الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Guidance For Submission

Version 5.0

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Saudi Food & Drug Authority

Drug Sector

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Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Author	Date	Comments
1.0	Licensing Department	11 September 2009	Initial draft for internal consultation
1.1	Licensing Department	20 May 2009	Draft revision
1.2	Licensing Department	06 June 2009	Draft revision
1.3	Licensing Department	28 June 2009	Revisions after management discussion
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3.0	Regulatory Affairs	17 December 2011	Published
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5.0	Executive Directorate of Regulatory Affairs	19 October 2022	Update (Next page shows the updated details)

What is New in Version No. 5.0?

The following table shows the update to the previous version:

Section	Description of change
Scope	**Update:** - General scope update
Multi-section	**Add:** - Document Requirements – Media - Document Requirements - System Compatibility - Document Requirements - Security - Document Requirements - Password Protection - Document Requirements - Virus Protection - eCTD Baseline Submission - Presentation of the eCTD File through eSDR (Extension Submission) - Migration Request **Update:** - New Marketing Authorization (MA) - Variations of MA - Renewal of MA - Inquiries **Delete:** - Registration Process - Structure and Content Submission - Presentation of the Product File - Document Requirements - Page Divider/ Tab - Update of Registered Product in eSDR System
Appendixes	**Add:** - Electronic Submission - Veterinary Non-eCTD electronic Submissions (VNeeS) - Rolling Submission - References and Guidelines - Price Certificate Forms - Cover Letter for Initial Submission - Cover Letter for Response to Inquiries - Application for Variation to a Marketing Authorization **Update:** - ICH Common Technical Document - Required Quantities of Samples. - Sample Form. - **Delete:** - GCC Module 1 Administrative Information - Data Requirements - Electronic Version of the Paper-Based Submission. - Target Performance Timelines.

Table of Content

ABBREVIATION AND ACRONYMS

API	Active Pharmaceutical Ingredient.
CPP	Certificate of Pharmaceutical Product.
CTD	Common Technical Document.
eCTD	Electronic Common Technical Document and it is an electronic equivalent to the CTD.
eSUBMISSION	Electronic Submission Via Saudi Drug Registration System.
eSDR	Saudi Drug Registration system.
FPP	Finished Pharmaceutical Product.
GCC-DR	Gulf Cooperation Council Drug Registration.
MA	Marketing Authorization.
MAA	Marketing Authorization Application.
NeeS	Non-eCTD electronic submission.
OCR	Optical Character Recognition.
PIL	Patient Information Leaflet.
RA	Regulatory Affair.
SA	Saudi Arabia
SADAD	Payment System established by the Saudi Central Bank to be the national Electronic Bill Presentment and Payment (EBPP) service provider for the Kingdom of Saudi Arabia (KSA).
SFDA	Saudi Food and Drug Authority.
SPC	Summary of Product Characteristics.
VNeeS	Veterinary Non-eCTD Electronic Submission.
WAVE	Set of inquiries from one or multiple departments sent to applicants during the assessment process.

1. INTRODUCTION

The Drug Sector in the Saudi Food & Drug Authority (SFDA) has developed *The Guidance for Submission* to assist applicants and industry in the preparation and submission of product applications for new Marketing Authorization (MA) as well as renewals and variations to existing products to the SFDA. The guidance provides an outline of how the regulatory framework will be managed with respect to product applications by the SFDA.

It is intended to provide clarification to applicants on how the Drug Sector in the SFDA manages information and material submitted in accordance with *The Regulatory framework for Drug Approvals.* Also, it provides assistance to comply with the requirements of filing and maintenance of their application.

Industry representatives, as well as the staff of the SFDA, are responsible for product application management and will implement this guidance and follow operational directions in various areas, including the handling of application information, procedures related to product assessment, clarification, and performance targets of product assessment.

This guidance will be updated regularly to reflect the current practices in regulatory sciences and to maintain its consistency and enhanced transparency. It is expected that this guidance and any amendments to it will create efficiency in product application management and reduce the number of clarification requests.

It should be noted that the SFDA has the right to request any information and data within the context of this guidance in order to adequately assess the safety, efficacy, and quality of any medicinal products available in the Kingdom of Saudi Arabia. The SFDA is committed to ensuring that such requests are justifiable and decisions are clearly documented.

2. SCOPE:

This guidance applies to the following **submission types**:

- New Marketing Authorization (MA)
- Variations of MA
- Renewal of MA
- eCTD Baseline Submission.
- Migration

All submitted information and material will be screened to ensure that it is complete and suitable to be reviewed. The same management principles will be applied consistently to all types of submission except the migration submission.

This guidance covers the preparation and filling requirements for submissions. It is based on various guidance's mentioned in Appendix F.

3. NEW MARKETING AUTHORIZATION APPLICATION

3.1 eSDR Online Application Form:

The applicant shall fill the application form through eSDR system as mentioned in *The User Manual* at eSDR website https://esdr.sfda.gov.sa/ (see Figure 1).

Note:

The company representative must verify that there is an account in (DENR) system before accessing eSDR system.

In order to accept the product that registered in the Gulf Health Council for the GCC States (GCC-DR), the company should do the following:

- Provide the GCC certificate number on the relevant field on eSDR application form.
- Add a copy of the GCC certificate in the 1.0 cover letter.
- Submit the product's last approved documents.

Important Notes:

- For the Verification and Abridged processes, please refer *to The Guideline of Registration According to Verification and Abridged.*
- For the priority review process refer *to The Guidance for Priority Review of Product Registration.*
- Appendix E contains the procedure and requirements for rolling submission.

