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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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207 1. Introduction

208 This document applies to all Applications using the electronic Common Technical Document
209 (eCTD) format in the ECOWAS region for all Centralised Procedures. All ECOWAS member
210 countries are urged to adopt the structure for National and Reliance Procedures as soon as
211 possible. Furthermore, this document applies to all types of medicinal Submissions and is not
212 limited to generic Applications.

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

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

220 The document contains:

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

223

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

- 226 • the ECOWAS CTD Guidance version 1.0 (2022),
- 227 • the ECOWAS eCTD Validation Criteria version 1.0
- 228 • the ECOWAS eCTD/eSubmission Q&A Document version 1.0

229

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

238 All documents are provided on the ECOWAS eCTD Website. [ECOWAS eCTD \(waho-
239 essmed.org/eCTD\)](https://www.ecowas-essmed.org/eCTD)

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

244

245 Comment about ICH eCTD 4.0

246 Internationally, the eCTD is currently implemented using the ICH eCTD Specifications version
247 3.2.2. The eCTD Specifications for version 4.0 has been released and some agencies are in
248 the process of implementing plans to migrate. It is the intention of ECOWAS to also migrate



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

251

252 **ECOWAS eSubmission Option**

253 All Applicants should begin their planning to move to eCTD immediately. For more information
254 on eCTD Preparation Tools please see section 5 of this specification. [ECOWAS eCTD \(waho-
255 essmed.org/eCTD\)](https://ecowas-essmed.org/eCTD)

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

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

270 **1.1. Terminology**

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

276 **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. <i>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.</i>
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. <i>Submission is a term consistent with the eCTD version 4.0 specifications but was often referred to as a Regulatory Activity in earlier specifications.</i>
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

277 1.2. Implementation / Transition Plan

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

283 1.2.1. ECOWAS Centralised Procedure

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



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

294 The initial phase will use the specifications version 1.0. If needed, adjustment to the
295 specifications, based on experiences gained during the initial phase, are expected
296 approximately 1 year after the launch. Updates to the specifications can be expected every 2-
297 3 years based on experience from other eCTD regions but will occur as often as needed.

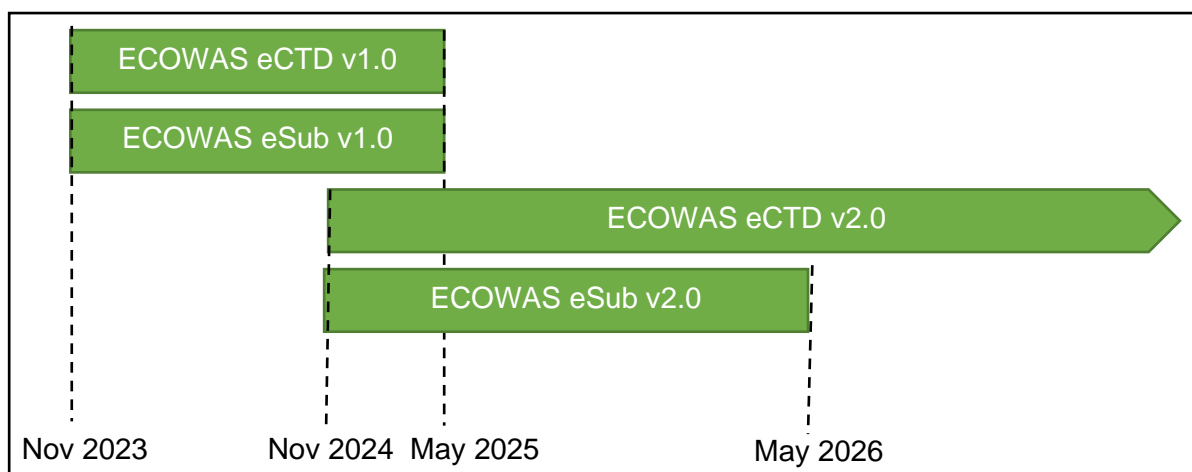
298 Companies with eCTD capabilities are encouraged to submit in the preferred eCTD format as
299 soon as possible.

300 Companies without eCTD capabilities shall move to the **temporary** eSubmission format for
301 any Applications not already in the Submission process. The eSubmission format defines a
302 predictable File and Folder naming convention and **does not require any additional**
303 **software to prepare the Applications beyond the office suites commonly found in any**
304 **regulatory office environment.**

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

308 **ECOWAS eCTD Implementation Timeline:**

- 309 • The ECOWAS eCTD version 1.0 shall be accepted effective immediately, officially starting
310 1 November 2023 and is planned for use for a period of 18 months for the purpose of the
311 eCTD initial phase.
- 312 • The ECOWAS eSubmission version 1.0 shall be accepted effective immediately, officially
313 starting 1 November 2023 and shall be used for all Applications not submitted in eCTD
314 format starting 1 February 2024.
- 315 • The ECOWAS eCTD and eSubmission Specification's version 2.0 are expected to be
316 released in November 2024 and shall be the only version accepted after 1 May 2025.
- 317 • Between 1 November 2024 and 1 May 2025, ECOWAS will accept both the version 1.0
318 and 2.0 versions of the specifications.
- 319 • ECOWAS will stop accepting eSubmissions and move to eCTD only starting 1 May 2026.
320 All applicants are expected to use the time until then to ensure their regulatory departments
321 are equipped to be able to continue their Applications in eCTD format.



322
323

324 **Figure 1 ECOWAS eCTD Implementation Timeline for Centralised Procedure**

325 **1.2.2. National and Reliance Procedures**

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

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



332 2. Preparing your ECOWAS eCTD Application

333 2.1. Obtaining the Applicant ID

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

335 To obtain your Applicant ID, please refer to the Portal Process Guide and visit the portal.

336 [ECOWAS eCTD \(waho-essmed.org/eCTD\)](https://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.

337 2.2. Obtaining the Application Number

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

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



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

342 2.3. Initial Sequence

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

345 2.4. Preparing the eCTD Cover Letter

346 The following new information shall be included in the Cover Letter in addition to what is
347 defined in the [ECOWAS-WAHO CTD Guidance](#) and National guidance for the Cover Letter:

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



- 350 *Example: e-ng-123456 Sequence 0010 Related Sequence 0008*
- 351 • A description of the eSubmission:
- 352 – Approximate Submission size, broken down by Module if unusually large submission.
- 353 – Type of electronic media, if not uploaded to an electronic portal.
- 354 – Any other characteristics concerning the media that may be important to know.
- 355 • A description of the software used to check the files for viruses and a statement as to
- 356 whether the Submission is virus free.
- 357 *Example: "The Sequence has been virus checked using SOFTWARE version VERSION*
- 358 *and is confirmed to be virus free."*
- 359 • The Regulatory and Technical contacts for the Submission, consistent with the eCTD
- 360 Envelope.
- 361 • Information about the validation including:
- 362 – The validation tool and version / validation profile used.
- 363 – Example: SOFTWARE VERSION / ECOWAS 1.0.1 Profile
- 364 – Any findings e.g., errors, warnings or possible missing documents as designated by
- 365 the Document Matrix that would be expected for your specific Submission Type.
- 366 • A paper copy of the Cover Letter should be included with the physical media containing
- 367 the eCTD if not uploaded to an electronic portal.

368 **2.5. eCTD Application Folder Naming Convention**

369 When submitting Sequences, the Sequence Folder must be provided along with the Working

370 Documents in an Application Folder.

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

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

373 If multiple Application Numbers are applied to an Application e.g., multiple strengths are

374 included in the same application, and the numbers are sequential, the range of numbers

375 should be identified. Range indicated does not need to repeat numbers that do not change.

376 Examples: e-wa-23-12345-8 | en-wa-23-12349-52 | e-wa-23-12399-402 | e-wa-23-12999-

377 3002 | etc.

378 If multiple Application Numbers are applied to an Application but the numbers are not

379 sequential, one of the Application Numbers should be selected as the master Application

380 Number. The master Application Number should be the first Application Number listed in the

381 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.

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



Sequences already submitted should not be submitted again!

383 2.6. Selecting a Media Format

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

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

- 389 • Compact Disc-Recordable (CD-R) conforming to the Joliet specification
- 390 • Digital Versatile Disc-Random Access Memory (DVD-RAM) Universal Disc Format
391 (UDF) standard
- 392 • Digital Versatile Disc-Recordable (DVD+R/-R) recorded in the Universal Disc Format
393 (UDF) standard
- 394 • Universal Serial Bus Media (USB) (2.0 or higher)
- 395 • 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!

