



Australian Government
Department of Health
Therapeutic Goods Administration

Transition to eCTD only for prescription medicines

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TGA Health Safety
Regulation

Historical consultation document

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Historical consultation document

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Purpose and scope

The purpose of this consultation is to provide an opportunity for industry, software vendors and other interested parties to comment on the proposed changes to allowable formats for prescription medicine¹ dossiers.

The proposed change to the allowable formats is one part of a broader electronic dossier reforms agenda to provide an updated electronic submissions platform that is appropriate for Australian stakeholders and observes and adopts some of the best-practice initiatives that are operating in the international environment. Providing a single, standardised dossier format forms part of this agenda.

The electronic Common Technical Document (eCTD) is the internationally recognised standard prescription medicine dossier format and as such the Therapeutic Goods Administration (TGA) is proposing a phased introduction for the mandatory use of the eCTD format for all prescription medicine dossiers.

In order to do this we need to understand the possible impacts on stakeholders. Through this consultation we seek to:

- Outline the objectives of the electronic dossier reforms being developed by the TGA, including the transition to only accepting dossiers in the eCTD format for prescription medicines;
- Outline the proposed phased transition timeframe for accepting eCTD only dossiers;
- Seek feedback on the proposed changes via the questions listed throughout the paper;
- Identify issues that might be faced by stakeholders as a result of this proposed change; and
- Use feedback received to assist with devising appropriate mechanisms to implement the proposed changes.

Background

Current dossier formats

Since 2011, the TGA has accepted medicine dossiers within an electronic format. The Non eCTD electronic Submission (NeeS) format was introduced first, followed by the eCTD format in 2015. Guidance on electronic formats released by the TGA in 2011 stated that *The NeeS format for electronic submission dossiers is an interim format and sponsors should plan to adopt the eCTD format for the lodgement of electronic submission dossiers*².

For prescription medicines, we currently expect dossiers to be submitted in either the eCTD or the NeeS format and aligning with the Common Technical Document (CTD) structure.

¹ Prescription medicine submissions relate to the registration – and subsequent variations to the registration – of human medicinal products described in Part 1 of Schedule 10 of the *Therapeutic Goods Regulations 1990*. This includes periodic safety update reports (PSURs) and active substance master files.

² Guidance – Electronic format requirements for industry for providing regulatory information March 2011 (page 5) <https://www.tga.gov.au/sites/default/files/consult-pm-nees-110321-a.pdf>

CTD

The CTD structure is a set of specifications for a dossier for the registration of medicines. It was developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and adopted by the TGA in 2004. It is a mandatory requirement that prescription medicines use this structure.

The CTD prescribes:

- the organisation of the dossier across 5 modules; and
- the order in which documents must appear so they are grouped logically and can be easily located.

This structure is internationally recognised as best practice for medicine dossiers.

eCTD

Electronic Common Technical Document (eCTD) is an electronic standard for the CTD, providing the means for transferring information from pharmaceutical companies to regulators. eCTD involves the submission of (mostly) PDF leaf documents, which are then stored in the eCTD directory structure and accessed through the XML backbone (index.xml). The files' integrity is guaranteed by the MD5 Checksum (Message-Digest algorithm 5 - a commonly used function for validating data integrity).

It is organised according to the ICH eCTD specifications and the current version of the Australian Module 1 specifications.

It is the TGA's expectation that once a dossier has been submitted in the eCTD format all subsequent submissions for that medicine will also be in eCTD.

NeeS

Non-eCTD electronic Submission (NeeS) is an alternative electronic standard to eCTD. It is used in a limited number of countries and consists of PDF files and a PDF table of contents linking all content for navigational purposes, and should be considered as a transitional stage towards the eCTD format.

NeeS differs from eCTD in that it does not contain an XML backbone or the quantity of MD5 Checksum values as defined by the ICH. It is, in essence, a collection of electronic files organised in folders and can be manually generated or compiled by publishing software.

NeeS was always envisaged to be an interim format, intended to assist with the transition from paper to the electronic format.

