



TH eCTD Specification

Module 1 and Regional Information

Version 0.92.1, Aug 2015

About the Food and Drug Administration Thailand - Bureau of Drug Control

- The Bureau of Drug Control has set a vision as an institute with reliability and good reputation in consumer protection. The public is thus assured of accessibility to safe and efficacious marketed pharmaceutical products of standard quality, to reliable and adequate information, and to advance technology. The Bureau promotes the production capacity of local pharmaceutical industries to the extent that they are able to export medicines of standard quality.
- The Bureau carries out its mission in consultation or cooperation with experts in science, medicine, pharmacy and public health, consumers, manufacturers, importers, distributors and retailers of drugs. It works closely with several other organizations (e.g. universities, industries, hospitals, health-care professional groups, consumer groups, other relevant agencies and foreign governments) in the drug development and review processes.

Version History

Version	Description of change	Working Group	Effective date
V0.90	Original draft publication for pilot implementation and industry review	Mr. Piya Chinmanee Wong Senior Pharmacist, Division of Pre-marketing Control Ms. Anchalee Jitruknatee Senior Pharmacist and Chief Drug IT Administrator	01/07/2014
V0.91	Inconsistencies with Schema updated. Updated Heading 1.3.1.3.3.1	Mr. Piya Chinmanee Wong Senior Pharmacist, Division of Pre-marketing Control Ms. Anchalee Jitruknatee Senior Pharmacist and Chief Drug IT Administrator	07/08/2014
V0.92	Update format of eSubmission Identifier Require document in Business Protocol	Mr. Piya Chinmanee Wong Senior Pharmacist, Division of Pre-marketing Control Ms. Anchalee Jitruknatee Senior Pharmacist and Chief Drug IT Administrator	07/10/2014
V0.92.1	Remove draft watermark and change in Introduction:Background	Ms. Anchalee Jitruknatee Pharmacist, Senior Professional Level and eCTD Project Manager Mr. Kritsada Limpananont Pharmacist, Professional Level and eCTD Project Deputy Manager	03/08/2015

Change Control

The TH regional specification is likely to change with time. After the initial implementation and pilot, it is expected that an update will be made to finalise the specifications based on internal and industry feedback. Additional factors that could affect the content of the specification include, but are not limited to:

- Change in the content of the Module 1 for the CTD, either through the amendment of information at the same level of detail, or by provision of more detailed definition of content and structure
- Change to the regional requirements for applications that are outside the scope of the CTD
- Update of standards that are already in use within the eCTD
- Identification of new standards that provide additional value for the creation and/or usage of the eCTD
- Identification of new functional requirements
- Experience of use of the eCTD by all parties, in particular Module 1

Feedback is welcome and encouraged. Please send any comments or questions to drug_esubmission@fda.moph.go.th . Common questions will be compiled into a Question and Answer document and updated as necessary <http://drug.fda.moph.go.th/eng> Subscribe to the eSubmission Update email list to receive notifications when the Question and Answers pages are updated.

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1. Glossary of Terms

Term	Definition
Application	The term Application is used for THAI FDA's medicine registration process and is the top group of a series of sequences for the same product (e.g. active ingredient). One Application is usually defined for the complete life cycle of the specific product.
eCTD	Electronic Common Technical Document – an electronic standard for the Common Technical Document (CTD) providing the means for transferring information from pharmaceutical companies to agencies.
Dossier	A collection of files and documents that contains data (administrative, quality, nonclinical and clinical) relating to a therapeutic good.
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICH E3	ICH Harmonised Tripartate Guidance Structure and Content of Clinical Study Reports
Leaf	Structural element delivering a document. It provides the link information to the document along with the title associated with the linked content.
Node Extensions	Additional heading structures beyond those defined by the specifications – generally equated to an additional subfolder in a defined section.
Regulatory Activity	The term Regulatory Activity is a subgroup of an Application which can be a group or series of related sequences for one approval process (e.g. one variation) One Regulatory Activity is usually defined for the lifecycle of the specific approval process.
RPS	Regulated Product Submission Release 1 (RPS) is a Health Level Seven (HL7) standard to facilitate the processing and review of regulated product information. It is the standard for the next eCTD version titled ICH eCTD v4.0.
Sequence	A sequence is a package of information bundled together in an electronic structure providing information to the agency. The contents of a sequence will depend on the regulatory activity type and whether it is the initial sequence of the regulatory activity or a follow-up providing additional data or changes.
Submission	Generic term that can refer to an application, a regulatory activity type and/or a sequence. Often used when not referring specifically to a particular hierarchical level of the application. The THAI FDA recognises that this definition differs from the legal definitions used under Thai law. This definition will be applied to this and related documents.
W3C	World Wide Web Consortium – international standards organization for the world wide web.

2. Introduction

This document specifies Module 1 and the regional information of 2.3.R and 3.2.R of the electronic Common Technical Document (eCTD) for Thailand (TH).

This document should be read together with the ICH eCTD Specification to prepare a valid eCTD submission for Thailand. The latest version of the ICH eCTD Specification can be found at: <http://www.ich.org/products/electronic-standards.html>.

In line with desires to create a structure friendly to harmonization with other regions, much of this guidance has been modelled from the Canadian and European guidance on creating an eCTD. Large portions of the text are based on explanations given in those documents which can be found in the [Reference](#) section of this document.

