
Regulatory Guidance for Submissions and Applications

Version 1.0

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Regulatory Guidance for Submissions and Applications

Version 1.0

Saudi Food & Drug Authority

Drug Sector

For Inquiries

SDR.Drug@sfda.gov.sa

For Comments

Drug.Comments@sfda.gov.sa

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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

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Preface

The Saudi Food and Drug Authority (SFDA) is undertaking significant reforms to develop and enhance its current product lifecycle regulatory system, including reviewing registration and variation procedures and their timelines. This aims to streamline the existing review pathways, which are currently classified by product type, aligning with internationally recognized best practices that prioritize products based on their importance.

This guidance will replace two previous documents—The Regulatory Framework for Drugs Approval and the Guidance for Submission Guideline—and will serve as the primary reference for all regulatory activities related to application submissions.

In light of the updates SFDA has made to registration pathways and their associated timelines, this guidance will come into effect on **January 1, 2027**.

Table of Content:

Abbreviation and Acronyms	8
Glossary	9
1. Introduction	12
2. Scope.....	12
3. Objective.....	13
4. Classification	13
5. Specific Submission/Application Pathways	13
5.1 Rolling Submission.....	13
5.2 Priority review	13
5.3 Designation Applications	14
Verification and abridged.....	14
Breakthrough Medicine Designation.....	14
Orphan Drug Designation	15
The New Accelerator Program for Drugs in Rare Diseases (NADR).....	15
Well-Established Use	15
6. Pre-Submission Meetings.....	16
7. Filing of Information to SFDA.....	16
7.1 eSDR Application form.....	16
7.2 Acceptable formats for filing applications:	16
8. Performance Targets.....	16
9. Submission Processing	17
9.1 New Marketing Authorization Application (MAA).....	17
9.2 Variations of MAA.....	22
9.3 Renewal of Marketing Authorization	26
10. MA cessation	28
APPENDICES	30
Appendix A: Related documents.....	30

Appendix B: Rolling Submission	31
Appendix C: Designation Request	33
Appendix D: Electronic Submission:	34
1. Common Technical Document (CTD).	34
2. Electronic Common Technical Document (eCTD)	34
3. Presentation of the eCTD File through eSDR (Extension Submission).....	35
Appendix E: Veterinary Non-eCTD electronic Submissions (VNeeS).....	36
Appendix F: File Formats.....	37
Appendix G: Document Requirements.....	40
Appendix H: Required Quantities of Samples	42
Appendix I: Performance Targets.....	44
Appendix J: Forms.....	47
Appendix K: Types of application for specific Product:	52

Abbreviation and Acronyms

API	Active Pharmaceutical Ingredients
BSE	Bovine spongiform encephalopathy
CEO	Chief Executive Officer
CTD	Common Technical Document
eCTD	Electronic Common Technical Document and it is an electronic equivalent to the CTD
e-Submission	Electronic Submission Via Saudi Drug Registration System.
eSDR	Saudi Drug Registration system.
GCC-DR	Gulf Cooperation Council Drug Registration.
KSA	Kingdom of Saudi Arabia
MA	Marketing Authorization
MAA	Marketing Authorization Application
MAH	Marketing Authorization Holder
NeeS	Non-eCTD electronic submission.
NPC	National Pharmacovigilance Center
OCR	Optical Character Recognition.
PIL	Patient Information Leaflet.
RA	Regulatory Affairs
SFDA	Saudi Food and Drug Authority
SPC	Summary of Product Characteristics.
TSE	Transmissible Spongiform Encephalopathy
VNeeS	Veterinary Non-eCTD Electronic Submission.

Glossary

Definitions for key terms used in this guide is listed below to ensure a unified understanding of the procedures and requirements:

Applicant	The company or its representative
Biologics	Biological products that are derived from biological sources or produced by using biotechnology methods such as vaccines, blood derivatives, recombinant proteins and gene/cell therapies.
Biosimilars	A biopharmaceutical product highly similar to an already approved reference product in terms of quality characteristics including structural and functional attributes and has no clinically meaningful differences.
Blood products	They are a wide range of medicinal product sourced from human blood or plasma (source material) that can be collected and tested at “Blood Establishments” and obtained by industrial process “Fractionation” of human plasma of a large number of donations (up to tens of thousands) that are pooled together
Common Technical Document (CTD)	An international harmonized format for submissions for approval of pharmaceuticals. The CTD provides a standardization of the presentation of the content
Dosage form	The finished formulation of a pharmaceutical product, e.g. tablet, capsule, suspension, solution for injection, suppository
Drug	An article intended for use in the diagnosis, cure mitigation, treatment, or prevention of disease and which is intended to affect the structure or function of the body
Drug Application	A drug application includes the application form and the product file
Generic (multisource) product	A product created to be equivalent to the innovative / brand name product in dosage form, strength, route of administration, quality, performance characteristics and therapeutic indication(s) ➤ Note: A drug application will be considered as generic if the innovative product is registered in one of the SRA irrespective of whether the innovative product is registered or not at SFDA.
Health product	Finished labeled products in pharmaceutical dosage forms, which are usually low risk ingredients that are intended to restore, correct or

modify physiological functions by external pharmacological, immunological or metabolic actions

Herbal product	Any plant or herb manufactured in a pharmaceutical dosage form, and presented with a medical claim.
Inquiry	A questions or clarifications posted in SDR system to be responded by the applicant
Known active substance	A new dosage form, strength, route of administration or indication of an active ingredient already marketed in Saudi Arabia
New (innovative) product	A product that includes new chemical entity and introduced by the innovator company (or the partner)
Novel recombinant protein	Novel medicinal products produced by biotechnology methods and other cutting-edge technologies. They include a wide range of recombinant products such as enzymes, hormones, monoclonal antibodies; except blood products and vaccines.
Marketing Authorization Applications (MAAs)	A formal submission by applicant to SFDA seeking approval to market a medicinal product.
Medicinal gas	Any gas or mixture of gases classified as a medicinal product
Radiopharmaceutical product	A radioactive drug that can be administered safely to humans for diagnostic and therapeutic purposes.
Reference number / sub-product number	Any combination of letters and numbers that is assigned to the transaction in order to follow it.
Renewal of marketing authorization	A process of renewing the marketing authorization license every five years.
SADAD	A system that links between the commercial sector and the local banks; it offers the ability to collect its customer payment electronically through all banking channels in KSA around the clock.
SFDA's pricing rules	<i>The Rules for Pharmaceutical Products Pricing</i> which include the general requirements and criteria for pricing a pharmaceutical product and constitute the general framework of the “Pharmaceutical Products Pricing Committee” to suggest the price.
Product file	The electronic version of the product file.