Other formats

Some dossiers associated with prescription medicines, such as Periodic Safety Update Reports (PSURs), minor variations and master files, are being submitted as a single PDF document rather than within the prescribed eCTD or NeeS formats. This practice is not sustainable as TGA aligns with global standards for dossier formats, and needs to utilise the data for other submissions.

Benefits of eCTD

eCTD was introduced within Australia in 2015, however it has been internationally utilised since 2003, following sign-off by the ICH Steering Committee with the purpose of standardising

dossier formats globally and making the process more efficient for sponsors and regulators. Globally regulators are dealing with increasing complexity and volumes of applications. A standardised dossier format will assist with managing the challenges associated with these complex applications. eCTD provides an opportunity to do this in collaboration with other regulators.

A recommended reading is a 2016 eCTD review article that states *Quality eCTD Submissions can save organisation money, increase the accuracy of the submission and decrease review times, giving your company a competitive advantage*³.

These benefits are stated to be:

- storing all data relating to a medicine in a single electronic location, reducing storage cost and time spent locating product data for older variations;
- use of enhanced electronic dossier management tools by regulators to search and group submissions; and
- globally streamlining dossier requirements and workflows due to consistencies across regulators³.

In 2010 a large survey viewed by 963 people was undertaken to quantify the advantages and disadvantages of eCTD compared to paper-based dossiers. This study demonstrated that although there were upfront outlays and difficulties when implementing eCTD, overall the benefits outweighed the disadvantages. For instance, there was a reduction in costs (when compared to the considerable paper dossier related costs) and substantial dossier compilation time savings once staff were adequately trained⁴.

The inherent advantages of the eCTD software were also cited, including better navigation and review, searchable and reusable content, and better lifecycle support as stated by users⁴.

Overall the literature is supportive of the eCTD format; however it acknowledges that appropriate planning, preparation and a clear knowledge of the regulatory requirements and the eCTD specifications are important elements in obtaining the benefits of eCTD.

Format functionality

eCTD and NeeS are both electronic formats that use the CTD structure, however eCTD offers enhanced functionality over NeeS including:

- lifecycle management (history of changes);
- reusing of files; and
- cross-referencing data.

This functionality assists with the efficient processing and timely evaluation of submissions.

On a weekly basis the TGA handles hundreds of submissions and a well-structured eCTD dossier which includes lifecycle management can streamline the administrative processing and

³ Raju Sama, Swarna Latha K, Sathish M, Gowthami Krishna M & Santhosh P, *Electronic Common Technical Document (eCTD): A Review of History, Benefits of Implementing, Challenges Modules, Risks Involved in eCTD Publishing and Quality Control*, International Journal of Pharmaceutical, Chemical and Biological Sciences 6(2) (2016):133-149. Page 146 for quote.

⁴ Andreas Suchanek & Herwig Ostermann, *The Electronic Common Technical Document (eCTD): An International Pro/Con Analysis of the Pharmaceutical Product Electronic Submission Process*, Drug Information Journal 46(1) (2012): 124-139.

evaluation of the dossier. The enhanced functionality and navigation ability of eCTD is particularly beneficial for the evaluation of large and complex dossiers. This makes eCTD essential for us to be able to appropriately manage large and/or concurrent submissions for a medicine, particularly where these submissions are evaluated by more than one branch.

Both NeeS and eCTD are electronically validated prior to being included on the TGA system. Our data demonstrates that the administrative burden of this receipt and validation process is greatly reduced when using eCTD as compared to NeeS.

Over a period of 4 weeks (May 2018) 27% of NeeS failed electronic validation, resulting in additional administrative work and delays to evaluation timeframes, affecting both the TGA and the sponsors involved. In the same time period, only 2% of eCTD files failed validation.

May 2018	Pass	Fail	Total
eCTD	482	10	492
NeeS	284	107	391

As the data above indicates, we experience significantly more validation errors with NeeS compared to eCTD. This may be due to the fact that some of the validation rules are difficult to manually adhere to for NeeS, for example maximum lengths for filenames.

