Australian Government
Department of Health
Therapeutic Goods Administration

eCTD withdrawals

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TGA Health Safety Regulation

Contents

About this guidance

This guidance is for sponsors who need to withdraw information from their electronic Common Technical Document (eCTD) dossier. It can also be used as best practice for Non eCTD electronic Submission (NeeS) withdrawals.

eCTD withdrawals

An eCTD withdrawal sequence is a notification of the removal of information from the submission view of the dossier (e-Identifier) due to the:

- removal of a product from the market
- withdrawal of a submission or application
- withdrawal of part of a submission or application.

It is used to revert a dossier back to a previous state and forms an integral part of the eCTD product lifecycle.

eCTD withdrawals ensure that the information within your eCTD dossier aligns with the information in the Australian Register of Therapeutic Goods (ARTG) and within the provisional ARTG record for submissions under evaluation.

Steps before an eCTD withdrawal

Prior to undertaking an eCTD withdrawal, you must notify us of the withdrawal of data by either:

- submitting a request to cancel an entry from the ARTG for a therapeutic good on the ARTG
- contacting the area with which you have been liaising during the evaluation to request the withdrawal of a submission or application that is currently under evaluation.

Withdrawal is permanent. Once an eCTD withdrawal sequence has been processed it cannot be 'un-withdrawn'.

Types of withdrawals

There are three types of withdrawals:

- entire product lifecycle withdrawal (e-Identifier)
- submission withdrawal (regulatory activity)
- partial withdrawal (some of the dossier or submission or sequence)

Entire product lifecycle withdrawal

An entire product lifecycle withdrawal removes **all** products and data contained within a dossier.

An entire product lifecycle withdrawal sequence should be submitted following the cancellation of all products from the ARTG.

Do not submit an entire product lifecycle withdrawal to transfer the sponsorship of the entire dossier (all products).

Example

ABC Pharmaceuticals are the sponsor of 2 pain relief medicines. The data for both medicines is included in the one dossier (e123456). ABC Pharmaceuticals makes a business decision to stop selling both of these medicines within Australia and cancels them from the ARTG. To ensure the dossier aligns with the ARTG they then submit an entire product lifecycle withdrawal sequence which flags all the information within e123456 as withdrawn, as shown in the table below:

Example of an entire product lifecycle withdrawal sequence

e123456 lifecycle				
Sequence	**Sequence Type**	**Sequence Description**	**Related Sequence**	**Submission Number**
~~0000~~	~~A – NCE New Chemical Entity~~	~~Initial~~	~~0000~~	~~PM-2017-12345-1-1~~
~~0001~~	~~Supplementary Information~~	~~Response to Request for Information~~	~~0000~~	~~PM-2017-12345-1-1~~
~~0002~~	~~Supplementary Information~~	~~Product Information~~	~~0000~~	~~PM-2017-12345-1-1~~
~~0003~~	~~Notification~~	~~Initial~~	~~0003~~	~~PM-0~~
~~0004~~	~~F – Major variation – new Strength~~	~~Initial~~	~~0004~~	~~PM-2020-54321-1-1~~
~~0005~~	~~Supplementary Information~~	~~Response to Request for Information~~	~~0005~~	~~PM-2020-54321-1-1~~
~~0006~~	~~Supplementary Information~~	~~Product Information~~	~~0005~~	~~PM-2020-54321-1-1~~

What to include in the withdrawal sequence

Document requirements

Provide a cover letter at module 1.0.1 only, and:

- include the finalised TBS cancellation forms as an attachment
- use the operation 'new'.

Sequence requirements

When providing the sequence:

- include Sequence Type: **Product Withdrawal {seq-type-57}**
- include Sequence Description: **Withdrawal {seq-desc-23}**
- use the therapeutic area prefix as the submission number (for example 'PM' for prescription medicines)
- provide the entire product lifecycle withdrawal sequence as a standalone sequence
- do not provide any other applications or data within this sequence
- relate the sequence to itself.

Submission withdrawal

A submission withdrawal is the removal of all the information related to a single submission that is currently under evaluation.

It will withdraw all information in all sequences related to the particular submission.

Submission withdrawals can only be actioned for active submissions prior to a decision being made.

Do not submit a submission withdrawal if:

- your submission has been rejected
- you have included multiple submissions in the one sequence and do not want to withdraw all submissions.

Please contact eSubmissions@health.gov.au for information on how to manage these cases.

Example

ABC Pharmaceuticals has an Extension of Indications (Type C) submission under evaluation (submission number PM-2019-12345-1-1). While PM-2019-12345-1-1 was under evaluation, ABC Pharmaceuticals made the decision not to progress with this submission. They notified the TGA of this decision in writing and submitted a submission withdrawal sequence to withdraw all information associated with PM-2019-12345-1-1, as shown in the table below:

Example of a submission withdrawal

e654321 lifecycle				
Sequence	**Sequence Type**	**Sequence Description**	**Related Sequence**	**Submission Number**
0000	Baseline	Reformat	0000	PM
~~0001~~	~~C - Extension of Indication~~	~~Initial~~	~~0001~~	~~PM-2019-12345-1-1~~

e654321 lifecycle				
Sequence	**Sequence Type**	**Sequence Description**	**Related Sequence**	**Submission Number**
~~0002~~	~~Supplementary Information~~	~~Response to Request for Information~~	~~0001~~	~~PM-2019-12345-1-1~~
0003	C – Extension of Indication	Withdrawal	0001	PM-2019-12345-1-1
0004	F – Major variation – new Strength	Initial	0004	PM-2020-00001-1-3

Only sequences associated with PM-2019-12345-1-1 are withdrawn when a submission withdrawal is used.

