Questions & Answers
Implementation of eCTD in South Africa
Introduction

This document is intended to provide clarity on guidelines and specifications for applications for the registration of medicines in eCTD format as well as the Validation Criteria. This document is meant to compliment the specifications and validation criteria by addressing common and/or expected questions and reflects the current situation. Over time, this document will be expanded regularly updated with changes in legislation and experience gained, to provide guidance on Best Practises and new expectations as they develop. It will also lay a foundation for future updates to the specifications Applicants should check for the current version of this document regularly to ensure they are in line with the latest expectations. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.
Guidelines and application forms are available from the office of the CEO and the website.

For clarification on Terminology, please see the Terminology tab or the Introduction section of the SAHPRA eCTD Specifications.

For general questions on eCTD, we encourage applicants to also familiarise themselves with the ICH eCTD Q&A document at:

Question Categories

The questions have been split up into 3 different tabs: 2.0 General, 3.0 eCTD, and 4.0 Archived. Within each of these topics questions have been categorised as:

(U) - Questions and Answers update from the previous Q&A

(N) - Questions and Answers included from release of Specification 3.0

Archived - Questions and Answers from previous Q&A, still relevant but no changes included, or updated to indicate no longer in practise.

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.1(U)	May-19	Related Sequence	Related sequences – must it be left open, or must <none> be included similar to Swiss?
2.2(U)	May-19	Related Sequence	Related sequences – should you not include the previously approved sequence when you start a new regulatory activity?
2.3(U)	May-19	Related Sequence	Related sequences - when should the related sequence be included?
2.4(U)	May-19	Submission type	Submission Type - What submission type should be used in the envelope when responding to a PEM and Clinical recommendation in one sequence?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.5(U)	May-19	Folders & Files	Folders & Files - It is correct that the way 3.2.R as defined fits into the ICH DTD, but where is it defined? Must the applicant submit using the recommended folder and file names specified by ICH?
2.6(U)	May-19	Folders & Files	Folders & Files -What is the correct file folder structure and names expected in 3.2.R?
2.8(U)	May-19	Validation	Validation: Path Length - The maximum length of path starting with the application folder is 180 although ICH allows 230. Is the maximum path length of 180 characters only for module 1 or for modules 2 to 5 as well?
2.11(U)	May-19	Validation	Validation - Is the folder structure checked during validation?
2.12(U)	May-19	Folders & Files	Folders & Files: "New" documents - Which documents must be included as "New"?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.13(U)	May-19	Folders & Files	New documents - Should documents that have to be included as "New" be placed in node extensions?
2.14(U)	May-19	Folders & Files	Leaf titles - What are the expectations for leaf titles?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.15(U)	May-19	Folders & Files	Leaf titles - What is the difference between a leaf title and a file name?
2.16(U)	May-19	Folders & Files	Validation template - Should hyperlinks be included in the validation template?
2.17(U)	May-19	Validation	Validation - How must "Best practice warnings" in validation be handled?
2.18(U)	May-19	MD5 Checksum	MD5 Checksum -Where must the MD5 checksum be submitted?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.20(U)	May-19	Folders & Files	Table of Contents - Should Tables of Contents include hyperlinks?
2.21(U)	May-19	Folders & Files	How do I ensure that thumbs.db files are not created on the CD/DVD that I submit to the Authority?
2.25(N)	Mar-24	Document Navigation	Hyperlinks - Should hyperlinks be created to the Literature Reference sections?
2.26(N)	Mar-24	Document Navigation	Hyperlinks - Can I hyperlink to content submitted in earlier Sequences?
2.27(N)	Mar-24	Document Navigation	Hyperlinks - Are intra-document hyperlinks required?
2.28(N)	Mar-24	Document Navigation	Hyperlinks - What inter-document hyperlinks should be created?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.29(N)	Mar-24	Document Navigation	Document Navigation - What expectations are there for Hyperlinks and Bookmarks
2.30(N)	Mar-24	Document Navigation	Hyperlinks - Should hyperlinks be created to Module 3 from Module 2?
2.31(N)	Mar-24	Document Navigation	Hyperlinks - Should hyperlinks be created to Module 4 from Module 2?
2.32(N)	Mar-24	Document Navigation	Hyperlinks - Should hyperlinks be created to Module 5 from Module 2 and Module 5.2?
2.33(N)	Mar-24	Baselines	Baselines - Are baselines required for the ZA eCTD 3.0?
2.34(N)	Mar-24	Baselines	Baselines - Can I provide proposed changes in my baseline?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.35(N)	Mar-24	Baselines	Baselines - Are baselines reviewed?
2.36(N)	Mar-24	Communication	Enquiries - Where should questions be sent about eCTDs or eSubmissions?
2.37(N)	Mar-24	Communication	Feedback - How will feedback be received on Applications submitted?
2.39(N)	Mar-24	Content	Post-Marketing Experience - Where should Post-Authorisation Information be provided?
2.40(N)	Mar-24	Envelope	Envelope: Defined List Codes - How do I know if the code I am using is valid?
2.41(N)	Mar-24	Envelope	Envelope - How should multiple values be provided when required?
2.42(N)	Mar-24	Envelope	Envelope: Submission codes - Will the application type codes still be the same?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.43(N)	Mar-24	Folders & Files	Document Granularity - How granular must I be with my documents? Is it better to keep them at a higher or lower level?
2.44(N)	Mar-24	Portal	Portal - What is the web address for the portal?
2.45(N)	Mar-24	Envelope	Envelope - What is an CIPC number?
2.46(N)	Mar-24	Portal	Portal - How is access to the portal managed?
2.47(N)	Mar-24	Portal	Portal - Can Applicants have multiple logins for multiple employees?
2.48(N)	Mar-24	Portal	Portal - Do I need to apply for an Applicant ID each time I want to submit a product?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.49(N)	Mar-24	Portal	Portal - Does the portal provide status information on the Applications/Submissions/Sequences submitted?
2.50(N)	Mar-24	Portal	Portal - On the BAU variation status will a date be included for the approvals
2.51(N)	Mar-24	Portal	What is the status of the Quantum portal? is this the same portal referred to for launch 1 July?
2.52(N)	Mar-24	Portal	The portal for now is only for eCTD submissions. As such, from 16 Apr till Jul?, will the FTP still be open for eSubmission applications? Otherwise, how will be submit eSubmission applications until the specifications and requirements are ready?
2.53(N)	Mar-24	eSubmissions	Please advice where we can submit e-submissions application for those dossiers that has not yet been converted to e-CTD?
2.54(N)	Mar-24	Security	Security - Is my data secure?
2.55(N)	Mar-24	Content	Content: PI/PIL - Where should documents for PI/PIL be placed in a New Application?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.56(N)	Mar-24	Content	Content: PI/PIL - Where should documents for PI/PIL be placed in a Response to Recommendations before Registration Approval?
2.57(N)	Mar-24	Content	PI/PIL - Where should documents for PI/PIL be placed in amendments proposed after Registration Approval?
2.58(N)	Mar-24	Content	PI/PIL - Where should documents for PI/PIL be placed in a Respones to Recommendations after Registration Approval?
2.59(N)	Mar-24	Content	PI/PIL - How should approved proposed content in the Product Information Clean sections be transferred to the Approved sections?
2.60(N)	Mar-24	Software Solutions	Software Solutions - Will SAHPRA provide a list of software solutions?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.61(N)	Mar-24	Software Solutions	Software Solutions - What should a company look for in an eCTD Publishing and Validation solution?
2.62(N)	Mar-24	Trigger File	Trigger File - Where do I find the trigger file?
2.63(N)	Mar-24	Trigger File	Trigger File - How do I complete the trigger file?
2.64(N)	Mar-24	Folders & Files	Folders & Files - Is it necessary to have a descriptive file name for documents submitted?
2.65(N)	Mar-24	Validation	Validation - Can I submit an application if there are validation Errors?
2.66(N)	Mar-24	eCTD Specification	Why is SAHPRA eCTD Specification 3.0 still based on the ICH eCTD Specification 3.2.2 version instead of the 4.0 which is the latest version that ICH has published
2.67(N)	Mar-24	eCTD Specification	Transition eCTD Specification 3.0 and implementation - eCTD 3.0 will be accepted from 1st of October. Is there a transition period until it´s mandatory, so a period where current and new version is accepted?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.68(N)	Mar-24	Admin Freeze March 2024	Admin Freeze - Will the Applicant be able to submit APIMF in this admin freeze period?
2.69(N)	Mar-24	Admin Freeze March 2024	Admin Freeze - Will the freeze affect the submission of the closed part of the DMF to SAHPRA?
2.70(N)	Mar-24	Admin Freeze March 2024	Admin Freeze - Please confirm all processes at SAHPRA will not be frozen, i.e applications in submission/review ?
2.71(N)	Mar-24	Admin Freeze March 2024	Admin Freeze: Veterinary Renewals - Will this be applicable to veterinary? We have a renewal response due for before 16th of April, must we also then only respond on the 16th?
2.72(N)	Mar-24	Admin Freeze March 2024	Admin Freeze: eCTD submissions - For dossiers not yet in eCTD but still in CTD and there is a recommendation to submit after the freeze period, what is the expectation on this/ what will be the approach in submitting the response?
2.73(N)	Mar-24	Admin Freeze March 2024	Admin Freeze: Variations - does this have impact on Type I variation implementation timelines?
2.74(N)	Mar-24	Admin Freeze March 2024	Admin Freeze - During the freeze period, will section 36 Applications also be frozen?
2.75(N)	Mar-24	Admin Freeze March 2024	Admin Freeze - Where do I submit my submission until the Portal goes live on 1 July 2024?
2.76(N)	Mar-24	Admin Freeze March 2024	Can I apply for an Application number during the Admin Freeze period?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.77(N)	Mar-24	DVP Portal	What happens to the DVP portal after the Admin Freeze and how will affect this the current Type IA amendments where it has an impact on the registration certificate? E.g., Addition of FPRC's?
2.78(N)	Mar-24	Product Cancellation	Product Cancellation - When a product is de-registered do we have to submit a variation of some sort to close the lifecycle
2.79(N)	Mar-24	Sequences	Sequence: Submitting a variation - Just clarification for sequence, if our dossier is already in eCTD and we're submitting a variation. According to the sequence tracking table, do we continue then to the next sequence e.g., current sequence is 0005, next sequence can be 0006 regardless of the new updates?
2.80(N)	Mar-24	Master Files	Master Files - Will this portal allow for the submission of SMFs once every 5 years as per the guideline?
2.81(N)	Mar-24	eSubmissions	eSubmissions - Just to check, industry may submit eSubmission variations without baseline till 1 Oct is that correct? From 1st Oct do eSubmissions fall away?
2.82(N)	Mar-24	eSubmissions	eSubmissions - Companies that are to-date still submitting variations as e-submission format, how will those be handled?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.83(N)	Mar-24	Working Documents	Working Documents - If we still need to do eCTD baseline submissions (i.e. seq 0000), will the baseline also not require MS word working documents?
2.84(N)	Mar-24	Working Documents	Working Documents - Where are they located according to the new SAHPRA eCTD 3.0 Specification?
2.85(N)	Mar-24	QOS/QIS in Baselines	Will these baselines require QOS/QIS? (If I remember correctly, eCTD baselines did not require QOS/QIS documents).
2.86(N)	Mar-24	Work grouping	Work grouping - Is work grouping the same as bundling?
2.87(N)	Mar-24	Envelope	Envelope: Contact - Is it advisable to put the person signing the dossier as per 1222 or the Responsible Pharmacist
2.88(N)	Mar-24	Communication	Communication: Key dates - Summarise the key dates for us.
2.89(N)	Mar-24	Content	Content - As only electronic submissions are made, is 1.2.2.4 still necessary?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Question
2.90(N)	Mar-24	Clinical Trial applications	Clinical Trial Applications - For the 5 April submissions of new clinical trial applications - would it still be through the 'old' process?
2.91(N)	Mar-24	Guidelines	Guidelines: eCTD Module 1 - Will the South African Specification for eCTD Regional Module 1 guideline be updated, and if so, when will it be published?
2.92(N)	Mar-24	Training	Training: Are there going to be more in-depth training for use of the system?
2.93(N)	Mar-24	Content	Content: Cover pages - Are cover pages for sections still required for eCTD and eSubmissions?
2.94(N)	Mar-24	eSubmissions	eSubmissions - All the recent submissions that are going to be imported into RIMS, will it include only eCTD submissions or both eSubmissions and eCTD submissions
2.95(N)	Mar-24	Master Files	Do we need to include all SMF numbers for all sites applied for (FPP, FPRC, FPRR, Packers).
2.96(N)	Mar-24	Correspondence	Correspondence - With the new trigger file, do we still need to sent SAHPRA email notification as proof of upload of submission?
2.97(N)	Mar-24	Submission Lead	Submission Lead - What is the Submission Lead?

