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

ECOWAS-WAHO eCTD Module 1 and Regional Information

Specification and Guidance for Use

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1. Introduction

This document applies to all Applications using the electronic Common Technical Document (eCTD) format in the ECOWAS region for all Centralised Procedures. All ECOWAS member countries are urged to adopt the structure for National and Reliance Procedures as soon as possible. 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. Guidance on what content should be provided for the different Submission Types is provided in the Document Matrix.

This ECOWAS eCTD Specification version 1.0 is based on the ICH eCTD version 3.2.2 Specification.

The document contains:

- guidance on the structure of an ECOWAS eCTD Application
- guidance on creating and validating your ECOWAS eCTD Sequences

Version 1.0 of the specifications and validation criteria will come into effect on 1 July 2022 for all centralised procedure applications and should be read in combination with:

- the ECOWAS CTD Guidance version 1.0 (2022),
- the ECOWAS eCTD Validation Criteria version 1.0
- the ECOWAS eCTD/eSubmission Q&A Document version1.0

The eCTD specification is designed to assist software vendors and technical staff with understanding the technical setup and creation of an eCTD. We encourage regulatory to read and understand the specifications at a high level but to not get bogged down in the technical details of section 4 ECOWAS Module 1 General Architecture. Regulatory should focus instead on the information provided in section 2 Preparing your ECOWAS eCTD Application and section 3 ECOWAS Regional Considerations, the ECOWAS-WAHO CTD Guidance, the ECOWAS-WAHO Validation Criteria sections 2, 4 and 6 and information clarified in the ECOWAS-WAHO Electronic Applications 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.

Comment about ICH eCTD 4.0

Internationally, the eCTD is currently implemented using the ICH eCTD Specifications version 3.2.2. The eCTD Specifications for version 4.0 has been released and some agencies are in the process of implementing plans to migrate. It is the intention of ECOWAS to also migrate

but do not expect this to be implemented for quite some time. We will follow suit once other regions have paved the way.

ECOWAS eSubmission Option

All Applicants should begin their planning to move to eCTD immediately. For more information on eCTD Preparation Tools please see section 5 of this specification. ECOWAS eCTD (waho-essmed.org/eCTD)

As a **temporary** steppingstone towards eCTDs, an eSubmission Specification is also being released parallel to these eCTD specifications for **temporary** use. Please note that eSubmissions will only be accepted for a limited time until 31 December 2024 for centralised procedures.

The eSubmission specifications reference this document extensively. Most of the rules, policies and validation criteria applied to the eCTD will also be applied to the eSubmission. The only major difference is that eSubmissions do not have the intelligent life cycle and node element information to build a cohesive picture over time. The simple structure of an eSubmission denies the authorities more and more of an efficient review the deeper into the product life cycle we go. **But the construction of an eSubmission can be done without a specialised eCTD builder which will enable applicants to begin submitting structured electronic Submissions immediately without any additional software requirements beyond what is typically already in place for regulatory personnel and the utilities/components provided by ECOWAS**.

1.1. Terminology

It is acknowledged that the terminology to describe electronic Applications differs between regions. In addition, there is an effort to harmonise terminology as we migrate to eCTD 4.0. ECOWAS has attempted to implement terminology, for the most part, consistent with the proposed terminology in the eCTD 4.0 specifications. To assist users interpreting this specification, a brief list of terms used in this document is described below:

Table 1 Terminology

Term	Definition
Application	A collection of electronic documents provided over a period of time. The Application refers to the entire life cycle of a registration filed under an Application-UUID. An Application is comprised of all Submissions and Sequences over time. *Application is a term consistent with the eCTD version 4.0 specifications but was often referred to as a Submission or Dossier in earlier specifications.*
Application-UUID	A universally unique identifier (UUID) as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 | ISO/IEC 9834-8:2005. It is a 128-bit label and is unique for practical purposes when generated according to the standard methods. A UUID can be created online using free Online UUID Generators. The same UUID will be used for all Sequences of an eCTD Application and cannot ever be changed.
Authority	Refers to the entity responsible for the evaluation and/or approval of applications for a particular region.

Term	Definition
Baseline	A Sequence providing information already submitted in another format. Content submitted in a Baseline Sequence beyond the administrative content should be identical to the content already submitted. No new content should be introduced in a Baseline Sequence.
BTI	Bioequivalence Trial Information
CRF	Case Report Form. A specialised document in clinical research. It should be study protocol driven, robust in content and have material to collect the study specific data. In many cases, CRFs only need be made available upon request.
Centralised Procedure	An application submitted to ECOWAS-WAHO collectively for the registration of a product in all ECOWAS countries. The Centralised Procedure can only be used on a pre-defined basket of products which has been deemed crucial for the region. The evaluation is coordinated by WAHO, but it is performed by a Lead Coordinating NMRA designated by WAHO. The results of the evaluation are then adopted by all ECOWAS countries.
CTD	Common Technical Document as defined by ICH and the WA-MRH Steering Committee. Modules 2-5 are based on the ICH internationally accepted structure for Quality, Nonclinical and Clinical Information. Module 1 and sections 2.3.R / 3.2.R Regional Information are defined by the WA-MRA Steering Committee. https://www.ich.org/page/ctd
ECOWAS	Economic Community of West African States
eCTD	Electronic Common Technical Document – an international electronic standard for the Common Technical Document (CTD) providing the means for transferring information from pharmaceutical companies to agencies. https://www.ich.org/page/electronic-standards-estri
EU	European Union. An economic and political union between 27 European countries.
Elements	XML Elements are defined structural components of the eCTD. They structure the content and data so that the application can be managed and displayed over the entire life cycle of the product.
Envelope	Contains the metadata relevant to the eCTD Sequence. Metadata are referred to as Envelope Elements. ICH and some regions refer to the Envelope as the Administrative Information.
eSubmission	Electronic Submission – a **temporary** alternative electronic standard to eCTD consisting of PDF Files and Folders using predictable file and folder names. See the separate specification document on eSubmissions for more information on this **temporary** solution.
GCC	Gulf Cooperation Council. A political and economic union of Arab states bordering the Gulf.
ICH	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Since its inception in 1990, ICH has gradually evolved to respond to increasingly global developments in the pharmaceutical sector. The ICH guidelines are applied by a growing number of regulatory authorities. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high-quality medicines are developed, and registered and maintained in the most resource efficient manner whilst meeting high standards. https://www.ich.org/
Leaf	Structural element of an eCTD Submission delivering a document. It provides the information about the file provided including a unique ID

Term	Definition
	and checksum, saved location, and life cycle operation along with the title associated with the linked content. Leaf titles are crucial for efficient evaluation of eCTDs. Evaluators will see the Leaf titles and **NOT** file names which are irrelevant for eCTD applications.
National Procedure	An application submitted to a particular ECOWAS country for the registration of a product in that country only.
NMRA	National Medicines Regulatory Authority
OCR	Optical Character Recognition. Process by which software recognises text within a digital image e.g., scanned document. It is a technology that recognizes text within a digital image. OCR software converts images into readable text that can be searched and copied.
QIS	Quality Information Summary as defined by the WHO
QOS	Quality Overall Summary as defined by the WHO
Reliance Procedure	An application submitted to a particular ECOWAS country for registration of a product in that country as well as other countries with which the evaluating Authority has agreements. Such "Mutual Recognition Procedures" are only possible if the receiving Authority has such agreements with the other countries. Information for each of the receiving Authorities should be included in the Envelope. The exact same Application should be provided to all concerned Authorities.
RTF	Rich Text Format is a word processing or operating system independent format.
Submission	A collection of Sequences covering a specific request which includes the first Sequence of the activity and any follow-up Sequences e.g., supplemental information, response to recommendations, withdrawals, etc. *Submission is a term consistent with the eCTD version 4.0 specifications but was often referred to as a Regulatory Activity in earlier specifications.*
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 Submission Type and whether it is the initial Sequence of the Submission or a follow-up providing additional data or changes.
WA-MRH	West Africa Medicines Regulatory Harmonization
WAHO	West African Health Organisation

1.2. Implementation / Transition Plan

The implementation of eCTD and eSubmissions in the ECOWAS region will follow different paths depending on the type of procedure used and which country will be performing the evaluation. The transition for the ECOWAS Centralised Procedure will begin immediately following the publishing of these specifications. The transition for each country's National Procedure will move in accordance with their individual national plans.

1.2.1. ECOWAS Centralised Procedure

The implementation of eCTD and eSubmissions for the ECOWAS Centralised Procedure will go through a multi-phase process starting with an initial phase commencing as soon at the specifications are released and launched to industry.

The initial specifications are a collection of best practices adopted from already established eCTD regions and adapted to the ECOWAS CTD structure as defined in June 2018 publication of Guidance for Preparation of Applications in the Common Technical Document (CTD) Format. Additional sections have been added based on feedback collected during the internal ECOWAS eCTD workshops held in November/December 2021 with all member states and best practice recommendations based on other eCTD regions as part of future Harmonisation expectations.

The initial phase will use the specifications version 1.0. If needed, adjustment to the specifications, based on experiences gained during the initial phase, are expected approximately 1 year after the launch. Updates to the specifications can be expected every 2-3 years based on experience from other eCTD regions but will occur as often as needed.

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

Companies without eCTD capabilities shall move to the **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 office suites commonly found in any regulatory office environment.**

Applications that do not conform to either the eCTD or eSubmission specifications after 1 October 2022 shall substantiate why they are not in compliance when submitting their application but will likely be rejected immediately.

ECOWAS eCTD Implementation Timeline:

- The ECOWAS eCTD version 1.0 shall be accepted effective immediately, officially starting 1 November 2023 and is planned for use for a period of 18 months for the purpose of the eCTD initial phase.
- The ECOWAS eSubmission version 1.0 shall be accepted effective immediately, officially starting 1 November 2023 and shall be used for all Applications not submitted in eCTD format starting 1 February 2024.
- The ECOWAS eCTD and eSubmission Specification's version 2.0 are expected to be released in November 2024 and shall be the only version accepted after 1 May 2025.
- Between 1 November 2024 and 1 May 2025, ECOWAS will accept both the version 1.0 and 2.0 versions of the specifications.
- ECOWAS will stop accepting eSubmissions and move to eCTD only starting 1 May 2026. All applicants are expected to use the time until then to ensure their regulatory departments are equipped to be able to continue their Applications in eCTD format.

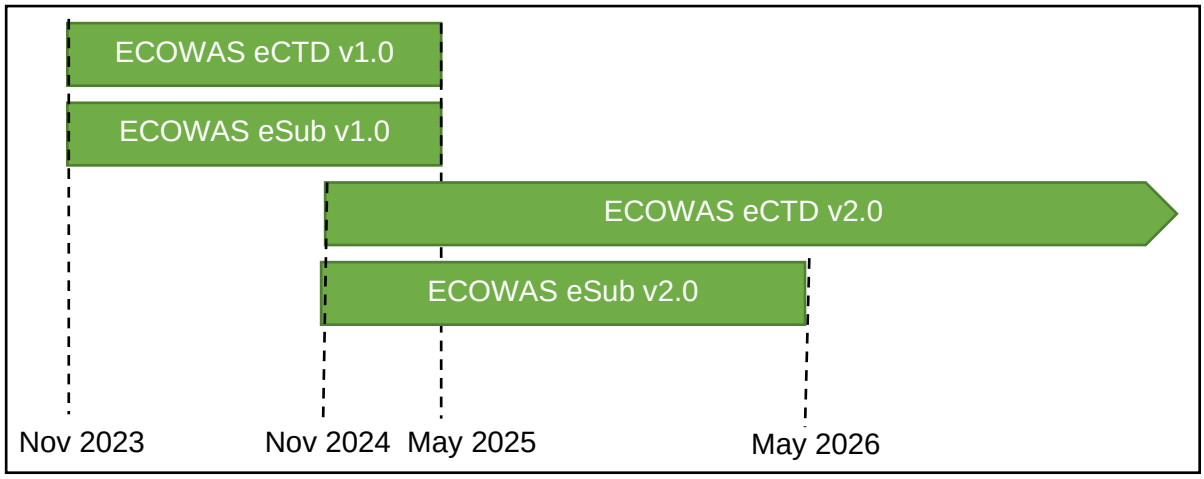

Figure 1 ECOWAS eCTD Implementation Timeline for Centralised Procedure

1.2.2. National and Reliance Procedures

Each of the ECOWAS member states shall provide information on their implementation timelines for the eCTD and eSubmission formats. The Lead Evaluating Authority will determine the format requirements for Reliance Procedures based on the formats required for their National Procedures.

ECOWAS will strive to provide up to date status information for all member countries and their timelines on the ECOWAS eCTD website. ECOWAS eCTD (waho-essmed.org/eCTD)

2. Preparing your ECOWAS eCTD Application

2.1. Obtaining the Applicant ID

You will need an Applicant ID before you submit your first Sequence in eCTD format.

To obtain your Applicant ID, please refer to the Portal Process Guide and visit the portal. ECOWAS eCTD (waho-essmed.org/eCTD)

The Applicant ID is valid for all future applications even through company name changes, etc. If two applicants with IDs were to merge, one of the 2 IDs would be designated for future use.

The Application Number is valid throughout the entire life cycle of a product unless split from a package as explained in section 3.10 Transfer of Applicants.

For National or Reliance Procedures please refer to national guidance on how to obtain an Applicant ID and Application Number. Please note that not all countries may have implemented Applicant IDs and will use the officially registered company name as an ID.

2.2. Obtaining the Application Number

Once an Applicant ID is obtained, it is not needed to ever apply for an Applicant ID again. The Applicant ID issued should be used for all future Applications.

To obtain an Application Number create a new Application in the Portal once logged in. See the Portal Process Guide for more information. ECOWAS eCTD (waho-essmed.org/eCTD)

For National or Reliance Procedures please refer to national guidance on how to obtain an Application Number.

2.3. Initial Sequence

The initial Sequence for all new Applications should be 0001 unless the first Sequence is a Baseline Submission. All initial Baseline Submissions should begin with **0000**.

2.4. Preparing the eCTD Cover Letter

The following new information shall be included in the Cover Letter in addition to what is defined in the ECOWAS-WAHO CTD Guidance and National guidance for the Cover Letter:

- The Application Number, the Sequence and Related Sequence in the subject line, consistent with the eCTD Envelope.

Example: e-ng-123456 Sequence 0010 Related Sequence 0008

- A description of the eSubmission:
  - Approximate Submission size, broken down by Module if unusually large submission.
  - Type of electronic media, if not uploaded to an electronic portal.
  - Any other characteristics concerning the media that may be important to know.
- A description of the software used to check the files for viruses and a statement as to whether the Submission is virus free.

  Example: "The Sequence has been virus checked using SOFTWARE version VERSION and is confirmed to be virus free."
- The Regulatory and Technical contacts for the Submission, consistent with the eCTD Envelope.
- Information about the validation including:
  - The validation tool and version / validation profile used.
  - Example: SOFTWARE VERSION / ECOWAS 1.0.1 Profile
  - Any findings e.g., errors, warnings or possible missing documents as designated by the Document Matrix that would be expected for your specific Submission Type.
- A paper copy of the Cover Letter should be included with the physical media containing the eCTD if not uploaded to an electronic portal.

2.5. eCTD Application Folder Naming Convention

When submitting Sequences, the Sequence Folder must be provided along with the Working Documents in an Application Folder.

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

Example: e-wa-23-12345 / f-wa-23-12345

If multiple Application Numbers are applied to an Application e.g., multiple strengths are included in the same application, and the numbers are sequential, the range of numbers should be identified. Range indicated does not need to repeat numbers that do not change.

Examples: e-wa-23-12345-8 | en-wa-23-12349-52 | e-wa-23-12399-402 | e-wa-23-12999-3002 | etc.

If multiple Application Numbers are applied to an Application but the numbers are not sequential, one of the Application Numbers should be selected as the master Application Number. The master Application Number should be the first Application Number listed in the Envelope.

The use of a Master Application Number can lead to issues if that Application Number is transferred to a new applicant without the other Application Numbers in the Application. Please seek advice from ECOWAS in this event.

Only the Sequence(s) being submitted should be included in the Application Folder submitted.

Sequences already submitted should not be submitted again!