Stringent Regulatory Authority (SRA)

Regulatory body that enforces stringent requirements for the approval and monitoring of medicinal products.

For human products: USFDA, European Medicine Agency (EMA), MHRA (UK), Swissmedic, Health Canada, TGA (Australia) and PMDA (Japan).

For veterinary products: European Medicine Agency, Veterinary Medicines Directorate (UK), Health Canada Drug Product Database, Australian Pesticides and Veterinary Medicines Authority, Food and Drug Administration (USA), United States Department of Agriculture, The French Agency for Veterinary Medicinal Products, Health Product Regulatory Authority (Ireland), Federal Office of Consumer protection and Food Safety & Paul Ehrlich Institute (Germany), New Zealand Food Safety, Federal Agency for Medicines and Health Products (Belgium), The Netherlands Veterinary Medicines Institute and Spanish Agency of Medicines and Medical Devices (Spain).

Synthetic Peptides	A peptide-based active pharmaceutical substance produced through chemical synthesis rather than biological expression systems, where the reference product is peptide drug product of recombinant deoxyribonucleic acid (rDNA) origin.
Validation (Business & technical)	The process of checking if documents satisfy a certain criterion
Vaccines	Preparations that contain antigenic substances capable of inducing a specific and active immunity against the infecting agent or the toxin or the antigen produced by it.
Variation	Any changes to a registered product have to be submitted to the SFDA.
Veterinary product	Any substance or combination of substances presented as having properties for treating or preventing disease in animals; or any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.
Wave	Set of inquiries from one or multiple departments sent to applicants during assessment process
Well -Established Use application	It is bibliographic applications that demonstrate the active substance has been in use for more than 10 years in a stringent regulatory authority (SRA), and its efficacy and safety have been well-established for the claimed therapeutic indication.

1. Introduction

The Drug Sector in Saudi Food & Drug Authority (SFDA) has developed this regulatory guidance to assist applicants in submitting applications for various types of drug products and illustrate the procedure to obtain, vary, or renew a marketing authorization. Timeframes for processing applications to market products in Saudi Arabia are also included in this document.

This guidance also describes how the Drug Sector in the SFDA manages submitted information and data, it helps applicants to comply with the requirements of filing and maintaining their application.

Applicants as well as 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 periodically to reflect the latest practices in regulatory sciences and maintain its consistency and enhance regulatory process efficiency. It is expected that this guidance will optimize product application management and reduce the number of clarification request and application deficiencies.

It should be noted that the SFDA has the right to request any information and data within the context of this guidance 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 that all decisions are clearly documented.

2. Scope

This guidance document applies to all types of drug submissions/applications including:

- New Marketing Authorization (MA)
- Variation of MA
- Renewal of MA
- MA Cessation

All submitted information and materials will be screened to ensure their completeness and readiness for scientific review. The same management principles will be applied consistently to all submission types.

3. Objective

The objectives of this guidance are:

- To clarify the procedures for submitting the applications to SFDA.
- To ensure that all submitted applications are complete and compliant with regulatory requirements.
- To clarify the process of reviewing and evaluating applications.

4. Classification

Applicant shall determine the product classification before filing the information (e.g., as a drug, a biologic, a medical device or a combination product).

SFDA established the [Product Classification System](#) for companies to classify their products, determine eligibility and identify whether a product is subject to registration. The classification exclusively based on the SFDA criteria and products classification guidance. It is an optional service for companies and does not replace registration in other electronic systems of the SFDA.

5. Specific Submission/Application Pathways

Information provided below is to inform applicants of certain submission/application pathways that require filing in a specific form.

5.1 Rolling Submission

Rolling submission is an ad hoc procedure that allows the 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. Please see appendix B for the processes and content of a rolling review submission.

5.2 Priority review

An applicant requesting priority review of a submission under the Guidance for Priority Review of Product Registration should send the application form along with the cover letter and supporting documents to the Saudi Drug Registration (SDR) SDR.Drug@sfda.gov.sa.

If the drug submission was granted priority review, the applicant must clearly state this in their cover letter by providing a copy of the email in the initial submission. For further information and management of priority review requests and submissions, refer to the [Guidance for Priority Review of Product Registration](#).

5.3 Designation Applications

The SFDA manages various designation request types, including [Orphan Drugs](#), [Breakthrough Medicine Program](#), Well-established use applications, [Verification and abridged applications](#), and [The New Accelerator Program for Drugs in Rare Diseases](#)

Applicants are required to complete the Designation Request Form (Appendix C) and send it to Designation.Drug@sfda.gov.sa

All submissions must comply with the criteria, Forms, documentation requirements, and timelines described in the relevant guidelines to ensure proper evaluation and processing by SFDA.

- [Verification and abridged](#)

The verification and abridged pathways offer an accelerated review that allows applicants to obtain marketing authorization in Saudi Arabia for products already approved by the United States (US) Food and Drug Administration (FDA), US Department of Agriculture (USDA), and/or European Medicines Agency (EMA).

Under this pathway, the applicant submits a complete dossier, including evidence of prior approval, together with all quality, safety, and efficacy data as described in [Verification and Abridged Pathways](#).