Figure 1: eSDR User Manual

3.2 File Presentation:

The applicant shall upload the complete dossier along with Module 1/Part 1 of selected documents as mentioned in *The Data Requirements for Human Drugs Submission and Data Requirements for Veterinary Medicinal Products*. The file format shall be according to the following:

1. eCTD for Human Products (Refer to Appendix A & D & F).
2. CTD for Herbal and Health Products (Refer to Appendix A & D & F).
3. VNeeS for Veterinary Products (Refer to Appendix B & D & F).

Each uploaded dossier shall include the following:

- All required modules according to Data requirements of the concerned product type (Human or Veterinary product type) (see Appendix F).
- Cover letter for initial submission (see Appendix G).

3.3 Business Validation:

The uploaded file will be reviewed by the Regulatory Affairs (RA) team, and the result would be either:

A. Accepting the File:

If the file is accepted, it will be forwarded directly to the concerned departments by the RA team and the applicant will be notified by email over the eSDR system.

B. Rejecting the File:

The file will be rejected if deficiencies are identified, and the deficiencies will be sent over the eSDR system; then, the status will be changed to (the file is incomplete). The applicant will be required to submit the requested information within the timeframes mentioned in *The Regulatory Framework for Drug Approval Guidance* and the clock will be started from the date of the rejection.

- If the applicant has provided the requested information within the timeframe, the file will be accepted, and forwarded directly to the concerned departments by RA Team and the applicant will be notified by email over the eSDR system.
- If the applicant fails to provide the requested information within the timeframe, the product application will be rejected; then the status will be changed to (the file is rejected due to exceeding the time limit).
- If the applicant exceeds the number of waves according to *The Regulatory Framework for Drug Approval guidance*, the product application will be rejected; then the status will be changed to (The request was rejected due to lack of requirements).

3.4 Response to Inquiry:

The applicant shall provide the following when responding to eSDR system inquires:

3.4.1 eSDR System:

3.4.1.1 General Inquiries:

- In module 1 (m1) section 1.9 *Response to Questions* (For Veterinary Products: Part 1 section 1a6) should include a document, which lists the inquiries with the corresponding narrative text response for each question. Each question should be followed by the name of section, page number and a hyperlink where the answer can be found in the concerned module. This submission shall include only questions and hyperlinks in 1.9 *Response to Questions* (For veterinary product: Part 1 section 1a6) and answers for each relevant section.

- Cover letter for response to inquiries (see Appendix G).

Note: The eSDR system enables the company representative to receive inquiries after being evaluated by all departments at once (as a wave). Please refer to *The User Manual* at eSDR system's website for more information about how to upload the file https://esdr.sfda.gov.sa/.

3.4.1.2 Laboratory Inquiries:

After submitting the product file, the company has to wait for an inquiry from the laboratories in eSDR system. Once the inquiry is posted in eSDR system the applicant should provide the following:

- Submit the required samples and working standards to the laboratories.
- A scan of the sample submission form - stamped/signed by the lab on the day of submitting the samples- has to be added under 1.3.5 Samples (For veterinary products: Part 1 section 1b5) on the uploaded file.

3.5 Registration Decision:

When the registration process is completed, the applicant shall receive a notification from eSDR website noting the decision either:

A. Accepted

The applicant should submit an electronic request to issue a product's certificate by going to eSDR system screen and choosing (my products) at the top of the screen. For more information about how to submit the electronic request please refer to *The User Manual* at eSDR website https://esdr.sfda.gov.sa/.

B. Or rejected

Note: the applicant has the right to submit an objection request according to the appeal policy (see subsection 3.6 Appeal)

3.6 Appeal:

Refer to the latest version of the appeal policy at SFDA website and *The User Manual* at eSDR website for more information about how and when to submit the Objection Request https://esdr.sfda.gov.sa/ (see Appendix G).

4 VARIATIONS OF MAA

A process of informing the Drug Sector of any minor or major changes in the product that already registered in Saudi Arabia.

4.1 eSDR Online Variation Request:

The applicant shall fill the application form through eSDR system as mentioned in *The User Manual* at eSDR website https://esdr.sfda.gov.sa/.

4.2 File Presentation:

The applicant shall upload the complete dossier along with Module 1/Part 1 of selected documents as mentioned at Appendix A&B. The file format shall be

1. eCTD for Human products (Refer to Appendix A & D & F).
2. CTD for Herbal and Health products (Refer to Appendix A & D & F).
3. VNeeS for veterinary products (Refer to Appendix B & D & F).

4.3 Business Validation:

The uploaded file will be reviewed by the RA Team and the result would be either

A. Accepting the File:

If the file is accepted, the applicant will be notified by email over the eSDR system. After that, the file will be forwarded directly to the concerned departments by RA Team; then the status will be changed to (at the relevant department).

B. Rejecting the File:

- The file will be rejected if deficiencies are identified, and the deficiencies will be sent over the eSDR system; then the status will be changed to (the file is incomplete). The applicant will be required to submit the requested information within the timeframes mentioned in *The Regulatory Framework for Drug Approval Guidance* and the clock will be started from the date of the rejection.

- If the applicant has provided the requested information within the timeframe, the file will be accepted, and the product application will be forwarded to the RA Team for further processing and assessment.
- If the applicant fails to provide the requested information within the timeframe, the product application will be rejected; then the status will be changed to (the file is rejected due to exceeding the time limit).
- If the applicant exceeds the number of waves according to *The Regulatory Framework for Drug Approval Guidance*, the product application will be rejected; then the status will be changed to (The request was rejected due to lack of requirements).

Note the company has the right to re-submit the request again. For more information, Please refer to *The User Manual* at eSDR system's website https://esdr.sfda.gov.sa/.

4.4 Response to Inquiry:

The applicant shall provide the following when responding to eSDR system inquires:

4.1 eSDR System:

4.1.1 General Inquiries:

- The module 1 (m1) section 1.9 *Response to Questions* (For Veterinary Products: Part 1 section 1a6) should include a document, which lists the inquiries with the corresponding narrative text response for each question. Each question should be followed by the name of section, page number and a hyperlink where the answer can be found in the concerned module. In this submission, there is only the questions and hyperlinks in 1.9 *Response to Questions* (For veterinary product: Part 1 section 1a6) and the answer in relevant section shall be included.