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Answer
2.1(U)	May-19	Related Sequence	When a new Regulatory activity is started and there is no related sequence, the related sequence should be indicated as the same sequence as what is being submitted in the envelope. This is according to the SAHPRA eCTD specification 3.0.
2.2(U)	May-19	Related Sequence	No, each Submission Type/Regulatory Activity starts with a new sequence with no related sequence. In the envelope/on the portal the related sequence should be indicated as the initial sequence of the submission.
2.3(U)	May-19	Related Sequence	The related sequence number describes the relationship of additional information to the original sequence or subsequent sequences within a Regulatory Activity/Submission. Therefore, it should be included for all sequences subsequent to the original submission sequence in a regulatory activity. Refer to the example on the use of the related sequence in 2.21 South African Specification for eCTD Regional - Module 1.
2.4(U)	May-19	Submission type	Pre-reg: **Submission type** will be NCE/New Generic (Multisource) etc. as per the initial sequence's submission type. **Sequence type:** Response to Clinical Recommendations and Response to Quality Recommendation. Variations (post-reg): **Submission type** will be according to the variation type as per the initial submission e.g., Type IB Clinical. Please refer to submission matrix for allowed combinations of variations. **Sequence type:** Please note that because you are responding to a specific submission evaluation, you cannot combine responses to separate submissions into one sequence. Therefore, your sequence type will be according to the initial submissions' response – e.g., Submission type for initial submission was Type IB Clinical, sequence type will therefore be Response to Clinical Recommendations.

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Answer
2.5(U)	May-19	Folders & Files	SAHPRA does not have a specified folder and file name for eCTD content beyond the top level folders within the Submission Unit folder of m1, m2, m3, m4, and m5. Each leaf element of the eCTD must reference the file correctly and provide an acceptable leaf title.
2.6(U)	May-19	Folders & Files	SAHPRA does not have a specified folder and file name for eCTD content beyond the top level folders within the Submission Unit folder of m1, m2, m3, m4, and m5. Each leaf element of the eCTD must reference the file correctly and provide an acceptable leaf title.
2.8(U)	May-19	Validation	There are limitations on overall path lengths in a normal MS Windows® environment. The ICH limitation was setup to ensure that there is enough space to setup an organisation structure on the authority side. The limitation allows for more flexibility in this matter and reduces the chances of file names being truncated when copied from one media to another. Note that the SAHPRA limit is not novel and has already been implemented by other authorities - for example EU, Switzerland, Australia, ECOWAS, etc.
2.11(U)	May-19	Validation	Yes, the xml folder structure will be checked during validation in accordance with the current validation criteria.
2.12(U)	May-19	Folders & Files	As indicated in the validation template and point 5.4 of guideline 2.23 Submission in eCTD format, the operation attribute of the following documents should be reflected as "new": •1.0.1 Letter of application •1.2.1 Application form •1.2.2.1 Proof of payment •1.2.2.4 Electronic copy declaration •1.5.2.1 Tabulated schedule of amendments (if applicable) •Changes to modules as per specification 3.0.

No.	Date Added	Category	Answer
2.13(U)	May-19	Folders & Files	No, node extensions should not be used. Additional descriptive text must be included in the leaf title to assist with identification of specific document (see expectations for leaf titles below). Please take note of the granularity for Mod 1.0, where the Note to Evaluator, is included as a seperate Node and should not be included as part of the Cover Letter and bookmarked as per previous practise. Leaf titles are helpful during the evaluation process. Please refer to Best Practise Guidance on Leaf Titles included in Specification 3.0.
2.14(U)	May-19	Folders & Files	Point 3.5 of guideline 2.23 Submission in eCTD format states: "As eCTD viewing tools will display all “new” leaf elements in a current or cumulative view, additional descriptive text has to be included in the leaf title to assist with identification of specific letters. This will help identify each letter of application leaf and the submission it is in, rather than having the letters named the same in each sequence." However, this should be applied where the operation attribute is always new or where multiple documents may be included e.g. 1.2.1, 1.7.3, 1.3.1.2 Leaf titles are an important part of eCTD submissions as they are displayed to the evaluator when evaluating an eCTD application. Including meaningful information in leaf titles makes submissions easier to navigate and makes evaluators' jobs easier.Please refer to Best Practise Guidance on Leaf Titles included in Specification 3.0. Leaf titles should be short, descriptive and distinguishing, especially in sections where multiple documents are being provided. The evaluator should not have to open the file to understand the content that is being provided. Leaf titles should be suitably descriptive for the current sequence and all possible life-cycle sequences.

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Answer
2.15(U)	May-19	Folders & Files	Both the PDF file name and the leaf title are used to identify and describe each file in the eCTD. The leaf title/description does not have to be the same as the PDF file name given to the file. A leaf title is what is seen by an evaluator when viewing an eCTD application via the XML file and Style Sheet. A file name is what is seen by an evaluator when viewing a folder structure without the XML and Style Sheet and viewed. For eCTDs the file names are unimportant except in cases specified. For eSubmissions, since no XML file is supplied, the file name is the only method available to identify the content. Attention should be given to 2.14 above in terms of leaf title expectations to ease navigation through eCTD submissions. Examples: File name: Leaf title: application-letter.pdf Letter of application (Initial application) application-form.pdf Application form 10 mg initial application pi.pdf Proposed Professional Information initial application avail.pdf Comparative dissolution study report
2.16(U)	May-19	Folders & Files	Yes, technical sections should be hyperlinked for ease of reference during Screening.
2.17(U)	May-19	Validation	For any Best Practice criteria that are not met (now referred to as Warnings), you must address these in the Cover Letter. Warnings generally lead to a less efficient evaluation so should be fixed whenever possible. It will be up to the SAHPRA to to decide whether the issues should be resolved. It is however recommended that the applicant provide sequences without any Warnings as continuous failure to fix Warnings with subsequent sequences, will result in SAHPRA rejecting any following sequences/submissions. Any adjustments should generally be addressed in the next Submission Unit.
2.18(U)	May-19	MD5 Checksum	This is no longer the practise to include outside of the submission.

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Answer
2.20(U)	May-19	Folders & Files	It is not required to hyperlink a document TOC. Instead, the entries of the TOC should be made available as Bookmarks. This provides constant access to all referenced content of the document without having to return to the TOC page.
2.21(U)	May-19	Folders & Files	CD/DVDs will only be accepted on request by the authority. Submissions will be handled via the Portal from 1 July 2024. thumbs.db files are Windows system database files automatically generated and contain small images used to view a folder in Thumbnail view. These are created when you browse through the folders to enable a faster indexing of the content. It is possible to turn off the automatic creation of such system files and this is encouraged. Please consult your IT and implement such settings.
2.25(N)	Mar-24	Document Navigation	A listing of literature references is normally provided in 2.4 of 4.3 and in 2.5 and 2.7.5 of 5.4. Hyperlinks between these are not required as long as the entry in the lists of Module 2 matches the leaf title / file name used in 4.3 / 5.4.
2.26(N)	Mar-24	Document Navigation	Yes, since the eCTD and eSubmission are contained in a predictable structure, it is possible to create hyperlinks to documents provided in earlier Sequences. Hyperlinks must be made using a relative path.
2.27(N)	Mar-24	Document Navigation	In general, it is always good practice and will improve the evaluation if intra-document hyperlinks are provided where the user is able to jump from one section of a document to another part referenced. However, if the documents are sufficiently bookmarked and the destination is adequately bookmarked, intra-document hyperlinks are not required.
2.28(N)	Mar-24	Document Navigation	SAHPRA would prefer that documents be properly bookmarked over adopting an extensive approach to hyperlinking. Hyperlinks between documents tend to get messy deep into the lifecycle with misleading or broken links. Hyperlinks should only be created when a distinct benefit would be provided for the evaluator. With that in mind, the frequent changes to Module 3 coupled with the detailed granularity of the Quality section means that hyperlinks to Module 3 are discouraged

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Answer
2.29(N)	Mar-24	Document Navigation	SAHPRA would prefer that documents be properly bookmarked than an extensive approach to hyperlinking be adopted. Hyperlinks between documents tend to get messy deep into the lifecycle with misleading or broken links. Hyperlinks should only be created when a distinct benefit would be provided for the evaluator.
2.30(N)	Mar-24	Document Navigation	The frequent changes to Module 3 coupled with the detailed granularity of the Quality sections making content location more predictable means that hyperlinks to Module 3 from 2.3 are discouraged. Bookmarks are preferred in these sections. Starting with Specification 3.0 this is no longer necessary and the validation template will be updated accordingly.
2.31(N)	Mar-24	Document Navigation	The lack of major changes to Modules 4 coupled with a less granular structure of the Study sections means that hyperlinks to Modules 4 are encouraged. Specifically: Any reference to a specific study in the 2.4 Overview or the 2.6 Written and Tabulated Summaries should be linked to that study in 4.2
2.32(N)	Mar-24	Document Navigation	The lack of major changes to Modules 5 coupled with a less granular structure of the Study sections means that hyperlinks to Modules 5 are encouraged. Specifically: Any reference to a specific study in the 2.5 Overview, the 2.7 Summaries and Synopsis of Individual Studies or 5.2 Tabular Listing of All Clinical Studies should be linked to that study in 5.3
2.33(N)	Mar-24	Baselines	No, Applicant's should continue with the next applicable business as usual sequence, no need to submit a baseline of the new specifications.
2.34(N)	Mar-24	Baselines	No, the baseline Sequence can only contain content previously submitted, and in most cases approved, in an earlier format. It is a reformatting of content previously provided and the Electronic Declaration Document should attest that no changes have been included in the sequence.