- [Breakthrough Medicine Designation](#)

The Breakthrough Medicine Program is intended to expedite the development and review of new drugs that can treat serious or life-threatening conditions where there is a lack of effective treatment options. Participation in the program is voluntary, and it involves early dialogue between drug developers and the SFDA to optimize development plans and accelerate evaluation. The goal is to ensure that promising drugs are made available as soon as possible, provided that their benefits outweigh their risks.

For more information regarding the criteria and procedure for submitting a request please refer to [the Guidance on Breakthrough Medicine Program](#).

- **Orphan Drug Designation**

The Orphan Drug designation process facilitates the development and approval of products intended for the diagnosis, prevention, or treatment of rare diseases that affect a small patient population.

The SFDA's orphan drug framework establishes eligibility criteria such as disease rarity, the absence of satisfactory treatments, or a significant benefit over existing options.

For comprehensive details on requirements, application procedures, and benefits granted under this designation, refer to [the Guidance for Orphan Drug Designation](#).

- **The New Accelerator Program for Drugs in Rare Diseases (NADR)**

The New Accelerator Program for Drugs in Rare Diseases (NADR) is intended to support and accelerate the development and authorization of drugs for rare, life-threatening, or seriously debilitating diseases with unmet medical needs.

To qualify for NADR designation, the product should be intended to prevent or treat a rare disease affecting fewer than 5 in 10,000 persons in Saudi Arabia, address an unmet medical need or provide a significant clinical benefit over available treatment options, and be either under active development or authorized elsewhere but not yet registered in Saudi Arabia for the proposed indication.

For comprehensive details on eligibility criteria, incentives, and the application process, refer to the [Regulatory Framework for Rare Diseases Drugs – The New Accelerator Program for Drugs in Rare Diseases](#)

- **Well-Established Use**

When an active substance has been used for more than 10 years within a stringent regulatory authority (SRA) and its efficacy and safety have been well established for the claimed therapeutic indication, the application for marketing authorization may be based on published scientific literature.

For comprehensive details on requirements under this designation, refer to [the Data Requirements for Human Drugs Submission](#).

6. Pre-Submission Meetings

Pre-submission meetings may be requested by the applicant prior to filing an application. Meetings can be conducted via a face to face meeting or virtually and an applicant may request a pre-submission meeting with the appropriate Directorate within the SFDA if they have any questions or concerns. For more details, please refer to [the Meeting Requirements Between Drug Sector and Applicants](#)

7. Filing of Information to SFDA

7.1 eSDR Application form

The applicant shall fill out the application form and pay fees related to the intended regulatory activity (i.e. initial application, variation, or renewal) through [eSDR system](#) as mentioned in the user manual. The applicant must verify that there is an account in the DENR system before accessing [eSDR system](#).

7.2 Acceptable formats for filing applications:

The file shall be uploaded to the following formats:

- eCTD for Human Products (Refer to Appendix A, D, F & G).
- CTD for Herbal and Health Products (Refer to Appendix A, D, F& G).
- VNeS for Veterinary Products (Refer to Appendix A, E, F& G).

Each uploaded dossier shall include the following:

- All required modules according to Data requirements of the concerned product type.
- Cover letter for initial submission or post registration activities (see Appendix J).
- The required pricing form, if applicable (refer to [Pricing Rules for Pharmaceutical products](#))

8. Performance Targets

The SFDA has set specific timelines and performance targets for reviewing applications submitted for initial marketing authorization, variation, or renewal. These performance targets are calculated immediately upon the commencement of the scientific evaluation, excluding the business validation phase. Evaluation is paused when clarification or

additional information is requested from the applicant and will be resumed upon receipt of responses; see Appendix I for performance targets.

9. Submission Processing

9.1 New Marketing Authorization Application (MAA)

The applicant shall fill out the application form and upload the file through [eSDR system](#).

For products registered in the Gulf Health Council for the GCC States (GCC-DR), the company should provide the following:

- The GCC certificate number in the relevant field on eSDR application form.
- A copy of the GCC certificate in the 1.0 cover letter.
- The product's latest approved documents.

Validation

The product file will be subjected to a validation process to ensure the application fulfills the requirements essential for scientific assessment. The validation involves two steps:

Technical validation

The SDR system will validate the submission automatically after the company uploads the file to SDR portal. The validation's result will be sent by email to the applicant through SDR system.

Business validation

The product file will be validated to ensure that all required information is included in the MA application prior to the start of the scientific assessment. Applicants are advised to refer to the relevant checklist, which highlights specific requirements and common deficiencies:

- [Checklist for Human Drug Applications](#)
- [Checklist for the Submission of Veterinary Product Applications](#)
- [Checklist for registration through the abridged and verification pathway](#)

If any information is missing or incorrect, an electronic inquiry will be sent through the SDR system and the status will be changed to (the file is incomplete), giving the

applicant 30 working days to complete the file. The applicant will have a maximum of two waves to respond to inquiries in the validation phase. Once the file is complete, it will then proceed to the next steps for assessment; and the applicant will receive an automatic notification through email.

The registration request will be rejected in the following cases:

- Failure to respond within 30 working days.
- Failure to provide the required documents or justify the absence of a document according to relevant SFDA guidelines, or exceeds the number of waves available.