- Cover letter for response to inquiries (see Appendix G)

Note: The eSDR system enables the company representative to receive inquiries after being evaluated by all departments at once (as a wave), please refer to *The User Manual* at eSDR website for more information about how to upload the file https://esdr.sfda.gov.sa/

4.5 Variation Decision:

When the assessment process is completed, the applicant shall receive a notification from eSDR website noting the decision:

A. Accepted

If the request is accepted and the variation is affecting the registration certificate, the applicant should print the certificate via eSDR system screen choosing (my products) at the top of the screen.

For more information about how to print Certifications please refer to *The User Manual* at eSDR website https://esdr.sfda.gov.sa/.

B. Partially accepted:

In case of accepting some of the submitted variations, the applicant should submit a new variation request, including the accepted variation only, while the current variation request will be rejected. The Company will be informed of the accepted and rejected variations via the registered eSDR email address.

C. Or rejected; the company has the right to submit a new variation request on eSDR supported by all relevant evidence.

5 RENEWAL OF MAA

An applicant shall submit a renewal request every five years – on a product that have already received a marketing authorization from the SFDA – within six months before the certificate expires through the following steps:

5.1 eSDR Online Renewal Request :

The applicant shall create a Renewal Request through eSDR system as mentioned in *The User Manual* at eSDR website https://esdr.sfda.gov.sa/.

5.2 File Presentation

The applicant shall upload the complete dossier along with Module 1/Part 1 of selected documents as mentioned in Appendix A&B. The file format shall be according to the following:

1. eCTD for Human products (Refer to Appendix A & D & F).
2. CTD for Herbal and Health products (Refer to Appendix A & D & F).
3. VNeeS for veterinary products (Refer to Appendix B & D & F).

Each uploaded dossier shall include all requirements modules according to Data requirements of the concerned product type (Human or Veterinary product type) (see Appendix F).

Important Notes:

- Human Pharmaceutical Products shall be submitted in accordance with The Data Requirements for the Renewal of Marketing Authorizations.
- The Renewal Application Form of Herbal, and Health products and updated Price Certificate for products subject to pricing shall be electronically submitted via eSDR.

5.3Business Validation:

The uploaded file will be reviewed by the RA Team and the result would be either:

A. Accepting the File:

If the file is accepted, the applicant will be notified by email through the eSDR system. After that, the file will be forwarded directly to the concerned departments by RA Team;

then the status will be changed to (at the relevant department).

B. Rejecting the File:

- The file will be rejected if deficiencies are identified, and the deficiencies will be sent over the eSDR system; then the status will be changed to (the file is incomplete). The applicant will be required to submit the requested information within the timeframes mentioned in *the Regulatory Framework for Drug Approval guidance* and the clock will be started from the date of the rejection.
- If the applicant has provided the requested information within the timeframe, the file will be accepted, and the product application will be forwarded to the RA Team for further processing and assessment.
- If the applicant fails to provide the requested information within the timeframe, the product application will be rejected; then the status will be changed to (the file is rejected due to exceeding the time limit).
- If the applicant exceeds the number of waves according to *the Regulatory Framework for Drug Approval guidance*, the product application will be rejected; then the status will be changed to (The request was rejected due to lack of requirements).

Note: The Company has the right to re-submit the request again. For more information, Please refer to *The User Manual* at eSDR system's website https://esdr.sfda.gov.sa/.

5.4 Response to Inquiry:

The applicant shall provide the following when responding to eSDR system inquires:

5.4.1 eSDR System:

5.4.1.1 General Inquiries:

- The module 1 (m1) section 1.9 Response to Questions (For veterinary product: Part 1 section 1a6) should include a document, which lists the inquiries with the corresponding narrative text responses for each question. Each question should be followed by the name of section, page number and a hyperlink where the answer can be found in the concerned module. In this submission, there is only the questions and hyperlinks in 1.9 *Response to*

Questions (For veterinary product: Part 1 section 1a6) and the answer in relevant section shall be included.

- Cover letter for response to inquiries (see Appendix G)

Note: The eSDR system enables the company representative to receive inquiries after being evaluated by all departments at once (as a wave), please refer to *The User Manual* at eSDR website for more information about how to upload the file https:/esdr.sfda.gov.sa/.

5.5Renewal Decision:

When the registration process is completed, the applicant shall receive a notification from eSDR website noting the decision either:

A. Accepted

Requesting to print the certificate by going to eSDR system screen by choosing (my products) at the top of the screen. For information about how to print Certifications please refer to *The User Manual* at eSDR website https://esdr.sfda.gov.sa/.

B. Or rejected.

Note: the applicant has the right to submit an objection request according to the appeal policy (See subsection. 5.6 appeal).

5.6 Appeal:

Refer to the latest version of the appeal policy at SFDA website and *The User Manual* at eSDR website for more information about how and when to upload the Objection Request https://esdr.sfda.gov.sa/(see Appendix G).

6 eCTD BASELINE SUBMISSION

A baseline submission is a compiled submission for the current status of the dossier, i.e., a resubmission of currently valid documents that have already been provided to SFDA but in another format. Where an eCTD application is being used for the first time as a variation or renewal application, applicants are obliged to submit a technical baseline for the product, as this will greatly facilitate the review process according to *SFDA Baseline eCTD Submission Requirements*.