2.6. Selecting a Media Format

Some electronic portals may have limits on the size of data packages that can be uploaded. Please refer to the country specific information to ensure your Application is within the allowed size.

If Sequences are not submitted via an electronic portal, you may use one of the following media formats:

- 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
- Universal Serial Bus Media (USB) (2.0 or higher)
- Portable External Hard Drive (USB 2.0 or higher).

We do not return the media!

The Submission may not be split, it must be submitted as a single unit!

Passwords and Double-Sided Discs are not allowed!

2.7. Validating the eCTD Sequence(s)

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

There are three types of eCTD validation findings:

- **ERROR** – Critical Pass/Fail finding:
  - Non-compliance will lead to rejection of the Sequence.
  - If errors are unavoidable, contact the receiving Authority before submitting the Sequence. Validation findings categorised as errors must be addressed in the cover letter with sufficient reasoning as to why the errors are unavoidable. Note that where automation is implemented, errors will lead to automatic rejection and an over-ride will be required of the automation process.
  - Refer to 2.7.1 Sequences with Errors or Warnings for further information.
- **WARNING** – Best Practice violations:
  - We recommend warnings be eliminated whenever possible as this will negatively affect the evaluation process.
  - Validation findings categorised as warnings must be addressed in the cover letter.

  - Repeated or excessive issues may result in a business rejection and request from the Authority for you to fix the Sequence and resubmit it. Evaluation will stop in this case until a corrected Sequence is provided.
- **INFO** – Information collected about the data being submitted. This includes:
  - A list of missing "Possible" documents as defined in the Document Matrix that might be required in the Sequence for the Submission Type declared in the Envelope.
  - Information about unusual life cycle operations.
  - Information about Study Tagging Files submitted, etc.
  - Information about content reuse within the same Sequence, from other Sequences in the same Application and from other Applications

Please make every effort to limit the number of warnings in Sequences. Any warnings that cannot be resolved shall be address in the Cover Letter.

You must validate your Applications prior to submitting to the Authority and provide a copy of your validation report in the Working Documents folder. For more information, see section 4.6.3 Working Documents

See section 5 eCTD Preparation Tools in this document for further information on suitable publishing and validation tools.

2.7.1. Sequences with Errors or Warnings

We will not process or even begin screening Sequences with validation errors unless specifically arranged prior to receipt of the Sequence. You will need to re-submit the Sequence without validation errors. Evaluation will not proceed until a Sequence free of validation errors has been provided. For further information or to discuss specific validation errors please contact eCTD@wahooas.org.

Sequences with errors will need to be corrected and resubmitted as the same Sequence Number.

If a sequence passes validation with no errors or warnings, it will be accepted by the authority. Any content deficiencies discovered during the screening/evaluation process will need to be addressed in a follow-up Sequence as part of the Application life cycle.

If a sequence passes validation with no errors but excessive warnings exist, the sequence may be rejected in the screening process depending on the nature and number of warnings present.

2.8. Submitting your eCTD Sequence(s)

If you can submit your Sequences via an electronic portal, please use the portal as this is the preferred method of submitting Sequences.

If submitting your sequence via physical Media Format, please refer to other guidance, ECOWAS or National, on the process of submitting in person.

It is the Applicants obligation to ensure the security of the Application until it is officially received by the target Authority. Once received, the target Authority will ensure data security.

Feedback on Validation

You will be notified if we have any issues during the validation of the eCTD Sequence using the contact details provided in the envelope.

3. ECOWAS Regional Considerations

This section includes additional points to consider when compiling your eCTD Sequence to ensure a high-quality Application and an efficient evaluation process.

3.1. File Formats

File formats refers to the accepted file type for documents within a Sequence. In most sections, the applicant is required to provide PDF files. In some sections, the source file e.g., MS Word or RTF should be provided either instead of the PDF or in addition to the PDF File.

Validated PDF Requirements

Requirement	Requirement Details
Source File	Where possible, PDFs should be generated from an electronic source file – for example MS Word.
PDF Version	All PDF files, in any module, should be version 1.4, 1.5, 1.6 or 1.7 except where a specific requirement for a later version is defined. Any PDF with version earlier than 1.4 will result in an error and full rejection of the entire Sequence.
External Links	No bookmarks or hyperlinks should reference a destination outside the eCTD Application(s) in the authority repository. Links to websites and email addresses should not be provided. Only links to files found in the same Sequence, same application or another application already submitted are permitted.
Inactive or Broken Links	No bookmarks or hyperlinks can be inactive or broken. All links must have a functioning valid destination.
Bookmarks	All documents with more than 5 pages that have multiple sections, tables, figures, references, etc., must contain bookmarks to aid the navigation through the document for the evaluator.
Inherit Zoom	All bookmarks and hyperlinks should have a magnification setting of “Inherit Zoom”.
PDF Annotations	PDFs cannot contain any annotations other than bookmarks and hyperlinks.
Security	No File Security should be applied including password protection or limitations to copy content.
PDF Initial View	Documents with bookmarks must show the bookmarks pane in their initial view. The Magnification and Page Layout should be set as "default".
Fast Webview	All PDFs should have the option for “Fast Webview” activated.

For a full account of the PDF Requirements, please refer to the ECOWAS Electronic Application Validation Criteria section 6 PDF Analysis.

General Source File Requirements

Requirement	Requirement Details
File Format	Source Files Should be provided in MS Word or RTF unless otherwise specified. The same format used to create the original file is preferred.
Security	No File Security should be applied including password protection or read-only settings.

3.1.1. Module 1

In addition to PDF, as defined by the ICH eCTD Specification Document, we will also accept XML and Microsoft (docx) or Rich Text Files (.rtf) where specified appropriate.

Currently, there are no structured exchange standards for content, but these may be introduced in the future for content such as the life cycle management tracking table, application forms, product information, etc.

Some countries may request original, source and/or processing documents e.g., Validation Reports in an external Working Documents folder located outside the official eCTD sequence package. These files may be in various file formats and any format is accepted in the Working Documents folder. Any unusual file formats e.g., files not in MS Word, RTF, PDF, or XML related files, should be addressed in the Cover Letter.

In some specified locations, the editable source files used to create the PDFs (Microsoft® Word or Rich Text Files) should be provided in addition to the PDFs. These shall be provided in the eCTD in the same location alongside the PDF Files provided. This will allow the content integrity to be secured via MD5 Checksums.

3.1.2. Module 2 to 5

In addition to the file formats defined for Modules 2 to 5 in the ICH eCTD Specification and the ICH Specifications for Study Tagging Files, we will allow comma separated value (CSV) and plain text (TXT) files in Modules 4 and 5 if appropriate.

3.2. Electronic Signatures

Electronic signatures will be crucial, particularly for authentication of electronic Submissions and documents, but are currently limited in use. We are currently accepting:

- Digital signatures as an adjunct to written signatures.
- Scanned signatures where the documents make up part of the checksum of an eCTD Sequence.
- Scanned documents with wet signatures where the document has then been OCRed.

3.3. Document Navigation Aids

Bookmarks and hyperlinks should be used to assist with navigation of the Application.

3.3.1. Bookmarks

Use bookmarks to assist us with navigating through PDF documents. We recommend that documents which have multiple headings, sections, tables, figures, references, or appendices AND more than five pages contain bookmarks. Bookmarks are not expected in Literature References; however individual references should be provided as separate files and uniquely identified.

The Validation Criteria mandates a check of any documents other than Literature References, which have more than five pages but do not contain bookmarks. A list of these will be created at validation. Excessive deficiencies may lead to rejection during the screening process or complications with the evaluation of your Application so should be avoided.

Bookmarks are the most useful navigation aid when done properly and are preferred over Table of Contents and Hyperlinks as they always remain up to date with the document's content.

3.3.2. Table of Contents

A Table of Contents (TOC), and/or if appropriate, a Table of Tables, Table of Figures, etc. can be placed on the first page for documents with multiple sections, tables, or figures.

If bookmarks are present, it is not necessary to hyperlink the TOC. Functioning bookmarks are preferred over a hyperlinked TOC. The Existence of TOCs is not validated, however the existence of bookmarks is. Invest your time in bookmarking your documents.

3.3.3. Document Title Pages

Document title pages are not necessary in an electronic Application and in fact have a negative impact on the evaluation efficiency as evaluators constantly must click to go to the next page to access the information they are seeking and have already identified via the eCTD backbone.

3.3.4. Hyperlinks

Use hyperlinks to aid navigation. A proper use of bookmarks and Leaf titles with section numbers can reduce the need for hyperlinks by encouraging the use of the eCTD index.xml and internal document navigation options. References in documents should use the Leaf titles used for those documents in the eCTD index.xml. If this is not done and the reference is not obvious, hyperlinks should be created.

Hyperlinks can cause confusion later in life cycle so the use of obvious hyperlinks should be avoided e.g., a reference in 2.3.S.1 to 3.2.S.1.1 Nomenclature is not necessary.

Module 3 uses a low level of granularity and is quite detailed in the definition of its content. Changes to the content are more frequent during later life cycle Sequences. It is therefore advised that the number of hyperlinks applied to Module 3 be limited and should be avoided if possible.

The structure for Module 4 and Module 5 however, is less defined and the content provided can vary greatly. Changes to the content is also less frequent during later life cycle Sequences. It is therefore encouraged that particular attention be applied to hyperlinks from the summaries in Module 2 to the referenced studies in Modules 4 and 5. In Particular, hyperlinks from the tabular listings of 2.6, the Synopsis of Individual Studies at 2.7.6 and the List of all Clinical Studies at 5.2 should be provided. Any reference in 2.4, 2.5, 2.6 or 2.7 to studies should be hyperlinked to the mentioned study.

If a reference is cited multiple times on a page, only the first instance needs to be hyperlinked.

External links – for example a website or email should not be provided. Enough information should be provided to enable a user to search for the link should it no longer be valid.

3.3.4.1. Mandatory Hyperlinks

The ECOWAS validation criteria will look for and confirm the existence of hyperlinks in

- 1.3.1 SmPC

- 1.0.5 Response and
- 1.2.3 Certificate (COA, CEP, etc.)

where hyperlinks to the referenced sections of the Application should be created.

Related Information and Guidance

ICH eCTD Specifications – Appendix 7

3.3.5. Document Granularity

For the ECOWAS Module 1 content, please provide documents at the lowest level of granularity defined – for example separate the Product Information documents per language, do not provide one document with all languages combined.

For Modules 2-5 please refer to the ICH M4(R4) Guideline on the Organisation of the Common Technical Document for Registration of Pharmaceuticals for Human Use for the appropriate expected granularity. Follow the lowest level of granularity defined for submitting documents.

ECOWAS recommends using the QOS template for 2.3.S and 2.3.P information. Additionally, single document summaries can be provided for 2.3.A and 2.3.R if applicable.

Note that the M4(R4) Guideline indicates a level of granularity companies can author at but asks that documents be combined into a single document for Submissions at sections 2.3.S, 2.3.P, 2.3.A and 3.2.P.2.

3.4. Empty or Missing eCTD Sections

- Provide detailed statements justifying the absence of expected data or specific CTD sections in the Cover Letter especially if the content is marked with W (Warning) or P (Possible) in the Document Matrix for the Submission Type being submitted.

Do not:

- Use documents with no substantive content – for example, documents that contain words like "not applicable" – in the eCTD structure. This creates unnecessary documents that must be included in the life cycle and causes delays for evaluators who must open and assess documents with no substantive content.

If excessive documents are found with no substantive content during the screening process, the sequence may be rejected although it passed initial validation.

- Provide a justification for content that is marked NV (Not Validated) in the Document Matrix for the Submission Type being submitted.

3.5. Study Tagging Files

We do not require you to provide Study Tagging Files (STFs) for evaluation. You can reuse content submitted in other regions where STFs have been used. If you do this make sure it conforms to the ICH specifications for study tagging files.

We will collect data about the number and size of ICH E3 16.3 CRFs and non ICH E3 documents for informational purposes as part of the Validation Criteria.

Related Information and Guidance

- ICH Specifications for Study Tagging Files – Guidance on the including of studies using the STF format.
- ICH E3 – Guidance on the Structure of Clinical Study Reports.

3.6. Updating eCTD Backbone Attributes

Updating ICH Attributes

Do not update XML backbone attributes – for example, manufacturer – during the eCTD life cycle, as these changes can lead to complexity in the evaluation process.

In instances where changes are more likely to occur – for example, manufacturer in 2.3.P / 3.2.P, a generic variable can be placed in the attribute field e.g., "MNF" and the manufacturer(s) represented by the variable can be declared and maintained in the General Note to Reviewer. Where Multiple P sections are provided due to a diluent, etc., "MNF1" and "MNF2" could be used even if in the beginning both components are the same manufacturer.

Updating ECOWAS Envelope Information

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

3.7. Reusing Files

All Sequences will be stored according to the Application Number which can then be used to make referencing possible to documents in other Sequences.

Do not submit the same document multiple times. Reusing content that has already been submitted and evaluated makes the evaluation process more efficient.

We accept and encourage you to reuse files when you:

- Need to submit a file several times within one Sequence.
- Need to submit a file again that has already been submitted in a previous Sequence.
- Need to submit a file again that has already been submitted in another eCTD Application (Application Number).

Referencing Content Submitted in Other eCTD Applications

If referencing content in another eCTD Application create the link in the xml file as shown, highlighted, in the following code:

```
<m1-4-3-clinical>
   <leaf ID="N3774598bcdd74d5891d954542c552eee" operation="new" xlink:href=
   "../../../../e000111/0000/m1/au/104-expert/1043-clinical/dr-k-boateng.pdf" checksum=
   "b6ba67a7740d12bcb938f2850baa584e" checksum-type="MD5">
       <title>Expert Dr. K. Boateng</title>
   </leaf>
   <leaf ID="N3ad8bf59e3fd4cb5bbd4f82b31350887" operation="new" xlink:href=
   "104-expert/1043-clinical/dr-a-ouattara.pdf"
checksum="bf30251122458c7c5c17dc3ed0002c1e"
   checksum-type="MD5">
       <title>Expert Dr. A. Ouattara</title>
   </leaf>
   <leaf ID="Ne0eeb59ae2f74ba5832965154db4cc13" operation="new" xlink:href=
   "104-expert/1043-clinical/dr-j-gomes.pdf"    checksum="f1e209870c05f15eef24f4b2e1e74a0f"
   checksum-type="MD5">
       <title>Expert Dr. J. Gomes</title>
   </leaf>
```

Figure 2 Referencing Content Submitted in Other eCTD Applications

This code (highlighted) directs the hyperlink out of the eCTD Application (and potentially eCTD application) and into the referenced eCTD Application using the Application Number of that eCTD application (referencing itself if directing into another Sequence of the same eCTD application).

Related Information and Guidance

ICH eCTD Specifications – Appendix 6

3.8. Baseline Sequences

It is highly recommended you provide a baseline when converting to eCTD from other formats:

- Paper
- Unstructured Electronic Files
- Structured eSubmissions – for example ECOWAS eSubmission v1.0

Baselines provides the essential information needed to create a foundation for the eCTD life cycle. In essence the baseline is a reSubmission of currently valid documents that you have already provided in another format. Access to these documents increases the efficiency of the evaluation of variations to the Application.

3.8.1. Cover Letter for Baselines

When submitting a baseline Sequence, you need to include a statement about each of the following points in the cover letter:

- The format used for the previous Submissions.
- When the previous Submissions were submitted.
- Verify that the formatting is the only change to the Application and that there are no changes to content.
- Verify that all the information in the baseline Sequence was in the previously submitted Submissions of the Application.

- Indicate any omissions that have not be provided in the baseline and verify that the omissions in the baseline Sequence do not cause the content to be misleading.

A tracking table summarising previous activities with key dates should be provided when possible.

Previous cover letters should be combined into a single bookmarked document and placed as an annex to the baseline cover letter when possible.

3.8.2. Converting to eCTD

When changing from the previous format to eCTD we recommend you:

- use a baseline Sequence as a start of an eCTD
- provide as much content as possible in the eCTD.

You can define the sections provided in a baseline Sequence, but make sure that any omissions do not cause the content to be misleading.