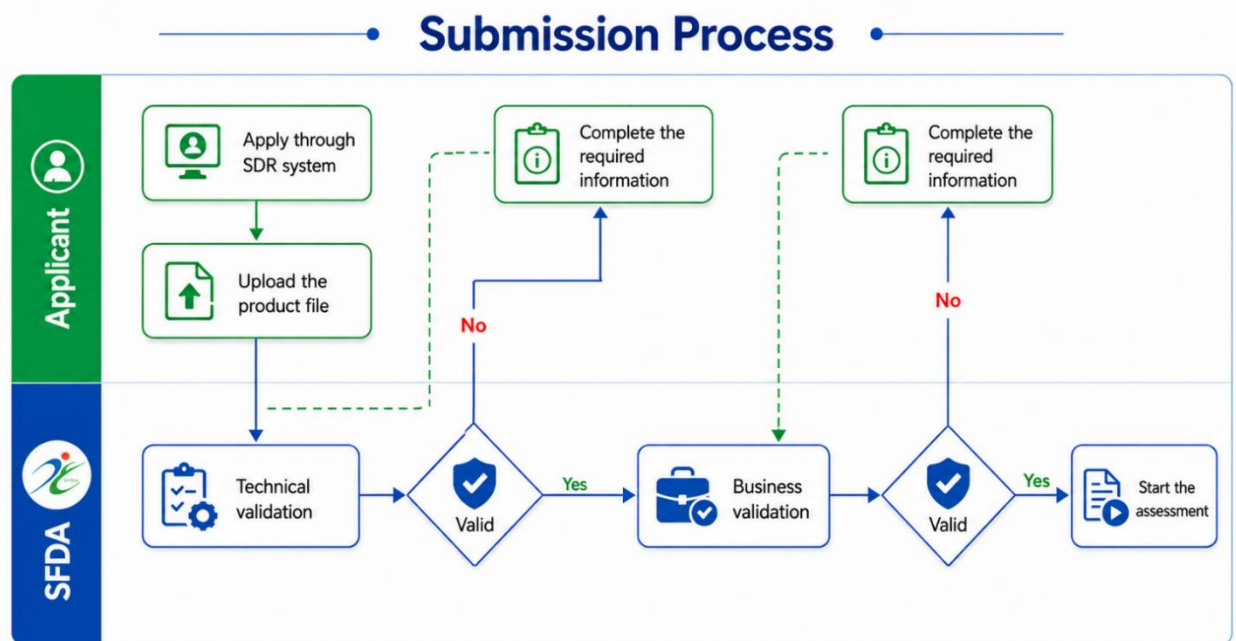


Figure 1: Validation process for marketing authorization application

Assessment

The MAA for different drug submission types subject to the following processes:

Evaluation / Inspection

1. The RA will distribute the registration request to the relevant departments to assess quality, safety and efficacy;
 - For Inspection: the department will check the manufacturer license statues; if manufacturing line is not approved:

- An inspection visit will be scheduled based on the availability of both inspectors and the company.
 - following the visit, an inspection report will be sent to the company
- 2. If additional information or clarification is required, an electronic inquiry will be posted through SDR system, and the applicant should respond within 60 working days.
- 3. Once the evaluation and inspection are completed, the registration request will be forwarded to the Pricing Department.

Testing

1. The registration request will be forwarded to the SFDA Central Laboratories.
2. If additional information or clarification is required, an electronic inquiry will be posted through [SDR system](#).

Note: Testing will not delay the registration of a product.

Pricing

1. The Pricing Department will review the product's price according to the "[Pricing rules for pharmaceutical products](#)".
2. If additional information or clarification is required, an electronic inquiry will be posted through the SDR system. A response should be received within 60 working days.
3. The suggested product's price will be forwarded to the Registration Committee.

Response to Inquiry:

The applicant may receive up to three (3) waves of inquiries during the assessment and pricing phases. Where applicable, the waves may be issued at the following stages of the assessment process:

- **First Wave (Early wave):** this wave may be issued at 25% of the assessment time, but only if inquiries/deficiencies are identified at this stage.
- **Second wave (Main wave):** issued at 60% of the assessment time, containing the consolidated inquiries from all departments involved in the assessment, including pricing.
- **Third wave (Outstanding inquiries wave):** issued at 85% of the assessment time to address outstanding matters identified in the later stages of assessment.

The registration request will be rejected in the following cases:

- Failure to respond within 60 working days.
- If the applicant provides an unsatisfactory response, fails to submit the required documents, or does not provide an acceptable justification for the absence of any required document in accordance with SFDA guidelines.
- Failure to resolve critical quality, safety, or efficacy deficiencies after the second inquiry wave.

Note: The SFDA may take a regulatory decision at any time during the assessment phase without issuing all, or any, of the inquiry waves.

The applicant shall provide the following when responding to [eSDR system](#) inquiries:

- **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 each inquiry alongside its corresponding narrative response. Each inquiry should be followed by the name of section, page number and a hyperlink(s) to the supportive document(s) where the answer can be found in the concerned module/part. This submission shall include only responses to inquiry(ies) and hyperlinks in 1.9 *Response to Questions* (For veterinary product: Part 1 section 1a6).
 - Cover letter for response to inquiries (see Appendix J).

The [eSDR system](#) enables the applicant to receive inquiries after being evaluated by all departments at once (as a wave). Please refer to *The User Manual* at [eSDR system's](#) for more information about how to upload the file.

- **Laboratory Inquiries:**

After submitting the product file, the inquiry will be posted in the eSDR system, requiring the applicant to provide the following::

- Submit the required samples, working standards and any related information/document to the laboratories.

- A scan of the sample submission form (see appendix J) - 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.