396 2.7. Validating the eCTD Sequence(s)

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

400 There are three types of eCTD validation findings:

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



- 413 – Repeated or excessive issues may result in a business rejection and request from
 414 the Authority for you to fix the Sequence and resubmit it. Evaluation will stop in this
 415 case until a corrected Sequence is provided.
- 416 • **INFO** – Information collected about the data being submitted. This includes:
- 417 – A list of missing "Possible" documents as defined in the Document Matrix that might
 418 be required in the Sequence for the Submission Type declared in the Envelope.
- 419 – Information about unusual life cycle operations.
- 420 – Information about Study Tagging Files submitted, etc.
- 421 – Information about content reuse within the same Sequence, from other Sequences in
 422 the same Application and from other Applications
- 423

424 Please make every effort to limit the number of warnings in Sequences. Any warnings that
 425 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

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

428 **2.7.1. Sequences with Errors or Warnings**

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

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

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

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

442 **2.8. Submitting your eCTD Sequence(s)**

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

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

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



449 **Feedback on Validation**

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

452



453 3. ECOWAS Regional Considerations

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

456 3.1. File Formats

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

460 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.

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

463 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.

464



465 **3.1.1. Module 1**

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

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

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

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

480 **3.1.2. Module 2 to 5**

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

484 **3.2. Electronic Signatures**

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

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

491 **3.3. Document Navigation Aids**

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

493 **3.3.1. Bookmarks**

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

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



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

506 **3.3.2. Table of Contents**

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

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

512 **3.3.3. Document Title Pages**

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

516 **3.3.4. Hyperlinks**

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

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

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

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

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

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

538 **3.3.4.1. Mandatory Hyperlinks**

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

- 540 • 1.3.1 SmPC



- 541 • 1.0.5 Response and
- 542 • 1.2.3 Certificate (COA, CEP, etc.)

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

544 **Related Information and Guidance**

545 [ICH eCTD Specifications](#) – Appendix 7

546 **3.3.5. Document Granularity**

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

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

553 ECOWAS recommends using the QOS template for 2.3.S and 2.3.P information. Additionally,
554 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.

555 **3.4. Empty or Missing eCTD Sections**

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

559 **Do not:**

- 560 • Use documents with no substantive content – for example, documents that contain
561 words like "not applicable" – in the eCTD structure. This creates unnecessary documents
562 that must be included in the life cycle and causes delays for evaluators who must open
563 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.

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

566 **3.5. Study Tagging Files**

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



570 We will collect data about the number and size of [ICH E3](#) 16.3 CRFs and non ICH E3
571 documents for informational purposes as part of the Validation Criteria.

572 **Related Information and Guidance**

- 573 • [ICH Specifications for Study Tagging Files](#) – Guidance on the including of studies using
574 the STF format.
- 575 • [ICH E3](#) – Guidance on the Structure of Clinical Study Reports.

576 **3.6. Updating eCTD Backbone Attributes**

577 **Updating ICH Attributes**

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

580 In instances where changes are more likely to occur – for example, manufacturer in 2.3.P /
581 3.2.P, a generic variable can be placed in the attribute field e.g., "MNF" and the
582 manufacturer(s) represented by the variable can be declared and maintained in the General
583 Note to Reviewer. Where Multiple P sections are provided due to a diluent, etc., "MNF1" and
584 "MNF2" could be used even if in the beginning both components are the same manufacturer.

585 **Updating ECOWAS Envelope Information**

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

588 **3.7. Reusing Files**

589 All Sequences will be stored according to the Application Number which can then be used to
590 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.

591 We accept and encourage you to reuse files when you:

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

596

597 **Referencing Content Submitted in Other eCTD Applications**



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

```
600 <m1-4-3-clinical>
601   <leaf ID="N3774598bcdd74d5891d954542c552eee" operation="new" xlink:href=
602     "../..../e000111/0000/m1/au/104-expert/1043-clinical/dr-k-boateng.pdf" checksum=
603     "b6ba67a7740d12bcb938f2850baa584e" checksum-type="MD5">
604     <title>Expert Dr. K. Boateng</title>
605   </leaf>
606   <leaf ID="N3ad8bf59e3fd4cb5bbd4f82b31350887" operation="new" xlink:href=
607     "104-expert/1043-clinical/dr-a-ouattara.pdf"
608   checksum="bf30251122458c7c5c17dc3ed0002c1e"
609   checksum-type="MD5">
610     <title>Expert Dr. A. Ouattara</title>
611   </leaf>
612   <leaf ID="Ne0eeb59ae2f74ba5832965154db4cc13" operation="new" xlink:href=
613     "104-expert/1043-clinical/dr-j-gomes.pdf" checksum="f1e209870c05f15eef24f4b2e1e74a0f"
614   checksum-type="MD5">
615     <title>Expert Dr. J. Gomes</title>
616   </leaf>
```

617 Figure 2 Referencing Content Submitted in Other eCTD Applications

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

622 Related Information and Guidance

623 [ICH eCTD Specifications](#) – Appendix 6

624 3.8. Baseline Sequences

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

- 626 • Paper
- 627 • Unstructured Electronic Files
- 628 • Structured eSubmissions – for example ECOWAS eSubmission v1.0

629

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

634 3.8.1. Cover Letter for Baselines

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

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



- 643 • Indicate any omissions that have not be provided in the baseline and verify that the
644 omissions in the baseline Sequence do not cause the content to be misleading.
645 A tracking table summarising previous activities with key dates should be provided when
646 possible.
- 647 Previous cover letters should be combined into a single bookmarked document and placed as
648 an annex to the baseline cover letter when possible.

649 **3.8.2. Converting to eCTD**

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

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

653

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

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

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

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

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

664 **3.8.3. Baseline Sequence – Required Identification**

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

667 **3.8.4. Ways to Submit a Baseline**

668 The baseline should:

- 669 • be submitted as Sequence 0000
670 • always be a separate Sequence
671 • only contain previously submitted/approved content
672 • never include new content

673

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

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



679 **3.8.4.1. Baselines Submitted as an Initial eCTD Sequence**

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

683 **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

684 **3.8.4.2. Baselines Submitted as Multiple Sequences**

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

688 When creating a baseline Sequence for the first time:

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

692

693 You can use multiple Sequences to submit a baseline.

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

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

701

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

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

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

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

710 **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

711

712 **Mid-Life Cycle Baselines of eCTD Applications**

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

716 **3.9. Work Grouping**

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

723 Work Grouping can lead to issues when:

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

726 For more information on how to handle Withdrawals and Rejections of Submissions that were
 727 part of Work Grouping please see section [4.5.2.3 Submission Withdrawals and Work Grouping](#)
 728 and [4.5.3.1 Rejected Submissions and Work Grouping](#).

729 **Related Information and Guidance**

- 730 • Submission Type Matrix – Guidance on which Submission Types can be combined in a
 731 single Submission. [ECOWAS eCTD \(waho-essmed.org/eCTD\)](http://waho-essmed.org/eCTD)



732 **3.10. Transfer of Applicants**

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

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

739 The eCTD Application is product specific and should be part of any transfer process. The
740 relinquishing Applicant must provide all sequences previously submitted to the acquiring
741 Applicant so that the Application life cycle can be continued, and historical content associated
742 with the evaluation remains intact at the authority. Even if only a partial transfer is done –
743 meaning not all the Application Numbers included in the Application were transferred, the
744 entire history of the Application must be given to the acquiring Applicant so that they can
745 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.