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Answer
2.35(N)	Mar-24	Baselines	No, they act as a foundation and reference for the evaluator and drastically increase the efficiency for the evaluation of changes. They are only looked at in relation to the review of new content. For eCTDs, they create a foundation for lifecycle operations so that "replace" and "delete" can be implemented correctly.
2.36(N)	Mar-24	Communication	Please send all questions and comments concerning eCTD or eSubmissions to eCTD@sahpra.org.za, using the template as provided on the website. We will make every effort to respond quickly acknowledging that many questions come at a time with looming deadlines.
2.37(N)	Mar-24	Communication	Validation reports will be sent to the emails listed in the envelope. At least one contact must be provided. Depending on the nature of the feedback, the appropriate available contact will be used. In addition any status on the application will be available via the Portal from 1 July 2024.
2.39(N)	Mar-24	Content	All Reports on Post- Marketing Experiences, Post Authorisation Information, PSURs, etc should be provided in section 5.3.6.
2.40(N)	Mar-24	Envelope	In the code XML file stored on the SAHPRA eCTD website, all entries indicate from which version of the file the code is valid. If the code has expired, the version of the file to which it was valid is also indicated.
2.41(N)	Mar-24	Envelope	Several of the envelope attributes can have multiple values e.g., Application Number, INN, APIDMF etc. Each value must be listed seperately as its own element. For examples please refer to the SAHPRA eCTD specifications. In addition, please refer to the ZA-envelop-xml Trigger File Instructions on how to create multiple values when creating the trigger file
2.42(N)	Mar-24	Envelope	No, the application type have been updated and seperate submission types are included with the updated eCTD Specifications. This was completely overhauled to reflect the types of submissions we are now accepting with the EU Variation guidance. Please refer to the eCTD website for the Application Types, Submission Types and etc.

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Answer
2.43(N)	Mar-24	Folders & Files	Documents should be broken down into manageable sections. The ICH M4(R4) should be consulted on this matter. The more granular you are able to make your documents, the more precise you are able to be later in lifecycles when ammendments are made to the application. If - for example, section 2.3 QOS was submitted as a single document, later changes to a single drug substance supplier would trigger a re-evaluation of the drug product section although nothing in that section had changed. If broken down into smaller pieces, the evaluation of later ammendments will be more efficient and faster. Please note that as specified in the ICH M4(R4) guidance, the sections 2.3.S, 2.3.P, 2.3.A and 3.2.P.2 should be submitted as one file and should not be broken down further.
2.44(N)	Mar-24	Portal	https://ectd.sahpra.org.za/
2.45(N)	Mar-24	Envelope	This is a number issued by the Companies and Intellectual Property Commission for the registration of a business.
2.46(N)	Mar-24	Portal	Access to the portal is managed via the Applicant's login ID. If you do not have an login ID you will first need to apply for one. You will receive your login ID via email which will then be your login for the portal. You will have to set your password on your first login. We encourage you to keep the login ID and password confidential and not to share it with unauthorised personel. If a member of your team leaves the company, we encourage you to change the password for your login ID so that your ex-team member will no longer have access to the portal and your company's application history.
2.47(N)	Mar-24	Portal	No, each applicant is issued one login for the system. The confidentiality of the login and password is the responsibility of the company.
2.48(N)	Mar-24	Portal	No, once a login ID is issued, you will use that ID for all future applications.

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Answer
2.49(N)	Mar-24	Portal	Yes, the portal will provide real-time status information on Applications/Submission/Sequences submitted
2.50(N)	Mar-24	Portal	Approval dates will be configured in the new Portal going live July 2024.
2.51(N)	Mar-24	Portal	The Portal that will be launched 01 July is new. Quantum will be integrated into this system.
2.52(N)	Mar-24	Portal	All applications/submissions will still be submitted onto the FTP portal until the Portal goes live on 1 July 2024. The new Portal is for eCTD and eSubmission. The trigger files for eSubmission is exactly the same as for eCTD and should be included in the submission to the FTP portal. Please refer to the Powerpoint of the Webinar presented 14 March 2024 and creating an xml trigger file on the eCTD website.
2.53(N)	Mar-24	eSubmissions	All dossiers for Orthodox and Biologicals should now be in eCTD, was mandated for 31 March 2022. For Complementary and Veterinay Medicine, there will be a transition phase as described in the presentation from 14 March 2024.
2.54(N)	Mar-24	Security	Yes, the principles of LEAST PRIVILEDGE is used for data access by granting users the minimum level of access required to perform their tasks. Data is stored on servers assigning appropriate access rights and permissions based on user roles and responsibilities on IT or System administrator level only.
2.55(N)	Mar-24	Content	For New Applications e.g., the first Sequence of a New Product Registration, all proposed PI/PIL documents should be provided in the approved sections At the time of Registration, the approved version should be in the approved section.

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Answer
2.56(N)	Mar-24	Content	For Responses to Recommendations before the Regisration Approval, the annotated version of all proposed PI/PIL documents should be proved in the annotated sections and the clean versions should be provided in the Approved versions in Mod 1.3. At the time of Registration, the approved version should be in the approved section.
2.57(N)	Mar-24	Content	For Amendments to the approved PI/PIL after Registration Approval, all clean versions of the proposed documents should be placed in the clean sections and all annotated versions of the documents should be placed in the annotated section in Mod 1.3. The currently approved version should not be replaced in the approved section until the proposed clean version is approved.
2.58(N)	Mar-24	Content	For Responses to Recommendations after the Registration Approval, the annotated version of all proposed PI/PIL documents should be provided in the annotated sections. The clean versions should be provided in the clean sections of Mod 1.3.
2.59(N)	Mar-24	Content	When the proposed PI/PIL placed in the Clean sections is approved, it is not necessary to submit a Sequence to provide the approved document in the Approved section. This can be done in the very next Sequence submitted. A comment should be placed in the Cover Letter indicating that the Approved Product Information approved in Sequence (indicate Sequence) has been placed in the Approved section. For an eCTD, the file should not be provided again. Instead, content reuse should be used to reference the file provided in the earlier sequence.
2.60(N)	Mar-24	Software Solutions	Please note that SAHPRA does not recommend any of the solutions. It is the responsibility of the companies to do their due diligence and ensure they acquire the right solution for their needs.

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Answer
2.61(N)	Mar-24	Software Solutions	Companies are encouraged to create User Requirements that summarise their needs in terms of functionality. There are a wide variety of solutions on the market both in terms of functionality and price and companies should select a solution that best fits their needs. A sample set of basic User Requirements is available on the ECOWAS website.
2.62(N)	Mar-24	Trigger File	We have provided an Excel file on the eCTD Website which can be used to create the trigger file in a more user-friendly manner
2.63(N)	Mar-24	Trigger File	The ZA-Envelope-XML Trigger File Instructions have been provided on the eCTD Website.
2.64(N)	Mar-24	Folders & Files	No, the file name is irrelevant in an eCTD. Applicants should ensure that leaf titles are descriptive and distiguishing, especially when multiple documents are being provided in the same section.
2.65(N)	Mar-24	Validation	No, applications will be validated when received and if any validation errors are found, it will be rejected before it can be imported into the evaluation software. If there are issues that cannot be rectified, the applicant should contact eCTD@sahpra.org.za for clarification. Any adjustments will need to be made the the same Submission Unit resubmitted once corrected.
2.66(N)	Mar-24	eCTD Specification	The 4.0 version is still only in pilot phase and still being defined with experience. 3.2.2 is supported already by vendor solutions and industry. There are options available in all price points and it is less technical.
2.67(N)	Mar-24	eCTD Specification	We will be accepting 3.0 starting in July 2024 but will be mandatory from 1 October 2024. We are announcing it now and providing the specifications now so that vendors and applicants have time to prepare accordingly.

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Answer
2.68(N)	Mar-24	Admin Freeze March 2024	The admin freeze applies to all submissions that were received via the FTP platform.
2.69(N)	Mar-24	Admin Freeze March 2024	The admin freeze applies to all submissions that were received via the FTP platform.
2.70(N)	Mar-24	Admin Freeze March 2024	The admin freeze applies to receipt of submissions via the sFTP and DVP platforms. Applications/Submissions received prior to the admin freeze will be processed accordingly.
2.71(N)	Mar-24	Admin Freeze March 2024	Yes. Please submit your response on 16 April 2024.
2.72(N)	Mar-24	Admin Freeze March 2024	All dossiers for Orthodox and Biologicals should now be in eCTD, was mandated for 31 March 2022. For Complementary and Veterinay Medicine, there will be a transition phase as described in the presentation
2.73(N)	Mar-24	Admin Freeze March 2024	Implementation timelines for Type I variations submitted before the admin freeze will not be impacted.
2.74(N)	Mar-24	Admin Freeze March 2024	Section 36 applications will not be affected since they are not submitted via the sFTP or the DVP.
2.75(N)	Mar-24	Admin Freeze March 2024	Please submit your submission the same way as before the Admin Freeze via the FTP Portal. Remember to include the new xml trigger file. Please refer to the eCTD website for instructions.
2.76(N)	Mar-24	Admin Freeze March 2024	You can still apply for an Application Number during the Admin Freeze period.

No.	Date Added	Category	Answer
2.77(N)	Mar-24	DVP Portal	The DVP portal will shut down together with the Admin Freeze. All variations (Type IA, Iain, IB and II) should be submitted in eCTD and will be imported into the system from 16 April 2024. Any variations submitted the DVP portal that is still in process, will still be processed accordingly. The summary as provided by the DVP will be replaced with a new document emailed from SAHPRA, until the Portal goes live in July 2024, where this will be provided to the applicant via the Portal.
2.78(N)	Mar-24	Product Cancellation	This would be a Cancellation. There is a Submission Type to handle this
2.79(N)	Mar-24	Sequences	There is no change in the sequences provided, always provide the next sequence numerically. How they are connected are managed via the related sequence number, submission types, sequence types. Please refer to Q&A sections pertaining to related sequences.
2.80(N)	Mar-24	Master Files	The process on submission of master files (including SMFs) will be communicated soonest.
2.81(N)	Mar-24	eSubmissions	eSubmissions for Orthodox and Biologicals fell away on 1 April 2022 if applicants were following published timelines. We now expect only eCTD submissions for these Submission Types and variations within these.
2.82(N)	Mar-24	eSubmissions	The expectation since 1 April 2022 is that they would switch over to eCTD. SAHPRA cannot be expected to be as efficient with eSubmissions, they lack the life cycle advantages of an eCTD so especially for variations, it is important that applicants move to eCTD.

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Answer
2.83(N)	Mar-24	Working Documents	The word files can be provided with the baseline if you are following 3.0, they will be still provided in the working documents folder for 2.1 sequences.
2.84(N)	Mar-24	Working Documents	The MS Word.docx or Rich Text Format (referred to as Source Documents) that were provided as Working Documents, should be placed alongside the PDF document within the appropriate sections of the eCTD using the life cycle operation New or Replace.
2.85(N)	Mar-24	QOS/QIS in Baselines	The QOS/QIS is not required in the baseline when converting to eCTD or when applications are split.
2.86(N)	Mar-24	Work grouping	Yes, it is the combining of submission types, multiple activities bundled into a single sequence
2.87(N)	Mar-24	Envelope	It can be either the person signing the dossier, the person responsible for technical issues or the Responsible Pharmacist. It is up to the Applicant to decide.
2.88(N)	Mar-24	Communication	Please see the 2.26 Roadmap for a summary. 1 July 2024: New Portal goes live. eCTD submissions mandatory for Orthodox and Biologicals (as per implementation in 2022). May submit with eCTD Specifications 3.0 and per current eCTD Specification. 1 October 2024: ONLY eCTD complying to Specification 3.0 will be accepted. Medical Devices, Veterinary and CAMs will be updated on the 2.26 Roadmap.
2.89(N)	Mar-24	Content	This is still required for eCTD Specification 3.0, however not for submission types Withdrawal and Cancellation. For more information please refer to the Guidance for the Submission of Regulatory Information in eCTD format. A new template pertaining to this section will be provided soonest. Please continue with current practise until communication in this regard has been sent out.