In most cases, it is sufficient to provide Modules 1-3 in your baseline Submission with a statement that the contents of Modules 4-5 will be made available upon request.

It is not necessary to provide administrative content from the previous format – for example, application forms, proof of payments, etc.

We prefer the baseline Sequence to consist of high-quality electronic source documents, but we will accept good quality scanned images. Please scan pages with Optical Character Recognition (OCR) when possible as this will help us search the text if necessary.

We do not evaluate the baseline and you do not need hyperlinks between documents.

3.8.3. Baseline Sequence – Required Identification

Use the Submission Type `Baseline` and Sequence Description "Initial" in the Envelope for the first baseline Sequence.

3.8.4. Ways to Submit a Baseline

The baseline should:

- be submitted as Sequence 0000
- always be a separate Sequence
- only contain previously submitted/approved content
- never include new content

The first new Submission – for example, the next variation – in eCTD format should then be submitted as Sequence 0001.

A Baseline can be submitted as a single initial Submission – Unit, or an iterative approach can be taken in which multiple baseline Sequences are provided over time as and when needed for the review of variations.

3.8.4.1. Baselines Submitted as an Initial eCTD Sequence

It is preferred that a baseline be submitted as a single Sequence and include all the relevant currently valid documents. This eliminates the need to build the baseline overtime and gives the evaluator the best overview of the product for an efficient evaluation process.

Table 2 Single Sequence Approach to a Baseline

Sequence	Submission Type	Sequence Type	Related Sequence
0000	Baseline	Initial	0000
0001	Extension of Indication	Initial	0001
0002	Extension of Indication	Response	0001
0003	Minor – Change in Tradename	Initial	0003
0004	Major – New Strength	Initial	0004

3.8.4.2. Baselines Submitted as Multiple Sequences

An iterative approach of building a baseline can be taken in which only the relevant sections related to a variation are submitted as a baseline followed by the proposed changes, supplying information as it is needed.

When creating a baseline Sequence for the first time:

- **Do** add documents previously submitted in the appropriate part of the eCTD structure with the attribute "NEW".
- **Do not** re-submit documents from previous eCTD Sequences.

You can use multiple Sequences to submit a baseline.

Example – one Sequence for the baseline for Module 3 or parts of Module 3 followed later by a Sequence for the baseline for Modules 4 and 5.

- **Do** use the Submission Type `Baseline` in each case.
- **Do** use the Sequence Type `Initial` on the first baseline Sequence.
- **Do** use the Sequence Type `Supplementary Information` on each of the baseline Sequences submitted later and indicate the Related Sequence Number of the Initial Sequence.

Make sure the related Sequence for a baseline references itself in the envelope metadata for the `Initial` Sequence.

Table 3 Multiple Sequence Approach to a Baseline demonstrates how to submit multiple baselines later in the eCTD life cycle.

In this example, the previously submitted content for a variation is submitted as a baseline prior to the initial Sequence for the Submission where it is needed.

These Sequences can be submitted together via an electronic portal or on the same electronic media. Each Sequence should have a cover letter explaining the purpose of the Sequence.

Table 3 Multiple Sequence Approach to a Baseline

Sequence	Submission Type	Sequence Type	Related Sequence
0000	**Baseline**	**Initial**	**0000**
0001	PI Change with Data	Initial	0001
0002	Extension of Indication	Initial	0002
0003	PI Change with Data	Response	0001
0004	**Baseline**	**Supplementary Information**	**0000**
0005	Major – New Strength	Initial	0005
0006	**Baseline**	**Supplementary Information**	**0000**
0007	Minor – Change in Tradename	Initial	0007
0008	Major – New Strength	Response	0005

Mid-Life Cycle Baselines of eCTD Applications

There may be rare circumstances where you may wish to submit a baseline of content previously submitted in the eCTD format. In such cases, you should send an email outlining your proposal to eCTD@wahooas.org to discuss the best approach.

3.9. Work Grouping

At times, an applicant may wish to submit more than one Submission in a single Sequence. In an eCTD Application this can be done through work grouping. The ECOWAS Envelope is designed to allow applicants to designate multiple Submission Types in a single Submission. Not all combinations of Submission Types, however, are allowed. Please refer to the Submission Type Matrix to understand which Submission Types can be combined with each other.

Work Grouping can lead to issues when:

- One of the Submissions combined in the Work Grouping is Withdrawn
- One of the Submissions combined in the Work Grouping is Rejected

For more information on how to handle Withdrawals and Rejections of Submissions that were part of Work Grouping please see section 4.5.2.3 Submission Withdrawals and Work Grouping and 4.5.3.1 Rejected Submissions and Work Grouping.

Related Information and Guidance

- Submission Type Matrix – Guidance on which Submission Types can be combined in a single Submission. ECOWAS eCTD (waho-essmed.org/eCTD)

3.10. Transfer of Applicants

If products are transferred from one applicant to another, the Application Numbers assigned to the products will continue to apply.

Multiple Application Numbers can be combined in a single Application – for example multiple strengths or duplicate products. If a transfer of only part of an Application is performed, the Acquiring Applicant must provide a Mid-Life Cycle Baseline as part of the Sequence confirming the transfer.

The eCTD Application is product specific and should be part of any transfer process. The relinquishing Applicant must provide all sequences previously submitted to the acquiring Applicant so that the Application life cycle can be continued, and historical content associated with the evaluation remains intact at the authority. Even if only a partial transfer is done – meaning not all the Application Numbers included in the Application were transferred, the entire history of the Application must be given to the acquiring Applicant so that they can provide the necessary Mid-Life Cycle Baseline when starting their new Application.

It is not enough for the relinquishing Applicant to give the documentation to the acquiring Applicant. The actual eCTD as it was submitted to the Authority must be provided so that proper life cycle management of the Application can continue.

Ideally, a Transfer of Applicant should only be undertaken when no Submissions or regulatory activities are ongoing or still under evaluation if possible. If the transfer takes place with open Submissions under evaluation, this should be addressed in the Cover Letter.

3.10.1. Basic Requirements for the Relinquishing Applicant

The relinquishing Applicant must:

- Include a Cover Letter confirming the transfer and, if applicable, address any open Submissions still under evaluation.
- Submit a Sequence using.
  - the Submission Type: `Transfer of Applicant – Relinquishing`
  - the Sequence Type: `Initial`
- No other content is required beyond the Cover Letter and Tracking Table.
- It is allowed to provide any pharmacovigilance information available up to the date of transfer.

The entire eCTD including the sequence of the Transfer of Applicant – Relinquishing must be provided to the acquiring applicant.

3.10.2. Basic Requirements for the Acquiring Applicant

If an Application is acquired that was previously submitted using the preferred eCTD format, the acquiring Applicant must continue to submit in that format, it is not possible to submit in any other format.

The Acquiring Applicant must have the entire eCTD including the sequence of the Transfer of Applicant – Relinquishing before they can submit their Transfer of Applicant – Acquiring sequence.

The acquiring Applicant must:

- Include a Cover Letter confirming the transfer and, if applicable, address any open Submissions still under evaluation.
- Submit a Sequence using.
  - the Submission Type: `Transfer of Applicant – Acquiring`
  - the Sequence Type: `Initial`
- Update any Applicant specific information – for example Company Registration Certificates, GMP Certificates, Letters of Authorisation, etc.
- If any open Submissions are to be withdrawn,
  - the Sequence(s) for the withdrawal(s) of those Submissions should be submitted together with the Sequence for Transfer in the next Sequence(s).
  - If Work Grouping was used on any of those submissions and some of the included Submissions should not be withdrawn, a Sequence should be provided re-establishing those submissions in the next Sequence.
- Any new Submissions and business as usual should proceed as normal in new Sequences once the transfer activities are complete.

3.10.3. Scenarios for Transfer of Applicants

3.10.3.1. Simple Transfer of Applicants

In a simple transfer, there is either only 1 Application Number, or all Application Numbers included in an Application are being transferred. In addition, there are no open Submissions or regulatory activities.

Table 4 Simple Transfer of Applicants

Applicant ABC	Applicant XYZ	Activity/Task
0001		Applicant ABC submits eCTD Application for product with Application Number e-NG123456
0002		Applicant ABC submits responses to recommendation and is approved, product is registered
0003		Applicant ABC sells product to Applicant XYZ and submits Sequence 0003 as `Transfer of Applicant – Relinquishing` to confirm transfer.
	0004	Applicant XZY submits Sequence 0004 as `Transfer of Applicant – Acquiring` to confirm transfer.
	0005	Applicant XYZ undertake business as usual

3.10.3.2. Transfer of Applicants with Withdrawal of Open Submissions

It is not recommended to perform a transfer with open Submissions – for example a regulatory activity is still under evaluation. If a transfer is done while a submission is open and the acquiring Applicant does not want to complete the evaluation on the open submissions, those submissions must be withdrawn by the acquiring Applicant.

Table 5 Transfer of Applicants with Withdrawal of Open Submissions

Applicant ABC	Applicant XYZ	Activity/Task
0001		Applicant ABC submits eCTD Application for product with Application Number e-NG123456
0002		Applicant ABC submits responses to recommendation and is approved, product is registered
0003		Applicant ABC submits a new Submission as `Major – Extension of Indication` with the Sequence Type `Initial`
0004		Applicant ABC sells product to Applicant XYZ and submits Sequence 0003 as `Transfer of Applicant – Relinquishing` to confirm transfer.
	0005	Applicant XZY submits Sequence 0005 as `Transfer of Applicant – Acquiring` to confirm transfer but indicates that the extension for a New Indication would no longer be sought.
	0006	Applicant XYZ submits a Sequence as `Major – Extension of Indication` with the Sequence Type `Withdrawal` and Related Sequence 0003. Sequence 0006 should be submitted together with Sequence 0005
	0007	Applicant XYZ undertake business as usual

3.10.3.3. Transfer of Applicants with Withdrawal of Open Submissions Part of Work Grouping

If Work Grouping was used and the acquiring Applicant is not interested in pursuing one of the Submissions that was grouped in the still open Submission, a withdrawal of the Submission will be required and a resubmission of the wanted activities will have to take place.

Table 6 Transfer of Applicants with Withdrawal of Open Submissions Part of Work Grouping

Applicant ABC	Applicant XYZ	Activity/Task
0001		Applicant ABC submits eCTD Application for product with Application Number e-NG123456
0002		Applicant ABC submits responses to recommendation and is approved, product is registered
0003		Applicant ABC submits a new Sequence using Work Grouping with the Submissions `Major – Extension of Indication` **and** `Pharmacovigilance` with the Sequence Type `Initial`

Applicant ABC	Applicant XYZ	Activity/Task
0004		Applicant ABC sells product to Applicant XYZ and submits Sequence 0003 as `Transfer of Applicant – Relinquishing` to confirm transfer.
	0005	Applicant XZY submits Sequence 0005 as `Transfer of Applicant – Acquiring` to confirm transfer but indicates that the extension for a New Indication would no longer be sought but that the Pharmacovigilance information still stands.
	0006	Applicant XYZ submits a Sequence as `Major – Extension of Indication` with the Sequence Type `Withdrawal` and Related Sequence 0003. Sequence 0006 should be submitted together with Sequence 0005
	0007	Applicant XYZ submits a Sequence as `Pharmacovigilance` with the Sequence Type `Initial` and Related Sequence 0007. Sequence 0007 should be submitted together with Sequence 0005 and 0006. No documents should be submitted other than the Cover Letter, only references to the files provided in Sequence 0003 should be created, reactivating the content submitted in the now withdrawn grouped activity.
	0008	Applicant XYZ undertake business as usual

3.10.3.4. Transfer of Applicants where not all Application Numbers of an Application are Transferred

If multiple Application Numbers have been grouped into a single Application, it is possible that the Applicant may want to sell one but not all of the strengths or duplicate products. In this event, the relinquishing Applicant will continue the original Application adjusting the Envelope information to exclude the products that have been sold. The acquiring Applicant, however, will need to submit a Mid-Life Cycle Baseline of the application up to the point of transfer.

The identifying Application Folder containing the application must be unique. The relinquishing Applicant must continue to use the Application Folder as used to date without change. If a master Application Number was used and that number is associated with the product sold, the acquiring Applicant will have to use a different name for their Application Folder. In this event, please contact ECOWAS for guidance on the Application Folder.

Table 7 Transfer of Applicants where not all Application Numbers of an Application are Transferred

Applicant ABC	Applicant XYZ	Activity/Task
0001		Applicant ABC submits eCTD Application for products with Application Numbers e-NG123456 and e-NG123457.

Applicant ABC	Applicant XYZ	Activity/Task
		The Application folder e-ng123456-7 is used.
0002		Applicant ABC submits responses to recommendation and Application is approved; products are registered.
0003		Applicant ABC sells product e-NG123456 to Applicant XYZ and submits Sequence 0003 as `Transfer of Applicant – Relinquishing` to confirm transfer. Cover Letter makes it clear that only the one product has been transferred.
	0004	Applicant XZY submits a New Application starting with Sequence 0004 (their first sequence) as Submission Type `Transfer of Applicant – Acquiring` to confirm transfer **and** `Baseline` providing the cumulative content from Sequences 0001-0003. The Sequence Type should be set to `Initial`. Preferably content is not physically provided for the Baseline but rather only references to the content provided in the earlier sequences are provided. The Application Folder is e-ng123456
	0005	Applicant XYZ submits a Sequence with Submission Type `Transfer of Applicant – Acquiring` and Sequence Type `Supplementary Information` to update any company specific documents – for example Company Registration Certificates, etc. Sequence 0005 should be submitted together with Sequence 0004.
	0006	Applicant XYZ undertake business as usual
0004		Applicant ABC undertake business as usual but only lists Application Number e-NG123457 in the Envelope. The Application Folder continues to be e-NG123456-7

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4. ECOWAS Module 1 General Architecture

4.1. Backbone File for ECOWAS Module 1

We have opted to use the same architecture used in the ICH Modules 2 to 5 of the eCTD and other multi-country regions e.g., EU and GCC. The ECOWAS eCTD is made up of a directory structure and a backbone of leaves in accordance with the ECOWAS Regional Document Type Definition (DTD).

The ECOWAS Module 1 eCTD backbone file is comprised of:

- a fixed eXtensible Markup Language (XML) root Element
- the eCTD Envelope Elements
- the eCTD heading Elements describing the sections where files are to be provided.

4.1.1. Creating the Module 1 eCTD backbone file

To create the ECOWAS Module 1 backbone file for a given Sequence

1. Create an XML file containing the standard XML Root Element with the appropriate XML declaration using authenticated eCTD preparation software.
2. Create the Envelope Elements containing the appropriate metadata values describing the Recipient, Application, Submission and Sequence.
3. Create Module 1 Heading Elements as needed for the Sequence:
4. Module 1 Heading Elements – organizing the ECOWAS Module 1 in accordance with the specifications.
5. Leaf Element – reference to each file being submitted along with other information such as eCTD checksum and life cycle information.
6. Name the ECOWAS Module 1 eCTD backbone file wa-regional.xml and place it in the wa subfolder within Module 1, i.e., within the m1 subfolder of the Sequence.
7. Validate the resulting backbone using a suitable eCTD validation tool. The validation should complain about a missing validation report in the Working Documents.
8. Fix any errors and warnings other than the missing validation report.
9. 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.
10. Validate the Sequence again until a perfect validation report is produced.
11. Replace the validation report in the 0001-workingdocuments folder with the final perfect validation report.
12. Follow the process to submit your Sequence.

4.1.2. Stylesheets

In addition to the ICH standard style sheet, the ECOWAS Module 1 is also provided with a standard stylesheet. These stylesheets can be used to create HTML renditions from the ICH/Regional backbones. These HTML renditions can be used to:

- View content.
- Display the complete Module 1 table of contents, i.e., all sections, irrespective of whether files are present in those sections.

- Display the ICH Module 2-5 table of content as provided in the ICH backbone.
- Enable you to use a browser to open the content.

You must submit eCTD Applications with the stylesheet.

Existence of the stylesheet is checked during the validation process.

4.1.3. Optional HTML File

An HTML rendition of the ICH and/or Regional backbone can be provided. If provided, the renditions must have been created using the style sheets provided in the “util” folder and must be placed beside the corresponding backbone file.