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

749 **3.10.1. Basic Requirements for the Relinquishing Applicant**

750 The relinquishing Applicant must:

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

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

761 **3.10.2. Basic Requirements for the Acquiring Applicant**

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

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



768 The acquiring Applicant must:

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

784 3.10.3. Scenarios for Transfer of Applicants

785 3.10.3.1. Simple Transfer of Applicants

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

789 **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

790

791 3.10.3.2. Transfer of Applicants with Withdrawal of Open Submissions

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

796 **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

797

798 **3.10.3.3. Transfer of Applicants with Withdrawal of Open Submissions Part of**
 799 **Work Grouping**

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

803 **Table 6 Transfer of Applicants with Withdrawal of Open Submissions Part of Work**
 804 **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 XYZ 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

805

806 **3.10.3.4. Transfer of Applicants where not all Application Numbers of an** 807 **Application are Transferred**

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

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

818 **Table 7 Transfer of Applicants where not all Application Numbers of an Application are** 819 **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



821 **4. ECOWAS Module 1 General Architecture**

822 **4.1. Backbone File for ECOWAS Module 1**

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

827 The ECOWAS Module 1 eCTD backbone file is comprised of:

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

831 **4.1.1. Creating the Module 1 eCTD backbone file**

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

- 833 1. Create an XML file containing the standard XML Root Element with the appropriate XML
 834 declaration using authenticated eCTD preparation software.
- 835 2. Create the Envelope Elements containing the appropriate metadata values describing the
 836 Recipient, Application, Submission and Sequence.
- 837 3. Create Module 1 Heading Elements as needed for the Sequence:
- 838 4. Module 1 Heading Elements – organizing the ECOWAS Module 1 in accordance with the
 839 specifications.
- 840 5. Leaf Element – reference to each file being submitted along with other information such
 841 as eCTD checksum and life cycle information.
- 842 6. Name the ECOWAS Module 1 eCTD backbone file wa-regional.xml and place it in the wa
 843 subfolder within Module 1, i.e., within the m1 subfolder of the Sequence.
- 844 7. Validate the resulting backbone using a suitable eCTD validation tool. The validation
 845 should complain about a missing validation report in the Working Documents.
- 846 8. Fix any errors and warnings other than the missing validation report.
- 847 9. Place the validation report in the 0001-workingdocuments folder and name it 0001-
 848 validation-report.* (if the Sequence is 0001). Note that the validation report can be of any
 849 format.
- 850 10. Validate the Sequence again until a perfect validation report is produced.
- 851 11. Replace the validation report in the 0001-workingdocuments folder with the final perfect
 852 validation report.
- 853 12. Follow the process to submit your Sequence.

854 **4.1.2. Stylesheets**

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

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



- 861 • Display the ICH Module 2-5 table of content as provided in the ICH backbone.
- 862 • Enable you to use a browser to open the content.
- 863 You must submit eCTD Applications with the stylesheet.
- 864 Existence of the stylesheet is checked during the validation process.

865 4.1.3. Optional HTML File

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



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

869 4.2. XML Root Element

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

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

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

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

881 **Figure 3 XML Root Element with Stylesheet**

882 4.3. Envelope Elements

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

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

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



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

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

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

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

907 Values for some Envelope elements are restricted with a Defined List. For more information

908 on the defined lists, please see section [4.3.3 The Defined Lists](#)

909



910 **4.3.1. Envelope Overview**

911 **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	

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

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



914 4.3.2. Submitting Multiple Values in the Envelope

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

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

```

918 <wa-envelope>
919   <application code-version="1.0" code="app-type-rp">
920     <application-uuid>aeb70241-6f46-4b72-8126-3e48d481960a</application-uuid>
921     <recipient code-version="1.0" code="ng">
922     <recipient code-version="1.0" code="bf">
923     <lead-nmra code-version="1.0" code="ng">
924     <application-number>e-wa-23-99991</application-number>
925     <application-number>e-wa-23-99992</application-number>
926     <applicant-id>NG123</applicant-id>
927     <applicant-name>Pharma Corp Ltd</applicant-name>
928     <inn>amoxicillin</inn>
929     <inn>codeine</inn>
930     <proprietary-name>afriCapsule 100mg</proprietary-name>
931     <proprietary-name>afriCapsule 200mg</proprietary-name>
932   </application>
933   <submission code-version="1.0" code="sub-type-mi-ch-pi">
934     <submission-lead code="sub-lead-pm" />
935     <submission-number>pm-wa-2023-12345-1</submission-number>
936     <submission-number>pm-wa-2023-12346-1</submission-number>
937   </submission>
938   <submission code-version="1.0" code="sub-type-mi-ch-prop-name">
939     <submission-lead code="sub-lead-pm" />
940     <submission-number>pv-wa-2023-12347-1</submission-number>
941     <submission-number>pv-wa-2023-12348-1</submission-number>
942   </submission>
943   <sequence code-version="1.0" code="sequence-type-initial">
944     <sequence-description>Add Strength to Prod Name</sequence-description>

```




```

945     <sequence-date>2023-05-20</sequence-date>
946     <sequence-number>0010</sequence-number>
947     <related-sequence-number>0010</related-sequence-number>
948 </sequence>
949 <contact code-version="1.0" code="contact-type-reg">
950     <contact-name>Dr. Chioma Abubakar</contact-name>
951     <contact-email>chioma.abubakar@pharma-inc.africa</contact-email>
952     <contact-phone>+234 123 456 7890</contact-phone>
953 </contact>
954 <contact code-version="1.0" code="contact-type-ag-nat">
955     <contact-name>Yacouba Koffi</contact-name>
956     <contact-email>yacouba.koffi@pharma-inc.africa</contact-email>
957     <contact-phone>+225 123 456 7890</contact-phone>
958 </contact>
959 </wa-envelope>
    
```

960 **Figure 4: Submitting Multiple Values in the Envelope**

961 **4.3.3. The Defined Lists**

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

964 The XML file specifies:

- 965 • a number for each version,
- 966 • a valid-from for each version,
- 967 • an expired date (if applicable).

```

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



973 **Figure 5 Defined List Version Validity**

974 Each coded value has:

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

980

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

981 **Figure 6 Defined List Code Validity**

982 Provide the `code` attribute value from the appropriate Element in the `wa-regional.xml` file. See the example XML code under section Figure
983 4: Submitting Multiple Values in the Envelope.

984 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
985 to the version information and the Sequence Date of Submission provided in the Envelope.

986 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
987 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
988 have been superseded.

989 **Related Information and Guidance**

- 990 • [eCTD Defined Lists](https://waho-essmed.org/eCTD) – Official defined list at [ECOWAS eCTD \(waho-essmed.org/eCTD\)](https://waho-essmed.org/eCTD)

991 **4.3.4. Envelope Attributes**

992 **4.3.4.1. Application Type**

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



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

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

998 *Example (National Procedure): app-type-np*

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

1000 **Figure 7 Envelope Element: Application Type**

1001 **Related Information and Guidance**

- 1002 • application-type – Official defined list for Application Type. [ECOWAS eCTD \(waho-essmed.org/eCTD\)](https://waho-essmed.org/eCTD)

1003 **4.3.4.2. Application Identifier**

1004 A universally unique identifier (UUID) as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 | ISO/IEC 9834-8:2005.

1005 It is a 128-bit label and is unique for practical purposes when generated according to the standard methods.

1006 The same UUID will be used for all Sequences of an eCTD application and cannot ever be changed.

1007 *Example: aeb70241-6f46-4b72-8126-3e48d481960a*

1008 `<app-uuid>aeb70241-6f46-4b72-8126-3e48d481960a</app-uuid>`

1009 **Figure 8 Envelope Element: Application Identifier**

1010 **4.3.4.3. Recipient**

1011 The Recipient element section contains all the Envelope information for the designated receiving country and Authority.

1012 Recipient is a coded list. The code should be placed as value in the Envelope.

1013 `<recipient code-version="1.0" code="ng">`



1014 **Figure 9 Envelope Element: Recipient**

1015 **Related Information and Guidance**

- 1016 • recipient – Official defined list for Recipient. [ECOWAS eCTD \(waho-essmed.org/eCTD\)](https://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.

1017

1018 **4.3.4.3.1. Centralised Procedure – Use of Recipient**

1019 ECOWAS – WAHO should be indicated. Only 1 Recipient should be listed.

1020 **Table 9 Example Use of Recipient in a Centralised Procedure**

Authority	Recipient
ECOWAS-WAHO	wa

1021

1022 **4.3.4.3.2. National Procedure – Use of Recipient**

1023 The receiving Authority should be indicated. Only 1 Recipient should be listed.

1024 **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

1025

1026 **4.3.4.3.3. Reliance Procedure – Use of Recipient**

1027 All receiving Authorities should be indicated. The Lead Evaluating NMRA responsible for the evaluation should be listed first. The information for
 1028 all other participating Authorities should be provided thereafter. Multiple Recipients should be listed using the same examples as indicated under
 1029 National Procedure.

1030 **Table 11 Example Use of Recipient in a Reliance Procedure**

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

1031 * Ghana is listed first because they are the designated Lead Evaluating NMRA for the evaluation of the Application.

1032

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

1033 * Nigeria is listed first because they are the designated Lead Evaluating NMRA for the evaluation of the Application.

1034 **4.3.4.4. Lead Evaluating NMRA**

1035 The Lead Evaluating NMRA Element indicates who will be responsible for the evaluation. This should not be confused with the Recipient. Only
 1036 one Lead Evaluating NMRA can be identified in a single Sequence.

1037 Lead Recipient is a coded list. The code should be placed as value in the Envelope.

1038

```

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



1039 **Figure 10 Envelope Element: Lead Evaluating NMRA**

1040 **Related Information and Guidance**

- 1041 • recipient – Official defined list for Lead Evaluating NMRA (the same list is used for both Recipient and Lead Evaluating NMRA). [ECOWAS](https://www.ecowas.org)
1042 [eCTD \(waho-essmed.org/eCTD\)](https://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.