• Registration Decision

The Registration Committee will review the registration request and issue a decision. The applicant will receive a notification from eSDR website noting the decision is one of the following:

- A. Approved; the applicant should issue the MA and print the registration certificate within three months of the approval notification.
- B. Approved with commitment: an approval issued for a registration application that meets the fundamental requirements for a positive registration decision based on the submitted documents, subject to post-approval commitments such as additional data/studies that do not affect the approval decision; the applicant should issue the MA and print the registration certificate within three months of the approval notification.
- C. Conditionally approved for effectively two years and subjected to specific obligations (please refer to the [conditional approval for human use](#))
- D. Rejected

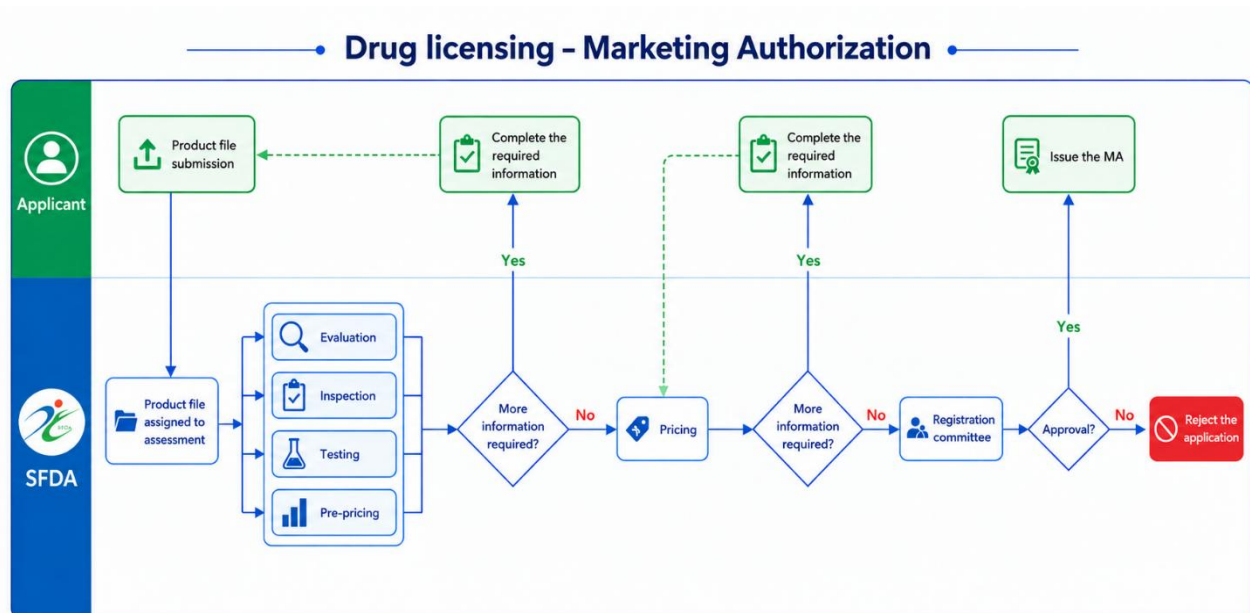


Figure 2: Assessment procedure for marketing authorization application

Appeal Process:

An applicant has the right to appeal the decision within 60 calendar days of notification, for more information refer to [The Policy of Appeal to Drug Sector Decisions](#).

However, the appeal application will not be accepted if it is submitted to address deficiencies in the original registration application. The applicant may submit up to two appeals, provided that no more than one appeal is submitted during each designated appeal period (i.e., the first appeal period and the second appeal period).

9.2 Variations of MAA

A process of informing the SFDA of any minor or major changes in the product that is already registered in Saudi Arabia. Applicants must follow [Guidelines for variations requirements](#) regarding variation classification, categorization and submission requirements.

Types of Variations:

A. Minor variations

- Type IA: Such minor variations do not require prior approval before implementation (“Do and Tell” procedure). Type IAIN variations should be submitted immediately, within 14 days following implementation. Other type IA variations, however, can be compiled in a single variation application, to be submitted to the SFDA no later than January 31st of each year.
- Type IB: minor variations that must be submitted to the SFDA by MAH before implementation, but do not require a formal approval. However, the MAH must wait a period of 60 working days to ensure that the application is deemed acceptable by the SFDA before implementing the change (“Tell, Wait and Do” procedure).

B. Major variations

- Type II: major variations in which there might be a significant impact on the Quality, Safety or Efficacy of a pharmaceutical product and require prior approval before implementation.

Submission

Applicant shall fill out the [application for variation to a marketing authorization](#).

Business Validation:

The application will be reviewed by the RA Team and validated to ensure that all information provided complies with the relevant requirements and guidelines.

1. If any information is missing or incorrect, an electronic inquiry will be forwarded to the applicant through the SDR system; then the status will be changed to (the file is incomplete). The applicant will be given an opportunity to complete the file within 30 working days. During the validation phase, the applicant will have a maximum of two waves to respond to inquiries and provide the requested information.
2. The completed application will proceed to the Assessment; and the status will be changed to (at the relevant department).

The variation application will be rejected in the following cases:

- Failure to respond within 30 working days.
- If the applicant chose incorrect variation type according to the [Guidelines for variations requirements](#), fails to include the required documents or justification for the absence of a document according to relevant SFDA guidelines, or exceeds the number of waves available (see appendix I: performance target).

The company may resubmit the request as described in the User Manual on the eSDR system's website <https://esdr.sfda.gov.sa/>.

Assessment

Depending on the type of variation, one or more departments may review the variation application.

Evaluation / Inspection:

1. The variation request will be distributed to the relevant related department – as required.
2. For the inspection related requests: the department will check the approval statues of the manufacturing line, if not approved:
 - An inspection visit will be scheduled based on the availability of both inspectors and the company.
 - Following the visit, an inspection report will be sent to the company (please, refer to the guidance of [Good Manufacturing Practice for Medicinal product](#)).

3. If additional information or clarification is required, an electronic inquiry will be posted through [eSDR system](#). The response should be received within 60 working days. Reports (recommendation for approval or rejection) will be collected by the RA. The request will be forwarded (if needed) to pricing and registration committee depending on the type of variation.

Pricing

1. The Pricing Department handles all variation requests that require pricing review in accordance with “[Pricing rules for pharmaceutical products](#)”.
2. If additional information or clarification is required, an electronic Inquiry will be posted through [eSDR system](#). A response should be submitted within 60 working days.
3. The suggested price will be forwarded to the Registration Committee.

The applicant will have a maximum of three (3) waves for assessment and pricing, and the SFDA has the right to take a decision at any time during the assessment phase, regardless of the number of remaining waves.