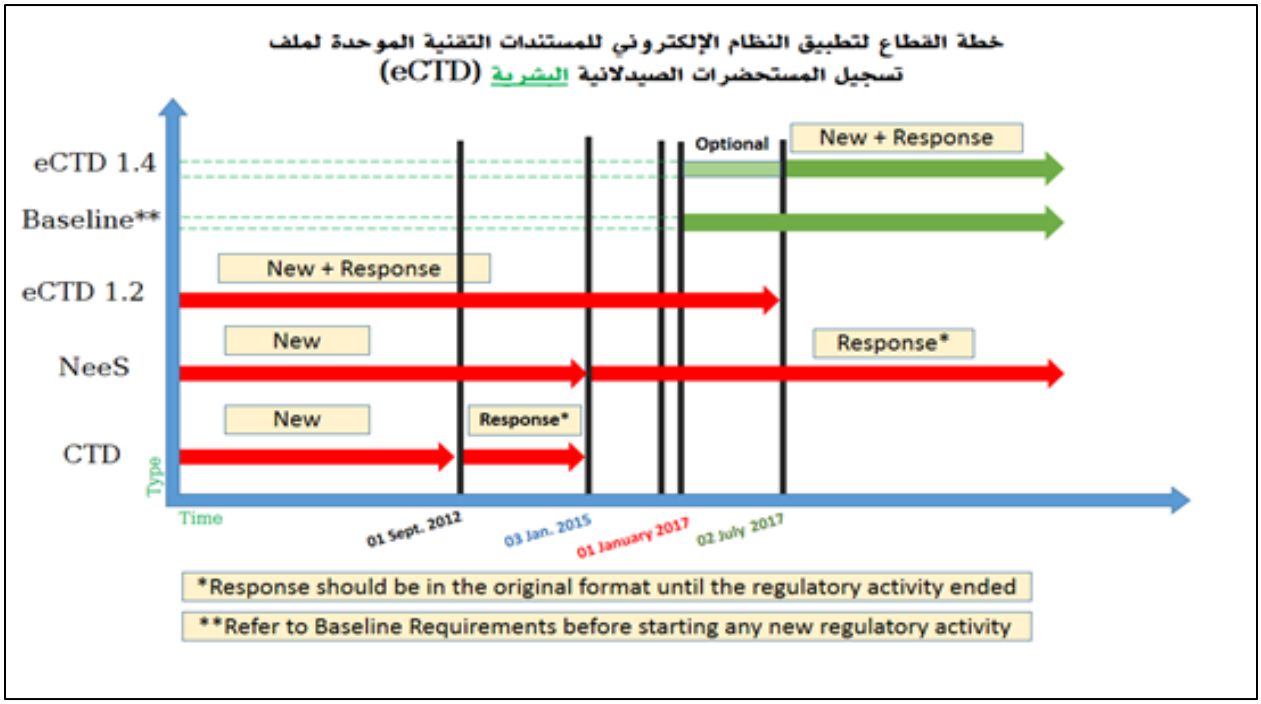

Figure 2: The SFDA timeline for eCTD

Important Notes:

- The Baseline should be submitted after completing all product regulatory activities at SFDA.
- The Baseline is applied only to human products.
- The requirements of Baseline eCTD submission are explained at *SFDA Baseline eCTD Submission Requirements* and published on the SFDA's website.
- The cover letter should include a declaration that indicates no new information, only the format dossier can be changed.
- The application form should be the latest approved regulatory activity by SFDA.

7 MIGRATION REQUEST

Migration is the process of transferring products from the old system (SDR) system to eSDR system. The migration will be applied on the completed request from the old SDR. After signing in to the system, the user should click on "My Migration Request" on the bar at the top of the page. From the Migration Requests page, the system provides a feature that allows the user to request new data migration, review a migration request with its status, and migration requests that's waiting action.

The applicant shall fill the application form through eSDR system as mentioned in *The User Manual* at eSDR website **https://esdr.sfda.gov.sa/**.

Note: The company representative must verify that there is an account in (DENR) system before accessing eSDR system.

8 DOCUMENT REQUIREMENTS

8.1 Legibility and Size:

All documents should be legible. The page size, including tables, shall be uniform.

8.2 Language:

The supporting information and documents – such as certificates and approval letters– must be either in Arabic or English. If documents are neither in Arabic nor English, a translation to English language (from an authorized translation office) and must be authenticated by the Saudi Embassy in the country of origin.

8.3 Format:

Currently, The SFDA does not accept CD or DVD (single or dual layer) submission for new application in eSDR. For more information, kindly refer to User Manual of eSDR **https://esdr.sfda.gov.sa/**.

8.4 System Compatibility:

The electronic submission (as provided) must be directly readable and usable on SFDA hardware and software.

Although it is the policy of the SFDA to maintain computer configurations and IT infrastructure in line with common office standards, the electronic information provided in the submission must not only be readable on the latest operating system but also support a reasonable number of previous versions of windows operating systems.

8.5 Security:

There are various aspects related to security. The physical security of the submission during transportation/transmission is the responsibility of the applicant. Once received within the SFDA, security and submission integrity is the sole responsibility of the SFDA. In this regard, it should be noted that the SFDA will take appropriate measures to prevent loss, unauthorized duplication and/or access or theft of regulatory information presented both on paper and electronic format that are distributed throughout the SFDA.

8.6 Password Protection:

One-time security settings or password protection of electronic submissions for security purposes is not acceptable during transportation/transmission from the applicant to the SFDA.

Applicants should also not include any file level security settings or password protection for individual files in the electronic submission.

Applicants should allow printing, annotations to the documents, and selection of text and graphics. The Internal security and access control processes in the SFDA maintain the integrity of the submitted files.

8.7 Virus Protection:

The applicant is responsible for checking the submitted documents for viruses. Checking must be performed with an up-to-date and well-recognized Anti-virus application.

After receipt of the submission at the SFDA, a similar internal virus check will be performed. If a virus is detected it can constitute grounds for refusal of the electronic submission.