1043

1044 **4.3.4.4.1. Centralised Procedure – Use of Lead Evaluating NMRA**

1045 The Authority designated as the Lead Coordinating NMRA by WAHO should be listed as the Lead Evaluating NMRA for Centralised Procedures.

1046 For Centralised Procedures, the Lead Coordinating NMRA may change over time as that role is passed on from one country to another but should
1047 remain constant for all Sequences related to a particular Submission.

1048 Unlike the Recipient Element, "wa" should not be used as the Lead Evaluating NMRA for Centralised Procedures. The actual Authority designated
1049 by WAHO as the current Lead Evaluating NMRA for Centralised Procedures should be indicated.

1050 **Table 12 Example Use of Recipient and Lead Evaluating NMRA in a Centralised Procedure**

Authority	Recipient	Lead Evaluating NMRA
ECOWAS-WAHO	wa	ng*

1051 * Where Nigeria – NAFDAC is the current designated Lead Coordinating NMRA designated to evaluate Centralised Procedures.

1052

1053 **4.3.4.4.2. National Procedure – Use of Lead Evaluating NMRA**

1054 The Recipient and Lead Evaluating NMRA should be identical for National Procedures.

1055 The Lead Evaluating NMRA should remain constant over the life cycle of the application for National Procedures. Should the Application Type
1056 be changed from National to Reliance at some point during the life cycle, the original evaluating NMRA will remain listed first and any additional
1057 countries signing on to the results of the evaluation and decision of the Lead Evaluating NMRA will be added as recipients as described under
1058 the Reliance Procedure section.

1059 **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

1060

1061 **4.3.4.4.3. Reliance Procedure – Use of Lead Evaluating NMRA**

1062 The main country responsible for evaluation should be listed for Reliance Procedures.

1063 **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

1064 * Ghana is designated Lead Evaluating NMRA for the evaluation of the Application. Results of evaluation will be adopted by The Gambia and Liberia per
 1065 Reliance agreements.
 1066

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



1067 * Nigeria is designated Lead Evaluating NMRA for the evaluation of the Application. Results of evaluation will be adopted by Sierra Leone per Reliance
 1068 agreements.

1069 **4.3.4.5. Application Number**

1070 For Centralised Procedures, each product will be assigned a unique Application Number. The Application Number is a combination of

- 1071 • the letter "e" for eCTDs or "f" for eSubmissions,
- 1072 • "wa" (West Africa) to identify an ECOWAS Centralised Procedure,
- 1073 • the year and
- 1074 • five digits.

1075 *Example: e-wa-23-12345 / f-wa-23-12345*

1076 An Application Numbers will be assigned to:

- 1077 • Each strength for products with multiple strengths.
- 1078 • Each form for products with multiple forms.
- 1079 • Each duplicate products, also – for example for all strengths and forms of the duplicate.

1080

1081 Multiple Application Numbers can be included in an Application depending on the Authorities policies for including multiple products in a single
 1082 Application. In some cases, it is appropriate to combine different strengths and any duplicates in a single Application, but many Authorities will
 1083 not allow the combination of different forms. In this case, a separate Application should be created for each form.

1084 **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

1085 * 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
 1086 time.
 1087

1088 Enter the Application Number assigned by the receiving Authority and use it as the name for the eCTD Application folder which contains Sequence
 1089 folders.

1090 Applications provided in the eCTD format will be prefixed with an "e".

1091 Application provided in the eSubmission format will be prefixed with an "f".

1092 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.

1093

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

1094 **Figure 11 Envelope Element: Application Number**

1095 See the example XML code in section 0 * Defined Lists are provided and maintained on the ECOWAS eCTD website: ECOWAS eCTD (waho-
 1096 essmed.org/eCTD)

1097 ** Attributes may vary from one Recipient to another. Elements not designated should be consistent across all recipients.



1098 Submitting Multiple Values in the Envelope.

1099 For National Procedures and Reliance Procedures, please refer to the national guidance on Application Numbers.

1100 **Related Information and Guidance**

- 1101 • Portal Process Guide – Explanation on how to obtain an Application Number in the Portal and be found at [ECOWAS eCTD \(waho-essmed.org/eCTD\)](https://waho-essmed.org/eCTD)

1103 **4.3.4.6. Applicant ID**

1104 The applicant’s Applicant ID as issued for the first Application should be used.

1105 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.

1107 *Example: ng123*

```
1108 <applicant-id>ng123</applicant-id>
```

1109 **Figure 12 Envelope Element: Applicant ID**

1110 For National Procedures and Reliance Procedures, please refer to the national guidance on Applicant IDs.

1111 **Related Information and Guidance**

- 1112 • Portal Process Guide – Explanation on how to obtain an Applicant ID in the Portal. [ECOWAS eCTD \(waho-essmed.org/eCTD\)](https://waho-essmed.org/eCTD).

1113 **4.3.4.7. Applicant Name**

1114 The applicant’s legal name as registered should be used.

1115 *Example: Pharma Corp Ltd*

```
1116 <applicant-name>Pharma Corp Ltd</applicant-name>
```

1117 **Figure 13 Envelope Element: Applicant Name**



1118 **4.3.4.8. International Non-proprietary Name(s) (INN)**

1119 The recognised International Non-proprietary Name should be given. It should be written in all lower-case letters and provided exactly as listed
1120 as INN without abbreviations.

1121 *Example: amoxicillin*

1122 `<inn>amoxicillin</inn>`

1123 **Figure 14 Envelope Element: INN**

1124 See the example XML code in section 0 * Defined Lists are provided and maintained on the ECOWAS eCTD website: ECOWAS eCTD (waho-
1125 essmed.org/eCTD)

1126 ** Attributes may vary from one Recipient to another. Elements not designated should be consistent across all recipients.



1127 Submitting Multiple Values in the Envelope.

1128 **4.3.4.9. Proprietary Name(s)**

1129 The name or proposed medicine (trade) name to be used on the Certificate of Registration.

1130 For Master Files, insert name of manufacturing site.

1131 *Example:* afriCapsule.

1132 `<proprietary-name>afriCapsule A</proprietary-name>`

1133 **Figure 15 Envelope Element: Proprietary Names**

1134 See the example XML code in section 0 * Defined Lists are provided and maintained on the ECOWAS eCTD website: ECOWAS eCTD (waho-
1135 essmed.org/eCTD)

1136 ** Attributes may vary from one Recipient to another. Elements not designated should be consistent across all recipients.



1137 Submitting Multiple Values in the Envelope

1138 **4.3.4.10. Submission Type**

1139 The Submission Element section contains all the Submission related information that is not related to a specific Sequence. Multiple Submission
1140 Element sections can be provided for a Recipient section if the combination is allowed in the Submission Type Matrix.

1141 The Submission Type must be indicated for the Submission Element indicating type of regulatory activities being undertaken with the Submission.

1142 When multiple Submissions are listed, follow-up (responses, supplemental information and/or withdrawals) should only list the Submissions that
1143 are directly affected by the content being submitted in the follow-up Sequence. For example, if a variation Submission and a pharmacovigilance
1144 Submission are combined in the first Sequence but only a response was required for the variation, the pharmacovigilance Submission would not
1145 be listed in the Envelope of the response.

1146 Once a Submission has started it is not possible to combine new Submissions with the responses of existing Submissions.

1147 We recommend whenever possible to avoid combining Submissions in a single Sequence, however combinations in line with the Submission
1148 Type Matrix will be allowed.

1149 Submission Type is a coded list. The code should be indicated in the Envelope.

1150 *Example: sub-type-na-gen*

1151 `<submission code-version="1.0" code="sub-type-na-gen">`

1152 **Figure 16 Envelope Element: Submission Type**

1153 See the example XML code in section 0 * Defined Lists are provided and maintained on the ECOWAS eCTD website: ECOWAS eCTD (waho-
1154 essmed.org/eCTD)

1155 ** Attributes may vary from one Recipient to another. Elements not designated should be consistent across all recipients.