The EU structure is being used as a proven structure and to increase reusability from applications already submitted in the EU region. Additional documents required by Thailand but not covered by the EU structure and not specifically addressed by this document will be added to section 1.A Additional Data.

Policy Objective

The objective is to ensure sponsors have access to all the information needed to provide a dossier to the THAI FDA in the eCTD format.

Policy Statement

This document outlines the creation of a regional backbone file according to the Thai Module 1 schema. This backbone file is to be used in the preparation and filing of medicine regulatory transactions in eCTD format established by the International Conference on Harmonisation (ICH).

Scope and Application

This document applies to all regulatory activities relating to medicines and being provided to the THAI FDA in eCTD format. Additional guidance documents that can or are meant to be read in conjunction with this guidance are listed in the [Reference](#) section.

Background

Given the desire to adopt the eCTD v4.0 / Regulated Product Submissions (RPS) in the foreseeable future, the decision has been made to move to a World Wide Web Consortium (W3C) Schema approach to define the new Module 1.

This specification will change over time. Future changes will be accompanied by a well thought out introduction to minimize the impact on industry and introduced at scheduled intervals to allow stability.

The version of this document is to be considered as an approved version to accompany the official acceptance of eCTD which intent to replace paper applications.

3. Business Protocol

Obtaining the eSubmission Identifier

Prior to filing the first regulatory transaction for an application in an electronic format, the applicant should submit a request to the THAI FDA online service to obtain an eSubmission identifier.

If the applicant wishes to provide single dossiers for the same active ingredient, dosage form and therapeutic group but has more than one strength, only one eSubmission identifier will be issued to cover all strengths.

A request for an eSubmission identifier should be made via website (THAI FDA e-logistic data base). The request will require the following information:

- Licensee Number
- Description of Application.
- Dosage Form
- INN or Generic Name
- Strength
- WHO ATC Code
- Sequence Type
- Application form
- CPP (In case of Importer)

The eSubmission Identifier will be issued within 10 days of application. The Applicant must check on the THAI FDA online service for a response informing them of their eSubmission Identifier. After receiving the identifier, the Applicant must then make an appointment for submission within 30 days.

The Cover Letter as Transmission Letter

A paper copy of the cover letter should be included with the submission to serve as a transmission letter.

The cover letter should include:

- The eSubmission identifier in the subject line;
- A description of the electronic submission including type and number of electronic media, approximate submission size, and if appropriate, characteristics concerning the media;
- A statement that the submission is virus free with a description of the software used to check the files for viruses;
- The regulatory and information technology points of contact for the submission; and
- A reference to the validation report, an indication of which validation tool and version was used as well as a statement addressing any issues found in the accompanying validation report.

The letter should not contain any scientific information. Responses to questions raised by THAI FDA should not be included in the cover letter, since they have been assigned a specific location in Module 1.R.

The paper copy of the cover letter will not be needed once the THAI FDA has a portal for the secure electronic transmission of data in place.

Validation Report

An electronic copy of the validation report created should be submitted. A folder should be created in the application folder named after the eSubmission identifier with the naming

convention of the sequence number followed by validation-report e.g. “0000-validation-report”. The validation report should be limited to only items listed in the validation criteria, additional checks should not be included.

Expected Structure of Submitted Media

Content should be submitted in an application folder named after the eSubmission identifier. The sequence folder and its contents should be placed in this application folder. If an application is too large and must be split and submitted on multiple items e.g. DVDs, the overall folder structure should be included on each media so that content can be easily merged.

Media Formats

The media formats acceptable when submitting an eCTD regulatory activity are:

- Compact Disc-Recordable (CD-R) conforming to the Joliet specification;
- Digital Versatile Disc-Random Access Memory (DVD-RAM) Universal Disc Format (UDF) standard;
- Digital Versatile Disc-Recordable (DVD+R/-R) recorded in the Universal Disc Format (UDF) standard;

Ensure that you do not use:

- double-sided discs,
- rewritable discs (protection, authenticity, and stability of information cannot be guaranteed),
- compressed or zipped files (except for validation reports).

Delivery of the eCTD Application

The Applicant will need to make an appointment and deliver the application personally at the Division of Policy System Development. The eCTD will be validated and imported into the THAI FDA Review System together with the applicant. Once accepted and submitted, the applicant will be given back their media to keep.

Feedback on Validation of Application

THAI FDA will inform applicants if there are problems experienced during the upload of an eCTD sequence during the appointment.

4. TH Regional Information

4.1. Regional Content

4.1.1. Module 1 Administrative and Prescribing Information

The ICH Common Technical Document (CTD) specifies that Module 1 should contain region-specific administrative and product information. The content and numbering of Module 1 for Thailand is modelled after the EU Module 1 content as described in the 2008 version of the [Notice to Applicants](#). Additional documents specifically required by Thailand not covered by the EU structure will be added to 1.A Additional Data.

The following items listed in the Notice to Applicants may be included for an initial submission:

- a cover letter,
- an application form(Form MA-1) ,
- product information documents,
- information on the experts (optional),
- specific requirements for different types of applications (if required),
- an environmental risk assessment,
- information relating to pharmacovigilance (optional),
- information relating to clinical trials (optional),
- information relating to paediatrics (optional).