The HTML renditions of the backbone files must not be referenced in the backbone files.

4.2. XML Root Element

All ECOWAS Module 1 backbone files will contain the standard XML root element.

The required text includes an XML declaration and the root element `ecowas-ectd` with its attributes linking this XML file to the XML definition.

The line breaks inside of the `ecowas-ectd` Element as shown in the following two excerpts are not mandatory.

```
<?xml version="1.0" encoding="UTF-8"?>
<!DOCTYPE wa:ecowas-ectd SYSTEM "../../util/dtd/wa-regional.dtd">
<?xml-stylesheet href="../../util/style/wa-regional.xsl" type="text/xsl"?>
<wa:ecowas-ectd dtd-version="1.0"
        xmlns:wa="http://ecowas.wa"
        xmlns:xlink="http://www.w3c.org/1999/xlink">
```

Figure 3 XML Root Element with Stylesheet

4.3. Envelope Elements

The XML Envelope is a key part of a regional eCTD specification. Each Element enables the correct identification of the administrative information needed by the receiving Authority to process the Application over time.

The Envelope information is provided for each receiving Authority (Recipient) in its entirety and is broken down into the following sections:

- **Application** – High level Application information valid for multiple if not all Submissions.
- **Submission** – Information relating to the Submission (regulatory activity) that is being submitted.
- **Sequence** – Information relating to the Sequence (sequence) that is being submitted.
- **Contact Details** – Information on who should be contacted should questions arise during the evaluation process.

Each Envelope Element is subject to a defined Constraint which are:

- **Mandatory** – The Element must exist to avoid validation errors.
- **Optional** – The Element can be used but will not cause validation errors/warnings if not included.

Each Envelope Element is subject to restrictions on Occurrences which are:

- **Single** – The Element can only occur once within the restraints of the parent Element in which it occurs.
- **Multiple** – The Element can occur multiple times within the restraints of the parent Element in which it occurs.
- **Unique** – The Element can occur multiple times within the restraints of the parent Element in which it occurs, however the values associated with the Element should be unique within the restraints.

Values for some Envelope elements are restricted with a Defined List. For more information on the defined lists, please see section 4.3.3 The Defined Lists

4.3.1. Envelope Overview

Table 8 Overview of the Envelope Elements

Element	Description	Constraint	Occurrence	Defined List*
wa-envelope	Root element for envelope meta-data			
application	Parent element for Application meta-data indicating Type	Mandatory	Single	X
application-uuid	Application Identifier	Mandatory	Single	
recipient	Parent element for Recipient meta-data indicating receiving authority	Mandatory	Unique	X
lead-nmra	Lead Evaluating NMRA	Mandatory	Single	X
application-number**	Application Number	Mandatory	Unique	
applicant-id**	Applicant ID	Mandatory	Single	
applicant-name**	Applicant Legal Name	Mandatory	Single	
inn	International Non-proprietary Name	Mandatory	Unique	
proprietary-name**	Proprietary Name(s)	Mandatory	Unique	
submission	Parent element for Submission meta-data indicating Type	Mandatory	Multiple	X
submission-lead**	Submission Lead	Mandatory	Single	X
submission-number**	Submission Number	Mandatory	Unique	
sequence	Parent element for Sequence meta-data indicating Type	Mandatory	Single	X
sequence-description**	Sequence Description	Mandatory	Single	
sequence-date	Sequence Date of Submission	Mandatory	Single	
sequence-number	Sequence Number	Mandatory	Single	
related-sequence-number	Related Sequence Number	Mandatory	Single	
contact**	Parent element for Contact meta-data indicating Type	Mandatory	Unique	X
contact-name**	Contact Name	Mandatory	Single	
contact-email**	Contact Email	Mandatory	Single	
contact-phone**	Contact Phone	Optional	Single	

* Defined Lists are provided and maintained on the ECOWAS eCTD website: [ECOWAS eCTD (waho-essmed.org/eCTD)]

** Attributes may vary from one Recipient to another. Elements not designated should be consistent across all recipients.

4.3.2. Submitting Multiple Values in the Envelope

You need to provide a separate Element for each entry when submitting multiple values for Envelope Elements such as Application Number, INN, Proprietary Name, Submission Type, Submission Number and Contact Type.

Use the following code as an example for the multiple values in the Envelope:

```
<wa-envelope>
     <application code-version="1.0" code="app-type-rp">
        <application-uuid>aeb70241-6f46-4b72-8126-3e48d481960a</application-uuid>
        <recipient code-version="1.0" code="ng">
        <recipient code-version="1.0" code="bf">
        <lead-nmra code-version="1.0" code="ng">
        <application-number>e-wa-23-99991</application-number>
        <application-number>e-wa-23-99992</application-number>
        <applicant-id>NG123</applicant-id>
        <applicant-name>Pharma Corp Ltd</applicant-name>
        <inn>amoxicillin</inn>
        <inn>codeine</inn>
        <proprietary-name>afriCapsule 100mg</proprietary-name>
        <proprietary-name>afriCapsule 200mg</proprietary-name>
     </application>
     <submission code-version="1.0" code="sub-type-mi-ch-pi">
        <submission-lead code="sub-lead-pm" />
        <submission-number>pm-wa-2023-12345-1</submission-number>
        <submission-number>pm-wa-2023-12346-1</submission-number>
     </submission>
     <submission code-version="1.0" code="sub-type-mi-ch-prop-name">
        <submission-lead code="sub-lead-pm" />
        <submission-number>pv-wa-2023-12347-1</submission-number>
        <submission-number>pv-wa-2023-12348-1</submission-number>
     </submission>
     <sequence code-version="1.0" code="sequence-type-initial">
        <sequence-description>Add Strength to Prod Name</sequence-description>
```

```
        <sequence-date>2023-05-20</sequence-date>
        <sequence-number>0010</sequence-number>
        <related-sequence-number>0010</related-sequence-number>
      </sequence>
      <contact code-version="1.0" code="contact-type-reg">
        <contact-name>Dr. Chioma Abubakar</contact-name>
        <contact-email>chioma.abubakar@pharma-inc.africa</contact-email>
        <contact-phone>+234 123 456 7890</contact-phone>
      </contact>
      <contact code-version="1.0" code="contact-type-ag-nat">
        <contact-name>Yacouba Koffi</contact-name>
        <contact-email>yacouba.koffi@pharma-inc.africa</contact-email>
        <contact-phone>+225 123 456 7890</contact-phone>
      </contact>
</wa-envelope>
```

Figure 4: Submitting Multiple Values in the Envelope

4.3.3. The Defined Lists

The defined lists are separate XML files maintained by ECOWAS containing a standard set of codes for the corresponding Envelope Element. The Defined lists are maintained independent of the specifications and can be updated at any time without the need to update the specifications.

The XML file specifies:

- a `number` for each version,
- a `valid-from` for each version,
- an `expired` date (if applicable).

```
<versions>
  <version number="1.0" valid-from="2023-01-01" expired="2024-06-30"/>
  <version number="2.0" valid-from="2024-01-01" expired="2024-11-30"/>
  <version number="2.1" valid-from="2024-05-20"/>
</versions>
```

Figure 5 Defined List Version Validity

Each coded value has:

- a code which is set and will not change over time,
- its own `valid-from-version` assigned, which defines the first version of the file where this code is valid,
- its own `valid-to-version` assigned if applicable, which defines the last version of the file where the code is valid,
- a description that correlates to the assigned code. The description can be edited over time should there be a need to change the terminology

```
<item code="seq-desc-6" valid-from-version="1.0" valid-to-version="2.0">Response to Request</item>
```

Figure 6 Defined List Code Validity

Provide the `code` attribute value from the appropriate Element in the `wa-regional.xml` file. See the example XML code under section Figure 4: Submitting Multiple Values in the Envelope.

Be sure the codes used are still valid in the current version of the defined list. We will validate Sequences to ensure that codes are valid according to the version information and the Sequence Date of Submission provided in the Envelope.

The defined lists are stored on the ECOWAS website at the link below. Changes to the files will be made independent to these specifications. It is expected that validation tools will dynamically use the lists on the website for validation. Versions will always be valid for 6 months after they have been superseded.

Related Information and Guidance

- eCTD Defined Lists – Official defined list at ECOWAS eCTD (waho-essmed.org/eCTD)

4.3.4. Envelope Attributes

4.3.4.1. Application Type

The Application element section contains all the Application related information that is not related to a specific Submission or Sequence. Only one Application element section can be provided for a Recipient section.

The Application Type must be indicated for the Application element indicating whether the application is a Centralised Procedure, a National Procedure, or a Reliance Procedure.

Application Type is a coded list. The code should be indicated in the Envelope.

Example (National Procedure): app-type-np

```
<application code-version="1.0" code="app-type-cp">
```

Figure 7 Envelope Element: Application Type

Related Information and Guidance

- application-type – Official defined list for Application Type. ECOWAS eCTD (waho-essmed.org/eCTD)

4.3.4.2. Application Identifier

A universally unique identifier (UUID) as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 | ISO/IEC 9834-8:2005.

It is a 128-bit label and is unique for practical purposes when generated according to the standard methods.

The same UUID will be used for all Sequences of an eCTD application and cannot ever be changed.

Example: aeb70241-6f46-4b72-8126-3e48d481960a

```
<app-uuid>aeb70241-6f46-4b72-8126-3e48d481960a</app-uuid>
```

Figure 8 Envelope Element: Application Identifier

4.3.4.3. Recipient

The Recipient element section contains all the Envelope information for the designated receiving country and Authority.

Recipient is a coded list. The code should be placed as value in the Envelope.

```
<recipient code-version="1.0" code="ng">
```

Figure 9 Envelope Element: Recipient

Related Information and Guidance

- recipient – Official defined list for Recipient. ECOWAS eCTD (waho-essmed.org/eCTD)

The same defined list on the ECOWAS eCTD website is applied to the Envelope Attributes Recipient, Lead Evaluating NMRA and to the Heading Element Attribute Country. The value “Common” should not be used in the Envelope, it should only be applied to the heading elements.

4.3.4.3.1. Centralised Procedure – Use of Recipient

ECOWAS – WAHO should be indicated. Only 1 Recipient should be listed.

Table 9 Example Use of Recipient in a Centralised Procedure

Authority	Recipient
ECOWAS-WAHO	wa

4.3.4.3.2. National Procedure – Use of Recipient

The receiving Authority should be indicated. Only 1 Recipient should be listed.

Table 10 Example Use of Recipient in a National Procedure

Authority	Recipient
Benin-ABRP	bj
Burkina Faso-ANRP	bf
Cabo Verde-ERIS	cv
Côte d'Ivoire-AIRP	ci
The Gambia-MCA	gm
Ghana-FDA	gh
Guinea-DNPM	gn
Guinea Bissau-DGFDSL	gw
Liberia-LMHRA	lr

Authority	Recipient
Mali-DPM	ml
Niger-ARP	ne
Nigeria-NAFDAC	ng
Senegal-ARP	sn
Sierra Leone-PBSL	sl
Togo-DPM	tg

4.3.4.3.3. Reliance Procedure – Use of Recipient

All receiving Authorities should be indicated. The Lead Evaluating NMRA responsible for the evaluation should be listed first. The information for all other participating Authorities should be provided thereafter. Multiple Recipients should be listed using the same examples as indicated under National Procedure.

Table 11 Example Use of Recipient in a Reliance Procedure

Authority	Recipient
Ghana-FDA-GH*	gh
The Gambia-MCA	gm
Liberia-LMHRA	lr

* Ghana is listed first because they are the designated Lead Evaluating NMRA for the evaluation of the Application.

Authority	Recipient
Nigeria-NAFDAC*	ng
Sierra Leone-PBSL	sl

* Nigeria is listed first because they are the designated Lead Evaluating NMRA for the evaluation of the Application.

4.3.4.4. Lead Evaluating NMRA

The Lead Evaluating NMRA Element indicates who will be responsible for the evaluation. This should not be confused with the Recipient. Only one Lead Evaluating NMRA can be identified in a single Sequence.

Lead Recipient is a coded list. The code should be placed as value in the Envelope.

```
<lead-nmra code-version="1.0" code="ng">
```

Figure 10 Envelope Element: Lead Evaluating NMRA

Related Information and Guidance

- recipient – Official defined list for Lead Evaluating NMRA (the same list is used for both Recipient and Lead Evaluating NMRA). ECOWAS eCTD (waho-essmed.org/eCTD)

The same defined list on the ECOWAS eCTD website is applied to the Envelope Attributes Recipient, Lead Evaluating NMRA and to the Heading Element Attribute Country. The value “Common” should not be used in the Envelope, it should only be applied to the heading elements.

4.3.4.4.1. Centralised Procedure – Use of Lead Evaluating NMRA

The Authority designated as the Lead Coordinating NMRA by WAHO should be listed as the Lead Evaluating NMRA for Centralised Procedures.

For Centralised Procedures, the Lead Coordinating NMRA may change over time as that role is passed on from one country to another but should remain constant for all Sequences related to a particular Submission.

Unlike the Recipient Element, "wa" should not be used as the Lead Evaluating NMRA for Centralised Procedures. The actual Authority designated by WAHO as the current Lead Evaluating NMRA for Centralised Procedures should be indicated.

Table 12 Example Use of Recipient and Lead Evaluating NMRA in a Centralised Procedure

Authority	Recipient	Lead Evaluating NMRA
ECOWAS-WAHO	wa	ng*

* Where Nigeria – NAFDAC is the current designated Lead Coordinating NMRA designated to evaluate Centralised Procedures.

4.3.4.4.2. National Procedure – Use of Lead Evaluating NMRA

The Recipient and Lead Evaluating NMRA should be identical for National Procedures.

The Lead Evaluating NMRA should remain constant over the life cycle of the application for National Procedures. Should the Application Type be changed from National to Reliance at some point during the life cycle, the original evaluating NMRA will remain listed first and any additional countries signing on to the results of the evaluation and decision of the Lead Evaluating NMRA will be added as recipients as described under the Reliance Procedure section.

Table 13 Example Use of Recipient and Lead Evaluating NMRA in a National Procedure

Authority	Recipient	Lead Evaluating NMRA
Benin-ABRP	bj	bj
Burkina Faso-ANRP	bf	bf
Cabo Verde-ERIS	cv	cv
Côte d'Ivoire-AIRP	ci	ci
The Gambia-MCA	gm	gm
Ghana-FDA	gh	gh
Guinea-DNPM	gn	gn
Guinea Bissau-DGFDSL	gw	gw
Liberia-LMHRA	lr	lr
Mali-DPM	ml	ml
Niger-ARP	ne	ne
Nigeria-NAFDAC	ng	ng
Senegal-ARP	sn	sn
Sierra Leone-PBSL	sl	sl
Togo-DPM	tg	tg

4.3.4.4.3. Reliance Procedure – Use of Lead Evaluating NMRA

The main country responsible for evaluation should be listed for Reliance Procedures.

Table 14 Example Use of Recipient and Lead Evaluating NMRA in a Reliance Procedure

Authority	Recipient	Lead Evaluating NMRA
Ghana-FDA*	gh	gh
The Gambia-MCA	gm	gh
Liberia-LMHRA	lr	gh

* Ghana is designated Lead Evaluating NMRA for the evaluation of the Application. Results of evaluation will be adopted by The Gambia and Liberia per Reliance agreements.

Authority	Recipient	Lead Evaluating NMRA
Nigeria-NAFDAC	ng	ng
Sierra Leone-PBSL	sl	ng

* Nigeria is designated Lead Evaluating NMRA for the evaluation of the Application. Results of evaluation will be adopted by Sierra Leone per Reliance agreements.

4.3.4.5. Application Number

For Centralised Procedures, each product will be assigned a unique Application Number. The Application Number is a combination of

- the letter "e" for eCTDs or "f" for eSubmissions,
- "wa" (West Africa) to identify an ECOWAS Centralised Procedure,
- the year and
- five digits.

Example: e-wa-23-12345 / f-wa-23-12345

An Application Numbers will be assigned to:

- Each strength for products with multiple strengths.
- Each form for products with multiple forms.
- Each duplicate products, also – for example for all strengths and forms of the duplicate.