1156 Submitting Multiple Values in the Envelope

1157 **Related Information and Guidance**

- 1158 • submission-type – Official defined list for Submission Type. [ECOWAS eCTD \(waho-essmed.org/eCTD\)](https://waho-essmed.org/eCTD)
- 1159 • Submission Type Matrix – A summary of which combination of Submission Types is allowed when referencing multiple Submissions in a
- 1160 single Sequence. [ECOWAS eCTD \(waho-essmed.org/eCTD\)](https://waho-essmed.org/eCTD)

1161 **4.3.4.11. Submission Lead**

1162 The Submission Lead identifies the group within the Authority which is expected to take the lead in the evaluation process for a particular
1163 Submission. A Submission lead should be indicated for each Submission Element section provided.

1164 Submission Type is a coded list. The code should be indicated in the Envelope.

1165 *Example (Prescription): sub-lead-pm*

1166 `<submission-lead code-version="1.0" code="sub-lead-pm" />`

1167 **Figure 17 Envelope Element: Submission Lead**

1168 **Related Information and Guidance**

- 1169 • submission-lead – Official defined list for Submission Lead. [ECOWAS eCTD \(waho-essmed.org/eCTD\)](https://waho-essmed.org/eCTD)

1170 **4.3.4.12. Submission Number(s)**

1171 The Submission number(s) applicable to the Sequence being submitted should be indicated.

1172 Within an Application, there will be multiple Submissions (regulatory activities). Each Submission should have a unique identifier within the
1173 Application which added to the Application Number creates a unique identifier overall for each Submission.

1174 Submission Numbers are made up of the following components.

1175 **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.

1176

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

1178



1179 If appropriate, multiple Submission numbers can be given for a particular Submission.

1180 *Example (Prescription Medicines): e-wa-23-12345-pm-wa-23-123-1*

1181 `<submission-number>e-wa-23-12345-pm-wa-23-123-1</submission-number>`

1182 **Figure 18 Envelope Element: Submission Number**

1183 See the example XML code in section 0 * Defined Lists are provided and maintained on the ECOWAS eCTD website: ECOWAS eCTD (waho-
1184 essmed.org/eCTD)

1185 ** Attributes may vary from one Recipient to another. Elements not designated should be consistent across all recipients.



1186 Submitting Multiple Values in the Envelope

1187 **Related Information and Guidance**

- 1188 • Portal Process Guide – Explanation on how to obtain a Submission Number in the Portal. [ECOWAS eCTD \(waho-essmed.org/eCTD\)](https://waho-essmed.org/eCTD)

1189 **4.3.4.13. Sequence Type**

1190 The Sequence Element section contains all the Sequence related information. It identifies what is happening to the Submission with the Sequence
1191 being submitted. Only one Sequence Element section can be specified per Sequence.

1192 The first Sequence of a Submission must always be *Initial*. Follow-up Sequences should indicate whether it is a *Response*,
1193 *Supplementary Information*, *Closing Information*, or a *Submission Withdrawal*.

1194 Sequence Type is a coded list. The code should be indicated in the Envelope.

1195 *Example (Initial): seq-type-initial*

1196

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

1197 **Figure 19 Envelope Element: Sequence Type**

1198 **Related Information and Guidance**

- 1199 • [sequence-type](#) – Official defined list for Sequence Type. [ECOWAS eCTD \(waho-essmed.org/eCTD\)](https://waho-essmed.org/eCTD)

1200 **4.3.4.14. Sequence Description**

1201 The Sequence Description element gives the applicant the opportunity to better describe what is being done in the Sequence. The following
1202 should be considered when providing a Sequence Description

- 1203 • **Make it Short, Precise and Distinguishing** – Don't write an extensive description, this should be done in the Cover Letter and/or
1204 Reviewer's Guide. Think of the description as a categorisation of the Sequence that will help distinguish it from a long list of Sequences
1205 provided.
- 1206 • **Avoid Repeating Information** – Don't indicate the Submission Type or the Sequence Type in the Description. Give us more precise
1207 details but keep in short.
- 1208 • **For Initial Sequence Types** – Give us more detail about the Submission Type



- 1209 • **For Supplemental Information** – Give us information on what is being provided
- 1210 • **For Responses** – Indicate the date of the recommendations e.g., "Response to 2021-11-20 LOQ"
- 1211 • **For Withdrawals** – Indicate a brief reason for withdrawal

1212 *Example (New Generic Medicine – Initial): New Application*

1213 *Example (New Generic Medicine – Response): Response to 2021-11-20 LOQ - Quality*

1214 *Example (Extension of Indication – Initial): Indication Psoriasis to be added*

1215 `<sequence-description>SmPC Changes to Blister Pack</sequence-description>`

1216 **Figure 20 Envelope Element: Sequence Description**

1217 **4.3.4.15. Sequence Date**

1218 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
 1219 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
 1220 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
 1221 the Submission Date.

1222 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
 1223 will cause validation warnings which must be addressed in the Cover Letter.

1224 The date should be provided using the format YYYY-MM-DD.

1225

1226 *Example – 2023-05-20*

1227 `<sequence-date>2023-05-20</sequence-date>`

1228 **Figure 21 Envelope Element: Sequence Date**

1229 **4.3.4.16. Sequence Number**

1230 Four-digit number matching the Sequence folder being submitted.



1231 Applications starting with a *Baseline* Submission Type should start with the Sequence 0000. If an iterative baseline approach is being used,
 1232 the first baseline Sequence should be 0000. Following baseline Sequences should simply fall in line with the next Sequence number available at
 1233 the time.

1234 New Applications without baseline Sequences should start with the Sequence 0001.

1235 *Example - 0001*

1236 `<sequence-number>0001</sequence-number>`

1237 **Figure 22 Envelope Element: Sequence Number**

1238 **4.3.4.17. Related Sequence Number**

1239 The Related Sequence Number is used to group Sequences belonging to the same Submission. This enables us to easily evaluate Sequences
 1240 associated with a particular Submission.

1241 All Sequences that belong to a specific Submission should contain the same four-digit number in the Related Sequence Number field as
 1242 demonstrated in the table:

1243 **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

1244 Each Initial Sequence of a Submission will reference itself.

1245 Each follow-up Sequence of a Submission will reference the initial Sequence of that Submission.

1246 The Related Sequence Number should be approached similar to the Submission ID described in the [US regional specification 2.5](#) and the Related
 1247 Sequence Number in the [AU regional specifications 3.1](#)

1248 *Example – 0001*

1249

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

1250 **Figure 23 Envelope Element: Related Sequence Number**

1251 **4.3.4.18. Contact Type**

1252 The Contact element section contains all the Contact related information for a particular Contact Type. Multiple Contact Elements are allowed as
 1253 long as they are unique in type, for example multiple Technical Contacts cannot be provided but a Quality Contact and a Clinical Contact are
 1254 allowed. At least one contact must be provided but multiple are not required.

1255 Contact information may be used by the evaluators or by the Authority to contact the Applicant on questions during the evaluation process.

1256 The Contact Type must be indicated for the Contact element

1257 Contact Type is a coded list. The code should be indicated in the Envelope.

1258 *Example (Quality Contact): contact-type-reg*

1259

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

1260 **Figure 24 Envelope Element: Contact Type**



- 1261 See the example XML code in section 0 * Defined Lists are provided and maintained on the ECOWAS eCTD website: ECOWAS eCTD (waho-
1262 essmed.org/eCTD)
- 1263 ** Attributes may vary from one Recipient to another. Elements not designated should be consistent across all recipients.



1264 Submitting Multiple Values in the Envelope

1265 **Related Information and Guidance**

- 1266 • contact – Official defined list for Contact Type. [ECOWAS eCTD \(waho-](https://ecowas.org/eCTD)
1267 [essmed.org/eCTD\)](https://ecowas.org/eCTD)

1268 **4.3.4.19. Contact Name**

1269 A Contact Name must be provided for each Contact Type. Only one name can be provided
1270 per Contact Type.

1271 *Example: Dr. Chioma Abubakar*

1272 `<contact-name>Dr. Chioma Abubakar</contact-name>`

1273 **Figure 25 Envelope Element: Contact Name**

1274 **4.3.4.20. Contact Email**

1275 A Contact Email must be provided for each Contact Type. Only one email address can be
1276 provided per Contact Type.

1277 *Example: chioma.abubakar@pharma-inc.africa*

1278 `<contact-email>chioma.abubakar@pharma-inc.africa</contact-email>`

1279 **Figure 26 Envelope Element: Contact Email**

1280 **4.3.4.21. Contact Phone**

1281 A Contact Phone number can be provided for each Contact Type but is not mandatory. Only
1282 one number can be provided per Contact Type. While this is an optional field, we encourage
1283 the applicant to provide phone numbers whenever possible.