In addition, other items such as answers to regulatory questions and rationale for variations documentation could also be included in Module 1.

It should be noted, that for subsequent submissions in the lifecycle of a medicinal product, e.g. for a variation, not all of the above mentioned types of document need to be included in Module 1. Consult the various legal documents for guidance on the exact documents to be submitted in such a case.

4.1.2. Module 2.3.R & 3.2.R Regional Information

2.3.R Regional Information

A brief description of the information specific to the region, as provided under 3.2.R should be included, where appropriate.

3.2.R Regional Information

Any additional drug substance and/or drug product information specific to the region should be provided in section 3.2.R of the application.

Where similar or relevant information has been provided in another section of Module 3 or where there is supporting or related information from other modules of the application, the applicant is encouraged to clearly cross-reference to the location of that information. Cross-referencing should be sufficiently detailed, so as to allow the appropriate information to be easily located within the dossier.

Applicants should include the following information in Module 3.2.R, where appropriate:

- Process validation scheme for the drug product
- Certificates of suitability
- Medical Device
- Supplier's declarations regarding compliance with packaging standards and colouring standards.

4.1.3. Node Extensions

Node extensions are a way of providing extra organisational information to the eCTD. The node extension should be visualised as an extra heading in the CTD structure and should be displayed as such when the XML backbone is viewed.

Consideration should be given regarding the impact of changing node extension structures during the lifecycle as this can lead to a higher level of complexity in the cumulative view of a submission.

The following rules govern the use of node extensions for TH:

- Node extensions must not be used where ICH-specified sub-headings already exist e.g. indication, manufacturer, drug substance, and drug product are all-ICH specified node extensions.
- Node extensions must only be used at the lowest level of the eCTD structure e.g. a node extension can be used at the level 5.3.5.1 but is not allowed at the level 5.3.
- Node extensions are mainly to be used to group together documents made up of multiple leaf elements e.g. a clinical study made up of separate files for the synopsis, main body and individual appendices could be grouped together under a node extension with the Study Identifier as its Title attribute.
- Node extensions may be nested as this is allowed by the eCTD DTD. However, as noted in Bullet 2, the first node extension must be at the lowest level in the eCTD structure e.g. in Module 5.3.7 a node extension may be added to group together files with the Study Identifier as Title attribute. Further node extensions may be added as children of the Study Identifier node, separating Case Report Forms (CRFs), if submitted, from individual patient listings.
- The content associated with a node extension can be placed in a separate sub folder in the submission; this is recommended for studies in Module 5 where study reports are provided as multiple files. However, there is no specific requirement for an additional subfolder.

4.1.4. Study Tagging Files

The THAI FDA does not currently have any plans to mandate study tagging files (STFs) for evaluation purposes however applicants wishing to re-use content submitted in other regions where STFs have been used can do so. If provided, STFs will be validated and must be conform to standards and [specifications](#). Also, data pertaining to the number and size of [ICH E3 16.3 CRFs](#) and non ICH E3 documents will be collected for informational purposes.

4.2. Regional File Formats

4.2.1. Module 1

In addition to the common format PDF, as defined by the [ICH eCTD Specification Document](#), XML will also be accepted whenever a structured exchange standard exists for the content. Currently there are no structured exchange standards for content, however it is expected that these may be introduced in the future for content such as the tracking table, application forms, etc.

Note that all PDF files included in an eCTD irrespective of the module should be v1.4, v1.5, v1.6 or v1.7 except where a specific requirement for a later version is defined (see [ICH Q&A](#) for further details regarding PDF version acceptability).

It is preferred that PDFs be generated from an electronic source. Signatures may be embedded as a graphic file in the PDF text if desired.

4.2.2. Modules 2 to 5

No additional file formats are defined for Modules 2 to 5 other than those mentioned in the [ICH eCTD Specification Document](#).

4.3. Use of Electronic Signatures

The use of advanced electronic signatures e.g. digital signatures, will be crucial in achieving pure electronic communication between the pharmaceutical industry and regulatory agencies, particularly for authentication of electronic submissions and documents contained therein. Currently the use of digital signatures for electronic submissions is not fully supported within the THAI FDA. Digital signatures can be used but only as an adjunct to any required written signatures. Scanned signatures would ordinarily be used where the documents make up part of the checksum of an eCTD submission.

4.4. Handling of Empty or Missing eCTD Sections

For new applications, including generic applications, detailed statements justifying the absence of data or specific CTD sections should be provided in the relevant Quality Overall Summary and/or Nonclinical/Clinical Overviews e.g. Module 2.3, 2.4, or 2.5. Note that placeholder documents highlighting no relevant content should not be placed in the eCTD structure. Such documents would create a document lifecycle for non-existent documents causing unnecessary complications and maintenance of the eCTD submissions.

For a generic application, there is no need to provide a justification for content that is typically absent.

4.5. Updating Backbone Attributes/Metadata

4.5.1. Updating ICH Attributes

Updating XML backbone attributes such as manufacturer during the eCTD lifecycle is possible, however, consideration should be given regarding the impact of changing backbone attributes during the lifecycle as this can lead to a higher level of complexity in the cumulative view of a submission.