ECOWAS-WAHO Electronic Applications 2.0 General Q&A

No.	Date Added	Category	Answer
2.90(N)	Mar-24	Clinical Trial applications	Preferred format for clinical trials is eCTD. We may make provisions for this under the eSubmission guideline to allow a stepping stone to eCTD.
2.91(N)	Mar-24	Guidelines	Yes, all eCTD related guidelines will be updated. The guidelines will be published on the eCTD website for comment.
2.92(N)	Mar-24	Training	Internally at SAHPRA, yes there will be training on the new system. For Industry, we will be having further webinars and workshops as we go along.
2.93(N)	Mar-24	Content	Including a cover page to a section is not required for eCTD and eSubmissions, in fact, we recommend that they are not included as part of your submission, as they tend to lessen efficiency of evaluators and is an unnessary administrative inclusion in your submission. Please refer to xxx
2.94(N)	Mar-24	eSubmissions	Only eCTD for Orthodox and Biologicals are imported into RIMS. If your submission is still in eSubmission, they need to be converted to eCTD (baseline) and be submitted with the next variation.
2.95(N)	Mar-24	Master Files	Yes, as future automation allows us to use the SMF numbers to prefill the registration certificates. This is also valid for all APIMFs/ VAMFs included in a submission.
2.96(N)	Mar-24	Correspondence	No, this is no longer required. Please check your inbox for notification of successful import (validation report) into SAHPRA's RIMS.
2.97(N)	Mar-24	Submission Lead	The submission lead is the Program at SAHPRA that is responsible for the application e.g., Orthodox vs. Biologicals vs. Veterinary etc. Pharmacovigilance should be used if PV is the only content in a Submission.

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.1(U)	May-19	Content	Content: Tracking table – must it be included in the letter or separately, and if separately, where and what is the file name?
3.2(U)	May-19	Content	Content: Note to Evaluator – must it be included in the letter or separately, and if separately, where and what is the file name?
3.3(U)	May-19	Application Number	Application Number - Is there a special form or format in which to apply for the application number?
3.4(U)	May-19	Application Number	Application Number - Must the request for an application number be faxed, or can it be e-mailed?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.5(U)	May-19	Application Number	Application Number - How long before submission must applicants request the application numbers(s)?
3.6(U)	May-19	Content	Content - Which working codes should be used for eCTD submissions, i.e. are there special working codes?
3.7(U)	May-19	Payments	Payments - At what stage should the application fees be paid?
3.11(U)	May-19	Correspondence	Correspondence - Will there be a special e-mail address for eCTDs?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.12(U)	May-19	Correspondence	Correspondence - How will committees'/evaluation units' recommendations be received?
3.13(U)	May-19	Content	Content - If modules 4 and 5 were submitted electronically before, what will happen to the submission – will it be reviewed as usual or must it be resubmitted as eCTD?
3.15(U)	May-19	eCTD Submissions	Screening Copy - Industry is happy that they no longer have to submit post-screening copies, but will they get confirmation that a product has passed screening/validation?
3.16(U)	May-19	Content	Content - Where must the copy of the Authority's letter with the validation outcome be included?
3.17(U)	May-19	eCTD Submissions	eCTD Submissions - How long will CTDs still be accepted after going live with eCTDs?
3.20(U)	May-19	CD/DVD	CD/DVD - Can a submission on the CD-Rom or DVD be compressed?
3.21(U)	May-19	Content	Content - Which documents are mandatory for all submission types.

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.22(U)	May-19	Content	Content: Module 1.2.2.4 - What is the expectation of the electronic copy declaration?
3.23(U)	May-19	Content	Content: Signatures - Are scanned signatures allowed in Module 1?
3.24(U)	May-19	Content	Which headers and footers may be included in the eCTD?
3.25(U)	May-19	CD/DVD	CD/DVD - Can I submit my eCTD on a re-writable DVD-RW or CD-RW?
3.27(U)	May-19	Application Number	Application Number - What happens if I have a delay in my submission and cannot submit my application within the 4 weeks after issuing of the application number?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.31(U)	May-19	Samples	Must I submit a sample with the screening copy?
3.32(U)	May-19	Payments	Payments - When should the registration fee be paid?
3.34 (U)	May-19	Content	Content: PI/PIL - How and where should the proposed, annotated and clean versions of the professional information (PI) and patient information leaflet (PIL) be included?
3.37(U)	May-19	Content	Content: Once-off Amendment - Should a request for a once-off amendment be included in the eCTD as a new sequence?
3.38(U)	May-19	Content	Content: QOS/QIS - Where must the QOS/QIS document be included
3.39(U)	May-19	Clones	Clones - How should the application for registration of a clone be handled?
3.40(U)	Mar-24	Submission Number	Submission Number - What is a Submission Number?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.41(U)	Mar-24	Submission Number	Submission Number - How do I apply for a Submission Number?
3.42(U)	Mar-24	Portal	Portal: Sequence - How do I upload a sequence via the Portal going live on 1 July 2024?
3.43(U)	Mar-24	Content	Content Reuse - Can I reference files already submitted in other Applications or Submission Units?
3.44(U)	Mar-24	Content	Content Reuse - If a file is required in multiple sections of the CTD structure, should it be published in each of the sections?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.45(U)	Mar-24	Life Cycle Mngt	If I submit in eCTD, can I later submit using variations or amendments in eSubmission?
3.46(U)	Mar-24	Content	Content: Note to Evaluator - Is it always necessary to provide a General Note to Reviewers?
3.47(U)	Mar-24	Structure	will you provide a word format of the eCTD new structure?
3.48(U)	Mar-24	Content	Content: Notes to Evaluator - When deleting sections/nodes that were moved to other part, do we need to add Notes to Evaluator -1.0 or we just move the docs ?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.49(U)	Mar-24	Admin Freeze 2024	Application Number - I have been issued an Application number that is valid for 8 weeks. We were planning to submit within the Admin Freeze period. How will this switch over now affect the timeline of my submission if we can only submit from 16 April (outside my allowed 8 weeks)? Do I need to contact SAHPRA and formally ask for an extention period or will it be taken into account?
3.50 (U)	Apr-24	Admin Freeze 2024	Please advise what will happen to the submissions already made since the 16th with the previous/incorrect version of the trigger file? Will SAHPRA upload these?
3.51(U)	Apr-24	eCTD Submissions	For a submission in response to a PV unit letter/recommendation, would the Submission Type be Pharmacovigilance or a Clinical variation code? And would the Submission Lead then be Pharmacovigilance or Orthodox?
3.52 (U)	Apr-24	Admin Freeze 2024	Can you kindly please advise when submissions made prior to the freeze period (for example on 19 March), will be transferred to the Unit? We received feedback that the submissions has not been transferred to the relevant Unit for review.
3.53 N)	Apr-24	eCTD Submissions	Will it be possible to submit a TOA and Name Change in the same submission if this is indicated in the trigger file?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.54 (U)	Apr-24	IT	We're getting an error message when entering our company details for the ftp site, please confirm that the ftp site has updated the 'host key'
3.55 (U)	Apr-24	eCTD Submissions	Are we able to proceed with a TOA if there is an open Type 2 variation from the Relinquishing Company?
3.56 (U)	May-24	Content	With SMF numbers what is required, just the number or the site name plus the number?
3.57 (U)	Apr-24	Application Number	Please verify that request for application numbers for already registered products may be submitted to applicationnumbers@sahpra.org.za
3.58 (U)	Apr-24	eCTD Submissions	Please explain the process for submitting a response to a query received during the freeze period for an application still in eSubmission format. Should we submit a baseline, the initial variation and the response in separate sequences?
3.59 (U)	Apr-24	Content	On the trigger file must we use the old format for related sequences or the new one?
3.60 (U)	Apr-24	eCTD Submissions	Can an applicant upload 0000 and 0001 in one upload with two XML files (one per sequence) or should a baseline be uploaded and we wait for the baseline to be downloaded by SAHPRA and then upload 0001?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.61 (U)	Apr-24	eCTD Submissions	As eSubmission variations are no longer accepted: Can the applicant submit a baseline dossier if variations (esp safety) are pending SAHPRA approval; as we cannot proceed with CMC variations until baseline is done?
3.62 (U)	Apr-24	eCTD Submissions	Will there be only one Related sequence number in future, no longer multiple (e.g. new registrations may have 0000 and other sequences if multiple quality recommendations responses are submitted)?
3.65 (U)	Apr-24	Content	If CAMS baselines were submitted in 2020 we must just load trigger files for each submission with sequence 0000 and must we notify SAHPRA that the trigger was uploaded?
3.66 (U)	Apr-24	Content	Current ToA: baseline by current acquiring applicant in eCTD format. Can the Module 1 information in the baseline reflect the acquiring applicant's details, showing updated module 1 updated in Module 1.5.2.1 (amendment schedule)?
3.67 (U)	Apr-24	Content	There is no Sequence Type option for Response - Biological. Please clarify/assist.

No.	Date Added	Category	Question
3.68 (U)	Apr-24	eCTD Submissions	Can we consider related sequence as mentioned in the tracking table? For query the related sequence would be the sequence no on which we received query. for variation it should be none?
3.69 (U)	Apr-24	eCTD Submissions	How should we submit a response to an initial variation that was submitted in eSubmission format? Should the response be in eCTD format as sequence 0001? What would the related sequence be for this? Would we also require a baseline for this, or can the baseline be submitted as a later sequence?
3.70 (U)	Apr-24	eCTD Submissions	For a product that is already in eCTD, where sequences already exist on the FTP server, I assume the ToHCR will just be the next sequence, prior to the new ceding and acquiring sequences in October?
3.71 (U)	Apr-24	eCTD Submissions	When the applicant submits baseline dossier with a variation, will the sequence still be 0000?
3.72 (U)	Apr-24	eCTD Submissions	For baseline requirements, can we only include those sections approved by SAHPRA, since a baseline is approved sections.
3.73 (U)	Apr-24	eCTD Submissions	Will applicants need to pay for the resubmission of open variations
3.74 (U)	Apr-24	Payments	When can we anticipate implementation or gazetting of the new proposed SAHPRA fees?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.75 (U)	Apr-24	eCTD Submissions	Baseline 0000 is only for baseline if its new product submission its 0001 right?
3.76 (U)	Apr-24	IT	Will SAHPRA be issuing any notifications to software vendors or is the availability of the technical files on the website considered sufficient notification of the new specification (3.0)
3.77 (U)	Apr-24	IT	Early on, on upload of xml, the sequence folder and xml disappear. This is not happening anymore, is this behaviour as intended?
3.78 (U)	Apr-24	eCTD Submissions	Can a baseline (SN0000) be submitted post submission of an urgent variation (SN0001)
3.79 (U)	Apr-24	eCTD Submissions	Regarding Application Numbers and Registration Numbers: Old Medicines were never registered - does one submit the baseline and variations with the application number only?
3.80 (U)	Apr-24	ToA	Does the process still exist to request transfer during the registration process?
3.81 (U)	Apr-24	ToA	For a product that is already in eCTD, where sequences already exist on the FTP server, I assume the ToHCR will just be the next sequence, prior to the new ceding and acquiring sequences in October?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.82 (U)	Apr-24	Content	For products that were registered many many years ago, it is not always possible to populate Modules 4 and 5. How do applicants then manage the baselines in this instance?
3.83 (U)	Apr-24	ToA	For ToHCR where a duplicate dossier has been submitted and only a duplicate dossier is ceded, what will be the process for submission of the ToHCR for a product deli
3.84 (U)	Apr-24	IT	Pharmacy Schools need to include IT in the curriculum. Should we not have a training session by SAHPRA ie Madelein on this new system.
3.85 (U)	Apr-24	eCTD Submissions	If you have not submitted the baseline yet but you have just received a CCR for a product, how to we respond to the CCR?
3.86 (U)	Apr-24	eCTD Submissions	Please explain the process for submissions of the following: PITE, SMF submissions, section 36 exemption requests, once-off batch exemptions, CPP requests, psychotropic permit requests. Have the submission processes changed for these submissions - please confirm for each.