1284 *Example: +234 123 456 7890*

1285 `<contact-phone>+234 123 456 7890</contact-phone>`

1286 **Figure 27 Envelope Element: Contact Phone**



1287 **4.4. Heading and Leaf Elements**

1288 **4.4.1. Module 1 Heading Elements**

1289 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.

1290 Content under the following headings should be provided when required as defined in the Document Matrix.

1291 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
1292 use and may not be mandatory. We encourage to regularly check for updates to the Document Matrix.

1293 Please refer to Appendix A: Best Practice Leaf Title Recommendations for guidance on how best to title content added to the defined sections.

1294 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.

1295

1296 **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	

1301

1302 **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	

1303



1304 **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	

1305

1306 **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	

1307

1308 **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	

1309

1310 **Table 26 Heading Elements 1.8 – Information Relating to Pharmacovigilance**



1311

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	

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

1318 4.4.2. Leaf Element

1319 The `leaf` elements provide the content for each heading element.

1320 These elements contain, the `title` element along with several other attributes, all based
 1321 upon the ICH eCTD definition provided in the [Electronic Common Technical Document
 1322 Specification \(Version 3.2.2\)](#).



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

```

1323 <m3-2-s-1-2-structure>
1324 <leaf
1325   ID="Nba62a4e215fb40479b4151fa38bd80ad"
1326   operation="replace"
1327   xlink:href="m3/32-body-data/32s-drug-sub/olive-abc/32s1-gen-info/structure.pdf"
1328   checksum="14f0984f1116ac9d4fe43d31c7fee14f"
1329   checksum-type="MD5"
1330   xml:lang="en"
1331   modified-file=" ../0000/index.xml#Nba62a4e215fb40479b4151fa38bd80ad">
1332   <title>Structure</title>
1333 </leaf>
1334 </m3-2-s-1-2-structure>
  
```

1335 Footnote: The line breaks in the above example have been created here to make the display of the
 1336 attributes more user friendly but will likely not be present in the actual XML file.

1337 Figure 28 Leaf Element Explained

1338 Each `Leaf` element contains the following attributes when appropriate:

- 1339 • **ID** – The ID attribute is intended to be a unique reference within the Submission that can
 1340 be used to reference the item from another item within the XML document.
- 1341 • **Operation** – Indicates the action being performed e.g., New, Replace, Delete or Append
- 1342 • **xlink:href** – Provides the reference (path) to the actual content file. Must be relative to the
 1343 application folder.
- 1344 • **Checksum** – The checksum value for the file being submitted. A checksum is a sequence
 1345 of numbers and letters used to check data for validity. If we know the checksum of the
 1346 original file, we can use a checksum utility to confirm the copy received and evaluated is
 1347 identical.
- 1348 • **Checksum Type** – The checksum algorithm used.
- 1349 • **Language** – The language of the content referenced. Some sections will have specific
 1350 language requirements depending on the country. If left empty or absent from the Leaf
 1351 definition, the language will be assumed to be English since English is the accepted
 1352 international language of the ICH eCTD Module 2-5. This attribute has been included in
 1353 the ECOWAS Leaf requirements to enable validation of language based on country
 1354 selected. Language should be included in all Module 1 Leaves in an ECOWAS application.
 1355 If it is left blank for any Module 1 leaf, a validation warning will result.



- 1356 • **Modified File** – Provides the location of the `Leaf` that is being modified (i.e., replaced,
 1357 appended, or deleted) by the `Leaf` element. The modified-file attribute points to the
 1358 "index.xml" file and the Leaf ID of the Leaf being altered.
- 1359 • **Title** – A practical name for the file being referenced by the `Leaf`. This is the only thing the
 1360 evaluator will see and should be descriptive and distinguishing, especially in sections
 1361 where multiple `Leaf` elements are being submitted.



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

1362 4.4.3. Element Attributes

1363 As defined in the Heading Element table's Attribute column, there are specific sections where
 1364 additional attribute information will need to be provided to identify:

- 1365 • **Country** – used to differentiate content when Application is submitted in multiple countries.
 1366 • **Language** – used to identify language of content provided. Specifically, to enable validation
 1367 of specific language requirements for countries.
 1368 • **Translation Status** – indicates whether the content provided is the original or a translated
 1369 copy.

1370 In addition, there are language requirements in certain sections for the Leaf Element.

1371 4.4.3.1. Country

1372 The ISO 2 letter country code should be used for the country attribute. For common data for
 1373 multiple countries in a Reliance Procedure or when addressing ECOWAS as a whole in a
 1374 Centralised Procedure, the unofficial 2 letter region code "wa" should be used.

1375 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

1376 **4.4.3.2. Translation Status**

1377 The translations status indicates whether the document is the original or a translated copy.
1378 This is important to understand should there be any conflicts of interpretations.

1379 **Table 31 Translation Status Defined List**

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

1380 **4.4.3.3. Language**

1381 Language can be applied to the Leaf element in all sections, it is not limited to the ECOWAS
1382 module 1.

1383 The ISO 2 letter language code should be used for the language attribute. Only the official
1384 ECOWAS languages are validated. The language attribute should be used where a specific
1385 language is required or in instances where translations are being provided, the language Leaf
1386 attribute will help to differentiate the content for the evaluators.

1387 For instances where an original copy is provided that is not in one of the ECOWAS languages
1388 e.g., sections 1.3.4.4 and 1.3.5.4, please indicate the language in the Leaf title as well as the
1389 language attribute.

1390 If the language attribute is left blank or is missing from a Leaf, it will be assumed that the
1391 content is provided in English. For sections that require another language, this will lead to a
1392 validation error.

1393 **Table 32 ECOWAS Language Defined List**

Language	
List Code	List Value
en	English
fr	French
pt	Portuguese

1394 **4.4.4. Node Extensions**

1395 Node extensions are additional heading structures beyond those defined by the specifications,
1396 generally equated to an additional subfolder in a defined section and are a way of providing
1397 additional information in the Sequence.

1398 The node extension should be visualised as an extra heading in the CTD structure and should
1399 be displayed when viewing the XML backbone.

1400 Node Extensions should not be changed during the life cycle once established. Note that
1401 changes in the Titles associated with the Node Extensions would constitute a change and
1402 must be avoided to prevent validation issues.



1403 General Rules for Using Node Extensions:

- 1404 • Only use node extensions at the lowest level of the eCTD structure.
- 1405 *Example – you can use a node extension at the level 5.3.5.1 but not at the level 5.3.*
- 1406 • Use node extensions to group documents made up of multiple Leaf elements.
- 1407 *Example – a clinical study made up of separate files for the synopsis, main body and*
- 1408 *individual appendices should be grouped together under a node extension with the Study*
- 1409 *Identifier as its Title attribute.*
- 1410 • Nest the node extensions but make sure the first node extension is at the lowest level in
- 1411 the eCTD structure.
- 1412 *Example – a node extension may be added in Module 5.3.7 to group together files with*
- 1413 *the Study Identifier as Title attribute. Further node extensions may be added as children*
- 1414 *of the Study Identifier node, separating Case Report Forms (CRFs), if submitted, from*
- 1415 *individual patient listings.*
- 1416 • Make `title` elements short, precise, and informative. Do not repeat information already
- 1417 categorized by heading elements.
- 1418 • Place the most important identifying/distinguishing information at the beginning so we do
- 1419 not have to scroll to the end of the title.
- 1420 • You can repeat the optional node extension and Leaf elements as required. The DTD will
- 1421 ensure the checksum-type attribute contains either "MD5" or "md5".
- 1422

1423 You can use the `node-extension` elements:

- 1424 • to define structures beyond the heading elements.
- 1425 • wherever a leaf element is allowed in the DTD.
- 1426 • to organise multiple files which are needed under a normal eCTD heading.
- 1427 *Example – nonclinical studies with multiple files provided in 4.2.*
- 1428 *Example – complex presentation of data in the analytical procedures and validation of*
- 1429 *analytical procedures sections of 3.2.S.4.2/3 and 3.2.P.5.2/3*
- 1430

1431 You must use the `node-extension` elements:

1432 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.

1433 Do not use the `node-extension` elements:

- 1434 • if ICH-specified sub-headings already exist
- 1435 *Example – do not use the following as node extensions:*
- 1436 – *indication*
- 1437 – *excipient*
- 1438 – *manufacturer*
- 1439 – *drug substance*
- 1440 – *drug product.*
- 1441 • 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.

1442 The node-extension structure complies with general [ICH eCTD specifications](#), but it is not a
 1443 blanket permission to use the structures anywhere or without consideration. You may email
 1444 eCTD@wahooas.org for advice if the usage is novel.