4.5.2. Updating TH Envelope Information

The TH envelope information can be updated during the lifecycle as is necessary to reflect changes in the application metadata e.g. adding and removing duplicate product names.

4.6. Bookmarks, TOCs and Hyperlinks

The evaluation process is made more efficient if content documents are prepared in such a manner that will aid the assessor to quickly and effectively locate content. The navigation through PDF documents is made easier, especially in larger documents, if bookmarks and/or TOCs are made available to quickly access information within the document. Based on experience in other regions, the THAI FDA recommends that documents with more than five pages and with multiple sections should provide a Table of Contents, and/or if appropriate, a Table of Table, Table of Figures, etc. on the first page of the document to ease further navigation through the document.

Hyperlinks are recommended when they would aid the evaluation in ways not already possible through the use of the eCTD index.xml and document navigation aids (bookmarks and TOCs). Applicants should consider when creating cross document hyperlinks that they can cause confusion later in lifecycle and therefore be distracting for an efficient review.

For more information on creating bookmarks and hyperlinks in PDF documents, please refer to Appendix 7 in the [ICH eCTD Specifications](#).

4.7. File Reuse

As prescribed in the Appendix 6 of the [ICH eCTD Specifications](#), the THAI FDA accepts and encourages applicants to make active use of file reuse. Applicants should not submit the same document multiple times. File reuse should be used when a file is submitted multiple times within one sequence, a file already submitted in an earlier sequence is being referenced again or if a file submitted in another application is being referenced in a new application.

Please note that the THAI FDA is implementing a flat repository structure to make cross application referencing possible. Links to content provided in other applications simply need to be directed out of the current application structure and into the structure of the corresponding application. Both the source and target applications should be in the same folder on the same level when references are created. All application will be stored using the eSubmission Identifier to make cross referencing easily predictable and possible.

5. TH Module 1 General Architecture

5.1. The Thai Module 1 Backbone File

The Thai Module 1 eCTD backbone file comprises three main components:

- A fixed eXtensible Markup Language (XML) root element;
- The envelope elements; and
- The eCTD heading elements describing the actual files provided.

Creating the Module 1 eCTD Backbone File

To create the Thai Module 1 backbone file for a given sequence:

1. Create an XML file with the appropriate XML declaration using an authenticated eCTD preparation software. See [The XML Root Element](#) below.
2. Create an envelope with elements containing the appropriate metadata values describing this sequence. See the [The Envelope Elements](#) below.
3. Create heading elements as needed for this sequence, as described in the [The Heading Elements](#) below. These elements will be of two broad types:
 - Heading elements, organizing the content in the Module 1 to meet the THAI FDA's review requirements.
 - Leaf elements, providing a file system reference to each file being submitted in the regulatory transaction as part of Module 1, along with other information such as eCTD check-sum and life-cycle information.
4. Name the Thai Module 1 eCTD backbone file th-regional.xml and place it in the th subfolder within the Module 1 i.e. m1 subfolder of the regulatory transaction.
5. Validate the resulting backbone using a suitable eCTD validation tool.

Style-Sheets

The TH Module 1 is provided with a standard style-sheet that is used to view content. Note that the style-sheet has been designed to display the complete Module 1 table of contents i.e. all sections, irrespective of whether files are actually present in those sections or not. The style-sheet is provided so that content in Module 1 can be opened using a browser by the applicant, the THAI FDA will not be using it to review content.

5.2. The XML Root Element

All Thai Module 1 backbone files prepared for the THAI FDA will contain the standard XML root element. Note that the required text includes an XML declaration and the root element `th_ectd` with its attributes linking this XML file to the XML definition prepared by the THAI FDA. The line breaks inside of the `th_ectd` element as shown in the excerpts below are not mandatory.

```
<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet href="../../../util/style/th-regional.xsl" type="text/xsl"?>
<th_ectd xmlns="th_ectd"
  xmlns:xlink="http://www.w3.org/1999/xlink"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  schema-version="0.92"
  xsi:schemaLocation="th_ectd ../../../util/dtd/th-regional.xsd">
```

5.3. The Envelope Elements

XML Element	Description	Constraint	Occurrence	Defined Values
esub-id	eSubmission Identifier	Mandatory	Single	
seq-type	Sequence Type	Mandatory	Single	X
reg-activity-lead	Regulatory Activity Lead	Mandatory	Single	X
licensee	Licensee	Mandatory	Single	
inn	INN or Generic Name	Mandatory	Multiple	
product-name	Product Name	Mandatory	Multiple	
sequence	Sequence Number	Mandatory	Single	
related-sequence	Related Sequence Number	Optional	Single	
seq-description	Sequence Description	Mandatory	Single	

eSubmission Identifier

Prior to submitting the first sequence of an eCTD, an eSubmission Identifier must be assigned. This is done by following the steps described in the Business protocol section of this document. The identifier must be entered as assigned in the envelope and should also to be used as the name for the application folder in which the sequence folders are submitted. The identifier is made up of a letter and seven digits.

Example: e1234567

Sequence Type

Identifies the type of activity that is being submitted with the sequence, either the regulatory activity type if it is the first sequence of the regulatory activity or supplementary information if it is a follow-up to information already submitted for the regulatory activity.