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.87 (U)	Apr-24	eCTD Submissions	Please advise how to complete the trigger file in the event of a post-reg submission wherein the variations submitted do not apply to every application number included in the submission. For e.g. 1 x Type IA applies to all strengths however 1 x Type IA applies to only one strength.
3.88 (U)	Apr-24	eCTD Submissions	What happens to esubmission variations submitted a year ago that have not received any SAHPRA feedback? Will we need to resubmit these as well?
3.89 (U)	Apr-24	eCTD Submissions	I submitted 3 sequences and haven't received an automated email
3.90 (U)	Apr-24	eCTD Submissions	I have submitted multiple sequences and have not received any automated notifications. How long after submission will we receive a failed submission notification? Sequences were submitted on Tuesday and Thursday.
3.91 (U)	Apr-24	eCTD Submissions	Can you confirm what the automated message should look like? No validation reports received in the email address included in the trigger file. will this only be received if the sequence fails validation? Currently we do not have a formal "proof of submission"
3.92 (U)	Apr-24	eCTD Submissions	Submission uploaded on Tuesday with no automated email received as yet.

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.93 (U)	Apr-24	eCTD Submissions	Just to confirm, for responses received after the freeze period, for applications still in eSubmission, should we submit a baseline, then the variation and then the response (3 sequences)?
3.94 (U)	Apr-24	eCTD Submissions	I have not received any feedback reports for submissions from Tuesday and Wednesday How long after submission will we receive a failed submission notification? Sequences were submitted on Tuesday and Thursday.
3.95 (U)	Apr-24	eCTD Submissions	Please clarify for the below: There are two sequences for clinical and PEM variations for the same application. When uploading these to the FTP, do we load a separate folder with the same application number naming convention or do we load one folder and drag both sequence folders and both xml trigger files in one folder. Thank you.
3.96 (U)	Apr-24	eCTD Submissions	We have clinical variations resubmitted since 2020, resubmitted again last year due to delays from SAHPRA, and now have to resubmit again. Will SAHPRA review and reprioritize these variations as they have been pending for longer.
3.97 (U)	Apr-24	IT	Will the variation status tracker still be used and updated?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.98 (U)	Apr-24	IT	I'm still experiencing issues to access the FTP since the freeze was lifted as it no longer connects to SAHPRA's FTP Can SAHPRA-IT assist where we have these issues?
3.99 (U)	Apr-24	eCTD Submissions	If we submitted a variation and received the queries before the freeze period, and now we have to submit the response with the ectd baseline, then can we include the original var and the responses together in seq 0001. How else will we manage this?
3.100 (U)	Apr-24	eCTD Submissions	Will SAHPRA be prioritising variations which have been in the system for long, so that applicant do not have to withdraw submissions before creating eCTD baselines
3.101 (U)	Apr-24	eCTD Submissions	What is the process for submitting SMFs - do we need to submit in sFTP and send email to SMF Unit? Would this be correct.
3.102 (U)	Apr-24	Payments	Will there be any change in fees?
3.103 (U)	Apr-24	Renewals	Has timelines been defined for SAHPRA recommendation to responses already submitted to SAHPRA?
3.104 (U)	Apr-24	Application Number	Once application numbers are generated automatically, for how long will they remain valid? There has always been a period of validity, by which one had to submit the application.

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.105 (U)	Apr-24	Content	For the applicant name are we allowed to include brackets eg XXXX (Pty) Ltd. Furthermore, we have not received any notifications if our uploads with the trigger files from 16th to 18th April have been successful or not.
3.106 (U)	Aug-24	Content	At approval of a new product we need to submit the final PI and PIL. Should this be submitted in a follow up sequence or via email?
3.107 (U)	Aug-24	Life Cycle Mngt	Can you please suggest, how the lifecycle operations are managed when a Applicant is switched from v2.1 to 3.1 for redefined sections for example 1.3.2, as DTD of the new version cannot cover redefined sections of the old version.
3.108 (U)	Aug-24	Content	Will you be only accepting .rtf format for Ms Word documents?
3.109 (U)	Aug-24	Application Number	If application number generated at time of submission, how will the applicant get advised on fees payable.
3.111 (U)	Aug-24	Portal	Will the login details be the same as for the FTP?
3.112 (U)	Aug-24	eCTD Submissions	Can type IA and type IB variations be bundled and include in one submission sequence?
3.115 (U)	Aug-24	Correspondence	Please provide email address to which application for an iterative baseline must be sent.

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.116 (U)	Aug-24	Application Number	Please confirm that a new application submitted in August 2024 according to the old spec will still be seq. 0000.
3.118 (U)	Aug-24	Content	Do baselines require a screening form, i.e. M1.8.
3.119 (U)	Aug-24	Portal	Is there any expectation that the mandatory date (currently the 1st October 2024) is likely to change?
3.120 (U)	Aug-24	Correspondence	Is specification 3.1 (released on 16th June 2024) still out for comments? If so, will there be a version 3.2 and when will it be released?
3.121 (U)	Aug-24	Correspondence	Please share the email address that applicants can expect to receive automated feedback from. So that we can check if whitelisting of address is required.
3.123 (U)	Aug-24	eCTD Submissions	What will the application folder name? Is it application ID or Application number? The clarity would be useful in cross application hyperlinking.
3.124 (U)	Aug-24	eCTD Submissions	Once the PI/PIL have been submitted in the closing sequence for a new registration, will the registration certificate be included in the dossier in a another closing sequence for the same application, or should it be included in the next variation submission? Should the PI/PIL rather be submitted as a response, and then the received registration certificate be included using the closing sequence?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
3.125 (U)	Aug-24	eCTD Submissions	For submission type - could response to recommendations options be added to the xml trigger files.
3.126 (U)	Aug-24	eCTD Submissions	For line extension where the concentration of the solution for injection is different to the approved product. What option should be selected, New strength, New dosage form or New application?
3.127 (U)	Aug-24	Content	Is there a specific template for notes to evaluator?
3.128 (U)	Aug-24	Samples	Will SAHPRA be accepting samples again? If yes, provide unit, address and any other process for MAH to deliver.
3.129 (U)	Aug-24	Life Cycle Mngt	For variation sequences is the lifecycling of M1.8 (new M.1.2.5) screening form and M3.2.R.8 QIS: 'Replace' or 'New'?
3.131 (U)	Aug-24	Content	Please confirm when a CPP is required?
3.133 (U)	Aug-24	Correspondence	Can you please provide the timelines when the Q & A document will be released.
3.139 (U)	Aug-24	IT	What if we get validation warning due to documents having digital signatures? Shall we ignore pdf warnings(Fast web view, Optimization, bookmarks for more than 5 pages)?

No.	Date Added	Category	Question
3.140 (U)	Aug-24	Renewals	ITO Renewal application: SAHPRA approval letters is required to be included (for evaluation of overall impact on quality, safety & efficacy of minor variations over the last 5 years). Where should it be included in M1? At this stage it seems best to be included in 1.3.1.2 for CEM approvals to be with the PI/PILs, in 1.5.2.2.2 for IRC approvals/DVP summaries to be with the registration certificate and in 1.5.2.1 for PEM (Quality) approvals to be with Tabulated Schedule of Amendments detailing the quality variations. Although validation criteria only allows 1 file in 1.5.2.1. Therefore, the PEM approvals has been moved to 1.5.A. Clarity/confirmation that this is acceptable or it be added to M1 structure will be appreciated.
	Sep-24		Would the relinquishing sequence need to be approved before the TOA sequence can be submitted by the new applicant, or can these be done after technical validation pass notification?
	Sep-24		As a manufacturer of generic API and API MF holder does one need to submit using eCTD 3.1 or through the new portal?If not now, does one expect to move from eSubmission to eCTD 3.1 for API MF at a later stage this year?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
	Sep-24		Please clarify the Pharmacovigilance information required prior to the transfer.
	Sep-24		Please provide details on PV submission? What should be submitted.
	Sep-24		Not sure if it is just me but I cannot access the 'Document Matrix' from the link in the new eCTD specification guideline. Could you kindly advise where this document can be found in order to see what documents are required for Relinquishing and Acquiring sequences?
	Sep-24		Do I understand correctly - will these baselines be reviewed and approved by SAHPRA now?
	Sep-24		As per point 4.2 of the Reliance guideline, there is an independent application of reliance for Quality & Bioequivalence and Clinical. If the applicant is following an abridged evaluation for Clinical, but full review for Q-BE, which evaluation pathway should be selected in the trigger file?
	Sep-24		Can we start submitting the dossiers with eCTD 3.1 before 01 Oct?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
	Sep-24		Why submitting a baseline by splitting the dossier? MAH already submitted all documents with previous submissions. If the dossier is splitted, the maybe new MAH will get all the previous submissions from former MAH
	Sep-24		When will the eCTD portal go live?
	Sep-24		Why must a replica be submitted by the same applicant? According to the Multiple Application guideline [SAHPGL-HPA-08_v3], a replica is "A copy of an already registered generic product, submitted by the same or by another applicant at any stage during the product life cycle of the registered product."

