Registration of Pharmaceutical Products for Human Use in the Economic Community of West African States

ECOWAS-WAHO eSubmission Module 1 and Regional Information

Specification and Guidance for Temporary Use

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1. Introduction

First and foremost, it must be emphasised that this Specification is a **temporary** solution to be used while companies have time to implement an Electronic Common Technical Document (eCTD) solution. Please pay close attention to the timelines set forth in the ECOWAS-WAHO eCTD Specifications. Companies should **not** see this Specification as an alternative to eCTD long-term.

eCTD is the preferred format for all ECOWAS countries as it enables a more efficient evaluation and provides a means to maintain a better overview of Applications over time with the use of life cycle operations which are absent from eSubmissions.

This Specification should be read together with the eCTD Specification as much of the information in the eCTD Specification also applies to the eSubmissions when possible. Much of this document will reference the eCTD Specification when appropriate.

This document applies to all Applications not submitted in eCTD format and applies to all Centralised Procedures and is intended to also be adopted by all members states for National and Reliance Procedures. Furthermore, this document applies to all types of medicinal Submissions and is not limited to generic Applications.

It is important to understand that the CTD structure is flexible and can be as detailed or as simple as the type of Submission requires. In some cases, content should be provided in most of the sections defined in Modules 1-5. In other cases, very little content will be required in Modules 4 and 5 and a varying degree of detail may be required in Modules 1-3. Guidance on what content should be provided for the different Submission Types is provided in the Document Matrix.

This ECOWAS eSubmission Specification is similar to NeeS (Non-eCTD electronic Submission) implemented in other regions – for example EU, Australia and GCC – but has some key differences such as:

- There are no requirements for PDF TOCs. ECOWAS countries will be using a utility that will automatically build an XML backbone based on folder and file names. No files submitted by the applicants will be altered during the creation of the backbone which will act as an electronic navigation and TOC for each Sequence submitted.
- There is a requirement to provide an envelope.xml file in the “wa” country folder. ECOWAS will make a utility available on the ECOWAS website that will assist in the creation of this file.

This document contains:

- guidance on the structure of an ECOWAS eSubmission Application for the ECOWAS CTD
- guidance on creating and validating your eSubmission Sequences

Version 1.0 of the Specifications and validation criteria will come into effect on 1 November 2023 and should be read in combination with:

- The ECOWAS CTD Guidance version 1.0 (2023 forthcoming)
- The ECOWAS eCTD Guidance version 1.0
- The ECOWAS eCTD Validation Criteria version 1.0
- The ECOWAS eCTD Q&A Document version 1.0

The eSubmission Specification is designed to assist regulatory staff with understanding the setup and creation of an eSubmission. We encourage regulatory to read and understand this document thoroughly and understand the eCTD Specifications at a high level but to not get bogged down in the technical details of section 4 of the ECOWAS-WAHO eCTD Specifications. Regulatory should focus on the information provided in the ECOWAS-WAHO CTD Guidance, the ECOWAS-WAHO Validation Criteria sections 2, 4 and 6 and information clarified in the ECOWAS-WAHO eCTD Q&A Document.

All documents are provided on the ECOWAS eCTD Website. ECOWAS eCTD (waho-essmed.org/eCTD)

The eCTD Specifications, eSubmission Specifications and Validation Criteria have all been translated and are being provided in French and Portuguese. Should there be any discrepancies however, the English version will be considered the master copy and interpretations will be based on what has been provided in the original English version.

1.1. Terminology

Refer to the ECOWAS eCTD Specifications for more information on Terminology.

1.2. Implementation / Transition Plan

It is highly recommended that all ECOWAS Authorities and Applicants submitting in the ECOWAS region move to quick adhere to the eSubmission format until the eCTD format can be used. The structured approach will increase the efficiency of evaluation and create more transparency in the application creation, review and maintenance processes.

1.2.1. ECOWAS Centralised Procedure

The implementation of eSubmission in ECOWAS countries is part of the initial phase of eCTD implementation commencing as soon at the Specifications are released and launched to industry.