The variation request will be rejected in the following cases:

- Failure to respond within 60 working days.
- If the applicant provided unsatisfied response/ requirements or did not include the required documents or justification for the missing documents according to relevant SFDA guidelines.

Response to Inquiry:

The applicant shall provide the following when responding to [eSDR system](#) 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 J)

The [eSDR system](#) enables the applicant to receive inquiries after being evaluated by all departments at once (as a wave).

Variation Decision:

When the assessment process is completed, the applicant shall receive a notification through [eSDR system](#) noting the decision:

A. Accepted

If the request is accepted and the variation affects the registration certificate, the applicant should issue a new certificate, for more information about how to print Certifications please refer to *The User Manual* at [eSDR system](#)

B. Partially accepted:

In case of accepting some of the submitted variations, the Company will be informed of the accepted and rejected variations via Committee Decision which can be found under the (My Request) tap in eSDR system.

C. Or rejected; the company has the right to submit a new variation request on [eSDR system](#) supported by all relevant evidence.

General notes:

- For variation affecting product price, the Registration Committee will review the variation request to determine approval or rejection, or to request further information (if needed). Once the SFDA CEO approves the meeting minutes, the applicant will be notified of the decision through [eSDR system](#).

For applications including more than one type of variation, the performance target will be calculated based on the longest procedure timeline. For example: if an application includes type 1B and type II, the total performance target for the application is 140 working days.

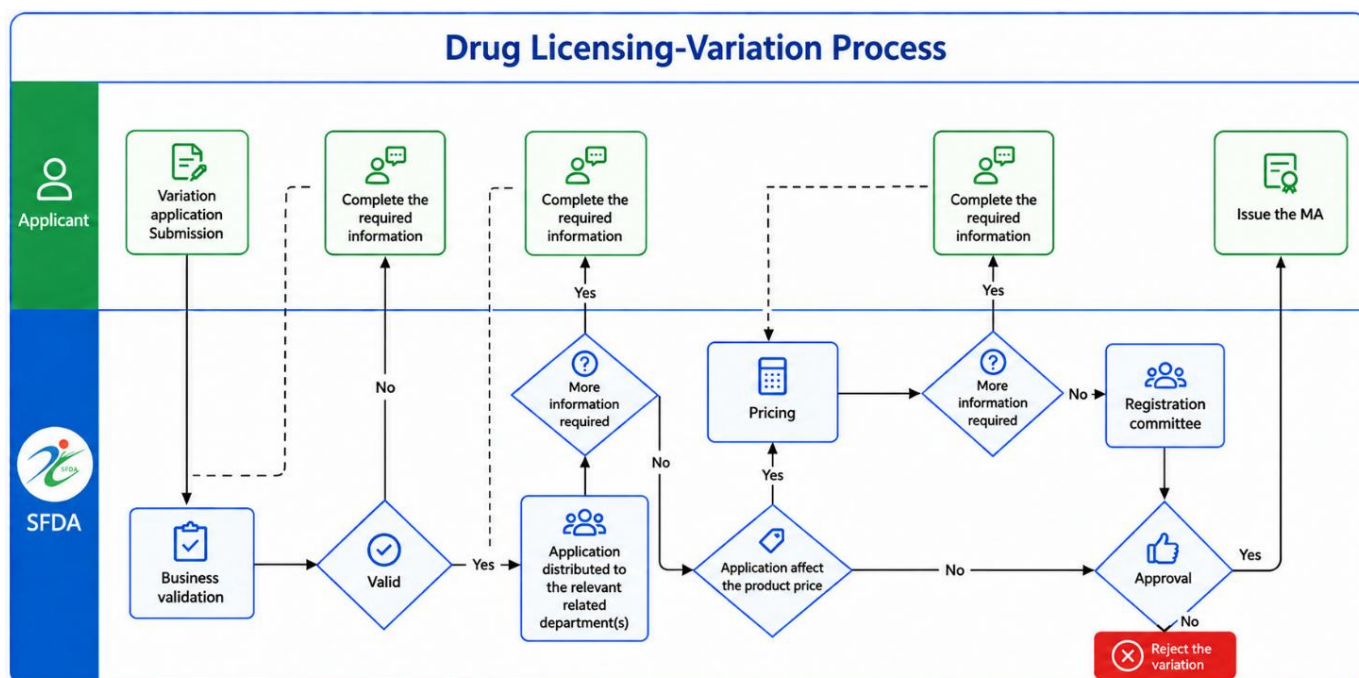


Figure 3: Variation procedure for marketing authorization application

9.3 Renewal of Marketing Authorization

The renewal application shall be submitted through the SDR system every five years. Renewal request must be submitted at least six months prior to the certificate expiry date.

The applicant shall upload the renewal file in accordance with the relevant guidelines:

- For human medicinal products, the renewal file shall follow the requirements described in the [data requirements for the renewal of marketing authorizations for human medicinal products](#).
- For veterinary medicinal products, the renewal file shall follow the requirements described in the [data requirement for renewal the marketing authorizations of veterinary medicinal products](#).
- For Herbal and Health Products, the renewal file shall follow the requirements described in the [data requirements for the renewal of marketing authorizations \(herbal and health products\)](#).

Submission

The applicant shall fill out the application form through [eSDR system](#).

Business Validation:

The product file will be validated to ensure that all provided information complies with the requirements and guidelines. If any information is missing or incorrect, an Inquiry will be forwarded to the applicant through [eSDR system](#). The applicant will be given an opportunity to complete the file within 30 working days. Once the file is complete, it will proceed to the Pricing Department

The renewal request will be rejected in the following cases:

- Failure to respond within 30 working days.
- Failure to provide acceptable clarifications.

The company may resubmit the request as described in the User Manual on the eSDR system's website <https://esdr.sfda.gov.sa/>.