Example: A : Pharmaceuticals - New Chemical Entity

Sequence Type	
List Value	Description
a-ph-newce	A: Pharmaceuticals - New Chemical Entity
a-ph-newse	A: Pharmaceuticals - New Salt or Ester of Existing Active Ingredient
a-ph-newdosage	A: Pharmaceuticals - New Dosage Form
a-ph-newroute	A: Pharmaceuticals - New Route of Administration
a-ph-newcomb	A: Pharmaceuticals - New Combination
a-ph-newothers	A: Pharmaceuticals - New Medicinal Product (Others)
a-ph-newgen	A: Pharmaceuticals - New Generic
a-ph-generic	A: Pharmaceuticals - Generic
a-ph-house	A: House Hold Remedies
b-bio-vaccine	B: Biologics - Vaccine
b-bio-blood	B: Biologics - Blood and Plasma Derived Product
b-bio-cell	B: Biologics - Cell- and Tissue- Based Therapy Product
b-bio-biotech	B: Biologics - Biotechnology Product
b-bio-biosimilar	B: Biologics - Biosimilar Product
b-bio-others	B: Biologics - Others
c-vet-newprod	C: Veterinary - New Medicinal Product
c-vet-newgeneric	C: Veterinary - New Generic Medicinal Product
c-vet-generic	C: Veterinary - Generic Medicinal Product
c-vet-premixed	C: Veterinary - Medicated Premixed
c-vet-bio	C: Veterinary - Biologics
d-traditional	D: Traditional Medicinal Product
f-var-major	F: Variation - Major Variation (MaV)
f-var-minor-pa	F: Variation - Minor Variation (MiV-PA)
f-var-minor-n	F: Variation - Minor Variation (MiV-N)
f-var-others	F: Variation - Others
g-clin-authapp	G: Clinical Trial Authorization Application
g-clin-authamend	G: Clinical Trial Authorization Amendments
h-review-smph	H: Review of SMP Application
h-riskmgtplan	H: Risk Management Plan
h-pv	H: Pharmacovigilance
h-psur	H: Periodic Safety Update Report
i-dmf	I: Drug Master Files
i-pmf	I: Plasma Master Files
i-vamf	I: Vaccine Antigen Master File
i-tmf	I: Tissue Master File
j-suppl	J: Supplementary Information
k-orphan	K: Orphan Drug Application
k-emergency	K: Emergency Used Application
z-undefined-regact	Z: Undefined Regulatory Activity

Regulatory Activity Lead

Identifies the group within the THAI FDA which is expected to take the lead in the review process.

Example: pharma

Defined Values	Description
Biologicals	Biological Product Review
Pharmaceuticals	Pharmaceutical Product Review
Pharmacovigilance	Pharmacovigilance Review

Licensee

The licensee name that is legally responsible for the application in Thailand. The official registered name of the company should be provided.

Example: Pharma Inc.

INN or Generic Name

The INN or Generic Name of the active ingredients used in the product.

Example: amoxicillin

Product Name

The name or proposed product (trade) name(s) to be used on the Certificate of Registration. If duplicate products are being submitted within one application, all products should be listed.

Example: incrediPill

Sequence Number

Four digit sequence number matching the sequence folder being submitted.

Example: 0000

Related Sequence Number

Four digit sequence number used for supplementary information indicating the initial sequence number of the regulatory activity.

Example: 0000

Sequence Description

The sequence description is used to provide a free text description of the submission. The description provided here should also be used in the node title for 1.0 Cover Letter and 1.R Response to Questions. It is encouraged that applicants provide a short, precise but informative description. It should not repeat information provided in the Sequence Type attribute but rather provide additional clarification to information being submitted. The list below provides a few examples for such a field:

- Initial Application: Initial Application
- Response: Response to LOQ dated 2014-06-13
- Response: Response to Validation Questions
- Response: Providing Quality Supplementary Information

5.4. The Heading Elements

The Thai Module 1 headings are based on the headings from the [EU specifications](#) (version 2.0). Additional structure has been added to some sections to better meet Thai requirements. In particular, an element has been specified for the tracking table, specific elements for the labelling, SPC and Package Leaflet as well as two additional elements for the Specific Requirements for Different Types of Applications. Some sections have been deemed not applicable while others have been designated as optional.

Content should be provided as leaf-nodes. The leaf-node element can be comprised of one or multiple leaf elements and/or node-extensions. Titles for the leaf-nodes should be descriptive and helpful for identifying the content and does not need to repeat information in the parent structure. In the following description of the heading elements, the leaf-node has been added where specific leaf title recommendations exist. Where the leaf-node is not specified, it is up to the applicant to provide an appropriate description of the content in the leaf title.

1.0 Cover Letter and Tracking Table

Section ID	Business Terminology	XML-Element
1.0	Cover	m1-0-cover
1.0.1	Tracking Table	m1-0-1-tracking
1.0.2	Cover Letter	m1-0-2-cover-letter

During lifecycle, the cover letter should always be submitted with the lifecycle operator new and the tracking table should be submitted with the lifecycle operator replace.

The suggested naming convention for the cover letter leaf title is the sequence number followed by the sequence description as provided in the envelope e.g. “0000 Initial Application”.