The enhanced validation criteria supported by compilation and publication software ensures consistent structure and content of eCTD dossiers. In addition, future automation of receipt and validation will be further developed for the eCTD format by the TGA, providing enhanced certainty of receipt and uploading.

Standardised format

In addition to the inherent benefits of the format, eCTD provides a standard dossier format commonly utilised by many international regulators and more widely used than NeeS. Indeed, it is mandatory that regulators of ICH member countries utilise this format as their main dossier format (while Australia is not an ICH member country, the TGA supports the progression towards standardised dossier formats).

Moreover, using eCTD will allow for increased opportunities to collaborate and work-share with comparable overseas regulators (CORs), as described within the International Considerations section below.

Access to expedited pathways

Within Australia, only sponsors submitting in the eCTD format have access to expedited pathways such as the priority review, provisional approval, and COR report-based pathways. The increased functionality and structured dossier format of eCTD facilitates faster evaluation through enhanced navigation and reduced regulatory effort, which supports expedited approvals.

The only pathway available to Category 1 submissions provided in the NeeS format is the 'Standard' Category 1 pathway which has a target timeframe of 220 working days. The priority review pathway and COR report-based process (120-175 working days) are examples of our current expedited pathways. It should be noted that similar to the standard pathway, the provisional approval pathway has a target timeframe of 220 working days, but submission in eCTD format is mandatory.

Category 1 / COR Pathway	eCTD	NeeS	Timeframe (WDs)
Standard pathway (includes milestone 1)	Ü	Ü	255*
PPF-only pathway	Ü	Ü	255*
COR B	Ü	Ü	175*
Priority pathway	Ü	Ü	150#
Provisional pathway	Ü	Ü	255*

*Legislated timeframes

#Target timeframes

Development of proposal

NeeS was introduced with the purpose of assisting sponsors to transition from paper to an electronic dossier format. For prescription medicines the NeeS format has successfully facilitated the transition to electronic dossiers. Now, in 2018 seven years after the introduction of electronic dossiers, the TGA is proposing to phase out the NeeS format and mandate the eCTD format. This proposed transition is in agreement with information provided to industry as early as March 2011⁵.

Further, this proposal is consistent with government policy and international direction, and incorporates feedback from Australian stakeholders.

Australian sponsor considerations

Uptake of eCTD

Data from our system has been collated to show the current breakdown of NeeS and eCTD dossiers.

	NeeS		eCTD	
	2017	2018*	2017	2018*
Dossiers	51%	47%	49%	53%
Submissions	58%	52%	42%	48%

*Data until 30 April 2018

Interrogation of this data indicates that industry has supported the uptake of eCTD for the larger submissions (i.e. New Chemical and Biological Entities, Biosimilars and New Combinations), with 95% of these submitted in eCTD between 1 January 2017 and 30 April 2018.

⁵ Guidance – Electronic format requirements for industry for providing regulatory information March 2011 (page 5) <https://www.tga.gov.au/sites/default/files/consult-pm-nees-110321-a.pdf>

Generally the uptake of eCTD has been highest for the Category 1 submissions while many of the minor variations continue to be submitted in NeeS. The high volume of minor variations is reflected in the NeeS versus eCTD percentages above.

Further examination of this data shows that the usage of eCTD by global companies is much more prevalent than for small Australian-only companies and therefore many of the transition support programs will be targeted towards smaller Australian-only companies.

Industry concerns regarding cost and training

In March 2018, the TGA undertook a survey of a subset of prescription medicine sponsors, consultants and manufacturers who have submitted dossiers in the past 2 years to more clearly understand their readiness to transition to eCTD. This survey was sent to 78 stakeholders, with 53 usable responses received.