Multiple Application Numbers can be included in an Application depending on the Authorities policies for including multiple products in a single Application. In some cases, it is appropriate to combine different strengths and any duplicates in a single Application, but many Authorities will not allow the combination of different forms. In this case, a separate Application should be created for each form.

Table 15 Application Numbers for Different Strengths, Forms and Duplicates

Product	Strength	Form	Application Number
afriCapsule HGC	200mg	Hard Gelatine Capsule	e-wa-23-00001
afriCapsule HGC HS	100mg	Hard Gelatine Capsule	e-wa-23-00002
afriCapsule HGC DS	400mg	Hard Gelatine Capsule	e-wa-23-00003
afriCapsule LFHC	200mg	Liquid-filled Hard Capsules	e-wa-23-00004
afriCapsule LFHC HS	100mg	Liquid-filled Hard Capsules	e-wa-23-00005
afriCapsule LFHC DS	400mg	Liquid-filled Hard Capsules	e-wa-23-00006
genCapsule* HGC	200mg	Hard Gelatine Capsule	e-wa-23-00007
genCapsule* HGC HS	100mg	Hard Gelatine Capsule	e-wa-23-00008

genCapsule* HGC DS	400mg	Hard Gelatine Capsule	e-wa-23-00009
genCapsule* LFHC	200mg	Liquid-filled Hard Capsules	e-wa-23-00010
genCapsule* LFHC HS	100mg	Liquid-filled Hard Capsules	e-wa-23-00011
genCapsule* LFHC DS	400mg	Liquid-filled Hard Capsules	e-wa-23-00012

* In this example, genCapsule is a duplicate product of afriCapsule. The products are identical, but an additional product name is being registered at the same time.

Enter the Application Number assigned by the receiving Authority and use it as the name for the eCTD Application folder which contains Sequence folders.

Applications provided in the eCTD format will be prefixed with an "e".

Application provided in the eSubmission format will be prefixed with an "f".

The ID will reference the two-letter country code of the receiving Authority or if filed as an ECOWAS procedure the code "wa" will be used.

```
<app-number>e-ng-999991</app-number>
```

Figure 11 Envelope Element: Application Number

See the example XML code in section 0 * Defined Lists are provided and maintained on the ECOWAS eCTD website: ECOWAS eCTD (waho-essmed.org/eCTD)

** Attributes may vary from one Recipient to another. Elements not designated should be consistent across all recipients.

Submitting Multiple Values in the Envelope.

For National Procedures and Reliance Procedures, please refer to the national guidance on Application Numbers.

Related Information and Guidance

- Portal Process Guide – Explanation on how to obtain an Application Number in the Portal and be found at ECOWAS eCTD (waho-essmed.org/eCTD)

4.3.4.6. Applicant ID

The applicant's Applicant ID as issued for the first Application should be used.

For Centralised Procedures, the Applicant ID is a combination of the country code where the company is registered and a running number for that country.

Example: ng123

```
<applicant-id>ng123</applicant-id>
```

Figure 12 Envelope Element: Applicant ID

For National Procedures and Reliance Procedures, please refer to the national guidance on Applicant IDs.

Related Information and Guidance

- Portal Process Guide – Explanation on how to obtain an Applicant ID in the Portal. ECOWAS eCTD (waho-essmed.org/eCTD).

4.3.4.7. Applicant Name

The applicant's legal name as registered should be used.

Example: Pharma Corp Ltd

```
<applicant-name>Pharma Corp Ltd</applicant-name>
```

Figure 13 Envelope Element: Applicant Name

4.3.4.8. International Non-proprietary Name(s) (INN)

The recognised International Non-proprietary Name should be given. It should be written in all lower-case letters and provided exactly as listed as INN without abbreviations.

Example: amoxicillin

```
<inn>amoxicillin</inn>
```

Figure 14 Envelope Element: INN

See the example XML code in section 0 * Defined Lists are provided and maintained on the ECOWAS eCTD website: ECOWAS eCTD (waho-essmed.org/eCTD)

** Attributes may vary from one Recipient to another. Elements not designated should be consistent across all recipients.

Submitting Multiple Values in the Envelope.

4.3.4.9. Proprietary Name(s)

The name or proposed medicine (trade) name to be used on the Certificate of Registration.

For Master Files, insert name of manufacturing site.

Example: afriCapsule.

```
<proprietary-name>afriCapsule A</proprietary-name>
```

Figure 15 Envelope Element: Proprietary Names

See the example XML code in section 0 * Defined Lists are provided and maintained on the ECOWAS eCTD website: ECOWAS eCTD (waho-essmed.org/eCTD)

** Attributes may vary from one Recipient to another. Elements not designated should be consistent across all recipients.

Submitting Multiple Values in the Envelope

4.3.4.10. Submission Type

The Submission Element section contains all the Submission related information that is not related to a specific Sequence. Multiple Submission Element sections can be provided for a Recipient section if the combination is allowed in the Submission Type Matrix.

The Submission Type must be indicated for the Submission Element indicating type of regulatory activities being undertaken with the Submission.

When multiple Submissions are listed, follow-up (responses, supplemental information and/or withdrawals) should only list the Submissions that are directly affected by the content being submitted in the follow-up Sequence. For example, if a variation Submission and a pharmacovigilance Submission are combined in the first Sequence but only a response was required for the variation, the pharmacovigilance Submission would not be listed in the Envelope of the response.

Once a Submission has started it is not possible to combine new Submissions with the responses of existing Submissions.

We recommend whenever possible to avoid combining Submissions in a single Sequence, however combinations in line with the Submission Type Matrix will be allowed.

Submission Type is a coded list. The code should be indicated in the Envelope.

Example: sub-type-na-gen

```
<submission code-version="1.0" code="sub-type-na-gen">
```

Figure 16 Envelope Element: Submission Type

See the example XML code in section 0 * Defined Lists are provided and maintained on the ECOWAS eCTD website: ECOWAS eCTD (waho-essmed.org/eCTD)

** Attributes may vary from one Recipient to another. Elements not designated should be consistent across all recipients.

Submitting Multiple Values in the Envelope

Related Information and Guidance

- submission-type – Official defined list for Submission Type. ECOWAS eCTD (waho-essmed.org/eCTD)
- Submission Type Matrix – A summary of which combination of Submission Types is allowed when referencing multiple Submissions in a single Sequence. ECOWAS eCTD (waho-essmed.org/eCTD)

4.3.4.11. Submission Lead

The Submission Lead identifies the group within the Authority which is expected to take the lead in the evaluation process for a particular Submission. A Submission lead should be indicated for each Submission Element section provided.

Submission Type is a coded list. The code should be indicated in the Envelope.

Example (Prescription): sub-lead-pm

```
<submission-lead code-version="1.0" code="sub-lead-pm" />
```

Figure 17 Envelope Element: Submission Lead

Related Information and Guidance

- submission-lead – Official defined list for Submission Lead. ECOWAS eCTD (waho-essmed.org/eCTD)

4.3.4.12. Submission Number(s)

The Submission number(s) applicable to the Sequence being submitted should be indicated.

Within an Application, there will be multiple Submissions (regulatory activities). Each Submission should have a unique identifier within the Application which added to the Application Number creates a unique identifier overall for each Submission.

Submission Numbers are made up of the following components.

Table 16 Submission Number Components Explained

Component	Description
Application Number	The Application Number applied to the product, strength, etc.
Submission Lead ID	Prefix identifying the Submission lead for evaluation purposes
Country Code	The country code of the receiving Authority where the Application is evaluated
Year	The year in which the first Sequence of the Submission was submitted
Running Number	3 digit running number for the year
Evaluation Stream	An identifier that can be used to manage resource load by the Authority and streamline the assignment of evaluation.

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1177 **Table 17 Submission Lead Prefixes for Submission Numbers**

Prefix	Submission Lead
bm	Biological Medicines
bp	Blood Products
cm	Complimentary Medicines
md	Medical Devices
mf	Master Files
pm	Pharmaceutical Medicines
pv	Pharmacovigilance
tm	Traditional Medicines

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If appropriate, multiple Submission numbers can be given for a particular Submission.

Example (Prescription Medicines): e-wa-23-12345-pm-wa-23-123-1

```
<submission-number>e-wa-23-12345-pm-wa-23-123-1</submission-number>
```

Figure 18 Envelope Element: Submission Number

See the example XML code in section 0 * Defined Lists are provided and maintained on the ECOWAS eCTD website: ECOWAS eCTD (waho-essmed.org/eCTD)

** Attributes may vary from one Recipient to another. Elements not designated should be consistent across all recipients.

Submitting Multiple Values in the Envelope

Related Information and Guidance

- Portal Process Guide – Explanation on how to obtain a Submission Number in the Portal. ECOWAS eCTD (waho-essmed.org/eCTD)

4.3.4.13. Sequence Type

The Sequence Element section contains all the Sequence related information. It identifies what is happening to the Submission with the Sequence being submitted. Only one Sequence Element section can be specified per Sequence.

The first Sequence of a Submission must always be `Initial`. Follow-up Sequences should indicate whether it is a `Response`, `Supplementary Information`, `Closing Information`, or a `Submission Withdrawal`.

Sequence Type is a coded list. The code should be indicated in the Envelope.

Example (Initial): seq-type-initial

```
<submission-unit code-version="1.0" code="seq-type-initial">
```

Figure 19 Envelope Element: Sequence Type

Related Information and Guidance

- sequence-type – Official defined list for Sequence Type. ECOWAS eCTD (waho-essmed.org/eCTD)

4.3.4.14. Sequence Description

The Sequence Description element gives the applicant the opportunity to better describe what is being done in the Sequence. The following should be considered when providing a Sequence Description

- **Make it Short, Precise and Distinguishing** – Don't write an extensive description, this should be done in the Cover Letter and/or Reviewer's Guide. Think of the description as a categorisation of the Sequence that will help distinguish it from a long list of Sequences provided.
- **Avoid Repeating Information** – Don't indicate the Submission Type or the Sequence Type in the Description. Give us more precise details but keep in short.
- **For Initial Sequence Types** – Give us more detail about the Submission Type

- **For Supplemental Information** – Give us information on what is being provided
- **For Responses** – Indicate the date of the recommendations e.g., "*Response to 2021-11-20 LOQ"*
- **For Withdrawals** – Indicate a brief reason for withdrawal

Example (New Generic Medicine – Initial): New Application

Example (New Generic Medicine – Response): Response to 2021-11-20 LOQ - Quality

Example (Extension of Indication – Initial): Indication Psoriasis to be added

```
<sequence-description>SmPC Changes to Blister Pack</sequence-description>
```

Figure 20 Envelope Element: Sequence Description

4.3.4.15. Sequence Date

The Sequence Date is a date field indicating the date the Sequence is submitted. This date should correlate as close as possible with the date on the Cover Letter and in the Application Form but must not be exact. The Sequence Date is mainly used to ensure the validity of the codes used from the Define Lists. Based on the Submission Date, the validation tools should check to ensure that the code used is valid at the time of the Submission Date.

Sequence Dates will be checked during validation to ensure they indicate a date within 30 days of the date of validation. Dates outside this period will cause validation warnings which must be addressed in the Cover Letter.

The date should be provided using the format YYYY-MM-DD.

Example – 2023-05-20

```
<sequence-date>2023-05-20</sequence-date>
```

Figure 21 Envelope Element: Sequence Date

4.3.4.16. Sequence Number

Four-digit number matching the Sequence folder being submitted.

Applications starting with a `Baseline` Submission Type should start with the Sequence 0000. If an iterative baseline approach is being used, the first baseline Sequence should be 0000. Following baseline Sequences should simply fall in line with the next Sequence number available at the time.

New Applications without baseline Sequences should start with the Sequence 0001.

Example - 0001

```
<sequence-number>0001</sequence-number>
```

Figure 22 Envelope Element: Sequence Number

4.3.4.17. Related Sequence Number

The Related Sequence Number is used to group Sequences belonging to the same Submission. This enables us to easily evaluate Sequences associated with a particular Submission.

All Sequences that belong to a specific Submission should contain the same four-digit number in the Related Sequence Number field as demonstrated in the table:

Table 18 Related Sequence Explained

Sequence Number	Related Sequence Number	Submission Type	Sequence Type
0001	**0001**	New NCE	Initial
0002	**0001**	New NCE	Supplementary Information
0003	**0001**	New NCE	Response
0004	**0004**	Major - New Dosage Form	Initial
0005	**0005**	Additional Tradename	Initial
0006	**0006**	SmPC Change with Data	Initial

0007	0004	Major - New Dosage Form	Supplementary Information
0008	0004	Major - New Dosage Form	Response
0009	0004	Major - New Dosage Form	Response
0010	0006	SmPC Change with Data	Response

Each Initial Sequence of a Submission will reference itself.

Each follow-up Sequence of a Submission will reference the initial Sequence of that Submission.

The Related Sequence Number should be approached similar to the Submission ID described in the US regional specification 2.5 and the Related Sequence Number in the AU regional specifications 3.1

Example – 0001

```
<related-sequence-number>0001</related-sequence-number>
```

Figure 23 Envelope Element: Related Sequence Number

4.3.4.18. Contact Type

The Contact element section contains all the Contact related information for a particular Contact Type. Multiple Contact Elements are allowed as long as they are unique in type, for example multiple Technical Contacts cannot be provided but a Quality Contact and a Clinical Contact are allowed. At least one contact must be provided but multiple are not required.

Contact information may be used by the evaluators or by the Authority to contact the Applicant on questions during the evaluation process.

The Contact Type must be indicated for the Contact element

Contact Type is a coded list. The code should be indicated in the Envelope.

Example (Quality Contact): contact-type-reg

```
<contact code-version="1.0" code="contact-type-reg">
```

Figure 24 Envelope Element: Contact Type

See the example XML code in section 0 * Defined Lists are provided and maintained on the ECOWAS eCTD website: ECOWAS eCTD (waho-essmed.org/eCTD)

** Attributes may vary from one Recipient to another. Elements not designated should be consistent across all recipients.

Submitting Multiple Values in the Envelope

Related Information and Guidance

- contact – Official defined list for Contact Type. ECOWAS eCTD (waho-essmed.org/eCTD)

4.3.4.19. Contact Name

A Contact Name must be provided for each Contact Type. Only one name can be provided per Contact Type.

Example: Dr. Chioma Abubakar

```
<contact-name>Dr. Chioma Abubakar</contact-name>
```

Figure 25 Envelope Element: Contact Name

4.3.4.20. Contact Email

A Contact Email must be provided for each Contact Type. Only one email address can be provided per Contact Type.

Example: hioma.abubakar@pharma*-inc.africa*

```
<contact-email>chioma.abubakar@pharma-inc.africa</contact-email>
```

Figure 26 Envelope Element: Contact Email

4.3.4.21. Contact Phone

A Contact Phone number can be provided for each Contact Type but is not mandatory. Only one number can be provided per Contact Type. While this is an optional field, we encourage the applicant to provide phone numbers whenever possible.

Example: +234 123 456 7890

```
<contact-phone>+234 123 456 7890</contact-phone>
```

Figure 27 Envelope Element: Contact Phone

4.4. Heading and Leaf Elements

4.4.1. Module 1 Heading Elements

The tables in this section list the Heading elements of the ECOWAS eCTD Module 1 v1.0 which should be provided in the <m1-wa> element.

Content under the following headings should be provided when required as defined in the Document Matrix.

Please refer to the CTD guidance for information on what is expected under each of these sections. Please note that some sections are for future use and may not be mandatory. We encourage to regularly check for updates to the Document Matrix.

Please refer to Appendix A: Best Practice Leaf Title Recommendations for guidance on how best to title content added to the defined sections.

The Attribute column indicates the additional information that will be required in the XML-Element. For technical details, please refer to the DTD.

The same defined list on the ECOWAS eCTD website is applied to the Envelope Attributes Recipient, Lead Evaluating NMRA and to the Heading Element Attribute Country. The value “Common” should not be used in the Envelope, it should only be applied to the heading elements.