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
	Sep-24		Good morning SAHPRA. I have the following questions: You've mentioned in the previous workshop the Q&A document on the eCTD portal website would be frequently updated, kindly advise on the next update publication, as it hasn't been updated since v5 in April. For TOA, kindly clarify why the sequence type is "Pharmacovigilance" and not "Inspectorate" With PV reports being part of the dossier, will all the submissions be done in an eCTD sequence? Are all PV submissions/interactions to be done by Regulatory in eCTD or will the SAHPRA PV email address still be used for PV responses? For eCTD splitting of application, does it apply to a dossier with 2 products with the same strength and dosage forms, but different presentations (i.e. Vial and cartridge)?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
	Sep-24		When withdrawing a sequence, its clear that "new" documents in the related sequence should be deleted, kindly confirm that we can keep "replaced" documents? Some clarity is required in this regard
	Sep-24		Since now the replicas can be submitted by the same applicant, what will happen to replica submissions submitted at SAHPRA by different applicants.
	Sep-24		Where there are two separate eCTDs (two different dosage forms) and now a PI/PIL safety update is submitted. The PI/PIL is a combined PI/PIL (has both dosage forms. Do we only submit the safety update variation once? Do we need to submit the same variation for each dosage form as next relevant seq no?
	Sep-24		SAHPRA has communicated that applicants are to submit using eCTD 3.1 from 01 Oct 2024. However, comment has been made here that SAHPRA will inform industry of when to submit in eCTD 3.1. Does that mean industry may submit using the current version until 3.1 implementation is communicated even if its after 01 Oct?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
	Sep-24		Good morning. When submitting a clinical variation (unrelated to a response to a PVC letter), should the submission lead be PV or Orthodox in the trigger file?
	Sep-24		Please confirm the Industry Workshop: Launch of the SAHPRA Engagement Portal will still take place on 2024/09/20?
	Sep-24		According to the SAHPRA Document Matrix - Version 2.1, for a new NCE and new generic (multisource) it is indicated that the PI and PIL should be included under the relevant annotated section, as it is indicated as "E". In the ZA-SAHPRA eCTD Specifications v3.1, line 1528 it is however stated that the Product Information for New Applications should be placed in the Approved section. Please clarify as this is contradicting the Document Matrix.
	Sep-24		When will this new TOA submission way be implementable? Until when will submission of TOA in previous way be acceptable.
	Sep-24		Do we have a guideline on line extension? If some documents in 32s are different does it still qualify to be a line extension application?

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
	Sep-24		Please clearly address the question regarding different evaluation pathways for Quality and Clinical in the updated Q&A document for future reference.
	Sep-24		Will the switch to v3 be immediate or will a window period be allowed where both v2 and v3 submissions be accepted?
	Sep-24		According to the SAHPRA Document Matrix - Version 2.1, the Tabulated Schedule of Amendments is indicated as "E" for a new generic (multisource). Please clarify what should be submitted here as everything is new in a new application and there won't be any amendments.
	Sep-24		Delete operation on sections that no longer exist in 3.1 don't appear in the XML, so won't be processed at the agency. There is a bug in the dtd. Please escalate to your technical dept
	Sep-24		Is SAHPRA going to give us a preview of what the new Portal will look Like , so that we can see what the end point looks like?
	Sep-24		Will all today's discussions be included in a Q&A doc or guideline. It is quite a bit of new information, which can be a bit confusing\

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
	Sep-24		I have a line extension with publishing team that I am hoping to submit by 30 September and is in old format. Will it still be accepted if v3.1 goes live before 1 October
	Sep-24		According to the SAHPRA Document Matrix - Version 2.1, 1.10.4.2 Declaration of Sameness & 1.10.5 RRA Reports are indicated as "E" for a NCE and new generic (multisource). It should be a "P" as not all new applications would follow a reliance pathway and RRA reports and Sameness Declarations would therefore not be applicable.
	Sep-24		According to the last workshop, confirmed about the release of the v3.1 specification with minor updates, can you please advise the release date of this specification
	Sep-24		"E"s are included for several submission types next to 1.10.4 Data Set Similarities in the document matrix. Please clarify as documents should be included at the lowest level of granularity defined as per the ZA-SAHPRA eCTD Specifications v3.1, line 473-474.

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Question
	Sep-24		Could you please indicate whether application for a new username and password for the new portal need to be applied for or is the username and password received by RP after completion all the required document still valid?
	Sep-24		Kindly review validation criteria 2.1.8 it validates the rule against the sequence type field which seems incorrect. Seems it needs to check against Submission Type
	Sep-24		Do the guideline specify how to combine a submission for master and duplicate
	Sep-24		Kindly advise on the publication of the eCTD 3.1 updated application letter and note to evaluator templates.
	Sep-24		Is submission of a trigger file already mandatory or will this only be applicable on 1st October?
	Sep-24		Just for confirmation. Is the new eCTD specification applicable to the veterinary products

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Answer
3.1(U)	May-19	Content	A Tracking Table is only required for a Baseline Submission, included as part of the Letter of Application, summarising previous activities with key dates.
3.2(U)	May-19	Content	The note to Evaluator has a specific subnode allocated. The purpose of the Note to Evaluator is to facilitate efficient review of the Sequence by the evaluator. If there are specificities concerning the eCTD Submission about which the evaluator(s) should be informed, it is highly recommended to provide this information in a structured document – please refer to SAHPRA eCTD specification 3.0
3.3(U)	May-19	Application Number	*Current practise until the Portal goes live in July 2024:* No, the applicant has to send a written request on the official company letterhead to the Authority for the attention of Operations & Administration with details of the application(s) to be submitted. There is planned changes to this process when the Portal goes live in July 2024. Please have a look-out for any communication in this regard. The proposed proprietary names should be indicated. The type of data to be submitted in support of safety and efficacy should also be indicated. *From 1 July 2024* the portal will assign the application number for the applicants as described in Q&A 3.4.
3.4(U)	May-19	Application Number	Current practise until the Portal goes live in July 2024: A letter on a company letterhead with an original signature is required. Currently, the request for an application number is mailed to a dedicated email address: applicationnumbers@sahpra.org.za. On the portal from 1 July: Once you have an login ID, you can login to the portal as your company. You will see a list of any previously submitted applications. Select New Application and fill in the information. An Application Number will be assigned and displayed.

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Answer
3.5(U)	May-19	Application Number	Current practise until the Portal goes live in July 2024: Eight weeks. Allow four weeks for allocation of numbers. From 1 July onwards: The portal will provide an Application Number instantaneously. Please note that the Application ID will not be the same as the Application Number, however, until the portal goes live in July the Application Number can be used as the Application ID for eCTD Application Folder Naming Convention. **For legacy Applications, please continue to use the previous Application Folder name as Application ID and Application Folder for all future Sequences.** It is important to use the same Application Folder for all future Sequences of the Application.
3.6(U)	May-19	Content	The working codes have been removed from the general guidelines. As the envelope will indicate to which unit the evaluation is assigned to, working codes are not required. Please refer to the submission matrix on the eCTD website for submission types, which should be included as part of the trigger file.
3.7(U)	May-19	Payments	The relevant fees must be paid when the initial submission is submitted and proof of payment included in 1.2.2.1. The fees payable will be indicated in the letter that will be sent with the application number/s. Please refer to payment guideline. The Proof of Payment should be included as part of your submission. There is planned changes to this process when the Portal goes live in July 2024. Please have a look-out for any communication in this regard.
3.11(U)	May-19	Correspondence	Yes, it is ectd@sahpra.org.za and is also provided on the eCTD website. This address is intended only for eCTD-related queries and not for submission of eCTD or other documents.

No.	Date Added	Category	Answer
3.12(U)	May-19	Correspondence	Committees' recommendations are coordinated in the eCTD office in HPA. The recommendations will be e-mailed to the applicant when all the relevant committee's'/evaluation unit's recommendations have been received, to allow for submission of a response with one timeline and in one sequence. Recommendations should not be sent to the applicant directly from an evaluation unit. The intention is that the correspondence will be received via the Portal, however, current practise still applies until further communication.
3.13(U)	May-19	Content	From 01 April 2016 the eCTD format is the only electronic format accepted for new applications for registration of New Chemical Entities and from 01 January 2017 for generics. Therefore the NeeS format previously accepted for Modules 4 and 5 will no longer be accepted for the file copy. Module 1-5 will be required for a baseline dossier for all applications that are currently not in eCTD format.
3.15(U)	May-19	eCTD Submissions	The Applicant will be notified of the validation results for every eCTD Sequence using the contact details provided in the envelope (the trigger file (pre July 2024) or the portal (post July 2024)) within minutes on upload of submission.
3.16(U)	May-19	Content	Mod 1.0.4
3.17(U)	May-19	eCTD Submissions	eCTD format is the only accepted format for Orthodox and Biological applications since 1 April 2022. Further discussions on eSubmisssion for Veterinary, CAMs, VAMF, APIMF, SMF, PMF will be discussed in future.
3.20(U)	May-19	CD/DVD	No longer applicable as all submissions should be submitted via the sFTP portal, or the new Portal going live on 1 July 2024
3.21(U)	May-19	Content	Please refer to the document matrix indicating required documents for individual submission types.

No.	Date Added	Category	Answer
3.22(U)	May-19	Content	This is still required for eCTD Specification 3.0, however not for submission types Withdrawal and Cancellation. For more information please refer to the Guidance for the Submission of Regulatory Information in eCTD format. A new template pertaining to this section will be provided soonest. Please continue with current practise until communication in this regard has been sent out.
3.23(U)	May-19	Content	Electronic signatures will be crucial, particularly for authentication of electronic Submissions and documents. We are currently accepting: •Digital signatures. Please see the Electronic Signature Guidelines Appendices. •Scanned signatures where the documents make up part of the checksum of an eCTD Sequence. •Scanned documents with wet signatures where the document has then been OCRed. Please note that all documents uploaded via the portal will be considered as signed and approved by the Applicant. It is therefore very important that Applicants secure their login to the Portal and ensure that only authorised personnel have access to upload and submit sequences.
3.24(U)	May-19	Content	In general, the requirements as described in the ICH eCTD guidance are sufficient but Headers and Footers **are not** required in electronic submissions since the electronic information provides the necessary information to identify the content. Applicants should just take care that Header and Footers are not misleading or confusing. Reusing content becomes difficult when specific sequence headers and footers are added and is therefore **not recommended** for eCTD submission.
3.25(U)	May-19	CD/DVD	No, to be submitted via the Portal or sFTP (up to 1 July 2024)
3.27(U)	May-19	Application Number	N/A as the portal will provide the Application Number

No.	Date Added	Category	Answer
3.31(U)	May-19	Samples	General information guideline provides guidance on this.
3.32(U)	May-19	Payments	The registration fee is payable on receipt of notification of registration.
3.34 (U)	May-19	Content	Proposed (Pre-reg), Annotated, Approved and Clean PI/PIL are all now included in Mod 1.3. Mod 1.5.5 is retired in the eCTD Specification 3.0.
3.37(U)	May-19	Content	At this stage it should be handled outside of the eCTD, as it is supposed to be a once-off occurrence only and should not affect the lifecycle of any of the approved documents in the eCTD. Please continue with current practise and erefer to relevant guidelines. Future changes will be communicated in due course.
3.38(U)	May-19	Content	This document should be included in Module 3.2.R.8 - Other, as a separate document with the leaf title QOS vxxx / QIS vxxx, as it will have its own life cycle. Both the source and the PDF documents should be included here as per Specification 3.0
3.39(U)	May-19	Clones	Please refer to the current guideline.
3.40(U)	Mar-24	Submission Number	The Submission Number(s) identify regulatory activities. Once the Product Application is approved, variations and/or amendments will take place. Each sequence must be associated with a submission. This is done via the Submission number and/or the Related Sequence Number.

