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.

No.	Date Added	Category	Question	Answer
2.1(U)	May-19	Related Sequence	Related sequences – must it be left open, or must <none> be included similar to Swiss?	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	Related sequences – should you not include the previously approved sequence when you start a new regulatory activity?	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	Related sequences - when should the related sequence be included?	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	Submission Type - What submission type should be used in the envelope when responding to a PEM and Clinical recommendation in one sequence?	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
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?	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	Folders & Files -What is the correct file folder structure and names expected in 3.2.R?	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	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?	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	Validation - Is the folder structure checked during validation?	Yes, the xml folder structure will be checked during validation in accordance with the current validation criteria.

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

No.	Date Added	Category	Question	Answer
2.15(U)	May-19	Folders & Files	Leaf titles - What is the difference between a leaf title and a file name?	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	Validation template - Should hyperlinks be included in the validation template?	Yes, technical sections should be hyperlinked for ease of reference during Screening.
2.17(U)	May-19	Validation	Validation - How must "Best practice warnings" in validation be handled?	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	MD5 Checksum -Where must the MD5 checksum be submitted?	This is no longer the practise to include outside of the submission.
2.20(U)	May-19	Folders & Files	Table of Contents - Should Tables of Contents include hyperlinks?	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	How do I ensure that thumbs.db files are not created on the CD/DVD that I submit to the Authority?	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	Hyperlinks - Should hyperlinks be created to the Literature Reference sections?	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	Hyperlinks - Can I hyperlink to content submitted in earlier Sequences?	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.

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2.27(N)	Mar-24	Document Navigation	Hyperlinks - Are intra-document hyperlinks required?	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	Hyperlinks - What inter-document hyperlinks should be created?	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
2.29(N)	Mar-24	Document Navigation	Document Navigation - What expectations are there for Hyperlinks and Bookmarks	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	Hyperlinks - Should hyperlinks be created to Module 3 from Module 2?	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	Hyperlinks - Should hyperlinks be created to Module 4 from Module 2?	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	Hyperlinks - Should hyperlinks be created to Module 5 from Module 2 and Module 5.2?	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	Baselines - Are baselines required for the ZA eCTD 3.0?	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	Baselines - Can I provide proposed changes in my baseline?	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.
2.35(N)	Mar-24	Baselines	Baselines - Are baselines reviewed?	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.

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2.36(N)	Mar-24	Communication	Enquiries - Where should questions be sent about eCTDs or eSubmissions?	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	Feedback - How will feedback be received on Applications submitted?	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	Post-Marketing Experience - Where should Post-Authorisation Information be provided?	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	Envelope: Defined List Codes - How do I know if the code I am using is valid?	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	Envelope - How should multiple values be provided when required?	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	Envelope: Submission codes - Will the application type codes still be the same?	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.
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?	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	Portal - What is the web address for the portal?	https://ectd.sahpra.org.za/
2.45(N)	Mar-24	Envelope	Envelope - What is an CIPC number?	This is a number issued by the Companies and Intellectual Property Commission for the registration of a business.
2.46(N)	Mar-24	Portal	Portal - How is access to the portal managed?	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.

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2.47(N)	Mar-24	Portal	Portal - Can Applicants have multiple logins for multiple employees?	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	Portal - Do I need to apply for an Applicant ID each time I want to submit a product?	No, once a login ID is issued, you will use that ID for all future applications.
2.49(N)	Mar-24	Portal	Portal - Does the portal provide status information on the Applications/Submissions/Sequences submitted?	Yes, the portal will provide real-time status information on Applications/Submission/Sequences submitted
2.50(N)	Mar-24	Portal	Portal - On the BAU variation status will a date be included for the approvals	Approval dates will be configured in the new Portal going live July 2024.
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?	The Portal that will be launched 01 July is new. Quantum will be integrated into this system.
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?	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	Please advice where we can submit e-submissions application for those dossiers that has not yet been converted to e-CTD?	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	Security - Is my data secure?	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	Content: PI/PIL - Where should documents for PI/PIL be placed in a New Application?	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.
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?	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	PI/PIL - Where should documents for PI/PIL be placed in amendments proposed after Registration Approval?	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	PI/PIL - Where should documents for PI/PIL be placed in a Respones to Recommendations after Registration Approval?	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.

No.	Date Added	Category	Question	Answer
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?	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	Software Solutions - Will SAHPRA provide a list of 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.
2.61(N)	Mar-24	Software Solutions	Software Solutions - What should a company look for in an eCTD Publishing and Validation solution?	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	Trigger File - Where do I find the 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	Trigger File - How do I complete the trigger file?	The ZA-Envelope-XML Trigger File Instructions have been provided on the eCTD Website.
2.64(N)	Mar-24	Folders & Files	Folders & Files - Is it necessary to have a descriptive file name for documents submitted?	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	Validation - Can I submit an application if there are validation Errors?	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	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	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	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?	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.
2.68(N)	Mar-24	Admin Freeze March 2024	Admin Freeze - Will the Applicant be able to submit APIMF in this admin freeze period?	The admin freeze applies to all submissions that were received via the FTP platform.
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?	The admin freeze applies to all submissions that were received via the FTP platform.
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 ?	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.