Table 19 Heading Elements 1.0 – Correspondence

Section ID	Title	XML-Element	Attribute
1.0	**Correspondence**	**m1-0-correspondence**	
1.0.1	Cover Letter	m1-0-1-cover-letter	Country
1.0.2	General Note to Reviewer	m1-0-2-reviewer-note	
1.0.3	Life Cycle Management Tracking Table	m1-0-3-tracking-table	
1.0.4	Correspondence Issued by the Regulatory Authority	m1-0-4-authority-correspondence	Country
1.0.5	Response to Information Solicited by the Regulatory Authority	m1-0-5-response	Country

1.0.6	Meeting Information	m1-0-6-meeting-info	
1.0.7	Request for Appeal Documentation	m1-0-7-request-appeal	

1297

1298 **Table 20 Heading Elements 1.2 – Administrative Information**

Section ID	Title	XML-Element	Attribute
1.2	**Administrative Information**	**m1-2-admin-info**	
1.2.1	Application Forms	m1-2-1-app-form	Country
1.2.2	Fee Forms	m1-2-2-fee-form	Country
1.2.3	Certification and Attestation Forms	m1-2-3-certification-attestation-form	
1.2.4	Compliance and Site Information	m1-2-4-compliance-site-info	
1.2.5	Authorization for Sharing Information	m1-2-5-auth-share-info	
1.2.6	Electronic Declaration	m1-2-6-electronic-declaration	
1.2.7	Trademark & Intellectual Property Information	m1-2-7-trademark-ip-info	
1.2.8	Screening Details	m1-2-8-screening-details	
1.2.A	Additional Administrative Information	m1-2-a-additional-admin-info	

1299

1300 **Table 21 Heading Element 1.3 – Product Information**

Section ID	Title	XML-Element	Attribute
1.3	**Product Information**	**m1-3-product-info**	
1.3.1	Summary of Product Characteristics	m1-3-1-smpc	Country
1.3.1.1	Approved - SmPC	m1-3-1-1-smpc-approved	
1.3.1.1.1	Approved - SmPC - English	m1-3-1-1-1-smpc-approved-en	Translation Status
1.3.1.1.2	Approved - SmPC - French	m1-3-1-1-2-smpc-approved-fr	Translation Status
1.3.1.1.3	Approved - SmPC - Portuguese	m1-3-1-1-3-smpc-approved-pt	Translation Status
1.3.1.2	Clean - SmPC	m1-3-1-2-smpc-clean	

Section ID	Title	XML-Element	Attribute
1.3.1.2.1	Clean - SmPC - English	m1-3-1-2-1-smpc-clean-en	Translation Status
1.3.1.2.2	Clean - SmPC - French	m1-3-1-2-2-smpc-clean-fr	Translation Status
1.3.1.2.3	Clean - SmPC - Portuguese	m1-3-1-2-3-smpc-clean-pt	Translation Status
1.3.1.3	Annotated - SmPC	m1-3-1-3-smpc-annotated	
1.3.1.3.1	Annotated - SmPC - English	m1-3-1-3-1-smpc-annotated-en	Translation Status
1.3.1.3.2	Annotated - SmPC - French	m1-3-1-3-2-smpc-annotated-fr	Translation Status
1.3.1.3.3	Annotated - SmPC - Portuguese	m1-3-1-3-3-smpc-annotated-pt	Translation Status
1.3.2	Patient Information Leaflet	m1-3-2-pil	Country
1.3.2.1	Approved - PIL	m1-3-2-1-pil-approved	
1.3.2.1.1	Approved - PIL - English	m1-3-2-1-1-pil-approved-en	Translation Status
1.3.2.1.2	Approved - PIL - French	m1-3-2-1-2-pil-approved-fr	Translation Status
1.3.2.1.3	Approved - PIL - Portuguese	m1-3-2-1-3-pil-approved-pt	Translation Status
1.3.2.2	Clean - PIL	m1-3-2-2-pil-clean	
1.3.2.2.1	Clean - PIL - English	m1-3-2-2-1-pil-clean-en	Translation Status
1.3.2.2.2	Clean - PIL - French	m1-3-2-2-2-pil-clean-fr	Translation Status
1.3.2.2.3	Clean - PIL - Portuguese	m1-3-2-2-3-pil-clean-pt	Translation Status
1.3.2.3	Annotated - PIL	m1-3-2-3-pil-annotated	
1.3.2.3.1	Annotated - PIL - English	m1-3-2-3-1-pil-annotated-en	Translation Status
1.3.2.3.2	Annotated - PIL - French	m1-3-2-3-2-pil-annotated-fr	Translation Status
1.3.2.3.3	Annotated - PIL - Portuguese	m1-3-2-3-3-pil-annotated-pt	Translation Status
1.3.3	Container Labels	m1-3-3-labels	Country
1.3.3.1	Approved - Container Labels	m1-3-3-1-labels-approved	
1.3.3.1.1	Approved - Container Labels - English	m1-3-3-1-1-labels-approved-en	Translation Status
1.3.3.1.2	Approved - Container Labels - French	m1-3-3-1-2-labels-approved-fr	Translation Status
1.3.3.1.3	Approved - Container Labels - Portuguese	m1-3-3-1-3-labels-approved-pt	Translation Status
1.3.3.2	Clean - Container Labels	m1-3-3-2-labels-clean	
1.3.3.2.1	Clean - Container Labels - English	m1-3-3-2-1-labels-clean-en	Translation Status
1.3.3.2.2	Clean - Container Labels - French	m1-3-3-2-2-labels-clean-fr	Translation Status

Section ID	Title	XML-Element	Attribute
1.3.3.2.3	Clean - Container Labels - Portuguese	m1-3-3-2-3-labels-clean-pt	Translation Status
1.3.3.3	Annotated - Container Labels	m1-3-3-3-labels-annotated	
1.3.3.3.1	Annotated - Container Labels - English	m1-3-3-3-1-labels-annotated-en	Translation Status
1.3.3.3.2	Annotated - Container Labels - French	m1-3-3-3-2-labels-annotated-fr	Translation Status
1.3.3.3.3	Annotated - Container Labels - Portuguese	m1-3-3-3-3-labels-annotated-pt	Translation Status
1.3.4	Foreign Labelling	m1-3-4-foreign-label	
1.3.4.1	Approved - Foreign Labelling - English	m1-3-4-1-foreign-en	Translation Status
1.3.4.2	Approved - Foreign Labelling - French	m1-3-4-2-foreign-fr	Translation Status
1.3.4.3	Approved - Foreign Labelling - Portuguese	m1-3-4-3-foreign-pt	Translation Status
1.3.4.4	Approved - Foreign Labelling - Original Language	m1-3-4-4-foreign-origin	Translation Status
1.3.5	Reference Product Labelling	m1-3-5-ref-prod-label	
1.3.5.1	Approved - Reference Product - English	m1-3-5-1-ref-prod-en	Translation Status
1.3.5.2	Approved - Reference Product - French	m1-3-5-2-ref-prod-fr	Translation Status
1.3.5.3	Approved - Reference Product - Portuguese	m1-3-5-3-ref-prod-pt	Translation Status
1.3.5.4	Approved - Reference Product - Original Language	m1-3-5-4-ref-prod-origin	Translation Status
1.3.6	Artwork and Samples	m1-3-6-artwork-samples	
1.3.6.1	Statement Confirming Submission of Samples	m1-3-6-1-statement-confirming-samples	
1.3.6.2	Artwork and Pictures of Samples	m1-3-6-2-artwork-samples	

Table 22 Heading Elements 1.4 – Information about the Experts

Section ID	Title	XML-Element	Attribute
1.4	**Information about the Experts**	**m1-4-info-experts**	
1.4.1	Quality	m1-4-1-quality	
1.4.2	Nonclinical	m1-4-2-nonclinical	
1.4.3	Clinical	m1-4-3-clinical	

Table 23 Heading Elements 1.5 – Environmental Risk Assessment

Section ID	Title	XML-Element	Attribute
1.5	**Specific Requirements for Different Types of Applications**	**m1-5-specific-requirements**	
1.5.1	Bioequivalence Trial Information	m1-5-1-bti	

Table 24 Heading Elements 1.6 – Environmental Risk Assessment

Section ID	Title	XML-Element	Attribute
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	

Table 25 Heading Elements 1.7 – Good Manufacturing Practice

Section ID	Title	XML-Element	Attribute
1.7	**Good Manufacturing Practice**	**m1-7-gmp**	
1.7.1	Date of Inspection of Each Site	m1-7-1-date-inspection-each-site	
1.7.2	Inspection Reports or Equivalent Documents	m1-7-2-inspection-reports	
1.7.3	GMP Certificates or Manufacturing Licences	m1-7-3-gmp-certificates	
1.7.3.1	API	m1-7-3-1-api	
1.7.3.2	FPP	m1-7-3-2-fpp	
1.7.4	Other GMP Documents	m1-7-4-other-gmp	

Table 26 Heading Elements 1.8 – Information Relating to Pharmacovigilance

Section ID	Title	XML-Element	Attribute
1.8	**Information Relating to Pharmacovigilance**	**m1-8-info-relating-to-pv**	
1.8.1	Pharmacovigilance Systems	m1-8-1-pv-systems	
1.8.2	Risk Management Plan	m1-8-2-risk-mngt-plan	

1311

1312 **Table 27 Heading Elements 1.9 – Individual Patient Data – Statement of Availability**

Section ID	Title	XML-Element	Attribute
1.9	**Individual Patient Data - Statement of Availability**	**m1-9-individual-patient-data**	

1313

1314 **Table 28 Heading Elements 1.10 – Foreign Regulatory Information**

Section ID	Title	XML-Element	Attribute
1.10	**Foreign Regulatory Information**	**m1-10-foreign-reg-info**	
1.10.1	Regional & Foreign Regulatory Status	m1-10-1-status	
1.10.2	WHO Type Certificate of Pharmaceutical Product (COPP)	m1-10-2-copp	
1.10.3	Data Set Similarities and Differences	m1-10-3-data-set-similarities	
1.10.4	Foreign Evaluation Reports	m1-10-4-foreign-evaluation-reports	

1315

1316 **Table 29 Heading Elements 1.A – Additional Data**

Section ID	Title	XML-Element	Attribute
1.A	**Additional Data**	**m1-a-additional-data**	
1.A.1	Country Specific Data	m1-a-1-country-specific-data	Country

1317

4.4.2. Leaf Element

The `leaf` elements provide the content for each heading element.

These elements contain, the `title` element along with several other attributes, all based upon the ICH eCTD definition provided in the Electronic Common Technical Document Specification (Version 3.2.2).

Note that the structure and information associated with a Leaf should be created automatically by the eCTD software.

```
<m3-2-s-1-2-structure>
<leaf
   ID="Nba62a4e215fb40479b4151fa38bd80ad"
   operation="replace"
   xlink:href="m3/32-body-data/32s-drug-sub/olive-abc/32s1-gen-info/structure.pdf"
   checksum="14f0984f1116ac9d4fe43d31c7fee14f"
   checksum-type="MD5"
   xml:lang="en"
   modified-file="../0000/index.xml#Nba62a4e215fb40479b4151fa38bd80ad">
   <title>Structure</title>
</leaf>
</m3-2-s-1-2-structure>
```

Footnote: The line breaks in the above example have been created here to make the display of the attributes more user friendly but will likely not be present in the actual XML file.

Figure 28 Leaf Element Explained

Each `Leaf` element contains the following attributes when appropriate:

- **ID** – The ID attribute is intended to be a unique reference within the Submission that can be used to reference the item from another item within the XML document.
- **Operation** – Indicates the action being performed e.g., New, Replace, Delete or Append
- **xlink:href** – Provides the reference (path) to the actual content file. Must be relative to the application folder.
- **Checksum** – The checksum value for the file being submitted. A checksum is a sequence of numbers and letters used to check data for validity. If we know the checksum of the original file, we can use a checksum utility to confirm the copy received and evaluated is identical.
- **Checksum Type** – The checksum algorithm used.
- **Language** – The language of the content referenced. Some sections will have specific language requirements depending on the country. If left empty or absent from the Leaf definition, the language will be assumed to be English since English is the accepted international language of the ICH eCTD Module 2-5. This attribute has been included in the ECOWAS Leaf requirements to enable validation of language based on country selected. Language should be included in all Module 1 Leaves in an ECOWAS application. If it is left blank for any Module 1 leaf, a validation warning will result.

- **Modified File** – Provides the location of the `Leaf` that is being modified (i.e., replaced, appended, or deleted) by the `Leaf` element. The modified-file attribute points to the "index.xml" file and the Leaf ID of the Leaf being altered.
- **Title** – A practical name for the file being referenced by the Leaf. This is the only thing the evaluator will see and should be descriptive and distinguishing, especially in sections where multiple `Leaf` elements are being submitted.

Operation – Append should only be used in connection with Study Tagging Files.

4.4.3. Element Attributes

As defined in the Heading Element table's Attribute column, there are specific sections where additional attribute information will need to be provided to identify:

- Country – used to differentiate content when Application is submitted in multiple countries.
- Language – used to identify language of content provided. Specifically, to enable validation of specific language requirements for countries.
- Translation Status – indicates whether the content provided is the original or a translated copy.

In addition, there are language requirements in certain sections for the Leaf Element.

4.4.3.1. Country

The ISO 2 letter country code should be used for the country attribute. For common data for multiple countries in a Reliance Procedure or when addressing ECOWAS as a whole in a Centralised Procedure, the unofficial 2 letter region code "wa" should be used.

Table 30 Country Defined List

Recipient	
List Code	**List Value**
wa	ECOWAS-WAHO
bj	Benin-ABRP
bf	Burkina Faso-ANRP
cv	Cabo Verde-ERIS
ci	Côte d'Ivoire-AIRP
gm	The Gambia-MCA
gh	Ghana-FDA
gn	Guinea-DNPM
gw	Guinea Bissau-DGFDSL
lr	Liberia-LMHRA
ml	Mali-DPM
ne	Niger-ARP
ng	Nigeria-NAFDAC
sn	Senegal-ARP
sl	Sierra Leone-PBSL

tg	Togo-DPM
common	Common

4.4.3.2. Translation Status

The translations status indicates whether the document is the original or a translated copy. This is important to understand should there be any conflicts of interpretations.

Table 31 Translation Status Defined List

Translation Status	
List Code	**List Value**
trans-type-orig	Original
trans-type-trans	Translation

4.4.3.3. Language

Language can be applied to the Leaf element in all sections, it is not limited to the ECOWAS module 1.

The ISO 2 letter language code should be used for the language attribute. Only the official ECOWAS languages are validated. The language attribute should be used where a specific language is required or in instances where translations are being provided, the language Leaf attribute will help to differentiate the content for the evaluators.

For instances where an original copy is provided that is not in one of the ECOWAS languages e.g., sections 1.3.4.4 and 1.3.5.4, please indicate the language in the Leaf title as well as the language attribute.

If the language attribute is left blank or is missing from a Leaf, it will be assumed that the content is provided in English. For sections that require another language, this will lead to a validation error.

Table 32 ECOWAS Language Defined List

Language	
List Code	**List Value**
en	English
fr	French
pt	Portuguese

4.4.4. Node Extensions

Node extensions are additional heading structures beyond those defined by the specifications, generally equated to an additional subfolder in a defined section and are a way of providing additional information in the Sequence.

The node extension should be visualised as an extra heading in the CTD structure and should be displayed when viewing the XML backbone.

Node Extensions should not be changed during the life cycle once established. Note that changes in the Titles associated with the Node Extensions would constitute a change and must be avoided to prevent validation issues.

General Rules for Using Node Extensions:

- Only use node extensions at the lowest level of the eCTD structure.
  Example – you can use a node extension at the level 5.3.5.1 but not at the level 5.3.
- Use node extensions to group documents made up of multiple Leaf elements.
  Example – a clinical study made up of separate files for the synopsis, main body and individual appendices should be grouped together under a node extension with the Study Identifier as its Title attribute.
- Nest the node extensions but make sure the first node extension is at the lowest level in the eCTD structure.
  Example – a node extension may be added in Module 5.3.7 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.
- Make `title` elements short, precise, and informative. Do not repeat information already categorized by heading elements.
- Place the most important identifying/distinguishing information at the beginning so we do not have to scroll to the end of the title.
- You can repeat the optional node extension and Leaf elements as required. The DTD will ensure the checksum-type attribute contains either "MD5" or "md5".