While both eSubmissions and eCTD are accepted, updates to the eCTD will trigger updates to the eSubmission requirements where applicable.

Companies with eCTD capabilities are encouraged to submit in the preferred eCTD format as soon as possible.

Companies without eCTD capabilities are **strongly recommended** to move to this **temporary** eSubmission format for any Applications not already in the Submission process. The eSubmission format defines a predictable File and Folder naming convention and **does not require any additional software** to prepare the Applications beyond the common office suites commonly found in any regulatory office environment. There should, therefore, be no issues for companies to adopt the new requirements.

Centralised Procedure Applications that do not conform to either the eCTD or eSubmission Specifications and validation criteria after 1 February 2024 will need to substantiate why they have not provided the more efficient and easier to evaluate format.

ECOWAS eCTD and eSubmission Implementation Timeline:

Refer to the ECOWAS eCTD Specifications for more information on Implementation timelines.

2. Preparing your ECOWAS eSubmission Application

ECOWAS will provide a utility in the eSubmission section of the ECOWAS-WAHO eCTD website that will simplify the creation of an ECOWAS-WAHO eSubmission. The Utility will:

1. Create a valid folder structure for your eSubmission
2. Create the required envelope.xml file for your eSubmission
3. Delete any empty folders that have not been filled with content for your eSubmission

Applicants simply will need to fill the folder structure with files named in accordance with the file naming convention specified in the ECOWAS-WAHO eCTD Validation Criteria.

Related Information and Guidance

- The ECOWAS-WAHO eSubmission Utility ECOWAS eCTD (waho-essmed.org/eCTD)
- ECOWAS-WAHO eCTD Validation Criteria ECOWAS eCTD (waho-essmed.org/eCTD)

2.1. Obtaining the Applicant ID and Application Number

Refer to the ECOWAS eCTD Specifications for the process of obtaining an Applicant ID and/or an Application Number. There is no difference in the process between eCTD and eSubmission. Preparing the eSubmission Cover Letter

2.2. The eSubmission Cover Letter

All requirements for the eCTD Cover Letter apply to the eSubmission Cover Letter. In addition to the eCTD requirements, however, a statement should be added to all eSubmission Cover Letters that updates the authority on the progress with moving to eCTD. This statement should include the following:

- Indicate the eCTD Implementation phase your company is currently in:

Table 1 eCTD Implementation Phases

Phase	Phase Title	Phase Description
Phase 1	Requirement Analysis	Understanding the Requirements
Phase 2	User Requirement Collection	Defining the Functionality Required specific to the Company and Regulatory Department
Phase 3	Solution Analysis	Looking at Solutions Options, Engaging with Solution Providers
Phase 4	Solution Selection & Budgeting	Identification of Solution and Budgeting for Solution Implementation
Phase 5	Solution Implementation	Installation, Validation and Training of Selected Solution

- Indicate your estimated timeline until when you will be able to begin submitting in eCTDs.
- If your estimated timeline has changed to a later date than indicated in earlier Sequences, provide a brief high-level explanation why the delay has occurred.

- Provide a statement acknowledging your understanding that eSubmission is not the preferred format.
- Provide a statement indicating you will begin providing Sequences in eCTD format before the eSubmission end of life on 1 May 2026 for Centralised Procedures. The deadline date must be included in the statement.

Example:
[COMPANY] is currently in phase 1 of eCTD implementation. We expect to be able to submit eCTDs by October 2025. We understand that eSubmission is not the preferred format and we confirm our commitment to begin submitting in the eCTD format before the eSubmission end of life deadline on 1 May 2026.

2.3. Compiling the eSubmission

To compile an eSubmission the simple steps below can be used. The information referenced in each of the steps is described in detail in this and the eCTD Specifications.