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Answer
3.41(U)	Mar-24	Submission Number	Submissions up to 1 July: Please refer to the Creation of XML trigger file instructions for creating a Submission Number. From 1 July 2024: Log in to the Portal using your login ID. For a new application, a Submission Number will be automatically assigned. For an existing application, select the Application and click on New Submission and fill in the information. A Submission Number will be assigned and displayed. Please remember for responses the Submission Number as assigned for evaluated sequence, should be used when uploading onto the portal.
3.42(U)	Mar-24	Portal	Log in to the Portal using your login ID. Select an Application and then select the submission. Click the upload option.
3.43(U)	Mar-24	Content	Yes and this is encouraged. Reusing content already submitted earlier helps reduce the amount that must be evaluated or at least allows an excelerated evaluation. Content reuse is allowed within the same Submission Unit, between Submission Units of the same Application and between Submission Units of different Applications. See the SAHPRA eCTD Specifications for more information on how content reuse should be implemented.
3.44(U)	Mar-24	Content	No, the file should only be published once and then referenced in each of the locations of the eCTD backbone. Cases of content reuse should be addressed in the General Note to Evaluator and you should indicate at which referenced location the document was physically published. See the SAHPRA eCTD Specifications for more information on how content reuse should be implemented.

No.	Date Added	Category	Answer
3.45(U)	Mar-24	Life Cycle Mngt	Once eCTD, Always eCTD. eCTD has a defined lifecycle management that allows the content to be filtered and viewed so that the evaluator (and the applicant) can see: 1) Current View of the application - all content from the past and current sequence are shown, however, replaced or deleted content is not shown 2) Sequence View - only the content provided in the selected sequence is shown 3) Submission View - only the content from Sequences associated with a selected Submission is shown 4) Approved View - only the content associated with Submissions tagged as Approved is shown The eSubmission lacks the XML infrastructure to be able to build the above views and are therefore, over time makes the evaluation less efficient. eSubmissions are based on the Sequence View only so the evaluator has to manually go back to piece together an overall picture which is time consuming and prone to mistakes.
3.46(U)	Mar-24	Content	It is always good practice to submit a General Note to Evaluators, especially in every "Initial" Sequence of a Submission. Assume that the evaluator that will be evaluating the Sequence is not the same as the evaluator that evaluated previous Sequences. The Note to Evaluators is your direct dialog to the Evaluator and is a good opportunity to address questions that you may be able to predict enabling you to reduce the number of iterations required for the evaluation.
3.47(U)	Mar-24	Structure	Please refer to Guideline 2.21 for changes in the eCTD structure.
3.48(U)	Mar-24	Content	Adding a reference/notes to the Notes to Evaluator would be a good idea and helpful for the evaluator.

No.	Date Added	Category	Answer
3.49(U)	Mar-24	Admin Freeze 2024	No extension request required. Please submit the application on the 16th of April 2024.
3.50 (U)	Apr-24	Admin Freeze 2024	They were corrected internally. Unless there were severe errors/blanks they were processed and uploaded on the system.
3.51(U)	Apr-24	eCTD Submissions	Both will be Pharmacovigilance.
3.52 (U)	Apr-24	Admin Freeze 2024	If you have received communication from SAHPRA that your submission was not successful, please re-upload and submit with a trigger file.
3.53 N)	Apr-24	eCTD Submissions	No. Please submit as separate sequences as separate units evaluate these.

No.	Date Added	Category	Answer
3.54 (U)	Apr-24	IT	Industry to follow the FTP guide.
3.55 (U)	Apr-24	eCTD Submissions	No. Please withdraw the Type ll, then submit the ToA sequence. This is only applicable from 1st October.
3.56 (U)	May-24	Content	Just SMF number.
3.57 (U)	Apr-24	Application Number	Answered in the Q&A Document.
3.58 (U)	Apr-24	eCTD Submissions	Answered in the Q&A Document.
3.59 (U)	Apr-24	Content	Please use the new format - do not use "none"
3.60 (U)	Apr-24	eCTD Submissions	Both can be uploaded in one file - so you will have both sequences in the root folder with their trigger files in the root folder

No.	Date Added	Category	Answer
3.61 (U)	Apr-24	eCTD Submissions	Answered in the Q&A Document.
3.62 (U)	Apr-24	eCTD Submissions	For pre-reg., yes you will have a related sequence number. For post-reg., you will have one related sequence number per variation grouping of sequences, i.e., variation and all responses have the related sequence of the variation submitted
3.65 (U)	Apr-24	Content	No notification is necessary, it will be automatically discovered when the trigger file is provided. The baseline can be provided in eCTD or eSubmission.
3.66 (U)	Apr-24	Content	The baseline (submitted by the acquiring applicant) must reflect the acquiring applicant's details.
3.67 (U)	Apr-24	Content	Answered in the Q&A Document

No.	Date Added	Category	Answer
3.68 (U)	Apr-24	eCTD Submissions	Do not use "none". The new related sequence number is in line with most other eCTD specifications. It is adopted so that all of the sequences related to a submission can be grouped with a common attribute.
3.69 (U)	Apr-24	eCTD Submissions	Answered in the Q&A Document
3.70 (U)	Apr-24	eCTD Submissions	SAHPRA will conduct a webinar relating to this. How this is done in your solution will need to be communicated to you by your software vendor. The new sequences will just need to be in 3.0. No past sequences. whether in 2.1 or 1.0, must be resubmitted.
3.71 (U)	Apr-24	eCTD Submissions	Baseline will be 0000 and variation will be 0001
3.72 (U)	Apr-24	eCTD Submissions	Yes
3.73 (U)	Apr-24	eCTD Submissions	No.
3.74 (U)	Apr-24	Payments	Not related to RIMS

No.	Date Added	Category	Answer
3.75 (U)	Apr-24	eCTD Submissions	For specification 3.0, yes.
3.76 (U)	Apr-24	IT	Already available on the SAHPRA website
3.77 (U)	Apr-24	IT	Answered in the Q&A Document
3.78 (U)	Apr-24	eCTD Submissions	No.
3.79 (U)	Apr-24	eCTD Submissions	The folder name should be the application number only.
3.80 (U)	Apr-24	ToA	The request for the TOA with motivation should be sent to the Inspectorate Unit for consideration.
3.81 (U)	Apr-24	ToA	As per specification 3.0, yes. Webinars on TOAs will be conducted closer to the time

No.	Date Added	Category	Answer
3.82 (U)	Apr-24	Content	To be addressed in the next RIMS update.
3.83 (U)	Apr-24	ToA	The acquiring applicant must submit a baseline and the TOA in sequence 0001. The application number of the duplicate must be used as the unique identifier.
3.84 (U)	Apr-24	IT	Trigger file training completed.
3.85 (U)	Apr-24	eCTD Submissions	Submit the eCTD baseline (0000), the variation in sequence 0001 and the response to the query for sequence 0001, in sequence 0002.
3.86 (U)	Apr-24	eCTD Submissions	This will be communicated and guidelines will be published

No.	Date Added	Category	Answer
3.87 (U)	Apr-24	eCTD Submissions	Applicants should not combine them. The cover letter would indicate what strength it relates to.
3.88 (U)	Apr-24	eCTD Submissions	No, they are in the process of evaluation. Only when a response is due then it should be submitted in eCTD
3.89 (U)	Apr-24	eCTD Submissions	They were likely not correctly filled in or they have not yet been processed.
3.90 (U)	Apr-24	eCTD Submissions	They were likely not correctly filled in or they have not yet been processed.
3.91 (U)	Apr-24	eCTD Submissions	The validation report is only provided for failed submissions. It is not provided for sequences that pass validation.
3.92 (U)	Apr-24	eCTD Submissions	They were likely not correctly filled in or they have not yet been processed.

No.	Date Added	Category	Answer
3.93 (U)	Apr-24	eCTD Submissions	Yes.
3.94 (U)	Apr-24	eCTD Submissions	They were likely not correctly filled in or they have not yet been processed.
3.95 (U)	Apr-24	eCTD Submissions	You should submit one sequence, wait for confirmation that it has passed validation and then submit the other one. If you submit them both at the same time and the first sequence fails the validation, both sequences would have to be resubmitted.
3.96 (U)	Apr-24	eCTD Submissions	If it was already submitted - you do not need to resubmit.
3.97 (U)	Apr-24	IT	Yes.

No.	Date Added	Category	Answer
3.98 (U)	Apr-24	IT	This was caused by an issue on the SAHPRA firewall, it has since been resolved.
3.99 (U)	Apr-24	eCTD Submissions	Applicants should consult SAHPRA.
3.100 (U)	Apr-24	eCTD Submissions	Only if you have a response do you convert to baselines
3.101 (U)	Apr-24	eCTD Submissions	Current process still applies, changes to process will be communicated
3.102 (U)	Apr-24	Payments	The fees stay as per fees regulations
3.103 (U)	Apr-24	Renewals	Not related to RIMS
3.104 (U)	Apr-24	Application Number	This will probably not matter, as they will come in into priority groups.

No.	Date Added	Category	Answer
3.105 (U)	Apr-24	Content	Yes, you can use the brackets.
3.106 (U)	Aug-24	Content	Via a closing sequence. Not via email
3.107 (U)	Aug-24	Life Cycle Mngt	Please look at the Specific Lifecycle Operations section in the eCTD Specs 3.1.
3.108 (U)	Aug-24	Content	Any format will be accepted.
3.109 (U)	Aug-24	Application Number	The application number should be applied for in advance on the portal.
3.111 (U)	Aug-24	Portal	No new credentials will be provided.
3.112 (U)	Aug-24	eCTD Submissions	Please refer to combininations allowed on the submission type matrix.
3.115 (U)	Aug-24	Correspondence	SAHPRA to answer.

No.	Date Added	Category	Answer
3.116 (U)	Aug-24	Application Number	Yes.
3.118 (U)	Aug-24	Content	No.
3.119 (U)	Aug-24	Portal	Date has changed to 01 November 2024.
3.120 (U)	Aug-24	Correspondence	Comments will only be included in a version 3.1.1 and will be minor.
3.121 (U)	Aug-24	Correspondence	Automator<no-reply@sahpra.org.za>
3.123 (U)	Aug-24	eCTD Submissions	Application ID.
3.124 (U)	Aug-24	eCTD Submissions	No - registration certificates can be submitted with

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Answer
3.125 (U)	Aug-24	eCTD Submissions	No it should be the same submission type as the one you are responding to.
3.126 (U)	Aug-24	eCTD Submissions	New strength.
3.127 (U)	Aug-24	Content	Reviewers Guide - No template.
3.128 (U)	Aug-24	Samples	SAHPRA to answer.
3.129 (U)	Aug-24	Life Cycle Mngt	Replace.
3.131 (U)	Aug-24	Content	Not required.
3.133 (U)	Aug-24	Correspondence	This is continually updated - please keep an eye out on the website.
3.139 (U)	Aug-24	IT	Please attend to warnings and errors. Q&A addresses this.

No.	Date Added	Category	Answer
3.140 (U)	Aug-24	Renewals	Approval letters or any correspondence from SAHPRA can be included in 1.0.3.
	Sep-24		There will be short interim until the Portal makes the application available for the acquiring applicant
	Sep-24		Please refer to APIMF guideline and communication from this team

No.	Date Added	Category	Answer
	Sep-24		Any PV information is given to the applicant who owns the product. Therefore it is the responsibility of the relinquishing applicant to ensure PV submissions are submitted before handing over to acquiring applicant
	Sep-24		Answered
	Sep-24		ectd.sahpra.org.za
	Sep-24		No
	Sep-24		Evaluation path for any type of reliance is: Abridged review
	Sep-24		Communication will go out from SAHPRA soonest

No.	Date Added	Category	Answer
	Sep-24		This ensures lifecycle of the application
	Sep-24		Communication will go out from SAHPRA soonest
	Sep-24		SAHPRA to look at Spec on this - we only have "replica-same" as submission type, and initial discussions indicated that only the same applicant can do the replica. We can propose something like a replica be submitted by the intial applicant, then do a TOA to the new applicant.