8.8 Authentication:

Authentication – also known as legalization – refers to the process whereby the origins of a document are attested. Authentications of documents are made to SFDA by the health authority and/or the ministry of foreign affairs in the country of origin, in addition to the Saudi Arabia Embassy or Consulate where the document had been issued. For more details, please refer to *the Data Requirements for Human Drugs Submission*, *Data Requirements for Veterinary Medicinal Products*, and *Data Requirements for Herbal and Health Products*.

9 APPENDICES

Appendix A: Electronic Submission:

The electronic version that accepted in SFDA based on the requirements are:

1. CTD for Herbal and Health Products.
2. eCTD for Human Products.
3. VNeeS for Veterinary Products.

1. Common Technical Document (CTD).

The **Herbal and Health product**, the applicant shall follow the structure of Common Technical Document (CTD) as shown in figure 3.

- Module 1: Administrative Information and prescribing Information
- Module 2: Common Technical Document Summaries
- Module 3: Quality
- Module 4: Non-Clinical Study Reports
- Module 5: Clinical Study Reports

Figure 1: Structure of Common Technical Document (CTD).

2. Electronic Common Technical Document (eCTD)

The eCTD is defined as an interface for industry or agency to transfer the regulatory information, taking into consideration the facilitation of the creation, review, lifecycle management and archival of the electronic submission.

The eCTD has the following components:

- Folder structure.
- Contents (files).

- XML backbone.

The folder structure has a hierarchical organization, and it holds the scientific and technical contents of the eCTD (divided into many files which are the same as those in the non-eCTDs, usually in PDF format).

The XML backbone is recognisable as 'index.xml' at the root level of the submission folder of an eCTD and provides two useful functions:

- It provides a hyperlinked table of contents of the entire submission when viewed in a web browser with a suitable style sheet
- It provides descriptive information ('metadata') on the files that make up the actual contents of the eCTD, as shown in figure 4.

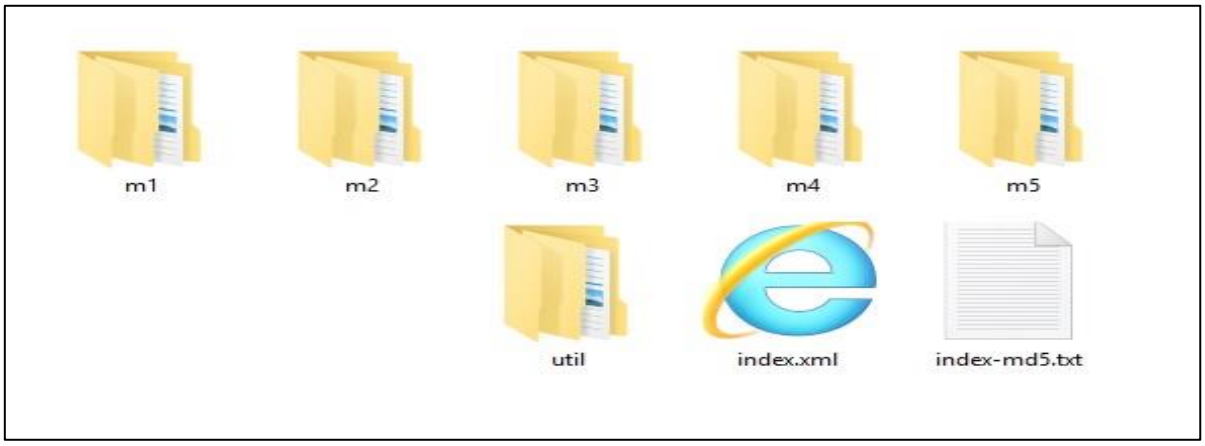

Figure 2: Structure of eCTD

3. Presentation of the eCTD File through eSDR (Extension Submission):

3.1 Implement the following in the envelope for the submission in eCTD format

Write (Product Number - Sub-Product Number(s) which intended to be submitted within the same seq. no.") in the reference number field.

3.2Presenting the Product Submission Regarding the Related Regulatory activity:

A. Products submitted for a new registration request (initial submission):

- To submit multi applications related to the same “Product Number” and have different strength, package type, or package size, the applicant can submit a combined eCTD file (combined dossier) with the same Sequence Number.

Note:

- To upload the combined dossier of the main product, the company must upload only a cover letter containing all related applications with the same sequence number in accordance with the accepted uploading method. (CTD and eCTD format)
- The Related Sequence field should always be filled out.

- To submit multi Applications related to the same “Product Number” with different dosage forms as a new registration application, the applicant must submit each sub-product in a separate Sequence Number within the same dossier.

B. For the products that were already submitted in separate dossiers in the initial submission, the company should continue with separate dossiers as submitted initially.

C. For the products that have already been submitted and the company would like to submit an additional Package Size, Package Type, Strength, the applicant can submit all/each new sub-product applications with a new separate Sequence Number within the same dossier(eCTD format).

Note:

- The additional dosage form can be added in a new separate sequence number as mentioned in (3.2.A) within the same dossier.

Appendix B: Veterinary Non-eCTD electronic Submissions (VNeeS)

The electronic version of the submission (e-submission) is based on the Executive summaries of the GCC veterinary law and the SFDA Regulatory Framework for Drug Approval. Later, SFDA will issue the detailed requirements of Veterinary Non-eCTD electronic Submissions (VNeeS).

E-submission applications should be regarded as an **interim** format and that applicants should be actively planning their move to full VNeeS submissions, and then to eCTD version 4.0. A separate guidance covering VNeeS submission is published on the SFDA website (appendix F).

An illustration of how to create an e-submission is shown in figure 5.

the following points should be considered for VNeeS submission:

1. The maximum length of the name of a single folder or file is 64 characters including extensions.
2. The folders or file names should be written in lower case only.
3. Create four folders and name them as p1, p2, p3, p4, respectively.
4. The folders and folder names in P1 are described in table 1.