1445 The optional `node-extension` element contains a single mandatory `title` element,
 1446 followed by at least one `Leaf` element, and can be followed by another optional `node-`
 1447 `extension` element.

1448 **4.4.5. Regional Information 2.3.R / 3.2.R**

1449 The general structure of the Regional Information is as follows:

- 1450 R Regional Information
- 1451 R.1 Production Documentation
- 1452 R.1.1 Executed Production Documents
- 1453 R.1.2 Master Production Documents
- 1454 R.2 Analytical Procedures and Validation Information
- 1455 R.3 Medical Devices
- 1456 R.4 Materials of Human and/or Animal Origin
- 1457 R.A Additional Regional Information

1458 **4.4.5.1. 2.3.R Regional Information Summary**

1459 2.3.R.1 and 2.3.R.2 are detailed in the QOS template. If appropriate, a separate document
 1460 should be provided with these sections when QIS is submitted. In addition, separate
 1461 documents can be provided if applicable listing the medical devices addressed in 3.2.R.3 and
 1462 a statement concerning products containing or using Materials of Human and/or Animal Origin
 1463 in 3.2.R.4. Separate documents will make the lifecycle management of the components more
 1464 independent.

1465 Any Additional Regional Information required or requested by individual member NMRAs
 1466 should be listed in a document provided under 2.R.A.

1467 All appropriate files can be placed directly under 2.3 Regional Information as Leaves with the
 1468 appropriate Structure Number and Title applied. The QOS and QIS should both be labelled
 1469 with the structure number 2.3.

1470 **4.4.5.2. 3.2.R Regional Information**

1471 Leaf elements in 3.2.R Regional Information heading must be provided using node extensions.
 1472 PDF files are not allowed as leaf elements directly under 3.2.R Regional Information heading.
 1473 Acceptable titles of the node extensions are as listed above. Structure numbers should be
 1474 included in the titles and should be complete e.g., 3.2.R.1.1 Executed Production Documents.

1475 Any Additional Regional Information required or requested by individual member NMRAs
 1476 should be provided as leaves in the 3.2.R.A Additional Regional Information node extension.
 1477 Each document should be provided separately and should have a Leaf Title clearly identifying
 1478 the content and for which country it is required.



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

1479 The exact naming convention of the titles of node extensions must be used when the node
1480 extension(s) is (are) created for the first time under this heading.

1481 If new or replaced leaves are provided in already existing node extensions under the 3.2.R
1482 Regional Information heading, the leaves must be provided under the existing node
1483 extensions, even if they don't follow the exact naming convention of the node extension title
1484 listed above. Warnings generated during the validation can be ignored, e.g., quickly explained
1485 in the Cover Letter.

1486 **4.5. Life Cycle Operations**

1487 The following four life cycle operations are defined under the [ICH eCTD specification](#):

- 1488 • New
- 1489 • Replace
- 1490 • Delete
- 1491 • Append

1492

1493 We encourage you to:

- 1494 • Use New, Replace, and Delete.
- 1495 • Only use Append as part of the Study Tagging Files (STF) as defined by the [ICH eCTD](#)
1496 [Backbone File Specification for Study Tagging Files](#). If you use Append for any other
1497 purpose, you will receive a validation error.



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

1498 **4.5.1. Specific Life Cycle Operations for ECOWAS**

1499 The nodes with specific life cycle operations mandated for an ECOWAS eCTD are
1500 summarised in Table 33 Nodes with Specific Life Cycle Operations. Adherence to these
1501 specific requirements will be validated.

1502 **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

1503 * The first time we receive a document in these sections the operation should be 'New'. Once a
 1504 document has been provided, the content should only be replaced in all future Sequences.

1505 ** Applies to all Subnodes with content e.g., Approved, Clean, Annotated, English, French, and
 1506 Portuguese.

1507

1508 The Tracking Table and the International Regulatory Status should both be presented in
 1509 tabular form and give an overview of the content. Updates to both should replace the table
 1510 provided in the earlier Sequence.

1511 Product Information for New Applications should be placed in the approved section. The Leaf
 1512 title should clearly state that it is the proposed product information. Once approved, the
 1513 proposed content should be replaced with the approved content and the Leaf title should be
 1514 updated to indicate approved and the date of approval.

1515 Once Product Information is approved, any proposed changes should be submitted in the
 1516 Clean section and an annotated copy of the proposals should be placed in the Annotated
 1517 section.

1518 **4.5.2. Life Cycle Operations for a Withdrawal**

1519 There are two types of withdrawals:

- 1520 • **Application Withdrawal** – The withdrawal of an entire product application.
- 1521 • **Submission Withdrawal** – The withdrawal of a just a Submission still under evaluation.
- 1522 The product Application should remain registered.

1523 **4.5.2.1. Application Withdrawal**

1524 When withdrawing an entire product life cycle history, the following attributes should be applied
 1525 in the `envelope` element:



- 1526 • The Submission Type should be set to "Application Withdrawal".
- 1527 • The Sequence Type should be set to "Initial".
- 1528 • The Sequence Description should be set to "Product Withdrawal".
- 1529 • Application Withdrawal should be considered a new Submission so the Sequence and the
- 1530 Related Sequence should be set to the next available Sequence.

1531

1532 The following life cycle rules should be applied:

- 1533 • A Cover Letter should be included as "New" and should include a reasoning why the
- 1534 product is being withdrawn.
- 1535 • No further content or life cycle is required.

1536 **4.5.2.2. Submission Withdrawal**

1537 When withdrawing a Submission, the following attributes should be applied in the `envelope`

1538 element:

- 1539 • The Submission Type should be consistent with the Type set in the Related Sequence.
- 1540 • The Sequence Type should be set to "Submission Withdrawal".
- 1541 • The Sequence Description should be set to "Withdrawal of..." and indicate the detail of the
- 1542 Submission that was indicated in the Description of the Related Sequence.
- 1543 • Submission Withdrawal is a new Sequence in the Submission still under evaluation so the
- 1544 Related Sequence should be set to the "Initial" Sequence of the Submission.

1545

1546 The following life cycle rules should be applied:

- 1547 • The Cover Letter should be the only document submitted as New
- 1548 • Content that was replaced by the Submission must be reset referencing the document
- 1549 that was previously referenced in the earlier Sequence using the replace operation. The
- 1550 document should NOT be provided again.
- 1551 • Content that was added as New in the Submission must be removed using the Delete
- 1552 operation.
- 1553 • If Work Grouping was done in the first Sequence... see the section below on how to
- 1554 address the reactivation of those activities. DO NOT remove any content belonging to
- 1555 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.

1556 **4.5.2.3. Submission Withdrawals and Work Grouping**

1557 If Work Grouping was done and other Submissions were included in the Initial Sequence that

1558 was originally submitted, those Submission will have to be extracted out of the Submission

1559 group of the withdrawn Submission.

1560 Work Grouping also means that the results of each Submission evaluation must be the same.

1561 This is why combinations of major Submission Types is not allowed as the likelihood that there

1562 would be different outcomes is higher in more complex Submission Types.



1563 If a withdrawal of a Submission is performed, it will technically show up as a withdrawal of all
1564 Submissions combined in the Initial Sequence of the Submission.

1565 In the Submission Withdrawal Sequence, the content related to the other Submissions not
1566 being withdrawn should NOT be replaced or deleted.

1567 Instead, and in addition to the Submission Withdrawal Sequence, a second Sequence should
1568 be submitted as a New Initial Submission in which all current content from the Submissions
1569 not being withdrawn is referenced again using the Replace operation. The documents should
1570 NOT be provided again, only referenced again using content reuse. For more information on
1571 content reuse, please see section 3.7 Reusing Files.

1572 **4.5.3. Life Cycle Operations for Rejected Submissions**

1573 If a Submission was submitted on its own without Work Grouping, no further action is required
1574 if a Submission is rejected. A Submission evaluation tool should be able to display content
1575 excluding the content and changes introduced in rejected Submissions.

1576 **4.5.3.1. Rejected Submissions and Work Grouping**

1577 If a Submission is rejected, it will technically show up as a rejection of all Submissions
1578 combined in the Initial Sequence of the Submission if Work Grouping was used.

1579 An additional Sequence should be submitted as a New Initial Submission in which all current
1580 content from the Submissions not rejected is referenced again using the Replace operation.
1581 The documents should NOT be provided again, only referenced again using content reuse.
1582 For more information on content reuse, please see section 3.7 Reusing Files.