In relation to the format in which dossiers are submitted to the TGA, responses showed that the majority of those surveyed maintain some medicines in NeeS and provide newer medicines in eCTD, as shown by the data below:

- eCTD only - 15% (8/53)
- Both eCTD and NeeS - 66% (35/53)
- NeeS only - 19% (10/53)

NeeS-only respondents stated cost, workload and training needs as the major reasons for remaining in NeeS. We plan to work with this group to encourage and streamline the transition by overcoming the highlighted barriers wherever possible.

Respondents that indicated they submit in both eCTD-and-NeeS were asked what percentage of their current product range is managed in NeeS. Nine (9) stated less than 50% and 22 stated greater than 50%, with an additional 4 not providing a response.

When asked about plans to transition to eCTD-only dossiers, 16 indicated they do not have a current plan to transition to eCTD for all submissions, citing the cost, training and workload required to transition older products as the main reasons for remaining in NeeS.

In addition to this, the majority of the NeeS-and-eCTD respondents stated that older products will remain in NeeS due to the small number of minor application types submitted and for convenience, while new products will continue to be submitted in eCTD.

For those with a transition plan, the timeframes ranged from '*well underway now*' to '*in 3 years*'.

Additional concerns that were raised as part of the survey included:

- a lack of eCTD expertise in Australian companies;
- business requirements to have eCTD publishing occur at global head offices and the impact of this on response timeframes; and
- a lack of clarity on baseline requirements and the process to transition to eCTD.

Further comments on these survey results will help shape our transition support programs.

Alignment with Australian Government policy

Digital Transformation Agenda

The Digital Transformation Agenda aims to deliver simpler, clearer and faster government services. To contribute to delivering this mandate, the Department of Health created a Digital Strategy⁶.

The transition to eCTD supports this agenda by enhancing TGA's regulatory efficiencies, thus further enabling the provision of expedited market authorisation pathways.

International Engagement framework

The Department of Health has developed an International Engagement framework⁷ to position the Department to align domestic and international agendas, address shared challenges with valued partners, and provide Australian leadership where appropriate.

This is central to our international efforts, with internationally harmonised standards helping reduce regulatory burden, enhance consumer access to innovative products and services, and avoid technical barriers to trade. Regulatory cooperation will prepare Australia for the implications of increased foreign investment and the impact of product shortages, while positioning us to offer and access reliable products in a growing international market.

International considerations

Enhance international collaboration and work-sharing

The [Review of Medicines and Medical Devices Regulation](#) (MMDR) recommended that we better utilise opportunities to work-share with CORs. To facilitate this work we must align our dossier formats. Globally, CORs are transitioning to eCTD-only dossiers. Therefore, to continue and to increase our collaboration, we must also transition. Health Canada, EMA and FDA are well underway with this transition.

As an observer on the ICH M8 IWG responsible for the development and implementation of eCTD, we are currently collaborating with other regulators on the development and revision of eCTD specifications, including fixes for the current version 3.2.2 and development of the version 4.0 specifications. To continue to collaborate and comment on this important work our focus needs to be on the eCTD format.

Proposed change

Based on the information highlighted above, the TGA proposes to mandate the use of the eCTD format for all prescription medicine dossiers.

⁶ Australia's National Digital Health Strategy - <https://www.digitalhealth.gov.au/about-the-agency/publications/australias-national-digital-health-strategy>

⁷ International Engagement - Our objectives: 3. Promote evidence-based international norms and standards to support robust health systems and better health in Australia and internationally - <http://www.health.gov.au/internet/main/publishing.nsf/Content/international-engagement-our-objectives#3>

Applications included in a future eCTD requirement

- Prescription medicine application types:
 - Category 1 applications via the standard pathway
 - § New Chemical Entity
 - § New Biological Entity
 - § Biosimilar
 - § New Combination
 - § Extension of Indications
 - § Major Variation
 - § New Generic Product
 - § Minor Variation
 - § Changes to PI involving the evaluation of data
 - § Extension of Indications – Generic Product
 - Additional Trade Name
 - Category 3 – Variation involving only chemistry, quality control and manufacturing information
 - Minor Variations
 - § MEC – Changes to PI where no evaluation is required
 - § SRR – Safety Related Request with or without evaluation of data
 - § SAR – Self Assessable Request
 - § 9D(1) – Correction of a Register Entry
 - § S14 – Consent under S14 to waive compliance
 - Notifications
- Other non-applications related to prescription medicines:
 - Master Files
 - Periodic Safety Update Reports
 - Risk Management Plans