1. Apply for an Applicant ID and login to the Portal using your Applicant ID once issued
2. Create a new Application and note the Application Number issued
3. Create a new Submission and note the Submission Number issued
4. Download the eSubmission Utility from the ECOWAS website and unzip in a location with a path not exceeding 75 characters (path should be as short as possible).
5. Use the eSubmission Utility to create the folder structure. See Utility Instructions for details.
6. Add all required files. Make sure files are prepared according to eCTD requirements and named according to the eSubmission file naming convention. See Validation Criteria for naming conventions.
7. Use the eSubmission Utility to create the envelope.xml file. See Utility Instructions for details.
8. Use the eSubmission Utility to remove any empty folders. See the Utility Instructions for details.
9. Validate the Sequence and produce a validation report using a validation tool that conforms to the ECOWAS-WAHO eSubmission validation criteria. The validation should complain about a missing validation report in the Working Documents.
10. Fix any errors and warnings other than the missing validation report.
11. Place the validation report in the 0001-workingdocuments folder and name it 0001-validation-report.* (if the Sequence is 0001). Note that the validation report can be of any format.
12. Validate the Sequence again until a perfect validation report is produced.
13. Replace the validation report in the 0001-workingdocuments folder with the final perfect validation report.
14. Login to the Portal using your Applicant ID and follow the process to submit your Sequence via the portal.

Related Information and Guidance

- The ECOWAS-WAHO eSubmission Utility [ECOWAS eCTD (waho-essmed.org/eCTD)]

2.4. eSubmission Application Folder Naming Convention

Name the eSubmission Application Folder after the Application Number with no further text.

Example: f-wa-22-12345

Refer to the ECOWAS eCTD Specifications for more information on Application Folder Naming Conventions. There is no difference in the process between eCTD and eSubmission.

2.5. Selecting a Media Format

Refer to the ECOWAS eCTD Specifications for more information on Media Format. There is no difference in the process between eCTD and eSubmission.

2.6. Validating the eSubmission Sequence(s)

You must validate your Sequence prior to submitting to us. The validation software that you use should be able to validate the ECOWAS Regional criteria. We also validate each eSubmission Sequence using the ECOWAS Validation Criteria.

An electronic copy of the validation report must be included in the Working Documents folder for each Sequence Submitted.

Refer to the ECOWAS eCTD Specifications for more information on Validating Sequences. There is no difference in the process between eCTD and eSubmission.

2.7. Submitting your eSubmission Sequence(s)

Refer to the ECOWAS eCTD Specifications for more information on Submitting your Sequences. There is no difference in the process between eCTD and eSubmission.

3. ECOWAS Regional Considerations

This section includes additional points to consider when compiling your eSubmission Sequence to ensure a high-quality Application and an efficient evaluation process. Most of the regional considerations are identical to those detailed in the eCTD Specifications.

3.1. File Formats

Refer to the ECOWAS eCTD Specifications for more information on File Formats.

The only difference between eSubmissions and eCTDs is that there is a structured exchange standard file expected to be compiled in the eSubmission – the envelope.xml. This file should be created using the eSubmission Utility available on the ECOWAS website. More information on this can be found in the 4.4 Envelope XML.

Related Information and Guidance

- The ECOWAS-WAHO eSubmission Utility ECOWAS eCTD (waho-essmed.org/eCTD)

3.2. Electronic Signatures

Refer to the ECOWAS eCTD Specifications for more information on Electronic Signatures.

The only difference between eSubmissions and eCTDs is that eSubmissions do not provide an MD5 checksum which is important in ensuring documents are not altered or tampered with once submitted by the applicant. eCTDs provide a higher level of security for the applicant. Documents with electronic signatures are less secure in a format without the MD5 checksum.

3.3. Empty or Missing eCTD Sections

Refer to the ECOWAS eCTD Specifications for more information on Empty or Missing Sections. There is no difference in the process between eCTD and eSubmission.

3.4. Updating Attributes Specific Folders

Updating Folder Names based on ICH eCTD Attributes

The following sections in the CTD structure have a specified folder structure in the eSubmission file and folder setup.