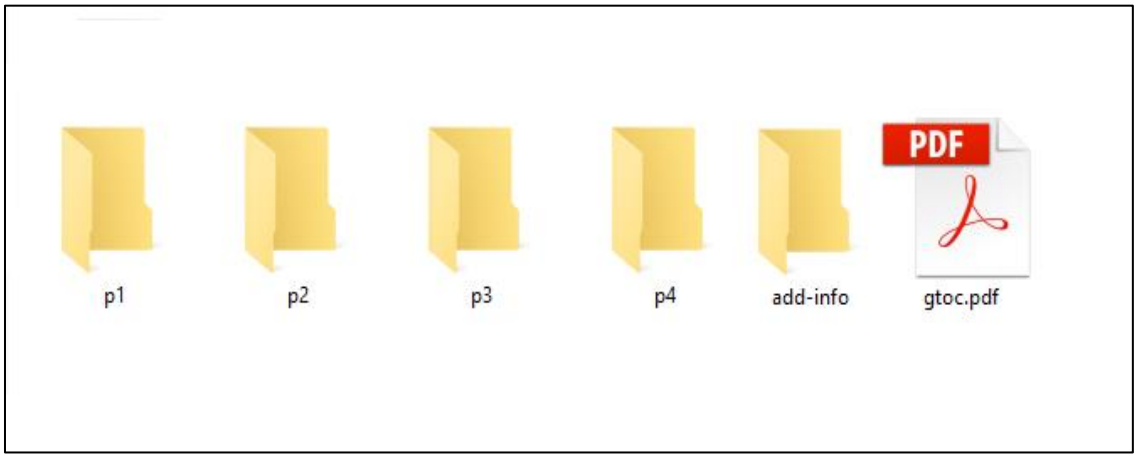

Figure 3: Structure of Veterinary Non-eCTD electronic Submissions (VNeeS).

Appendix C: Required Quantities of Samples

The following table shows the required quantities of the samples for different sample types:

Table 1: The Required Quantities of the Samples.

عينات الادوية البشرية والبيطرية والعشبية والحيوية		
Dosage Forms	**Volume or Weight**	**Required Quantity**
Tablets (Oral, Sublingual, Chewable, etc.)	N/A	100 Tabs
Capsules	N/A	100 Caps
Syrups/Suspensions/Emulsions/solutions	Less than or equal 1 L	10 Bottles
Syrups/Suspensions/Emulsions	More than 1L	6 Bottles
Solutions(peritoneal &Heamodialysis)	More than 5 Liters	4 Bottles/Bags
Eye/Ear/Nasal Drops	All volumes	20 Pcs
Creams/Ointments/Gels/Lotions	Less than 15 gm	15 Tubes
Creams/Ointments/Gels/Lotions	More than 15 gm	12 Tubes
Raw Materials	0.5 ml	24 Pcs
Ampoules/Vials/Injections	Less than or equal 1 ml	100 Pcs
Ampoules/Vials/Injections	2 – 5 ml	30 Pcs
Ampoules/Vials/Injections	More than 5 ml	20 Pcs
IV Fluids	Less than 500 ml	15 Samples
IV Fluids	More than or equal 500 ml	10 Samples
Injectable powder	Less than or equal 50 mg	30 Pcs
Injectable powder	More than 50 mg	20 Pcs
Plasma bags	N/A	20 Bags
Blood Bags	N/A	8 Bags
Administration devices	N/A	6 Pcs
Transdermal Patches	N/A	50 Patches
Inhalers	N/A	30 Pcs
Sachets	Less than 5 gm	50 Pcs
Sachets	5-10 gm	20 Pcs
Sachets	More than 10	15 Pcs
Suppositories	N/A	100 Pcs
Vaginal Ovules	N/A	100 Ovules
Shampoos	N/A	10 Pcs
Mouthwash	N/A	10 Bottles
Lozenges	N/A	100 Pcs
Sprays (Nasal, Topical, etc.)	N/A	15 Bottles
Sponge (e.g. Tichosil)	All size of sponge	20 Samples
Protein powder	1 kg or less	3 Bottles
Protein powder	More than 1 kg	2 Bottles
Blood product solutions	100 mL and more	10 Bottles
Blood product solutions	50 mL and less	20 Bottles

Important Notes:

- The batch number of the provided samples must conform to the finished product certificate of analysis (1.7.3) (For veterinary product: Part 1 section 1a43).
- The applicant should provide Primary Reference Standard not less than 500 mg with its storage condition specifications (expiry date not less than one year) and a certificate of analysis that proof the potency of the standard.
- Samples should have at least an expiry date of 6 months from the lab receiving date.
- If the applicant couldn't know the required samples, please contact the SFDA at the email: sdr.drug@sfda.gov.sa.
- The SFDA has the right to ask for additional quantities if needed.
- The SFDA has the right to ask for analysis tools and/or primary reference standards if needed.

Appendix D: File Formats

General Requirements:

Generally, the relevant information must be structured according to the requirements of the Common Technical Document (CTD). The accepted file formats are:

- PDF
- For graphics: Joint Photographic Experts Group (JPEG), Portable Network Graphics (PNG), Scalable Vector Graphics (SVG) or Graphic Interchange Format (GIF).

Portable Document Format:

PDF is an open, de facto, published format created by Adobe Systems Incorporated (http://www.adobe.com). It is not necessary to use a product from Adobe or from any specific company to produce PDF documents. PDF is accepted as a standard format for documents defined in this specification. The following recommendations support the creation of PDF files that agencies can review effectively. To ensure that PDF files can be accessed efficiently, **PDF files should be no larger than 100 megabytes**.