1.2 Application Form

Section ID	Business Terminology	XML-Element
1.2	Application Forms	m1-2-forms
1.2.1	Application Form	m1-2-1-form
1.2.1.1	<Sequence Number> <Description>	leaf-node
1.2.2	Annexes	m1-2-2-annexes
1.2.2.1	<Sequence Number> <Description of Annex>	leaf-node

During lifecycle, the application form should normally be submitted with the lifecycle operator new unless under rare occasions a correction to an application form already submitted is being provided in which case, replace can be used.

The application form should be placed under 1.2.1 and the suggested naming convention for the leaf title is the sequence number followed by a description of the file being submitted e.g. “0000 Application Form New Generic”.

Any annexes to be provided e.g. declaration documents from the applicant including Proxy Letter, Letter of Authorization, and Certificates such as CPP CFS and GMP should be provided under 1.2.2 and the suggested naming convention for the leaf title is the sequence number followed by a brief, precise and recognizable identification of the Annex content.

1.3 Product Information

Section ID	Business Terminology	XML-Element
1.3	Product Information	m1-3-pi
1.3.1	SPC, Labelling and Package Leaflet	m1-3-1-spc-label-pl
1.3.1.1	Labelling	m1-3-1-1-label
1.3.1.1.1	<Description of Labelling>	leaf-node
1.3.1.2	SPC	m1-3-1-2-spc
1.3.1.3	Package Leaflet	m1-3-1-3-pl
1.3.1.3.1	Package Leaflet - Thai	m1-3-1-3-pl-th
1.3.1.3.2	Package Leaflet - English	m1-3-1-3-pl-en
1.3.1.3.3	Package Leaflet - Other Language	m1-3-1-3-pl-ot
1.3.1.3.3.1	<Language> <Description>	leaf-node
1.3.2	Mock-up	m1-3-2-mockup
1.3.3	Specimen	m1-3-3-specimen
1.3.4	Consultation with Target Patient Groups	m1-3-4-consultation
1.3.5	Product Information already approved in Other States	m1-3-5-approved
1.3.5.1	Foreign Regulatory Status	m1-3-5-1-status
1.3.5.2	Foreign Product Information	m1-3-5-2-pi
1.3.5.2.1	<Country> <Product Information Type>	leaf-node
1.3.5.3	Data Similarities and Differences	m1-3-5-3-similarities
1.3.6	Braille	m1-3-6-braille

The Product Information should be provided in PDF format within the eCTD. Working documents are not needed and do not need to be provided within the eCTD framework for Thailand.

The Product Information section for Thailand reflects a more granular and defined approach than that of the EU specifications. Both the sections for Product Information and the Product Information already approved in other Countries have been expanded to define the product information type and languages expected as well as a breakdown of the type of information wanted where the product information has already been approved in other countries.

1.3.1 Product Information has been broken down into three specific sections for Labelling, SPC and the Package leaflet. No other product types are expected. If one file is submitted for this section, it should be submitted under 1.3.1.1 Labelling.

The leaf title provided for 1.3.1.1 Labelling should describe the labelling that is being provided. Multiple documents can be provided or all information can be combined in one document.

1.3.1.3 Package Leaflet has been broken down into language sections for English, Thai and Other languages and it is recommended that separate files be submitted for each language.

1.3.4 Consultation with Target Patient Groups is not required for Thai applications but can be provided.

1.3.5 Product Information already approved in other Countries has been broken down into three sections. One file should be provided for the Foreign Regulatory Status as a tabular summary. During the lifecycle, the status should always use the operator replace. Details of Foreign Product Information should be provided, especially if already approved in ASEAN, EU, US, Canada, Australia or PIC/S regulated countries. The leaf title provided for 1.3.5.2 should indicate the originating country and product information type being provided. Data Similarities and Differences should be provided using the THAI FDA form. During the lifecycle, the Data Similarities and Differences file should always use the operator replace.

1.3.6 Braille should be an option but should be provided if braille is to be used in the production information and packaging.

1.4 Information about the Experts

Section ID	Business Terminology	XML-Element
1.4	Information about the Experts	m1-4-expert
1.4.1	Quality	m1-4-1-quality
1.4.2	Non-Clinical	m1-4-2-non-clinical
1.4.3	Clinical	m1-4-3-clinical

Section 1.4 is optional. It can be provided but is not required for Thai applications.

1.5 Specific Requirements for Different Types of Applications

Section ID	Business Terminology	XML-Element
1.5	Specific Requirements for Different Types of Applications	m1-5-specific
1.5.1	Information for Bibliographical Applications	m1-5-1-bibliographic
1.5.2	Information for Generic, 'Hybrid' or Bio-similar Applications	m1-5-2-generic-hybrid-bio-similar
1.5.2.1	Information for Generic Application	m1-5-2-1-generic
1.5.2.2	Information for 'Hybrid' Applications	m1-5-2-2-hybrid
1.5.2.3	Information for Bio-similar Applications	m1-5-2-3-bio-similar
1.5.3	(Extended) Data/Market Exclusivity	m1-5-3-data-market-exclusivity
1.5.4	Exceptional Circumstances	m1-5-4-exceptional-circumstances
1.5.5	Conditional Marketing Authorisation	m1-5-5-conditional-ma
1.5.6	Additional Trade Name Declarations	m1-5-6-trade-name
1.5.7	Co-marketed Medicines Declarations	m1-5-7-co-marketed

This section has been taken from the EU structure and additional types of applications have been added. Section 1.5.2 has been broken down into three sections and given a section number to make expectations and cross referencing clearer.