Table 2 Attribute Specific Subfolders

Section	Section Title	Attribute Specific Subfolders
1.0.1	Cover Letter	Country (Use Country Code)
1.0.4	Correspondence Issued by the Regulatory Authority	Country (Use Country Code)
1.0.5	Information Solicited by the Regulatory Authority	Country (Use Country Code)
1.2.1	Application Form	Country (Use Country Code)
1.2.2	Form Fees	Country (Use Country Code)
1.3.1	Summary of Product Characteristics	Country (Use Country Code)
1.3.2	Patient Information Leaflet	Country (Use Country Code)
1.3.3	Container Labels	Country (Use Country Code)
1.A	Additional Data	Country (Use Country Code)

Section	Section Title	Attribute Specific Subfolders
3.2.S	Drug Substance	Substance-Manufacturer
3.2.P	Drug Product	Product-Dosage-Manufacturer
3.2.P.4	Control of Excipients	Excipient
3.2.A.3	Excipients	Excipient
5.3	All Clinical Study Reports	Study ID-Study Description
5.3.5	Reports of Efficacy and Safety Studies	Indication

To ensure consistency between the Sequences, the attributes specific subfolders should not be altered over time, as these changes can lead to complexity in the evaluation process.

In instances where changes are more likely to occur – for example, manufacturer in 3.2.P a generic variable can be placed in the folder name e.g. “mnf” and the manufacturer represented by the variable can be declared and maintained in the General Note to Reviewer.

A Warning will result in the validation report if folders are introduced that are not unique in later life cycle Sequences. This could lead to rejection of the eSubmission Sequence if the need of unique folder is not substantiated by the Submission Type.

Keep in mind the restrictions on folder length (64 characters) and total path length (180 characters) when creating the subfolders. Values should be abbreviated. They need to be short, precise, and distinguishing. Folder and path lengths are validated.

Updating the ECOWAS envelope.xml File

The ECOWAS envelope information presented in the envelope.xml file can be updated during the life cycle as is necessary to reflect changes in the metadata - for example, changing, adding and removing product names.

3.5. Document Navigation Aids

Refer to the ECOWAS eCTD Specifications for more information on Document Navigation Aids. There is no difference in the requirements between eCTD and eSubmission.

3.6. Reusing Files

File reuse is not allowed in eSubmissions. Files should be provided in all sections where they would be referenced. A detailed listing of all files that appear multiple time in different locations in the eSubmission should be included in the General Note to Reviewer. In addition, an entry in the Electronic Declaration Document should be added that will indicate that all copies of the content provided in multiple locations are identical.

The inability to reuse content reduces the efficiency of the evaluation and is one of the reasons why eCTDs are the preferred format.

3.7. Baseline Sequences

It is highly recommended you provide a Baseline when converting to eSubmission from other formats:

- Paper
- Unstructured Electronic Files

Refer to the ECOWAS eCTD Specifications for more information on Baseline Sequences. There is no difference in the expectations or reasoning between eCTD and eSubmission.

3.8. Work Grouping

Work Grouping is not allowed for eSubmissions. It is expected that a separate Sequence will be submitted for each Submission. Combinations of multiple Submissions in a single Sequence complicates the life cycle and becomes difficult to manage without the life cycle operations associated with eCTD Applications.

If multiple Submissions are listed in the envelope.xml file for eSubmissions, a validation Error will occur.

3.9. Study Tagging Files

Study Tagging Files are a product of eCTD Applications and cannot be provided in an eSubmission. Only the content defined in the ICH E3 Structure and Content of Clinical Study Reports should be included when appropriate. Case Report Forms and Individual Patient Listings should be provided in the CTD section 5.3.7 when appropriate.

3.10. Transfer of Applicants

Refer to the ECOWAS eCTD Specifications for more information on Transfer of Applicants. There is no difference in the process between eCTD and eSubmission.

4. ECOWAS eSubmission General Architecture

An eSubmission relies on a structured and predictable approach to the presentation of content. The structured presentation enables a validation of content which increases the quality of Applications and saves time during the screening and evaluation process.

