government
Department of Health
Therapeutic Goods Administration

Submitting data in the NeeS format

Steps to submit a NeeS sequence

Version 1.1, March 2021

TGA Health Safety Regulation

Contents

This information is for sponsors and manufacturers wanting to submit data in the NeeS 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 a NeeS sequence to the TGA.

This guidance does not cover:

û the application process.

û what data is required within your sequence.

Process Overview

Complete the following steps to submit your data in the NeeS format:

Step 1: Check that NeeS is an accepted format

Step 2: Ensure you have a Client ID

Step 3: Get an e-Identifier

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 NeeS is an accepted format

ü NeeS can be used for:

- biologicals;
- over-the-counter medicines;
- registered complementary medicines;
- assessed listed medicines;
- ingredients for listed medicines;
- master files;
- some prescription medicine applications.

NeeS cannot be used for prescription medicines under the:

- provisional approval pathway;
- priority review pathway;
- comparable overseas regulator (COR) report-based process;
- PPF only pathway.

The electronic Common Technical Document (eCTD) is the preferred format for all prescription medicine applications. Refer to Submitting data in the eCTD format for information on how to submit an eCTD sequence.

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.

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 Australian NeeS Envelope form 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).

In general, an e-ID:

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

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

For NeeS your e-ID will start with an 'n'. For example, n012345.

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

You can compile a NeeS sequence manually, via an eCTD compilation and publication software or a consultant.

Populating the NeeS envelope form

In this step you will need to populate the Australian NeeS envelope form XML. 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 tradename 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 NeeS Specifications and validation criteria, particularly if you are manually compiling your sequence;
- ensure all the information within the NeeS Envelope Form 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;
- make sure your sequence numbers progress in chronological order.

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 failures and best practice 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 failures

Resolve validation failures before you upload your 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 and titled with the **e-ID\sequence-number**, for example n123456\0002.

You can submit your sequence through:

- email for submissions under 30 MB 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 100 MB 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

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