You can use the `node-extension` elements:

- to define structures beyond the heading elements.
- wherever a leaf element is allowed in the DTD.
- to organise multiple files which are needed under a normal eCTD heading.
  Example – nonclinical studies with multiple files provided in 4.2.
  Example – complex presentation of data in the analytical procedures and validation of analytical procedures sections of 3.2.S.4.2/3 and 3.2.P.5.2/3

You must use the `node-extension` elements:

for all clinical studies and content provided in 5.3

Note that if node extensions are not used for clinical studies an error will result in the validation.

Do not use the `node-extension` elements:

- if ICH-specified sub-headings already exist
  Example – do not use the following as node extensions:
  – *indication*
  – *excipient*
  – *manufacturer*
  – *drug substance*
  – *drug product.*
- if it not the lowest level of the eCTD Structure

Note that if node extensions are used where ICH subheadings already exist or at a level that is not the lowest level an error will result in the validation.

The node-extension structure complies with general ICH eCTD specifications, but it is not a blanket permission to use the structures anywhere or without consideration. You may email eCTD@wahooas.org 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 can be followed by another optional `node-extension` element.

4.4.5. Regional Information 2.3.R / 3.2.R

The general structure of the Regional Information is as follows:

R Regional Information
R.1 Production Documentation
R.1.1 Executed Production Documents
R.1.2 Master Production Documents
R.2 Analytical Procedures and Validation Information
R.3 Medical Devices
R.4 Materials of Human and/or Animal Origin
R.A Additional Regional Information

4.4.5.1. 2.3.R Regional Information Summary

2.3.R.1 and 2.3.R.2 are detailed in the QOS template. If appropriate, a separate document should be provided with these sections when QIS is submitted. In addition, separate documents can be provided if applicable listing the medical devices addressed in 3.2.R.3 and a statement concerning products containing or using Materials of Human and/or Animal Origin in 3.2.R.4. Separate documents will make the lifecycle management of the components more independent.

Any Additional Regional Information required or requested by individual member NMRAs should be listed in a document provided under 2.R.A.

All appropriate files can be placed directly under 2.3 Regional Information as Leaves with the appropriate Structure Number and Title applied. The QOS and QIS should both be labelled with the structure number 2.3.

4.4.5.2. 3.2.R Regional Information

Leaf elements in 3.2.R Regional Information heading must be provided using node extensions. PDF files are not allowed as leaf elements directly under 3.2.R Regional Information heading. Acceptable titles of the node extensions are as listed above. Structure numbers should be included in the titles and should be complete e.g., 3.2.R.1.1 Executed Production Documents.

Any Additional Regional Information required or requested by individual member NMRAs should be provided as leaves in the 3.2.R.A Additional Regional Information node extension. Each document should be provided separately and should have a Leaf Title clearly identifying the content and for which country it is required.

A Warning will be reported if the naming of the title is not followed.

The exact naming convention of the titles of node extensions must be used when the node extension(s) is (are) created for the first time under this heading.

If new or replaced leaves are provided in already existing node extensions under the 3.2.R Regional Information heading, the leaves must be provided under the existing node extensions, even if they don't follow the exact naming convention of the node extension title listed above. Warnings generated during the validation can be ignored, e.g., quickly explained in the Cover Letter.

4.5. Life Cycle Operations

The following four life cycle operations are defined under the ICH eCTD specification:

- New
- Replace
- Delete
- Append

We encourage you to:

- Use New, Replace, and Delete.
- Only use Append as part of the Study Tagging Files (STF) as defined by the ICH eCTD Backbone File Specification for Study Tagging Files. If you use Append for any other purpose, you will receive a validation error.

Note that any unauthorised use of Append will result in rejection of the Sequence.

4.5.1. Specific Life Cycle Operations for ECOWAS

The nodes with specific life cycle operations mandated for an ECOWAS eCTD are summarised in Table 33 Nodes with Specific Life Cycle Operations. Adherence to these specific requirements will be validated.

Table 33 Nodes with Specific Life Cycle Operations

Section ID	Business Terminology	Life cycle Operation	Validation Severity
1.0	**Correspondence**		
1.0.1	Cover letter	New	Error
1.0.2	General Note to Reviewer	New	Error

Section ID	Business Terminology	Life cycle Operation	Validation Severity
1.0.3	Life cycle Management Tracking Table	Replace*	Error
1.2	**Administrative Information**		
1.2.1	Application Forms	New	Warning
1.2.2	Fee Forms	New	Error
1.3	**Product Information**		
1.3.1**	Summary of Product Characteristics	Replace*	Error
1.3.2**	Patient Information Leaflet	Replace*	Error
1.3.3**	Container Labels	Replace*	Error
1.3.4**	Foreign Labelling	Replace*	Error
1.3.5**	Reference Product Labelling	Replace*	Error
1.8	**Information Relating to Pharmacovigilance**		
1.8.1	Risk Management Plan	Replace*	Error
1.10	**Foreign Regulatory Information**		
1.10.1	Regional & Foreign Regulatory Status	Replace*	Error

* The first time we receive a document in these sections the operation should be 'New'. Once a document has been provided, the content should only be replaced in all future Sequences.
** Applies to all Subnodes with content e.g., Approved, Clean, Annotated, English, French, and Portuguese.

The Tracking Table and the International Regulatory Status should both be presented in tabular form and give an overview of the content. Updates to both should replace the table provided in the earlier Sequence.

Product Information for New Applications should be placed in the approved section. The Leaf title should clearly state that it is the proposed product information. Once approved, the proposed content should be replaced with the approved content and the Leaf title should be updated to indicate approved and the date of approval.

Once Product Information is approved, any proposed changes should be submitted in the Clean section and an annotated copy of the proposals should be placed in the Annotated section.

4.5.2. Life Cycle Operations for a Withdrawal

There are two types of withdrawals:

- **Application Withdrawal** – The withdrawal of an entire product application.
- **Submission Withdrawal** – The withdrawal of a just a Submission still under evaluation. The product Application should remain registered.

4.5.2.1. Application Withdrawal

When withdrawing an entire product life cycle history, the following attributes should be applied in the `envelope` element:

- The Submission Type should be set to "Application Withdrawal".
- The Sequence Type should be set to "Initial".
- The Sequence Description should be set to "Product Withdrawal".
- Application Withdrawal should be considered a new Submission so the Sequence and the Related Sequence should be set to the next available Sequence.

The following life cycle rules should be applied:

- A Cover Letter should be included as "New" and should include a reasoning why the product is being withdrawn.
- No further content or life cycle is required.

4.5.2.2. Submission Withdrawal

When withdrawing a Submission, the following attributes should be applied in the `envelope` element:

- The Submission Type should be consistent with the Type set in the Related Sequence.
- The Sequence Type should be set to "Submission Withdrawal".
- The Sequence Description should be set to "Withdrawal of…" and indicate the detail of the Submission that was indicated in the Description of the Related Sequence.
- Submission Withdrawal is a new Sequence in the Submission still under evaluation so the Related Sequence should be set to the "Initial" Sequence of the Submission.

The following life cycle rules should be applied:

- The Cover Letter should be the only document submitted as New
- Content that was replaced by the Submission must be reset referencing the document that was previously referenced in the earlier Sequence using the replace operation. The document should NOT be provided again.
- Content that was added as New in the Submission must be removed using the Delete operation.
- If Work Grouping was done in the first Sequence… see the section below on how to address the reactivation of those activities. DO NOT remove any content belonging to the other Submissions using the Delete operation.

When the Sequence Description is set to Withdrawal, the validation rules ensuring that documents for the Submission Type are included are suspended.

4.5.2.3. Submission Withdrawals and Work Grouping

If Work Grouping was done and other Submissions were included in the Initial Sequence that was originally submitted, those Submission will have to be extracted out of the Submission group of the withdrawn Submission.

Work Grouping also means that the results of each Submission evaluation must be the same. This is why combinations of major Submission Types is not allowed as the likelihood that there would be different outcomes is higher in more complex Submission Types.

If a withdrawal of a Submission is performed, it will technically show up as a withdrawal of all Submissions combined in the Initial Sequence of the Submission.

In the Submission Withdrawal Sequence, the content related to the other Submissions not being withdrawn should NOT be replaced or deleted.

Instead, and in addition to the Submission Withdrawal Sequence, a second Sequence should be submitted as a New Initial Submission in which all current content from the Submissions not being withdrawn is referenced again using the Replace operation. The documents should NOT be provided again, only referenced again using content reuse. For more information on content reuse, please see section 3.7 Reusing Files.

4.5.3. Life Cycle Operations for Rejected Submissions

If a Submission was submitted on its own without Work Grouping, no further action is required if a Submission is rejected. A Submission evaluation tool should be able to display content excluding the content and changes introduced in rejected Submissions.

4.5.3.1. Rejected Submissions and Work Grouping

If a Submission is rejected, it will technically show up as a rejection of all Submissions combined in the Initial Sequence of the Submission if Work Grouping was used.

An additional Sequence should be submitted as a New Initial Submission in which all current content from the Submissions not rejected is referenced again using the Replace operation. The documents should NOT be provided again, only referenced again using content reuse. For more information on content reuse, please see section 3.7 Reusing Files.

4.6. Files and Folders

4.6.1. File and Folder Naming Conventions

Naming conventions for the content files are not part of the validation criteria for the ECOWAS eCTD.

You may use files submitted in other regions without re-naming, but:

- Ensure all content is referenced by the appropriate XML files for efficient navigation.
- Provide precise but informative Leaf titles to aid reviewers.
- Ensure the basic construction of the eCTD is maintained.
- Adhere to the basic ICH eCTD rules for folder and file names:
  - Use alphanumeric lower-case characters only – for example a-z & 0-9.
  - Do not use spaces.
  - Do not use any special characters other than the hyphen "-".
- Adhere to the naming conventions as described in Table 34 Minimum Naming Conventions Matrix

You may also use the naming convention defined for the temporary eSubmission solution, however, please note that it is planned to phase those specifications out over time and once eliminated, no naming conventions will be updated or further provided.

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Folders	Files	Description
e-wa-23-123456		Application folder with Application Number e.g., e-wa-23-123456
0001		Sequence folder with four-digit number e.g., 0001
	index.xml	Index file in accordance with ICH
	index-md5.txt	MD5 checksum in accordance with ICH
	index.html	HTML file for ICH Modules 2-5 (optional)
m1		Content folder for Module 1 Documents in Accordance with ICH
wa		ECOWAS Country Specific Folder
	wa-regional.xml	ECOWAS Regional Index File for Module 1
	wa-regional.html	HTML File for ECOWAS Regional Module 1 (optional)
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 Folder in Accordance with ICH
	wa-regional.dtd	ECOWAS Regional Backbone DTD for Module 1
	wa-envelope.mod	Defined Information for the ECOWAS Envelope as referenced by DTD
	wa-leaf.mod	Defined Information for the ECOWAS leaves as referenced by DTD
	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
	wa-regional.xsl	Style Sheet for ECOWAS Regional Backbone

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4.6.2. Folder and File Name – Path Length

Ensure the overall length of the folder and file name path, starting from the Sequence number, does not exceed 180 characters, for any file in any module.

We acknowledge it is less than the overall path length indicated in the ICH specifications but consistent with or more generous than other eCTD regions.

4.6.3. Working Documents

For each Sequence submitted, a corresponding Working Documents folder shall also be submitted – “0001-workingdocuments”. A Validation Report shall be submitted with each sequence. The Validation Report can be provided in any format but must be named validation-report.* and must be placed directly in the Working Documents folder.

The existence of the Validation Report in the Working Documents folder is validated and will cause an Error and rejection if not provided.

For more information on content expected in the Working Documents folder, please refer to national guidance.

4.6.4. Source Documents

Source Documents (MS Word or Rich Text Format) for Product Information provided in 1.3.1, 1.3.2 and 1.3.3 shall be submitted along with PDF files in the appropriate Module 1 sections using the life cycle operation New or Replace. Hyperlinks should be placed in the PIL PDFs. No Hyperlinks are required in any of the Word Files.

Source File Requirements

Requirement	Requirement Details
1.3.1 SmPC	Word File in addition to the PDF
1.3.2 PIL	Word File in addition to the PDF
1.3.3 Container Labels	Word File in addition to the PDF

Source Documents for 2.3 should be provided for the QOS/QIS, no PDF files are required. Source Documents are not required for 2.3.A or 2.3.R summaries:

If content is provided in 3.2.A and/or 3.2.R, a brief summary can be provided as a single document for each section in 2.3 and labelled as 2.3.A Appendices and 2.3.R Regional Information respectively. Please see the CTD Guidance for more information on content expectations of the 2.3.R/3.2.R Regional Information.

Source File Requirements

Requirement	Requirement Details
2.3 QOS	Word File Only, no requirement for PDF
2.3 QIS	Word File Only, no requirement for PDF

5. eCTD Preparation Tools

5.1. General Information about Solutions

ECOWAS does not mandate or recommend any particular software to prepare an eCTD Submission. eCTD is an international standard and any solution capable of producing a valid eCTD will be able to provide an Application compatible with any solution the ECOWAS Authority has chosen to use for evaluation.

It is important to note that the evaluation tool used by an Authority should in no way influence the solution selected by an Applicant. Any eCTD created by any eCTD Tool that is conform to ECOWAS requirements will work with any eCTD evaluation solution that is also conform to the ECOWAS requirements. Please be wary of solution providers that would argue differently.

We recommend you, as the applicant:

- Prepare the eCTD using an authenticated commercial eCTD preparation tool.
  There is a wide variety of options available, both in terms of multiple vendors and of approaches – for example:
  - Installed Software
  - Software as a Service
  - Service Providers
  - Cost & Level of Functionality
- Find a solution which supports current and ongoing ECOWAS eCTD requirements AND meets your overall business needs.
- Validate the prepared Sequences using an authenticated commercial eCTD validation tool.

eCTD validation tools are not just XML checkers or parsers, they evaluate the technical content of the Sequence for the eCTD Application. We recommend, you use a validation tool that:

- supports checking current and ongoing ECOWAS eCTD requirements
- minimises the possibility of technical validation errors which can cause delays in the overall regulatory process.

5.2. Solution Selection Process

ECOWAS encourages companies to undergo a proper selection process in which their overall business needs are documented in the form of User Requirements.

A sample set of user requirements has been made available on the ECOWAS website at the link listed below. This is a comprehensive list of requirements and companies should review these and give priority to features that would be important or essential for their business needs. Items not deemed necessary should be removed from their customised User Requirements. Note that the more requirements in your user requirements, the more costly the solutions will likely be.

ECOWAS eCTD (waho-essmed.org/eCTD)

Please note that the solution selected may feature as a part of future company audits by authorities as it will play a key role in data security and integrity of content submitted. Be sure the implementation is documented and validated in accordance with normal quality management practices.

5.3. Specific Solution Information

A list of eCTD Preparation Tools and eCTD Validation Tools can be found on the ECOWAS website at the link below. ECOWAS does not by any means mandate or recommend any of the solutions listed on the website and has not independently confirmed any of the solutions ability to comply with the ECOWAS requirements. It is up to the Applicant to ensure they select a solution that can prove they are able to create and validate an eCTD according to the ECOWAS requirements. The list provided as a simple courtesy but is by no means comprehensive.

ECOWAS eCTD (waho-essmed.org/eCTD)

Vendors that would like to add their solutions to this list should contact ECOWAS via email at eCTD@wahooas.org and the following information:

- Name of the company as it should be listed
- URL for the link to you company's website
- Type of solution you provide e.g., eCTD Preparation Tool or eCTD Validation Tool

6. Appendix A: Best Practice Leaf Title Recommendations

Shaded sections are eCTD elements where Leaf elements should not be added. No documents should be created at that granularity. These are only listed here for organisational purposes.

Some titles include values in brackets – for example [DESCRIPTION]. These variables should be replaced with the item indicated in brackets. Note that variable components can be provided in any of the official ECOWAS languages.