What to include in the withdrawal sequence

Document requirements

Provide both:

- cover letter at module 1.0.1
  - include the withdrawal email notification as an attachment
  - use the operation 'new'
- tracking table at module 1.0.2
  - use the operation 'replace'
  - do not remove the withdrawn sequences from the tracking table.

Recommended lifecycle operations

There is no need to delete the withdrawn documents from the dossier.

Sequence requirements

When providing the sequence:

- include the Sequence Type: the initial sequence type used for the submission, for example **C – Extension of Indication {seq-type-5}**
- include the Sequence Description: **Withdrawal {seq-desc-23}**
- relate the sequence to the initial submission sequence
  - ensure all sequences related to the submission list the initial submissions sequence as a related sequence
- provide the submission withdrawal sequence as a standalone sequence
- do not provide any other applications or data within this sequence.

Partial withdrawal

A partial withdrawal is the removal of part of your dossier or part of your submission. This can include:

- withdrawal of some strengths or dosage forms included within the dossier
- withdrawal of part of an active submission.

A partial withdrawal is required following the:

- formal notification to the TGA of the withdrawal of part of a submission that is currently under evaluation
- cancellation from the ARTG of some of the products within the eCTD dossier.

A partial withdrawal is **not required** to change a tradename or when transferring sponsorship.

Examples

Withdrawal of one dosage form

ABC Pharmaceuticals are the sponsor of 2 pain relief medicines, one liquid dose form and one tablet. The data for both medicines is included in e123456. ABC Pharmaceuticals make a business decision to stop selling the pain tablet within Australia and cancels it from the ARTG. They then submit a partial withdrawal sequence to remove only the information relating to the tablet.

Example of a partial withdrawal sequence for one dosage form

e123456 lifecycle				
Sequence	**Sequence Type**	**Sequence Description**	**Related Sequence**	**Submission Number**
0000	A – NCE New Chemical Entity	Initial	0000	PM-2017-12345-1-1
0001	Supplementary Information	Response to Request for Information	0000	PM-2017-12345-1-1
0002	Supplementary Information	Product Information	0000	PM-2017-12345-1-1
0003	Notification	Initial	0003	PM-0
0004	Undefined regulatory activity	Withdrawal	0004	PM

Partial withdrawal of a submission

ABC Pharmaceuticals has an Extension of Indication (Type C) submission under evaluation. The submission contains applications for multiple dosage forms. During the evaluation ABC

Pharmaceuticals decide not to progress with the Extension of Indication for the liquid dosage form. They submit a partial withdrawal sequence to remove the information relating to the liquid dosage form.

Example of a partial withdrawal sequence of a submission

e654321 lifecycle				
Sequence	**Sequence Type**	**Sequence Description**	**Related Sequence**	**Submission Number**
0000	Baseline	Reformat	0000	PM
0001	C – Extension of Indication	Initial	0001	PM-2019-12345-1-1
0002	Supplementary Information	Response to Request for Information	0001	PM-2019-12345-1-1
0003	Supplementary Information	Withdrawal	0001	PM-2019-12345-1-1

What to include in the withdrawal sequence

Partial withdrawal due to ARTG cancellation

Document requirements

Provide both:

- cover letter at module 1.0.1
  - state which product/s, ARTG number/s and tradename/s have been cancelled from the ARTG
  - use the operation ‘new’
- tracking table at module 1.0.2
  - use the operation ‘replace’.

Recommended lifecycle updates

Remove documents associated with the cancelled products such as labels and PI.

Ensure that you:

- list the removed documents in the cover letter
- justify any validation warning(s) that may occur in the cover letter
- use the operation ‘delete’.

Sequence requirements

When providing the sequence:

- include the Sequence Type: **Undefined Regulatory Activity {seq-type-52}**
- include the Sequence Description: **Withdrawal {seq-desc-23}**
- use the therapeutic area prefix as the submission number (for example 'PM' for prescription medicines)
- provide the partial withdrawal sequence as a standalone sequence
- do not provide any other applications or data within this sequence
- relate the sequence to itself.

Partial withdrawal due to partial submission withdrawal

Document requirements

Provide both the:

- cover letter – use the operation 'new'
- tracking table – use the operation 'replace'.

Recommended lifecycle updates

Remove the documents associated with the withdrawal product/s such as labels and PI.

Ensure that you:

- list the removed documents in the cover letter
- justify any validation warning(s) that may occur in the cover letter
- use the operation 'delete'.

Amend documents that mention all products to remove reference for withdrawn product(s), and:

- list the amended documents in the cover letter
- include an assurance that no changes beyond removing the reference to the withdrawn product(s) have been made
- use the operation 'replace'.

Sequence requirements

When providing the sequence:

- include the Sequence Type: **Supplementary information {seq-type-45}**
- include the Sequence Description: **Withdrawal {seq-desc-23}**
- provide the partial withdrawal sequence as a standalone sequence
- do not provide any other applications or data within this sequence
- relate the sequence to the initial submission sequence.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	BSRR / PMAB / MRD	30 November 2020

Therapeutic Goods Administration

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