4.1. eSubmission Folders

The CTD structure can be presented in electronic form using the ICH recommended folders and file names in the ICH eCTD Specifications. Since ECOWAS does not have a recommended naming convention for its eCTD Module 1, a folder naming convention has been specified in the eSubmission Folder and File Names tab of the ECOWAS-WAHO eCTD Validation Criteria which should be followed for all eSubmissions.

The folders for the ECOWAS Module 1 are based on the Heading Elements of the eCTD Specification and are designed to promote a logical order for the folders when displayed in the Windows Explorer®. A leading “0” has been added in front of the second level section number to allow proper sorting of content in the order intended. For example, the folder for 1.2 has been designated as 102 in the naming convention.

As an exception, the folders created for Module 5 study reports should be made up of the Study ID (Study Number) along with a short, precise, and distinguishing description. This will help the evaluator differentiate between the studies provided without having to open them.

An empty folder structure is created by the eSubmission Utility available on the ECOWAS website for download. eSubmission Utility This is meant to simplify the creation of the necessary folder structure so that applicants can simply fill the folder structure with the necessary files.

The attributes specific folders listed in section 3.4 Updating Attributes Specific Folders must follow the eCTD rules on naming conventions detailed in the ICH eCTD Specifications. In particular these rules forbid:

- the use of any spaces
- the use of any special characters other than the hyphen “-“
- the use of any CAPITAL letters

In addition, values placed in the attribute specific folders should be abbreviated and the applicant should take care to ensure that folder names do not exceed 64 characters.

Applicants should delete any empty folders from their Sequence using the eSubmission Utility, only folders with content should be included.

Additional folder structures beyond the defined structure are not allowed. Use the variable filenames to group and identify like content you want to organise together.

Related Information and Guidance

- The ECOWAS-WAHO eSubmission Utility
- ECOWAS-WAHO eCTD Validation Criteria

The following will result in Validation Errors

- The use of spaces, special characters, and capital letters in folder names
- Attribute specific folders with more than 64 characters
- Empty folders
- Additional Folder Structures beyond the defined structure

4.2. eSubmission File Names

The file names used in Modules 2-5 should conform to those provided in the eSubmission Folder and File Names tab of the ECOWAS-WAHO Validation Criteria which are in line with those recommended by ICH in the ICH eCTD Specifications with the exceptions listed below.

- **Literature References** – ICH refers to a naming convention for references placed in 3.3, 4.3 and 5.4 as “reference-1.pdf”, “reference-2”, etc. This is not helpful or intuitive for the evaluator. Instead, the author and year should be used. References in the documents of the Application to the Literature References should refer to the author and year as used in the file names.
- **Study Reports** – ICH refers to a naming convention for all studies in Module 4.2 and 5.3 as “study-report-1”, study-report-2”, etc. This is not helpful or intuitive for the evaluator. Instead, the Study ID (Study Number) should be used along with a short, precise, and distinguishing description. In Module 5 study reports where a multiple file approach has been taken, the description should clearly identify the study component, ideally in line with the ICH E3 Structure and Content of Clinical Study Reports guidance.

Since ECOWAS does not have a recommended naming convention for its eCTD Module 1, a file naming convention has been specified in the eSubmission Folder and File Names tab of the Validation Criteria which should be followed for all eSubmissions.

The optional PDF TOCs are indicated in Blue. If you are using a system that creates eSubmissions with PDF TOCs, your system likely is also able to create eCTDs. Please investigate and move to the preferred eCTD format as soon as possible.

PDF TOCs are not necessary in the ECOWAS eSubmission

Variable Filename Components

Variable Filename Components in the ICH eCTD Specifications usually follow the concept of fixed filename followed by a unique number starting with 1 to ensure that each filename is unique. Numbered files do not provide helpful or intuitive information for the evaluator so meaningful variables should be provided instead.