Section 1.5.6 should be included when the application seeks the registration of an additional trade name for an existing registered prescription medicine. This may be either:

- a stand-alone additional trade name application
- in combination with other application types

For example, an extension of indications in addition to the additional trade name.

Please note that trade names are to:

- identify the products within a range of dose forms and strengths
- include distinguishing letters so they are not confused with those already in the Thai Register of Medicinal Product
- identify the strengths of the active ingredients in the trade name for fixed combinations.

The trade names proposed must not:

- be registered already (unless a further identifier is proposed)
- be inappropriate (for example, must not be advertorial)
- look or sound like other trade names (potential to cause prescribing and dispensing errors).

Section 1.5.7 should be included when:

- a cross-licensing agreement exists between the applicant of the application and a third party applicant
- the third party sponsor authorises the THAI FDA to use information on its product (that is either on the Thai Register of Medicinal Product or under evaluation) for the benefit of the first party's application
- the applicant's product will be identical or very similar to the third-party's product

Please note that you must ensure the third party has lodged their data before lodging the application. Failure to provide the third party's data may result in an application being considered not effective.

To avoid delays in evaluating the application, requests to make corrections or variations to the Thai Register of Medicinal Product entry for the third party's already registered product must be submitted to the THAI FDA well in advance of lodging the co-marketed medicine application.

1.6 Environmental Risk Assessment

Section ID	Business Terminology	XML-Element
1.6	Environmental Risk Assessment	m1-6-environrisk
1.6.1	Non-GMO	m1-6-1-non-gmo
1.6.2	GMO	m1-6-2-gmo

Only one file should be provided for 1.6 Environmental Risk Assessment. It is not allowed to provide content in both 1.6.1 and 1.6.2.

1.7 Information relating to Orphan Market Exclusivity

Section ID	Business Terminology	XML-Element
1.7	Information relating to Orphan Market Exclusivity	m1-7-orphan
1.7.1	Similarity	m1-7-1-similarity
1.7.2	Market Exclusivity	m1-7-2-market-exclusivity

Not applicable for Thai eCTDs. This section should not be used.

1.8 Information relating to Pharmacovigilance

Section ID	Business Terminology	XML-Element
1.8	Information relating to Pharmacovigilance	m1-8-pharmacovigilance
1.8.1	Pharmacovigilance System	m1-8-1-pharmacovigilance-system
1.8.2	Risk-management System	m1-8-2-risk-management-system

During lifecycle, 1.8.2 Risk management plan should always use the lifecycle operator replace.

1.9 Information relating to Clinical Trials

Section ID	Business Terminology	XML-Element
1.9	Information relating to Clinical Trials	m1-9-clinical-trials

Currently there is no mandate for information to be provided for this section, however, the THAI FDA would appreciate a statement to the effect that clinical trials performed outside Thailand meet ethical requirements.

1.10 Information relating to Paediatrics

Section ID	Business Terminology	XML-Element
1.10	Information relating to Paediatrics	m1-10-paediatrics

Currently there is no mandate for information to be provided for this section, however, the THAI FDA would appreciate any appropriate information on this topic to be provided if available.

1.R Responses to Questions

Section ID	Business Terminology	XML-Element
1.R	Responses to Questions	m1-responses
1.R.1	<Sequence Number> <Sequence Description>	leaf-node

When responding to questions posed by the THAI FDA, a document addressing these questions should be provided. Where possible, hyperlinks should be created linking the topic addressed with the sections where changes have been made. The leaf title should provide the sequence number and the sequence description as provided in the envelope e.g. "0000 Response to LOQ – Quality from 2014-06-04".

1.A Additional Data

Section ID	Business Terminology	XML-Element
1.A	Additional Data	m1-additional-data

Any data provided that would not logically belong in one of the specified sections can be provided in the 1.A Additional Data section. The leaf title should be descriptive of the content being provided.

5.5. The Node Extension Element

Structures beyond the heading elements can be defined through node extension elements. In addition, wherever a leaf element is allowed in the schema, a node-extension element is also allowed. The node-extension structure allows the sponsor to effectively make arbitrary heading structures as desired. This advanced concept can be helpful in organizing multiple large collections of files which are all needing to be placed under a single normal eCTD heading.

The fact that the schema allows the node-extension structure is in compliance with general [ICH eCTD specifications](#), but should not be interpreted as a blanket permission to use the structures anywhere or without consideration. Sponsors may use these structures where needed to assist reviewers but may want to contact the THAI FDA for advice if the usage is novel.

The optional node-extension element contains a single mandatory title element, followed by at least one leaf element, and followed by another optional node-extension element. The element can be repeated.

The node extension title element should be short, precise and informative. Information already categorized by heading elements need not be repeated. The most important identifying information should be placed at the beginning to prevent reviewers from having to scroll to the end of the title.

5.6. The Leaf Elements

Content for each heading element is provided through leaf elements. This optional element contains one other element, the title element along with a number of attributes, all based upon the ICH eCTD definition provided in the [Electronic Common Technical Document Specification \(Version 3.2.2\)](#). This element can be repeated. The schema will additionally ensure the checksum-type attribute contains either “MD5” or “md5”.