The following points can be made in relation to PDF files:

- Files must be legible with PDF version 1.4 or higher
- PDF files produced from an electronic source document are highly preferred over PDF files produced from scanned paper, since those 'electronic' PDF files provide the maximum functionality to the the RA Team in terms of search and print capabilities, and copy and paste functionality. The overviews/summaries in the CTD Module 2 should always be generated from an electronic source document.
- If scanning is unavoidable, readability and file size must be balanced; the following document layouts are recommended: resolution 300 dpi (photographs up to 600 dpi), avoid gray scale or color where possible, use only lossless compression techniques.
- If colors other than black are used, the colored pages must be tested on a black and white printer for acceptable reproduction and legibility prior to submission.
- Pages must fit on an A4 sheet of paper.
- Landscape-oriented tables must automatically appear on screen.

Text Searchable Files:

Applicants are requested to ensure that all submissions contain the maximum amount of text searchable content. Documents with searchable text will aid the assessor, or any other user, in searching for specific terms and also in copying and pasting information into another document, such as an assessment report. The SFDA recognizes that not all documents need to be a text-searchable. This appendix provides some guidance about what must be text searchable and the ways to ensure that files are created appropriately.

Documents that must always be text searchable:

The PDF should be produced wherever possible from a text source, such as MS Word. The document must be OCR if it has been scanned from its source document.

- Key administrative documents in Module 1 including: Cover Letter, application form, SPC, labeling and PIL documents, & the main body ~~of~~ text of Risk Management Plans.
- All Module 2 files. (Highly preferred)
- All Module 3 files. (Highly preferred)
- The main body of text and main tables in modules 4 and 5.

Documents Which are not required to be text searchable:

The PDF should be produced wherever possible from a text source, such as MS Word. but if sourced from a scanned original then there is no need for OCR.

- Any original Certificate of Pharmaceutical Product
- Any original Certificate to confirm that the product is free from BSE/TSE
- Any original GMP certificate
- Any original certificate of analysis
- Any manufacturer's licenses
- Any certificates of suitability
- Any Manufacturing Authorization

- Any literature references sourced from journals, periodicals and books (except when these are used in a bibliographic application so support the main claims of the application).
- Any page with a signature that does not contain other information key to the understanding of the submission
- Applicants should consider providing signatures on separate pages from key text in reports, overviews, etc.

Use of Electronic Signatures:

The use of advanced electronic signatures (digital signatures) will be crucial in achieving pure electronic communication between the pharmaceutical industry and regulatory agencies, particularly for authentication of electronic submissions and documents contained therein. Saudi Arabia is therefore developing a long-term strategy to implement digital signatures. Currently however, the use of digital signatures for electronic submissions within the kingdom of Saudi Arabia is not fully supported and digital signatures should therefore not be used.

Appendix E: Rolling Submission

Rolling submission is an ad hoc procedure that allows SFDA to continuously assess the data for upcoming highly promising medicinal products as they become available. A rolling review can only be used for products of strategic importance in addressing unmet medical needs. On a case-by-case basis, rolling submission is available only for Conditional Approval to accelerate every step of the regulatory pathway.

This appendix describes general processes applicable to the submission and review of portions of an application.

- **Content of a Rolling Review Submission**

- Identification of the submission in the cover letter as a REQUEST FOR ROLLING REVIEW in bold, uppercase letters.
    - Each submission occurs preferably in eCTD format with an application form to the newly available data, based on *The Guidance for Submission, GCC Module 1 Specifications*, and *The Data Requirements for Human Drugs Submission* ,unless there is an exemption letter issued by SFDA.
    - Any exemption letter shall be provided in section 1.0 Cover Letter.
    - Rolling submission plan outlining the sequence and timelines of the subsequent study data (planned and in progress) submission, if available, should also be provided.

- **Portions of an Application Eligible for Rolling Submission:**

  Generally, SFDA accepts a complete section only for submission, such as the entire CMC (chemistry, manufacturing, and controls), pre-clinical, or clinical sections. Occasionally, it may, in its discretion, accept less than a complete section if it determines that such a subsection would constitute a reviewable unit and be useful in making a decision.

- **Review of Portions of an Application for Conditional Approval:**

  Following the rolling review, once SFDA considers that the data package is sufficiently complete to proceed to formal regulatory submission, submission by the company of the formal conditional approval application is expected. The duration of the procedure will depend on the amount of data not yet assessed as part of rolling review submissions.

- **Rolling Submission Request**

To plan for such rolling submission:

- applicants should make the initial contact through the SDR.drug@sfda.gov.sa mailbox with:
  - A justification for assessing the product via rolling submission procedure;
  - Data supporting the proposed role of the product.
  - Rolling submission plan with timelines of submissions.
- Permission to proceed with a rolling submission: applicants will receive SFDA decision through SDR.drug@sfda.gov.sa within 10 working days.
- SFDA also encourages applicants to request a pre-submission meeting to present their development and submission plans, and it is committed to provide guidance on application and support throughout the process.

Appendix F: References and Guidelines

The data requirements for each application will differ, and depend on the drug submission type. However, all the required data should be in accordance with the CTD structure. Please refer to the following documents published on the website:

- *The GCC Data requirements for Human Drugs Submission – Content of the Dossier.*
- *Data requirements for Herbal and Health Products submission – content of the dossier.*
- *Data requirements for Veterinary products.*
- *The GCC Data Requirements for the Renewal of Marketing Authorization.*
- *Data Requirements for the Renewal of Marketing Authorizations (Herbal and Health Products).*
- *GCC Guidelines for Bioequivalence*
- *GCC Guidelines for Stability testing of API's and FPP's*
- *GCC Guidance for Presenting the SPC, PIL and Labelling Information*
- *Guidance for Naming of Medicinal Products.*
- *Top Deficiencies in Validation and Assessment Phases of Herbal and Health Products.*
- *Guidelines for Variation Requirements.*
- *Registration According to Verification and Abridge.*
- *Guidance for Graphic Design of Medication Packaging.*
- *GCC Guideline on the specifications for provision of an electronic submission for a veterinary medicinal product (VNeeS).*
- *Guideline for Pharmacovigilance for Veterinary Products.*
- *Regulatory Framework for Drug Approval*
- *GCC Module 1 Specifications*
- *Baseline eCTD Submission Requirements.*
- *Drug Master File (DMF): Guidance for submission.*
- *Guidance for Priority Review of Product Registration.*

The latest versions of SFDA's guidance and other related documents are available on the website at the following address: https://www.sfda.gov.sa/ar/regulations?tags=2

Appendix G: Forms

Regulatory Forms*:

a) Application for Variation to a Marketing Authorization.

b) Permanent Cessation of Marketing of Medicinal Product form.

c) Request for Priority Review Designation.

d) Tables mentioned in the GCC Data Requirements for Human Drugs Submission.

e) Bioequivalence Study Summary Template.