Do not use filenames like:

- analytical-procedure-1.pdf
- analytical-procedure-2.pdf
- analytical-procedure-3.pdf

Do use filenames like:

- analytical-procedure-id.pdf
- analytical-procedure-limitimpurity.pdf
- analytical-procedure-qualityimpurity.pdf

Note that the variable component does not have to be in English. For applications in French or Portuguese speaking markets, any word or phrase can be used that will help the evaluator identify the content.

The ICH numbering system is appropriate for files provided in the eCTD format because the eCTD provides an alternative Title element in the XML backbone. The Title is descriptive, and it is all the evaluator sees. Evaluators do not see the actual filename in an eCTD.

The ICH numbering system is NOT appropriate for files provided in the eSubmission format because the evaluator only sees the filename to identify the content. No alternate Title element exists.

Filename variables are validated for eSubmissions and if a numbered approach is used, validation warnings will occur because this will negatively affect the evaluation efficiency.

NOTE: The numbered approach is accepted in eCTD applications where emphasis is placed on providing descriptive leaf titles.

Related Information and Guidance

- The ECOWAS-WAHO eSubmission Utility ECOWAS eCTD (waho-essmed.org/eCTD)
- ECOWAS-WAHO eCTD Validation Criteria ECOWAS eCTD (waho-essmed.org/eCTD)
- ICH E3 Structure and Content of Clinical Study Reports guidance

4.3. Folder and File Name – Path Length

Refer to the ECOWAS eCTD Specifications for more information on the Folder and File Name – Path Length. There is no difference in the restrictions between eCTD and eSubmission.

4.4. Envelope XML

ECOWAS has provided an eSubmission Utility to enable applicants to automatically create the envelope.xml file required by eSubmissions without the need for an additional software solution. Instructions on how to use the utility to create the envelope.xml are provided in the utility itself.

Refer to the ECOWAS eCTD Specifications for more information on Envelope Elements.

The only difference between the eCTD Envelope and the eSubmission Envelope is that the eSubmission Envelope does not allow multiple Submissions to be combined in a single

Sequence. A separate Sequence must be submitted for each Submission in the eSubmission format.

If multiple Submissions are listed in the envelope.xml file for eSubmissions, a validation Error will occur.

Related Information and Guidance

- Sample envelope.xml [ECOWAS eCTD (waho-essmed.org/eCTD)]

4.5. eSubmission Headings

Refer to the ECOWAS eCTD Specifications for more information on Headings. The eCTD Headings should be integrated into the documents submitted to make clear identification of the content as evaluator friendly as possible.

Comprehensive Table of Content of Life Cycle Operations

All Headings are the same as in the eCTD with the exception that eSubmissions have an additional heading:

Table 3 Additional Heading for eSubmission 1.1 – Table of Contents

Section ID	Title
1.1	**Comprehensive Life Cycle Table of Content**

The Comprehensive Life Cycle Table of Content is designed to provide the evaluator the ability to manually put together information automatically provided by eCTD Applications. The deeper into the life cycle the Application progresses i.e., the more Sequences that are submitted, the more important the table becomes for the evaluation.

The table gives the evaluator information on which Sequence folder to refer to when looking for the latest information submitted and the latest approved information.

Every CTD Heading where content is provided, and every file should be included in the table.

The table should provide the following information:

- Section
- Heading Title
- Last Sequence where Content was Submitted
- Life Cycle Operation that would have been applied in eCTD format – for example New, Replace or Delete
- Last Sequence where Content was Approved