The leaf title element should be short, precise and informative. Information already categorized by heading elements need not be repeated. The most important identifying information should be placed at the beginning to prevent reviewers from having to scroll to the end of the title.

5.7. Files and Folders

5.7.1. File and Folder Naming Conventions

Naming conventions for the content files are irrelevant for electronic review. The naming conventions required by the EU are suggested and recommended but are not validated as a Pass/Fail or best practices criteria for eCTDs submitted to the THAI FDA. Instead, information should be provided by the validation tools as to where naming conventions have not been followed. This data will be collected for informational purposes only. It is, however, required that all file and folder names be submitted in English and not in Thai.

All content must be referenced by the appropriate XML files for efficient navigation. Applicants should concentrate on providing precise but informative leaf titles to aid reviewers.

While naming conventions for content will not be validated as a Pass/Fail criteria, it is expected that the basic construction of the eCTD be maintained and adherence to the following naming conventions will be required.

Folder	File	Description
e1234567		Application folder with eSubmission identifier e.g. e1234567
0000		Sequence folder with four digit sequence number e.g. 0000
	index.xml	Index file in accordance with ICH
	index-md5.txt	MD5 checksum in accordance with ICH
m1		Content folder for Module 1 documents in accordance with ICH
	th	Thai country specific folder
	th-regional.xml	Thai regional index file for Module 1
m2		Content folder for Module 2 documents in accordance with ICH
m3		Content folder for Module 3 documents in accordance with ICH
m4		Content folder for Module 4 documents in accordance with ICH
m5		Content folder for Module 5 documents in accordance with ICH
util		Util folder in accordance with ICH
	dtd	DTD and schema folder in accordance with ICH
	th-regional.xsd	Thai regional backbone schema for Module 1
	xlink.xsd	W3C schema for XLink 1.1 (referenced from th-regional.xsd)
	xml.xsd	W3C schema for XML namespace (referenced from th-regional.xsd)
	ich-ectd-3-2.dtd	ICH DTD for Modules 2 to 5
	style	Style sheet folder in accordance with ICH
	ectd-2-0.xsl	ICH style sheet for Modules 2 to 5
	th-regional.xsl	Style sheet for Thai regional backbone
0000-validation-report		Folder for validation report to be provided with the submitted sequence.

5.7.2. Folder and File Name Path Length

The overall folder and file name path length starting from the sequence number should not exceed 180 characters, for any file in any module. This is a TH regional requirement based on existing requirements in the EU. It is acknowledged that this is less than the ICH agreed overall path length.

6. eCTD Preparation Tools

The THAI FDA does not mandate or recommend any particular software product for eCTD preparation. However, based upon other agency observations and experience the THAI FDA recommends that applicants:

- Prepare the eCTD using an authenticated commercial eCTD preparation software. There are a wide variety of options available to sponsors for commercial eCTD preparation software, both in terms of multiple vendors and in terms of approaches e.g. installed software, software as a service, service providers. Sponsors are encouraged to find a solution which supports current and ongoing TH eCTD requirements and meets their overall business needs.
- Validate the prepared regulatory activity using an authenticated commercial eCTD validation tool.

Sponsors are encouraged to use a validation tool which supports checking current and ongoing TH eCTD requirements. These validation tools are not just XML checkers or parsers, but actually evaluate the technical content of the regulatory activity. There are numerous options available to sponsors, several of which are free. This minimizes the possibility of technical validation errors with eCTD regulatory transactions sent to the THAI FDA which introduce delays into the overall regulatory process.

A list of validation tools that the THAI FDA feels support the Thai validation requirements will be maintained on the THAI FDA website at <http://drug.fda.moph.go.th/eng> . Vendors of validation tools are encouraged to demonstrate their tool's compliance and will be listed if they are in-line with validation criteria.

7. References

The following documents should be read in connection with this specification to ensure conformity with overall eCTD requirements. Where applicable, these specifications should be followed unless otherwise stated in this specification document.

[ICH Electronic Common Technical Document Specification \(Version 3.2.2\)](#)

[ICH The eCTD Backbone File Specification for Study Tagging Files \(Version 2.6.1\)](#)

[eCTD Specification and Related files](#) – ICH links to specifications and related files including change control process, change request forms and their Q&A document.

[Notice to Applicants Volume 2 B\(June 2006\)](#), Medicinal products for human use. Presentation and format of the CTD dossier. Provides information on expected content for the CTD. The THAI FDA will adopt these expectations unless expectations are otherwise stated in the Section 5.4

[TH Regional Specification and Validation Criteria](#) – source document for Module 1 elements, envelope attributes, eCTD Validation criteria and naming conventions for the TH Module 1 sections added by this specification and not covered by the EU naming conventions. The numbering of the validation criteria has been maintained to correlate with EU criteria. Where requirements were removed, no renumbering of remaining requirements was done. Requirements that were added were appended to the EU criteria.

The following documents were referenced during the creation of this specification and many sections were modelled on their content.

[AU eCTD Specification](#)

[EU Module 1 eCTD Specification \(Version 2.0\)](#)

[Guidance Document: Creation of the Canadian Module 1 Backbone](#)