Not included in a future eCTD requirement

The following are out of the scope for filing in eCTD:

- Medical Devices
- Listed Medicines

- Designation and Determination applications

The following can be provided within the eCTD format, however filing in eCTD is not mandatory:

- Biologicals / Biological Master Files
- Clinical Trials
- Over the Counter Medicines
- Registered Complementary Medicines



1. Do you agree with the included and not included lists?

Proposed implementation strategy

Based upon data on the usage of eCTD and the numbers of submissions involved, the TGA proposes a staged approach for the transition to eCTD for prescription medicines, as outlined below.

Stage 1 – eCTD mandatory First Quarter 2019

- New Chemical Entity (NCE)
- New Biological Entity (NBE)
- Biosimilar
- New Combination Medicine

Stage 2 – eCTD mandatory 1 October 2019

- Extension of Indications
- Major Variation
- New Generic Product
- Changes to PI involving the evaluation of data

Stage 3 – eCTD mandatory 1 July 2020

- Extension of Indications – Generic Product
- Additional Trade Name
- Category 3 – Variation involving only chemistry, quality control and manufacturing information
- Minor Variations
 - MEC – Minor Editorial Change
 - SRR – Safety Related Request with or without evaluation of data

- SAR – Self Assessable Request
- 9D(1) – Correction of a Register Entry
- S14 – Consent under S14 to waive compliance
- Notifications
- Master Files
- Periodic Safety Update Reports (PSURs)

Rationale for timeline

A staged transition has been proposed as it balances the requirements of the TGA and the needs of sponsors.

The proposed transition aims to:

- allow time for an increased number of eCTD suppliers to enter the Australian market and/or current supplier to achieve economies of scale
- provide time for local affiliates to more effectively leverage eCTD resources provided by a global head office
- allow time for smaller Australian-only companies to source appropriate eCTD resources
- allow uptake of SME Assist in the transition period.

The benefits of eCTD such as enhanced navigation, searchability and lifecycle management are particularly evident when evaluating large and complex dossiers. As such the larger and/or 'more complex' application types have been included within Stages 1 and 2 to ensure the efficiencies of eCTD are incorporated where the need is greatest.

Stage 1

eCTD mandatory First Quarter 2019

95%⁸ of Stage 1 dossiers are submitted in the eCTD format.

The uptake of eCTD within applications types in Stage 1 is already very high. In addition, sponsor feedback indicates that new registrations are likely to be submitted in eCTD rather than Nees. This stage therefore presents an opportunity to confirm a full transition with minimal changes for the majority of sponsors.

Stage 2

eCTD mandatory 1 October 2019

64%¹¹ of Stage 2 dossiers are submitted in the eCTD format.

Data indicates that the majority of these sponsors already have experience submitting in eCTD with 83% having submitted at least one eCTD dossier to the TGA. Meaning, many of these

⁸ Data from 1 January 2017 to 30 April 2018

sponsors already have some knowledge of and infrastructure for eCTD available, even though not all of their submissions are in the eCTD format.

Stage 3

eCTD mandatory across all applications 1 July 2020

41%¹¹ of Stage 3 dossiers are submitted in the eCTD format.

Stakeholders have indicated via survey responses that older products for which only minor amendments are undertaken will continue to be submitted in NeeS. The data reflects this, with 51% of category 3 and 25% of section 9D changes submitted in eCTD.

Acknowledging the lower uptake of eCTD within this group, the proposed transition plan allows greater time for sponsors submitting in NeeS-only to implement an appropriate system to manage eCTD moving forward.



1. Do you support the staged approach?
2. Do you support the timing of the stages?

Implications

The potential mandating of the eCTD format presents an additional activity for those sponsors who still submit using the NeeS format.