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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?	Yes. Please submit your response on 16 April 2024.
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?	All dossiers for Orthodox and Biologicals should now be in eCTD. For Complementary and Veterinay Medicine, there will be a transition phase as described in the presentation as it relates to those applications and applicable formats
2.73(N)	Mar-24	Admin Freeze March 2024	Admin Freeze: Variations - does this have impact on Type I variation implementation timelines?	Implementation timelines for Type I variations submitted before the admin freeze will not be impacted.
2.74(N)	Mar-24	Admin Freeze March 2024	Admin Freeze - During the freeze period, will section 36 Applications also be frozen?	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	Admin Freeze - Where do I submit my submission until the Portal goes live on 1 July 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	Can I apply for an Application number during the Admin Freeze period?	You can still apply for an Application Number during the Admin Freeze period.
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?	The DVP portal will no longer take in any new submissions as of 20 March 2024. 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 through the DVP portal up to 20 March 2024 -- that is still in process, will be completed and processed in the DVP accorddingl and "View Only Access" will remain available until 30 September 2024. For new applications done in eCTD through the FTP portal as from 16 April - they will be processed in the central system as part of Life Cycle management for a particular products and a similar summary will be provided as previoulsy available on the DVP -- it will be emailed to the applicants during the April to July period but thereafter it will be automatically emailed when the process is completed -- via the new SAHPRA portal come 1 July 2024
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	This would be a Cancellation. There is a Submission Type to handle this
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?	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	Master Files - Will this portal allow for the submission of SMFs once every 5 years as per the guideline?	The process on submission of master files (including SMFs) will be communicated soonest.

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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?	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	eSubmissions - Companies that are to-date still submitting variations as e-submission format, how will those be handled?	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.
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?	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	Working Documents - Where are they located according to the new SAHPRA eCTD 3.0 Specification?	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	Will these baselines require QOS/QIS? (If I remember correctly, eCTD baselines did not require QOS/QIS documents).	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	Work grouping - Is work grouping the same as bundling?	Yes, it is the combining of submission types, multiple activities bundled into a single sequence
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	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	Communication: Key dates - Summarise the key dates for us.	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	Content - As only electronic submissions are made, is 1.2.2.4 still necessary?	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.
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?	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	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?	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	Training: Are there going to be more in-depth training for use of the system?	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.

No.	Date Added	Category	Question	Answer
2.93(N)	Mar-24	Content	Content: Cover pages - Are cover pages for sections still required for eCTD and eSubmissions?	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	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	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	Do we need to include all SMF numbers for all sites applied for (FPP, FPRC, FPRR, Packers).	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	Correspondence - With the new trigger file, do we still need to sent SAHPRA email notification as proof of upload of submission?	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	Submission Lead - What is the 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.

No.	Date Added	Category	Question	Answer
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?	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	Content: Note to Evaluator – must it be included in the letter or separately, and if separately, where and what is the file name?	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	Application Number - Is there a special form or format in which to apply for the 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	Application Number - Must the request for an application number be faxed, or can it be e-mailed?	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.
3.5(U)	May-19	Application Number	Application Number - How long before submission must applicants request the application numbers(s)?	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	Content - Which working codes should be used for eCTD submissions, i.e. are there special working codes?	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.

No.	Date Added	Category	Question	Answer
3.7(U)	May-19	Payments	Payments - At what stage should the application fees be paid?	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	Correspondence - Will there be a special e-mail address for eCTDs?	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.
3.12(U)	May-19	Correspondence	Correspondence - How will committees'/evaluation units' recommendations be received?	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	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?	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	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?	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	Content - Where must the copy of the Authority's letter with the validation outcome be included?	Mod 1.0.4
3.17(U)	May-19	eCTD Submissions	eCTD Submissions - How long will CTDs still be accepted after going live with eCTDs?	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	CD/DVD - Can a submission on the CD-Rom or DVD be compressed?	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	Content - Which documents are mandatory for all submission types.	Please refer to the document matrix indicating required documents for individual submission types.
3.22(U)	May-19	Content	Content: Module 1.2.2.4 - What is the expectation of the electronic copy declaration?	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.

No.	Date Added	Category	Question	Answer
3.23(U)	May-19	Content	Content: Signatures - Are scanned signatures allowed in Module 1?	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	Which headers and footers may be included in the eCTD?	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	CD/DVD - Can I submit my eCTD on a re-writable DVD-RW or CD-RW?	No, to be submitted via the Portal or sFTP (up to 1 July 2024)
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?	N/A as the portal will provide the Application Number
3.31(U)	May-19	Samples	Must I submit a sample with the screening copy?	General information guideline provides guidance on this.
3.32(U)	May-19	Payments	Payments - When should the registration fee be paid?	The registration fee is payable on receipt of notification of registration.
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?	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	Content: Once-off Amendment - Should a request for a once-off amendment be included in the eCTD as a new sequence?	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	Content: QOS/QIS - Where must the QOS/QIS document be included	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	Clones - How should the application for registration of a clone be handled?	Please refer to the current guideline.
3.40(N)	Mar-24	Submission Number	Submission Number - What is a 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.