Pricing

1. The Pricing Department will review the price in accordance with the “[Pricing rules for pharmaceutical products](#)”.
2. If additional information or clarification is required, an inquiry will be posted through [eSDR system](#). A response should be submitted within 60 working days.
The approved price will be forwarded to the product licensing

Applicant can print the certificate through [eSDR system](#) and click “my product” at the top of the page.

The renewal request will be rejected in the following cases:

- Failure to respond within 60 working days.
- Failure to provide acceptable clarifications.

• Drug Licensing-Renewal Process •

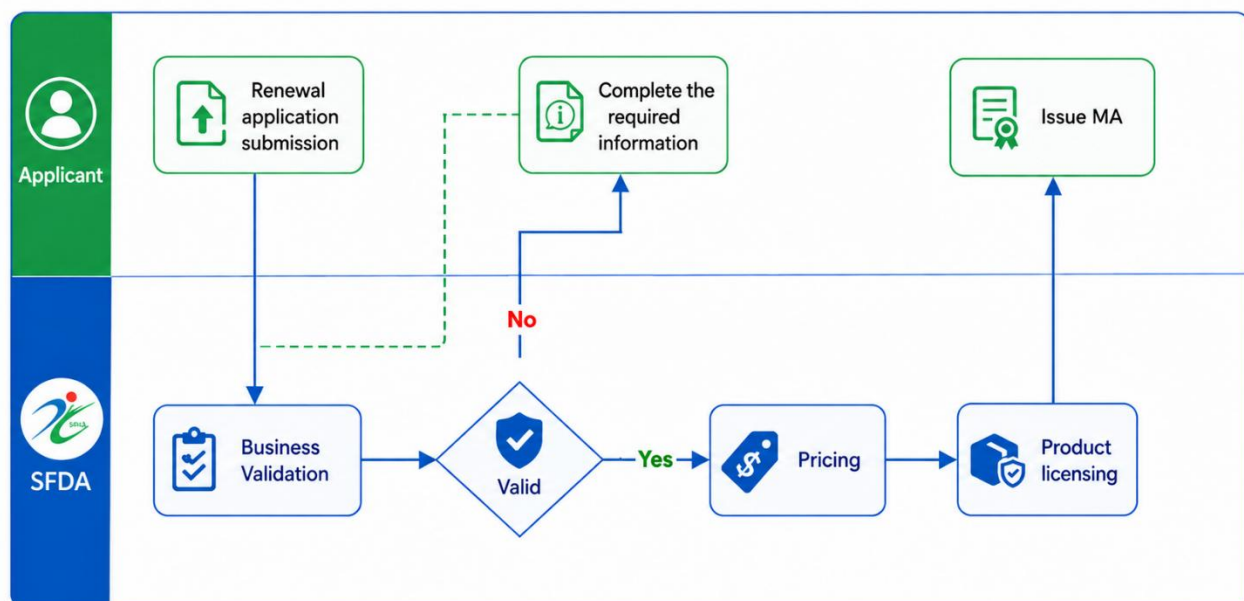


Figure 4: Renewal procedure for marketing authorization application

Appeal process:

The applicant has the right to submit an objection request in accordance with [The Policy of Appeal to Drug Sector Decisions](#).

10. MA cessation

The cessation of an application shall be submitted through the SDR system, attaching technical file for the product to be ceased according to the file structure for each product type. The technical file must include the following contents:

- Cover Letter
- A signed and sealed [Permanent Cessation of Marketing of Medicinal Product form](#) for each product, to be included in section 1.2 of the CTD file.
- A letter from the MAH stating the cessation request, to be included in the Additional Data folder.

Review and Timeline

- Cessation requests will be referred to the relative departments for review.
- Upon review completion the request will be forwarded to committee for the final decision

- Review period: 60 working days from the date the request is complete and referred for review.

Important notes before submitting

- Carefully state the reason for cessation, as the company will be contacted to discuss the reasons and address the challenges, if possible.
- If the reason for cessation is a manufacturing cessation, the applicant recommended to clearly state the reasons preventing the transfer of production to an alternative manufacturing site.
- If the product continues to be registered in other countries, clear justifications must be provided for its cessation in the Saudi market.
- SFDA encourages companies to request a pre-submission meeting before submitting the application to discuss options and address challenges, if any.

APPENDICES

Appendix A: Related documents

Please refer to SFDA's website for the latest versions of the documents

- The Implementing Regulations of the Law of Pharmaceutical and Herbal Establishments and Products
- Registration Rules of Pharmaceutical, Herbal and Health Product Manufacturers and their Products
- Veterinary Products Act and Regulation in GCC
- Pricing rules for pharmaceutical products
- Data Requirements for Human Drugs Submission
- Data Requirement for Herbal & Health Products Submission
- Data Requirements for the Renewal of Marketing Authorizations for human medicinal products
- Data Requirements for the Renewal of Marketing Authorizations Herbal and Health Products
- Guidelines for Variation Requirements
- Data Requirements for Veterinary Medicinal Products
- Data Requirement for Veterinary Herbal Medicinal Products
- Data Requirements for Renewal the Marketing Authorizations of Veterinary Medicinal Products

Appendix B: Rolling Submission

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 should be preferably in eCTD format and includes an application form to the newly available data, All submissions must comply with [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 for subsequent study data submissions (planned and in progress), 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 the SFDA considers that the data package is sufficiently complete to proceed to formal regulatory submission, the applicant is expected to submit a formal Conditional Approval application. 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 C: Designation Request

نموذج طلب تعيين					
☐ طلب جديد ☐ متابعة ☐ استشارة					النشاط التنظيمي
☐ مبتكر ☐ حيوي ☐ جنيس					نوع المستحضر
	الاسم التجاري		الاسم العلمي		Sub-Product Number
	رقم التواصل		مقدم الطلب	☐ نعم ☐ لا	المستحضر تحت الدراسة
	في حال الإجابة بنعم (يرجى تحديد الدول)	☐ نعم ☐ لا	هل المستحضر تحت الدراسة عالمياً	☐ نعم ☐ لا	هل المستحضر مسجل عالمياً
☐ طلب تعيين لمساري التجسير والتوثيق ☐ طلب تعيين دواء واعد ☐ طلب تعيين دواء يتيم ☐ طلب تعيين دواء ذو استخدام راسخ (well - established use)					الموضوع
☐ مصنع محلي ☐ مصنع أجنبي ☐ وكيل ☐ مستودع ☐ مكتب استشارات (يتم ذكر اسم المكتب وإرفاق التفويض)					مقدم الطلب
					وصف الطلب

Appendix D: 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. VNeS for Veterinary Products.