Section	Best Practice Leaf Title
1.0	**Correspondence**
1.0.1	[SEQUENCE] Cover Letter [DESCRIPTION]
1.0.2	[SEQUENCE] General Note to Reviewer
1.0.3	[SEQUENCE] Lifecycle Management Tracking Table
1.0.4	Correspondence [DATE] [AUTHORITY] [DESCRIPTION]
1.0.5	Response [DATE OF CORRESPONDENCE FROM AUTHORITY] [AUTHORITY] [DESCRIPTION]
1.0.6	Meeting Information [DESCRIPTION]
1.0.7	Request for Appeal Documentation [DESCRIPTION]
1.2	**Administrative Information**
1.2.1	[SEQUENCE] App Form [PRODUCT] [STRENGTH] [DESCRIPTION]
1.2.2	[SEQUENCE] Fee Forms [DESCRIPTION]
1.2.3	Certification and Attestation Forms [DESCRIPTION]
1.2.4	Compliance and Site Information [DESCRIPTION]
1.2.5	Authorization for Sharing Information [DESCRIPTION]
1.2.6	[SEQUENCE] Electronic Declaration [DESCRIPTION]
1.2.7	Trademark & Intellectual Property Information [DESCRIPTION]
1.2.8	[SEQUENCE] Screening Details [DESCRIPTION]
1.2.A	Additional Administrative Information [DESCRIPTION]
1.3	**Product Information**
1.3.1	**Summary of Product Characteristics**
1.3.1.1	**Approved - SmPC**
1.3.1.1.1	Approved - SmPC – English [FORMAT]
1.3.1.1.2	Approved - SmPC - French [FORMAT]
1.3.1.1.3	Approved - SmPC - Portuguese [FORMAT]
1.3.1.2	**Clean – SmPC**
1.3.1.2.1	Clean - SmPC - English [FORMAT]
1.3.1.2.2	Clean - SmPC - French [FORMAT]
1.3.1.2.3	Clean - SmPC - Portuguese [FORMAT]
1.3.1.3	**Annotated – SmPC**
1.3.1.3.1	Annotated - SmPC - English [FORMAT]
1.3.1.3.2	Annotated - SmPC - French [FORMAT]
1.3.1.3.3	Annotated - SmPC - Portuguese [FORMAT]
1.3.2	**Patient Information Leaflet**
1.3.2.1	**Approved - PIL**
1.3.2.1.1	Approved - PIL - English [FORMAT]
1.3.2.1.2	Approved - PIL - French [FORMAT]
1.3.2.1.3	Approved - PIL - Portuguese [FORMAT]

Section	Best Practice Leaf Title
1.3.2.2	**Clean – PIL**
1.3.2.2.1	Clean - PIL - English [FORMAT]
1.3.2.2.2	Clean - PIL - French [FORMAT]
1.3.2.2.3	Clean - PIL - Portuguese [FORMAT]
1.3.2.3	**Annotated – PIL**
1.3.2.3.1	Annotated - PIL - English [FORMAT]
1.3.2.3.2	Annotated - PIL - French [FORMAT]
1.3.2.3.3	Annotated - PIL - Portuguese [FORMAT]
1.3.3	**Container Labels**
1.3.3.1	**Approved - Container Labels**
1.3.3.1.1	Approved - Container Labels - English [FORMAT]
1.3.3.1.2	Approved - Container Labels - French [FORMAT]
1.3.3.1.3	Approved - Container Labels - Portuguese [FORMAT]
1.3.3.2	**Clean - Container Labels**
1.3.3.2.1	Clean - Container Labels - English [FORMAT]
1.3.3.2.2	Clean - Container Labels - French [FORMAT]
1.3.3.2.3	Clean - Container Labels - Portuguese [FORMAT]
1.3.3.3	**Annotated - Container Labels**
1.3.3.3.1	Annotated - Container Labels - English [FORMAT]
1.3.3.3.2	Annotated - Container Labels - French [FORMAT]
1.3.3.3.3	Annotated - Container Labels - Portuguese [FORMAT]
1.3.4	**Foreign Labelling**
1.3.4.1	Approved - Foreign Labelling - English
1.3.4.2	Approved - Foreign Labelling - French
1.3.4.3	Approved - Foreign Labelling - Portuguese
1.3.4.4	Approved - Foreign Labelling - Original Language [LANGUAGE]
1.3.5	**Reference Product Labelling**
1.3.5.1	Approved - Reference Product - English
1.3.5.2	Approved - Reference Product - French
1.3.5.3	Approved - Reference Product - Portuguese
1.3.5.4	Approved - Reference Product - Original Language [LANGUAGE]
1.3.6	**Artwork and Samples**
1.3.6.1	Statement Confirming Submission of Samples
1.3.6.2	Artwork and Pictures of Samples [DESCRIPTION]
1.4	**Information about the Experts**
1.4.1	Quality
1.4.2	Nonclinical
1.4.3	Clinical
1.5	**Specific Requirements for Different Types of Applications**
1.5.1	Bioequivalence Trial Information
1.6	**Environmental Risk Assessment**
1.6.1	Non-GMO
1.6.2	GMO
1.7	**Good Manufacturing Practice**
1.7.1	Date of Inspection of Each Site
1.7.2	Inspection Reports or Equivalent Documents

Section	Best Practice Leaf Title
1.7.3	**GMP Certificates or Manufacturing Licences**
1.7.3.1	API [API] [MANUFACTURER]
1.7.3.2	FPP [MANUFACTURER] [DOSAGE]
1.7.4	Other GMP Documents [DESCRIPTION]
1.8	**Information Relating to Pharmacovigilance**
1.8.1	Pharmacovigilance Systems
1.8.2	Risk Management Plan
1.9	**Individual Patient Data - Statement of Availability**
1.10	**Foreign Regulatory Information**
1.10.1	Regional & Foreign Regulatory Status
1.10.2	WHO Type Certificate of Pharmaceutical Product (COPP)
1.10.3	Data Set Similarities and Differences
1.10.4	Foreign Evaluation Reports [COUNTRY] [DATE]
1.A	**Additional Data**
1.A.1	[DESCRIPTION]
2	**Summaries and Overviews**
2.2	Introduction
2.3	QOS
2.3	QIS
2.3.A	Appendices
2.3.R	Regional Information
2.4	Nonclinical Overview
2.5	Clinical Overview
2.6	**Nonclinical Written and Tabulated Summaries**
2.6.1	Introduction
2.6.2	Pharmacology Written Summary
2.6.3	Pharmacology Tabulated Summary
2.6.4	Pharmacokinetics Written Summary
2.6.5	Pharmacokinetics Tabulated Summary
2.6.6	Toxicology Written Summary
2.6.7	Toxicology Tabulated Summary
2.7	**Clinical Summary**
2.7.1	Summary of Biopharmaceutic Studies and Associated Analytical Methods
2.7.2	Summary of Clinical Pharmacology Studies
2.7.3	Summary of Clinical Efficacy
2.7.4	Summary of Clinical Safety
2.7.5	Literature References
2.7.6	Synopses of Individual Studies
3	**Quality**
3.2	**Body of Data**
3.2.S	**Drug Substance**
3.2.S.1	**General Information**
3.2.S.1.1	Nomenclature
3.2.S.1.2	Structure
3.2.S.1.3	General Properties

Section	Best Practice Leaf Title
3.2.S.2	**Manufacturer**
3.2.S.2.1	Manufacturer
3.2.S.2.2	Description of Manufacturing Process and Process Controls
3.2.S.2.3	Control of Materials
3.2.S.2.4	Controls of Critical Steps and Intermediates
3.2.S.2.5	Process Validation and/or Evaluation
3.2.S.2.6	Manufacturing Process Development
3.2.S.3	**Characterisation**
3.2.S.3.1	Elucidation of Structure and Other Characteristics
3.2.S.3.2	Impurities
3.2.S.4	**Control of Drug Substance**
3.2.S.4.0	Control Strategy Summary
3.2.S.4.1	Specification
3.2.S.4.2.1	Analytical Procedure [DESCRIPTION]
3.2.S.4.3.1	Validation of Analytical Procedure/Method/Assay [DESCRIPTION]
3.2.S.4.4	Batch Analyses
3.2.S.4.5	Justification of Specification
3.2.S.5	Reference Standards or Materials [DESCRIPTION]
3.2.S.6	Container Closure System
3.2.S.7	**Stability**
3.2.S.7.1	Stability Summary and Conclusions
3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment
3.2.S.7.3	Stability Data
3.2.P	**Drug Product**
3.2.P.1	Description and Composition of the Drug Product
3.2.P.2	Pharmaceutical Development
3.2.P.3	**Manufacture**
3.2.P.3.1.1	Manufacturer [MANUFACTURER]
3.2.P.3.2	Batch Formula
3.2.P.3.3	Description of Manufacturing Process and Process Controls
3.2.P.3.4	Controls of Critical Steps and Intermediates
3.2.P.3.5	Process Validation and/or Evaluation
3.2.P.4	**Control of Excipients**
3.2.P.4.1	Compendial Excipients
3.2.P.4.1	Specifications
3.2.P.4.2	Analytical Procedures
3.2.P.4.3	Validation of Analytical Procedures
3.2.P.4.4	Justification of Specifications
3.2.P.4.5	Excipients of Human or Animal Origin
3.2.P.4.6	Novel Excipients
3.2.P.5	**Control of Drug Product**
3.2.P.5.0	Control Strategy Summary
3.2.P.5.1	Specification
3.2.P.5.2.1	Analytical Procedure [DESCRIPTION]
3.2.P.5.2.1	Method [DESCRIPTION]
3.2.P.5.2.1	Assay [DESCRIPTION]

Section	Best Practice Leaf Title
3.2.P.5.3.1	Validation of Analytical Procedure/Method/Assay [DESCRIPTION]
3.2.P.5.4	Batch Analyses
3.2.P.5.5	Characterisation of Impurities
3.2.P.5.6	Justification of Specifications
3.2.P.6	Reference Standards or Materials [DESCRIPTION]
3.2.P.7	Container Closure System
3.2.P.8	**Stability**
3.2.P.8.1	Stability Summary and Conclusion
3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment
3.2.P.8.3	Stability Data
3.2.A	**Appendices**
3.2.A.1	Facilities and Equipment [MANUFACTURER] [API if applicable]
3.2.A.2	Adventitious Agents Safety Evaluation [MANUFACTURER] [API if applicable]
3.2.A.3	**Excipient**
3.2.A.3.1	Excipient [EXCIPIENT]
3.2.R	**Regional Information**
3.2.R.1	**Production Documentation**
3.2.R.1.1	Executed Production Documents [DESCRIPTION]
3.2.R.1.2	Master Production Documents [DESCRIPTION]
3.2.R.2	Analytical Procedures and Validation Information [DESCRIPTION]
3.2.R.3	Medical Devices [DESCRIPTION]
3.2.R.4	Materials of Human and/or Animal Origin [DESCRIPTION]
3.2.R.A	Additional Regional Information [DESCRIPTION]
3.3	[AUTHORS(S), DATE] e.g., Smith, 2018
4	**Nonclinical Study Reports**
4.2	**Study Reports**
4.2.1	**Pharmacology**
4.2.1.1	[STUDY ID] [DESCRIPTION]
4.2.1.2	[STUDY ID] [DESCRIPTION]
4.2.1.3	[STUDY ID] [DESCRIPTION]
4.2.1.4	[STUDY ID] [DESCRIPTION]
4.2.2	**Pharmacokinetics**
4.2.2.1	[STUDY ID] [DESCRIPTION]
4.2.2.2	[STUDY ID] [DESCRIPTION]
4.2.2.3	[STUDY ID] [DESCRIPTION]
4.2.2.4	[STUDY ID] [DESCRIPTION]
4.2.2.5	[STUDY ID] [DESCRIPTION]
4.2.2.6	[STUDY ID] [DESCRIPTION]
4.2.2.7	[STUDY ID] [DESCRIPTION]
4.2.3	**Toxicology**
4.2.3.1	[STUDY ID] [SPECIES] [ROUTE OF ADMIN] [DESCRIPTION]
4.2.3.2	[STUDY ID] [SPECIES] [ROUTE OF ADMIN] [DURATION] [DESCRIPTION]
4.2.3.3	**Genotoxicity**
4.2.3.3.1	[STUDY ID] [DESCRIPTION]

Section	Best Practice Leaf Title
4.2.3.3.2	[STUDY ID] [DESCRIPTION]
4.2.3.4	**Carcinogenicity**
4.2.3.4.1	[STUDY ID] [SPECIES] [DESCRIPTION]
4.2.3.4.2	[STUDY ID] [DESCRIPTION]
4.2.3.4.3	[STUDY ID] [DESCRIPTION]
4.2.3.5	**Reproductive and Developmental Toxicity**
4.2.3.5.1	[STUDY ID] [DESCRIPTION]
4.2.3.5.2	[STUDY ID] [DESCRIPTION]
4.2.3.5.3	[STUDY ID] [DESCRIPTION]
4.2.3.5.4	[STUDY ID] [DESCRIPTION]
4.2.3.6	[STUDY ID] [DESCRIPTION]
4.2.3.7	**Other Toxicity Studies**
4.2.3.7.1	[STUDY ID] [DESCRIPTION]
4.2.3.7.2	[STUDY ID] [DESCRIPTION]
4.2.3.7.3	[STUDY ID] [DESCRIPTION]
4.2.3.7.4	[STUDY ID] [DESCRIPTION]
4.2.3.7.5	[STUDY ID] [DESCRIPTION]
4.2.3.7.6	[STUDY ID] [DESCRIPTION]
4.2.3.7.7	[STUDY ID] [DESCRIPTION]
4.3	[AUTHORS(S), DATE] e.g., Smith, 2018
5	**Clinical Study Reports**
5.2	Tabular Listing of all Clinical Studies
5.3	**Clinical Study Reports**
5.3.1	**Reports of Biopharmaceutic Studies**
5.3.1.1	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.1.2	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.1.3	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.1.4	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.2	**Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials**
5.3.2.1	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.2.2	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.2.3	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.3	**Reports of Human Pharmacokinetic (PK) Studies**
5.3.3.1	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.3.2	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.3.3	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.3.4	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.3.5	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.4	**Reports of Human Pharmacodynamic (PD) Studies**
5.3.4.1	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.4.2	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.5	**Reports of Efficacy and Safety Studies**
5.3.5.1	[STUDY ID] [TYPE OF CONTROL] [E3 SECTION] [DESCRIPTION]
5.3.5.2	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.5.3	[STUDY ID] [E3 SECTION] [DESCRIPTION]

Section	Best Practice Leaf Title
5.3.5.4	[STUDY ID] [E3 SECTION] [DESCRIPTION]
5.3.6	[DESCRIPTION] [DATES]
5.3.7	[STUDY ID] [DESCRIPTION]
5.4	[AUTHORS(S), DATE] e.g., Smith, 2018

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7. Change Control

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

- eCTD AU Module 1 and Regional Information
- EU Module 1 eCTD Specification
- GCC Module 1 eCTD Specification
- SG-HSA Module 1 and Regional Information
- The eCTD Backbone Files Specification for US Module 1
- ICH eCTD Specifications v3.2.2
- ICH eCTD Specifications v4.0

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

- Changes in the Content of the Module 1 for the CTD
- Update of Standards that are already in use within the eCTD
- New Standards for Creating and/or Using eCTD
- New Functional Requirements
- Experience with Using eCTD, in particular Module 1.
- Updates to the Processes at the NMRAs - Automation

We will:

- Provide a Practical Timeframe for Future Changes to Minimize Impact on Industry. In general, a transition time of at least 6 months is provided to migrate to new specifications.
- Introduce Changes at Scheduled Intervals to allow Stability.

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

8. Version History

The ECOWAS eCTD Project Team consists of:

Name	Organisation / Position	Project Designation
Mrs Sybil Nana Ama Ossei-Agyeman-Yeboah	WAHO Ag. Principal Professional Officer, Public Health	Project Lead
Mrs Oluwafunmike Sopein-Mann	WAHO Project Coordinator	Project Regulatory Coordinator
Mr Damola Olajide	WAHO IT Coordinator	Project IT Coordinator
Mr Abayomi Akinyemi	NAFDAC IT Manager	Project IT Advisor
Mr Kent Briggs	VECTOR Managing Director	Lead Regulatory Consultant
Mr Andrew Gilchrist	VECTOR Technical Director	Lead IT Consultant

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 DTD e.g., version 1.1, 1.2, 1.3.
- Changes in the specification document that do not trigger changes to the DTD 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	2023-07-01