No.	Date Added	Category	Question	Answer
3.41(N)	Mar-24	Submission Number	Submission Number - How do I apply for a 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(N)	Mar-24	Portal	Portal: Sequence - How do I upload a sequence via the Portal going live on 1 July 2024?	Log in to the Portal using your login ID. Select an Application and then select the submission. Click the upload option.
3.43(N)	Mar-24	Content	Content Reuse - Can I reference files already submitted in other Applications or Submission Units?	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(N)	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?	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.
3.45(N)	Mar-24	Life Cycle Mngt	If I submit in eCTD, can I later submit using variations or amendments in eSubmission?	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(N)	Mar-24	Content	Content: Note to Evaluator - Is it always necessary to provide a General Note to Reviewers?	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(N)	Mar-24	Structure	will you provide a word format of the eCTD new structure?	Please refer to Guideline 2.21 for changes in the eCTD structure.

No.	Date Added	Category	Question	Answer
3.48(N)	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 ?	Adding a reference/notes to the Notes to Evaluator would be a good idea and helpful for the evaluator.
3.49(N)	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?	No extension request required. Please submit the application on the 16th of April 2024.

No.	Date Added	Category	Question	Answer
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	Noted.
2.9	May-19	Validation	Validation - Must the Extedo validator tool be used?	Any validator tool may be used that has been proven to comply with the SAHPRA validation criteria.
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?	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	Bookmarks - When should bookmarks be included?	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	Publishing - What does it mean when the "export" of the submission is referred to?	This is equivalent to "create" or "publish" the eCTD.
2.23	May-19	Validation	Validation - Are hyperlinks checked during validation of the submission?	Yes, refer to the current SA eCTD validation criteria for specific information.
2.24	May-19	Folders & Files	References - Should published references which are included in Modules 4.3 and 5.4 be text searchable?	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	Correspondence - If questions are asked, what is the time frame to get answers?	It will depend on whether the question relates to technical or business aspects.
3.9(U)	May-19	CD/DVD	CD/DVD - How many copies of the CD/DVD must be submitted?	This is no longer applicable
3.10(U)	May-19	CD/DVD	CD/DVD - How must the CD/DVD be submitted?	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	Screening copy - Is a screening copy required as for paper CTD 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.

No.	Date Added	Category	Question	Answer
3.18	May-19	eCTD Submissions	eCTD Submissions - Will eCTDs go into a faster queue?	Due to more efficient processes, the entire registration process should be quicker for eCTDs.
3.19	May-19	Software Solutions	Software Solutions - Will SAHPRA provide a list of preferred software vendors?	No, applicants are free to choose any software vendor, provided that the eCTDs will comply with the prescribed requirements.
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?	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	Application Number - Must I include the registration number in the envelope when I submit amendments for a registered product?	No, the application number must still be used.
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?	Application numbers must be included as separate elements, e.g. 470001 470002
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?	Proprietary names must be included as separate elements, e.g. Name 10 mg Name 20 mg
3.33	May-19	Content	Content - Where must I submit the comparability report for an application for registration of a biosimilar?	At this stage this report should be submitted in Module 3.2 R.8 Other
3.35	May-19	Content	Content: PSUR - Where must a PSUR be submitted?	This should be submitted in module 5.3.6
3.36	May-19	Content	Content - Should a request for a section 36 exemption be submitted in the eCTD as a new sequence?	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.

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.
Style Sheet	Used together with XML to define font and style of content displayed.

Abbreviation/Acronym	Definition
Act	The Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended
API	Active Pharmaceutical Ingredient
CTD	Common Technical Document
DTD	Document Type Definition
eCTD	electronic Common Technical Document
ICH	International Council for Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
PEM	Pharmaceutical Evaluation Management
PI	Professional Information
PIL	Patient Information Leaflet
PSUR	Periodic Safety Update Report
Q&A	Question and Answer documents
QIS	Quality Information Summary
QOS	Quality Overall Summary
SAHPRA	South African Health Products Regulatory Authority
Swissmedic	Swiss Agency for Therapeutic Products

Term	Definition
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.

Abbreviation/Acronym	Definition
ZA/SA	South Africa

Change Control

The following documents were referenced during the initial creation of this Q&A Document

- Questions & Answers - Implementation of eCTD in South Africa

Version	Date	Component	Change Description
1.0	1-Nov-23	General	Initial Version for Industry Release
		eCTD	Initial Version for Industry Release

Please send any feedback, comments, or questions to:
eCTD@sahpra.org.za

Version History

Versioning Guide

Versions to the specifications will be handled as follows:

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

Version	Description of Change	Author	Effective Date
1.0		SAHPRA	1-May-13
2.0			1-Feb-16
3.0			1-Apr-16
4.0		SAHPRA	1-May-19
4.0	Conversion to excel format for ease of navigation. Q&A feedback on launch of specification 3.0	SAHPRA	Mar-24