Resources and training

Considering that, currently, only 48% of submissions are submitted in eCTD, the mandating of the eCTD format within Australia over the next two years is likely to increase the demand for:

- publication software;
- training; and
- publication services.

Stakeholders within the software publication industry should give due consideration to this.

There will also be increased demand for resources from global publishing centres. Australia mandating eCTD creates an opportunity for local affiliates to engage with publishing houses and global head offices to discuss requirements.

Cost

The cost of eCTD publishing software has been reported by sponsors as a barrier to adopting the eCTD format.

There are a number of options and price points available in the Australian and international markets and the most cost effective method to implement eCTD will depend on each company's unique requirements.

For example, a small Australian company submitting between 0 to 3 minor submissions to the TGA each year may determine that it is more cost and time effective to outsource eCTD

publishing to an eCTD consultant. While a slightly larger company submitting more than 10 submissions to the TGA each year may decide to invest in eCTD publishing software and the associated training.

Considerations should be given to the different eCTD options and which product type aligns with your business requirements.

Managing older products - baselines

A baseline is the resubmission of currently valid documents that have previously been provided to the TGA in another format such as NeeS or paper.

Baselines are not mandatory when transitioning to eCTD, however they are useful to collate all the information associated with a product. Baselines or partial baselines can be submitted at any time during the product lifecycle and should not be a hurdle for transition to eCTD.



1. Please outline any additional hurdles and also strategies to mitigate these hurdles.

Proposed transitional arrangements

Education

In order to foster greater understanding of eCTD, we plan to undertake:

- A sponsor education and awareness program on the strategies and benefits of transitioning to the eCTD format, including information on baselines and the best ways to transition older products;
- Updates to eCTD guidance on the TGA website;
- Presentations on the transition program at a range of conferences and meetings; and
- Engagement with SME Assist to provide support.

Collaboration

To ensure that the transition to eCTD formatted dossiers is smooth, we will be seeking input from industry and vendors along the way, facilitated via:

- Working groups / meetings; and
- Vendor presentations.

Advice

To assist with specific issues in transitioning to eCTD, we will be available for pre-eCTD transition meetings to discuss transition plans and technical issues. We will also accept test dossiers from sponsors with limited eCTD experience.



1. Are there any other tools or services the TGA could provide to assist with the transition?

Additional reforms

Moving all prescription medicine application types to an eCTD format will allow us to develop further enhancements to the dossier submission process including:

- Updates to the regional Australian specifications;
- Dossier submission gateway; and
- Implementation of ICH eCTD version 4.0.

Significant collaboration with industry will be needed to deliver these reforms.

As Australian sponsors and the TGA obtain a greater understanding of the efficiencies of eCTD, further enhancements to the regional specifications are needed. The TGA is proposing to amend the Australian regional specifications in 2019 to:

- align more closely with the prescription medicine application types; and
- allow further automation of processing steps.

In addition to specification updates, the TGA is also planning work on the electronic submission gateway. The gateway will allow sponsors to upload dossiers rather than provide them via email or on CD. The web gateway will be connected to our validator and dossier management system, allowing the dossier to be automatically validated and uploaded to our system at any time. The eCTD format, with the XML backbone and envelope will allow the data to be forwarded directly to the relevant TGA section, significantly reducing the administration processing time.

This work is also preparing Australia for our transition to the ICH version 4.0 eCTD specifications, which will feature enhanced functionality over version 3.2.2. Based on the initial proposed timeline, the TGA will begin a transition period in late 2020, following other CORs. To ensure harmonisation and global collaboration, it is important that Australia progresses to eCTD version 4.0 in a similar timeframe to ICH members. The timeframe for transition to eCTD-formatted dossiers has been determined with eCTD version 4.0 in mind.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Prescription Medicines Authorisation Branch	October 2018
V1.1	Amended Stage 1 Implementation Date	Prescription Medicines Authorisation Branch	October 2018

Historical consultation document

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