Price Forms according to SFDA Pharmaceutical Pricing Rules*:

a) Price Certificate Form.

b) New Pricing Form.

c) Price Appeal Form.

d) Price Reevaluation Request Form.

e) Price Revision at Renewal Form.

*** Note:** Please visit SFDA's website for downloading Regulatory and Price Forms.

COVER LETTER FOR INITIAL SUBMISSION

هذا النموذج يساعد المتقدم على كتابة خطاب تغطية
This is a template to assist the applicant in writing a cover letter

سعادة نائب الرئيس التنفيذي لشؤون الدواء **سلمه الله**

الهيئة العامة للغذاء والدواء

السلام عليكم ورحمة الله وبركاته

نتقدم إلى سعادتكم بطلب الحصول على تسجيل المستحضر الموضحة بياناته أدناه، علما بأنه تم إرفاق جميع البيانات والدراسات المطلوبة مع هذا الخطاب:

Sub-Product No.		**الرقم المرجعي الفرعي**
Trade Name		**الاسم التجاري**
Generic Name		**الاسم العلمي**
Strength		**التركيز**
Dosage Form		**الشكل الصيدلاني**
Pack size		**حجم العبوة**
Manufacturer		**الشركة الصانعة**
MAH		**الشركة المسوقة**
Agent		**الوكيل**
Authorized Consultant Office (if Available) *		**المكتب الاستشاري المفوض بالتقديم***
This Product has	☐ **Priority** ☐ **GCC** ☐ **2nd Brand**	**نوع التقديم**
Company Representative		**ممثل الشركة/ الوكيل**
Email		**البريد الإلكتروني**
Mobile		**رقم الجوال**

***Must be filled if deputation letter has been given to a consultant office to submit this product file**

وتقبلوا سعادتكم خالص التحية والتقدير،،،

مدير شركة .....

الاسم:

التوقيع

التاريخ

ختم الشركة

COVER LETTER FOR RESPONSE TO INQUIRIES

هذا النموذج يساعد المتقدم على كتابة خطاب تغطية
This is a template to assist the applicant in writing a cover letter

سعادة نائب الرئيس التنفيذي لشؤون الدواء **سلمه الله**

الهيئة العامة للغذاء والدواء

السلام عليكم ورحمة الله وبركاته

نتقدم إلى سعادتكم بالرد على الملاحظات/ النواقص المرسلة لنا على نظام سدر للمستحضر الموضحة بياناته أدناه، علما بأنه تم إرفاق جميع البيانات والدراسات المطلوبة في النسخة الإلكترونية المرفقة:

Sub-Product No.	
Trade Name	
Generic Name	
Strength	
Dosage Form	
Pack size	
Manufacturer	
MAH	
Agent	
Authorized Consultant Office (if available)	
Submission No.	
Response to	☐ **New Registration** ☐ **Renewal** ☐ **Variation**
Response to Department *	☐ **Quality** ☐ **Safety/Efficacy** ☐ **Medication Errors** ☐ **Testing** ☐ **Inspection** ☐ **Pricing** ☐ **NPC**
This product has	☐ **Priority** ☐ **GCC** ☐ **2nd Brand**
Company Representative	
Email	
Mobile No.	

***The applicant can respond to more than one department's inquiry in one submission**

وتقبلوا سعادتكم خالص التحية والتقدير،،،

مدير شركة .....

الاسم:

التوقيع

التاريخ

ختم الشركة

SAMPLES FORM

هذا النموذج يساعد المتقدم على كتابة نموذج العينات
This is a template to assist the applicant in writing a sample form

Product information:

Sub-Product No.		**الرقم المرجعي**
Trade Name		**الاسم التجاري**
Strength		**التركيز**
Dosage Form		**الشكل الصيدلاني**
Pack size		**حجم العبوة**
Storage condition		**شروط التخزين**
Marketing Company		**الشركة المسوقة**
Manufacturer		**الشركة الصانعة**
MAH (Agent)		**الوكيل**
Sample Quantity		**عدد العينات للتحليل**
Batch No.		**رقم التشغيلة**
Expiry Date		**تاريخ انتهاء الصلاحية**
Storage condition		**شروط التخزين**

Primary Reference (Working) Standard:

Reference standard name		**اسم المادة الفعالة**
API Weight		**وزن المادة الفعالة**
Storage condition		**شروط التخزين**
Expiry Date		**تاريخ انتهاء الصلاحية**
Potency of the standard		**درجة النقاوة للمادة القياسية**

Company information:

Agent		**الوكيل**
Company representative's name		**مندوب الوكيل**
Email		**البريد الإلكتروني**
Mobile No.		**رقم الجوال**

STAMP
SFDA central Laboratories

CONTACT ADDRESS

Saudi Food and Drug Authority – Drug Sector

4904 Northern Ring Road – Hittin District – Unit Number: 1

Riyadh 13513 – 7148

Kingdom of Saudi Arabia

Tel: 19999

E-mail: sdr.drug@sfda.gov.sa