Table 4 Example Comprehensive Life Cycle Table of Content

Section	Heading Title	Last Submitted	Life cycle Operation	Last Approved
1	Administrative Information and Prescribing Information			
1.0	Correspondence			
1.0.1	Cover Letter			
1.0.1	Nigeria			
1.0.1	0001 Cover Letter New Application	0001	New	
1.0.1	0002 Cover Letter Response to Recommendations 2021-11-20	0002	New	
1.0.1	0003 Cover Letter Changes to SmPC	0003	New	
1.0.1	0004 Cover Letter Changes to SmPC	0004	New	
1.0.1	0005 Cover Letter New Strength	0005	New	
- - -	- - -			
1.3.1	Summary of Product Characteristics			
1.3.1.1	Approved SmPC			
1.3.1.1.1	Approved SmPC – English	0004	Replace	0004
- - -	- - -			
1.3.1.2	Clean SmPC			
1.3.1.2.1	Clean SmPC – English	0004	Replace	0003
- - -	- - -			
1.3.1.3	Annotated SmPC			
1.3.1.3.1	Annotated SmPC – English	0004	Replace	0003
- - -	- - -			
2	Common Technical Document Summaries			
2.2	Introduction	0001	New	0001
2.3	Quality Overall Summary			
2.3.1	Introduction	0001	New	0001
2.3.S	Drug Substance – Amoxicillin	0001	New	0001
2.3.P	Drug Product – Tablet	0005	Replace	0001
- - -	- - -			

In the above example:

- Cover Letter
  - A New Cover Letter has been submitted with each Sequence.
- Product Information
  - Was approved in Sequence 0002 when the New Application was approved
  - Was updated in Sequence 0003 placing the clean and annotated copies in 1.3.1.2 and 1.2.1.3. The changes were subsequently approved.
  - Was updated again in Sequence 0004.
    - The approved SmPC from Sequence 0003 was placed into 1.3.1.1 replacing the file that was approved in Sequence 0002.
    - The proposed clean and annotated copies were placed in 1.3.1.2 and 1.2.1.3 showing they replace the previously proposed copies, but the last approved copy is found in Sequence 0003.
- Drug Product
  - The Drug Product Summary is being updated as part of the Application for a New Strength in Sequence 0005.

– The evaluator can see that the latest information can be found in Sequence 0005 but that the last approved content can be found in Sequence 0001.

The complex management of when content was last submitted, and which Sequence contains the content last approved is automatically managed in eCTD. It is one of the major reasons eCTD is the preferred format.

4.6. Life Cycle Operations

Life cycle Operations are not possible in the eSubmission format as it lacks the XML elements to manage and track changes in the Application over time.

The inability to Life cycle Operations reduces the efficiency of the evaluation and is one of the major reasons why eCTDs are the preferred format.

4.7. Working Documents

Refer to the ECOWAS eCTD Specifications for more information on Working Documents. There is no difference in the requirements between eCTD and eSubmission.

5. eCTD Preparation Tools

Refer to the ECOWAS eCTD Specifications for more information on eCTD Preparation Tools.

6. Change Control

The following documents were referenced during the creation of this Specification:

- eCTD AU Module 1 and Regional Information

Factors that could affect the content of the Specification include, but are not limited to:

- Changes in the ECOWAS CTD Guidance
- Changes in the ECOWAS eCTD Specifications

We will:

- Provide a Practical Timeframe for Future Changes to Minimize the Impact on Industry.
- Introduce Changes at Scheduled Intervals to allow Stability.

Please send any feedback, comments, or questions to eCTD@wahooas.org.

7. Version History

The ECOWAS eCTD Project Team consists of:

Name	Organisation / Position	Project Designation

Versioning Guide

Versions to the Specifications will be handled as follows:

- Major Versions will be triggered by changes in the Envelope or Heading Elements e.g., version 1.0, 2.0, 3.0
- Minor Versions will be triggered by all other changes that require updates to the Schema e.g., version 1.1, 1.2, 1.3
- Changes in the Specification document that do not trigger changes to the Schema will be identified by a number suffixing the minor version number e.g., version 1.01, 1.02, 1.03
- All Major Versions will begin with the minor version 0 and no document version number will be applied until changes to the document have been issued. For both the minor versions and document changes the version number will be a single character running from 1-9 and then a-z if necessary.

Version	Description of Change	Author	Effective Date
v1.0	Initial version	ECOWAS eCTD Project Team	2023-11-01