1583



1584 **4.6. Files and Folders**

1585 **4.6.1. File and Folder Naming Conventions**

1586 Naming conventions for the content files are not part of the validation criteria for the ECOWAS
1587 eCTD.

1588 You may use files submitted in other regions without re-naming, but:

- 1589 • Ensure all content is referenced by the appropriate XML files for efficient navigation.
- 1590 • Provide precise but informative Leaf titles to aid reviewers.
- 1591 • Ensure the basic construction of the eCTD is maintained.
- 1592 • Adhere to the basic ICH eCTD rules for folder and file names:
 - 1593 – Use alphanumeric lower-case characters only – for example a-z & 0-9.
 - 1594 – Do not use spaces.
 - 1595 – Do not use any special characters other than the hyphen "-".
- 1596 • Adhere to the naming conventions as described in Table 34 Minimum Naming
1597 Conventions Matrix

1598

1599 You may also use the naming convention defined for the temporary eSubmission solution,
1600 however, please note that it is planned to phase those specifications out over time and once
1601 eliminated, no naming conventions will be updated or further provided.

1602



1603 **Table 34 Minimum Naming Conventions Matrix**

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

1604



1605 **4.6.2. Folder and File Name – Path Length**

1606 Ensure the overall length of the folder and file name path, starting from the Sequence number,
1607 does not exceed 180 characters, for any file in any module.

1608 We acknowledge it is less than the overall path length indicated in the ICH specifications but
1609 consistent with or more generous than other eCTD regions.

1610 **4.6.3. Working Documents**

1611 For each Sequence submitted, a corresponding Working Documents folder shall also be
1612 submitted – “0001-workingdocuments”. A Validation Report shall be submitted with each
1613 sequence. The Validation Report can be provided in any format but must be named validation-
1614 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.

1615 For more information on content expected in the Working Documents folder, please refer to
1616 national guidance.

1617 **4.6.4. Source Documents**

1618 Source Documents (MS Word or Rich Text Format) for Product Information provided in 1.3.1,
1619 1.3.2 and 1.3.3 shall be submitted along with PDF files in the appropriate Module 1 sections
1620 using the life cycle operation New or Replace. Hyperlinks should be placed in the PIL PDFs.
1621 No Hyperlinks are required in any of the Word Files.

1622 **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

1623
1624 Source Documents for 2.3 should be provided for the QOS/QIS, no PDF files are required.
1625 Source Documents are not required for 2.3.A or 2.3.R summaries:

1626 If content is provided in 3.2.A and/or 3.2.R, a brief summary can be provided as a single
1627 document for each section in 2.3 and labelled as 2.3.A Appendices and 2.3.R Regional
1628 Information respectively. Please see the CTD Guidance for more information on content
1629 expectations of the 2.3.R/3.2.R Regional Information.

1630 **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

1631



1632 5. eCTD Preparation Tools

1633 5.1. General Information about Solutions

1634 ECOWAS does not mandate or recommend any particular software to prepare an eCTD
 1635 Submission. eCTD is an international standard and any solution capable of producing a valid
 1636 eCTD will be able to provide an Application compatible with any solution the ECOWAS
 1637 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.

1638 We recommend you, as the applicant:

- 1639 • Prepare the eCTD using an authenticated commercial eCTD preparation tool.
 1640 There is a wide variety of options available, both in terms of multiple vendors and of
 1641 approaches – for example:
- 1642 – Installed Software
 - 1643 – Software as a Service
 - 1644 – Service Providers
 - 1645 – Cost & Level of Functionality
- 1646 • Find a solution which supports current and ongoing ECOWAS eCTD requirements AND
 1647 meets your overall business needs.
- 1648 • Validate the prepared Sequences using an authenticated commercial eCTD validation
 1649 tool.

1650

1651 eCTD validation tools are not just XML checkers or parsers, they evaluate the technical
 1652 content of the Sequence for the eCTD Application. We recommend, you use a validation tool
 1653 that:

- 1654 • supports checking current and ongoing ECOWAS eCTD requirements
 1655 • minimises the possibility of technical validation errors which can cause delays in the
 1656 overall regulatory process.

1657 5.2. Solution Selection Process

1658 ECOWAS encourages companies to undergo a proper selection process in which their
 1659 overall business needs are documented in the form of User Requirements.

1660 A sample set of user requirements has been made available on the ECOWAS website at the
 1661 link listed below. This is a comprehensive list of requirements and companies should review
 1662 these and give priority to features that would be important or essential for their business
 1663 needs. Items not deemed necessary should be removed from their customised User
 1664 Requirements. Note that the more requirements in your user requirements, the more costly
 1665 the solutions will likely be.



1666 [ECOWAS eCTD \(waho-essmed.org/eCTD\)](http://waho-essmed.org/eCTD)

1667 Please note that the solution selected may feature as a part of future company audits by
1668 authorities as it will play a key role in data security and integrity of content submitted. Be sure
1669 the implementation is documented and validated in accordance with normal quality
1670 management practices.

1671 **5.3. Specific Solution Information**

1672 A list of eCTD Preparation Tools and eCTD Validation Tools can be found on the ECOWAS
1673 website at the link below. ECOWAS does not by any means mandate or recommend any of
1674 the solutions listed on the website and has not independently confirmed any of the solutions
1675 ability to comply with the ECOWAS requirements. It is up to the Applicant to ensure they select
1676 a solution that can prove they are able to create and validate an eCTD according to the
1677 ECOWAS requirements. The list provided as a simple courtesy but is by no means
1678 comprehensive.

1679 [ECOWAS eCTD \(waho-essmed.org/eCTD\)](http://waho-essmed.org/eCTD)

1680 Vendors that would like to add their solutions to this list should contact ECOWAS via email at
1681 eCTD@wahooas.org and the following information:

- 1682
- 1683 • Name of the company as it should be listed
 - 1684 • URL for the link to you company's website
 - Type of solution you provide e.g., eCTD Preparation Tool or eCTD Validation Tool

1685



1686 6. Appendix A: Best Practice Leaf Title Recommendations

1687 Shaded sections are eCTD elements where Leaf elements should not be added. No
1688 documents should be created at that granularity. These are only listed here for organisational
1689 purposes.

1690 Some titles include values in brackets – for example [DESCRIPTION]. These variables should
1691 be replaced with the item indicated in brackets. Note that variable components can be
1692 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

1693



1694 7. Change Control

1695 The following documents were referenced during the creation of this specification:

- 1696 • [eCTD AU Module 1 and Regional Information](#)
- 1697 • [EU Module 1 eCTD Specification](#)
- 1698 • [GCC Module 1 eCTD Specification](#)
- 1699 • [SG-HSA Module 1 and Regional Information](#)
- 1700 • [The eCTD Backbone Files Specification for US Module 1](#)
- 1701 • [ICH eCTD Specifications v3.2.2](#)
- 1702 • [ICH eCTD Specifications v4.0](#)

1703

1704 Factors that could affect the content of the specification include, but are not limited to:

- 1705 • Changes in the Content of the Module 1 for the CTD
- 1706 • Update of Standards that are already in use within the eCTD
- 1707 • New Standards for Creating and/or Using eCTD
- 1708 • New Functional Requirements
- 1709 • Experience with Using eCTD, in particular Module 1.
- 1710 • Updates to the Processes at the NMRAs - Automation

1711

1712 We will:

- 1713 • Provide a Practical Timeframe for Future Changes to Minimize Impact on Industry. In
1714 general, a transition time of at least 6 months is provided to migrate to new
1715 specifications.
- 1716 • Introduce Changes at Scheduled Intervals to allow Stability.

1717

1718 Please send any feedback, comments, or questions to eCTD@wahooas.org.

1719



1720 8. Version History

1721 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

1722

1723 Versioning Guide

1724 Versions to the specifications will be handled as follows:

- 1725 • Major Versions will be triggered by changes in the Envelope or Heading Elements e.g.,
1726 version 1.0, 2.0, 3.0.
- 1727 • Minor Versions will be triggered by all other changes that require updates to the DTD e.g.,
1728 version 1.1, 1.2, 1.3.
- 1729 • Changes in the specification document that do not trigger changes to the DTD will be
1730 identified by a number suffixing the minor version number e.g., version 1.01, 1.02, 1.03.
- 1731 • All Major Versions will begin with the minor version 0 and no document version number
1732 will be applied until changes to the document have been issued. For both the minor
1733 versions and document changes the version number will be a single character running
1734 from 1-9 and then a-z if necessary.

1735

Version	Description of Change	Author	Effective Date
v1.0	Initial version	ECOWAS eCTD Project Team	2023-07-01

1736