No.	Date Added	Category	Answer
	Sep-24		Only the PV sequence type is PV. TOA's sequence type will be initial. SAHPRA to answer on PV submissions - as far as I know they can only come in now via the eCTD. Splitting of applications can be done for several types of situations. A few examples are indicated in the specification.

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Answer
	Sep-24		Replaced documents should be deleted in to sequence you are submitting the withdrawal
	Sep-24		Will still be evaluated if already submitted
	Sep-24		Safety update should be submitted for both applications seperately
	Sep-24		Communication will go out from SAHPRA soonest

No.	Date Added	Category	Answer
	Sep-24		Orthodox / Biological
	Sep-24		Yes
	Sep-24		Document Matrix will be revisited
	Sep-24		When specification 3.1 goes love.
	Sep-24		Part of guidelines to be updated by SAHPRA. If sections differ, evaluation is required, therefore could not be considered as line extension

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Answer
	Sep-24		Ok
	Sep-24		Communication will go out from SAHPRA soonest
	Sep-24		Document Matrix will be revisited
	Sep-24		Refered to Lorenz - will give feedback soonest
	Sep-24		Portal workshop
	Sep-24		Yes

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Answer
	Sep-24		Submit before 30 September
	Sep-24		Document Matrix will be revisited
	Sep-24		V3.1.1 will probably only be early next year. Please take note there are no Schema or technical updates, and update only includes minor typographical and definition updates
	Sep-24		Document Matrix will be revisited

ECOWAS-WAHO Electronic Applications 3.0 eCTD Q&A

No.	Date Added	Category	Answer
	Sep-24		Portal workshop
	Sep-24		This is already in process of being corrected by Lorenz
	Sep-24		Answered
	Sep-24		No templates on these documents will be provided
	Sep-24		Already mandatory from April for Orthodox/Biologicals
	Sep-24		Not yet. Will be communicated when it is.

ECOWAS-WAHO Electronic Applications 4.0 Archived

No.	Date Added	Category	Question
2.7	May-19	Folders & Files	Folders & Files: Node extensions - It is important to check that software vendors can support node extensions as described for 3.2.R
2.9	May-19	Validation	Validation - Must the Extedo validator tool be used?
2.10	May-19	Folders & Files	Folders & Files: Naming convention - Was the naming convention changed in line with ICH, e.g. API changed to Drug Substance?
2.19	May-19	Bookmarks	Bookmarks - When should bookmarks be included?
2.22	May-19	Publishing	Publishing - What does it mean when the "export" of the submission is referred to?
2.23	May-19	Validation	Validation - Are hyperlinks checked during validation of the submission?

ECOWAS-WAHO Electronic Applications 4.0 Archived

No.	Date Added	Category	Question
2.24	May-19	Folders & Files	References - Should published references which are included in Modules 4.3 and 5.4 be text searchable?
3.8	May-19	Correspondence	Correspondence - If questions are asked, what is the time frame to get answers?
3.9(U)	May-19	CD/DVD	CD/DVD - How many copies of the CD/DVD must be submitted?
3.10(U)	May-19	CD/DVD	CD/DVD - How must the CD/DVD be submitted?
3.14	May-19	eCTD Submissions	Screening copy - Is a screening copy required as for paper CTD submissions
3.18	May-19	eCTD Submissions	eCTD Submissions - Will eCTDs go into a faster queue?
3.19	May-19	Software Solutions	Software Solutions - Will SAHPRA provide a list of preferred software vendors?

ECOWAS-WAHO Electronic Applications 4.0 Archived

No.	Date Added	Category	Question
3.26	May-19	Application Number	Application Number - Which application number do I have to fill in the envelope, when I file a line extension?
3.28	May-19	Application Number	Application Number - Must I include the registration number in the envelope when I submit amendments for a registered product?
3.29	May-19	Envelope	Envelope: Application Number - In which format should application numbers be included in the envelope when the eCTD pertains to more than one product or product strength, i.e. 470001/2, or 470001, 470002 or as separate elements?
3.30	May-19	Envelope	Envelope: Proprietary Name - In which format should proprietary names be included in the envelope when the eCTD pertains to more than one product or product strength?
3.33	May-19	Content	Content - Where must I submit the comparability report for an application for registration of a biosimilar?
3.35	May-19	Content	Content: PSUR - Where must a PSUR be submitted?
3.36	May-19	Content	Content - Should a request for a section 36 exemption be submitted in the eCTD as a new sequence?

No.	Date Added	Category	Answer
2.7	May-19	Folders & Files	Noted.
2.9	May-19	Validation	Any validator tool may be used that has been proven to comply with the SAHPRA validation criteria.
2.10	May-19	Folders & Files	The ICH specification and DTD are unchanged for South Africa in terms of technical requirements. Local guidelines refer to content.
2.19	May-19	Bookmarks	Provide bookmarks for documents exceeding 5 (five) pages that contain multiple headings/sections, tables, figures in all modules. Provide enough bookmarks for easy navigation in the document. For documents with a ToC, bookmarks for each item listed in the ToC should be provided including all tables, figures, publications, other references and appendices. Refer to the Guidance for submission of regulatory information in eCTD format.
2.22	May-19	Publishing	This is equivalent to "create" or "publish" the eCTD.
2.23	May-19	Validation	Yes, refer to the current SA eCTD validation criteria for specific information.

ECOWAS-WAHO Electronic Applications 4.0 Archived

No.	Date Added	Category	Answer
2.24	May-19	Folders & Files	If these references are used to support the indications claimed for the application, and are cross-referenced in the package insert, they would have to be text searchable (OCR scanned). The EMA guidance for industry on providing regulatory information in electronic format, version 4.0 of April 2016 , includes a very useful guidance on text searchable documents in Annex 2, which could be used at this stage.
3.8	May-19	Correspondence	It will depend on whether the question relates to technical or business aspects.
3.9(U)	May-19	CD/DVD	This is no longer applicable
3.10(U)	May-19	CD/DVD	This is no longer to practise to submit CD/DVD's. Please contact SAHPRA if the need arises to submit in this format.
3.14	May-19	eCTD Submissions	No, there is no separate screening submission for eCTD. Screening (validation) and application fees are paid with the initial submission. Compliance with all screening/validation requirements results in the submission being ready for evaluation without “post-screening” copies being submitted as for paper submissions.
3.18	May-19	eCTD Submissions	Due to more efficient processes, the entire registration process should be quicker for eCTDs.
3.19	May-19	Software Solutions	No, applicants are free to choose any software vendor, provided that the eCTDs will comply with the prescribed requirements.

ECOWAS-WAHO Electronic Applications 4.0 Archived

No.	Date Added	Category	Answer
3.26	May-19	Application Number	All application numbers assigned to the current submission have to be listed in the envelope. In the letter of application a clear reference has to be made to which originally issued application number this line extension belongs. The first issued application number for a product line is the identifier for the eCTD application.
3.28	May-19	Application Number	No, the application number must still be used.
3.29	May-19	Envelope	Application numbers must be included as separate elements, e.g. 470001 470002
3.30	May-19	Envelope	Proprietary names must be included as separate elements, e.g. Name 10 mg Name 20 mg
3.33	May-19	Content	At this stage this report should be submitted in Module 3.2 R.8 Other
3.35	May-19	Content	This should be submitted in module 5.3.6
3.36	May-19	Content	This will depend on the type of exemption applied for (once-off or permanent), and will be handled on a case-by case basis. It should therefore be discussed with the eCTD office.

ECOWAS-WAHO Electronic Applications 5.0 Terminology

Term	Definition
Annotated Version	Product Information - Annotated Versions are provided when changes are made to files previously provided. The annotated file shows mark-ups highlighting the changes so that evaluators can see what has been changed within the document.
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.
Bookmarks (PDF)	An electronic table of contents stored within the PDF that allows navigation throught the file content to find specific information quickly.
Clean Version	Product Information - Clean Versions are provided when changes are made to files previously provided. The clean file shows how the file will look if approved without any mark-ups to distract from the finished version.
Content Reuse	Only allowed in eCTD applications, a single file is referenced at multiple locations in application. It is possible to reuse a file from the same sequence, from an earlier sequence of the same application, or from a sequence of another application. Content Reuse enables a "fast track" of the evaluation of certain parts because the content is not being resubmitted, the content that has already been evaluated at another location is guaranteed the same.
Electroni Declaration Document	A statement indicating that the electronic files with signatures are representative of actual signed documents and that any documents that have been provided multiple times (in eSubs) are identical in content.
Envelope	Administrative information provided in electronic form so that it can be read automatically by a machine enabling automation.
File Name (eSub)	Becomes the heading displayed to the evaluator for eCTD submissions. While defined, each file name has both a core and a variable component sot that more descriptive information can be provided.
Hyperlink Relative Path	A hyperlink whose properties allow it to function even if it is moved and stored in another location. If inter-document hyperlinks are created, then both files are moved and their relative location to each other is not altered e.g., the folder is moved to another location.
Hyperlink, Inter-document	hyperlinks where the source and target are located in different documents.
Hyperlink, Intra-document	Hyperlinks where the source and target are both located in the same document.
Initial Sequence of an Application	The very first sequence of an application, the first package of information provided.
Leaf Title (eCTD)	The heading displayed to the evaluator for eCTD submissions which describes the content of the electronic file provided.
MD5 Checksum	A security fingerprint of the file. Each file has a unique identifier and if any content is changed in the document, the fingerprint is changed.

Term	Definition
Style Sheet	Used together with XML to define font and style of content displayed.
XML	An electronic language (eXtensible Markup Language) that enables a customisable display of documents with the use of browsers (internet). Allows a precise definistion of the Common Technical Document and ensures a consistent look and feel for all applications recieved.

ECOWAS-WAHO Electronic Applications 5.0 Terminology

Term	Abbreviation/Acronym
Annotated Version	Act
Baseline	API
Bookmarks (PDF)	CTD
Clean Version	DTD
Content Reuse	eCTD
Electroni Declaration Document	ICH
Envelope	PEM
File Name (eSub)	PI
Hyperlink Relative Path	PIL
Hyperlink, Inter-document	PSUR
Hyperlink, Intra-document	Q&A
Initial Sequence of an Application	QIS
Leaf Title (eCTD)	QOS
MD5 Checksum	SAHPRA

Term	Abbreviation/Acronym
Style Sheet	Swissmedic
XML	ZA/SA

ECOWAS-WAHO Electronic Applications 5.0 Terminology

Term	Definition
Annotated Version	The Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended
Baseline	Active Pharmaceutical Ingredient
Bookmarks (PDF)	Common Technical Document
Clean Version	Document Type Definition
Content Reuse	electronic Common Technical Document
Electroni Declaration Document	International Council for Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
Envelope	Pharmaceutical Evaluation Management
File Name (eSub)	Professional Information
Hyperlink Relative Path	Patient Information Leaflet
Hyperlink, Inter-document	Periodic Safety Update Report
Hyperlink, Intra-document	Question and Answer documents
Initial Sequence of an Application	Quality Information Summary
Leaf Title (eCTD)	Quality Overall Summary
MD5 Checksum	South African Health Products Regulatory Authority

Term	Definition
Style Sheet	Swiss Agency for Therapeutic Products
XML	South Africa