1. Common Technical Document (CTD).

The **Herbal and Health product**, the applicant shall follow the structure of Common Technical Document (CTD):

- 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

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.

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.

3.2 Presenting the Product Submission Regarding the Related Regulatory activity

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

- To submit multi applications for 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 multiple 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 products that have already been submitted, if 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 E: 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. Detailed requirements for Veterinary Non-eCTD electronic Submissions (VNeeS) will be issued by the SFDA at a later date.

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 3.2. Please refer to the [GCC specification for veterinary products](#).

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.

Appendix F: File Formats

General Requirements:

Generally, relevant information must be structured according to the Common Technical Document (CTD) requirements. 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 Adobe or any other specific company to produce PDF documents. PDF is accepted as the 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 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 assist 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) is essential for achieving pure electronic communication between the pharmaceutical industry and regulatory agencies, particularly for authentication of electronic submissions and their contained therein.

Appendix G: Document Requirements

1. Legibility and Size:

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

2. Language:

The supporting information and documents – such as certificates and approval letters– must be provided either in Arabic or English languages. Documents issued in other languages must be accompanied by a certified English translation from an authorized translation office. Such translations must be authenticated by an Apostille or the Saudi Embassy in the country of origin.

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/>.

4. System Compatibility:

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

While the SFDA maintains computer configurations and IT infrastructure in line with common office standards, submitted electronic information must be compatible not only with the latest operating systems but also with a reasonable number of previous Windows systems versions.

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 are the sole responsibility of the SFDA. In this regard, the SFDA will take appropriate measures to prevent loss, unauthorized duplication and/or access or theft of regulatory information presented in both paper and electronic format that are distributed throughout the SFDA.

6. Password Protection:

One-time security settings or password protection for electronic submission 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. Once submitted, the Internal security and access control processes of the SFDA will ensure the integrity of the submitted files.

7. Virus Protection:

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

Upon receipt of the submission, the SFDA will perform an internal virus scan. The detection of a virus may constitute grounds for the immediate rejection of the electronic submission.

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](#).

Appendix H: Required Quantities of Samples

The following table shows the required quantities of the samples for different dosage forms:

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. TachoSil)	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 match the batch number stated in 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 I: Performance Targets

- The performance target in any step will STOP if a clarification or information is needed from the applicant, and resume once the response received.
- Days are counted as working days.
- All timelines shown below include only the actual assessment time and do not include the validation phase or the time taken for the registration committee to issue a decision

➤ New Marketing Authorization Application

Registration pathway	Performance target
Regular A: This pathway applies to the following products - Innovative and biological products that are not eligible under any other pathways and registered in SRA. - Fourth and subsequent biosimilar products and registered in SRA. - Second to fifth generic products. - Herbal and health products. - Well -Established Use Products	205
Regular B: This pathway applies to the following products - Innovative and biological products that are not eligible under any other pathways and <u>not</u> registered in SRA. - Fourth and subsequent biosimilar products and <u>not</u> registered in SRA. - Sixth and subsequent generic products. - Synthetic peptides products	250
Priority Review This pathway applies to the following products: - First generic products. - First, second and third biosimilars. - Products within the Incentive program, product eligibility will be assessed on a case-by-case basis, please refer to the link for more details. - Products within RAID program. - Products within NADR program.	160

- Products that meet the three conditions stated in the Pharmaceutical Industry Transfer and Localization Initiative: 1. The product must be one of the following: ○ Innovative (originator) Drug. ○ Biological products or biosimilar. ○ First, Second, or third generic Drug. ○ Drugs included in the incentive list. ○ Pharmaceutical products targeted for industrial localization opportunities within government entities 2. Manufacturing must take place entirely within the Kingdom, with the manufacturer carrying out all production steps locally (Full Manufacturing); however, for biological products, partial manufacturing—comprising one of the key production steps (API manufacturing, formulation, or fill-and-finish, but excluding secondary packaging)—may be accepted. 3. The local manufacturer must be the sole source for manufacturing the product. In addition to the products comply with criteria stated in the Guidance for Priority Review of Product Registration.	
Verification	30
Abridged	60
Breakthrough medicines	60

➤ **Variation Application**

Variation type	Performance target
Minor variations	
Type IA	30
Type IB	60
Major variations	
Regular Type II	140
Priority Type II	100
Abridged Type II	60

➤ **Renewal Application**

Renewal	Performance target
Renewal	40

Appendix J: 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

سلمه الله

سعادة نائب الرئيس التنفيذي لقطاع الدواء

الهيئة العامة للغذاء والدواء

السلام عليكم ورحمة الله وبركاته

نتقدم إلى سعادتك بطلب الحصول على تسجيل المستحضر الموضحة بياناته أدناه، علماً 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	☐ Regular pathway ☐ Breakthrough Designation ☐ Orphan Designation ☐ Verification Designation ☐ Abridged Designation ☐ Priority designation ☐ GCC ☐ 2nd Brand	نوع التقديم
Company Representative		ممثّل 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 سعادتك خالص التحية والتقدير،،،

مدير شركة

الاسم:

التوقيع

التاريخ

ختم الشركة

COVER LETTER FOR POST REGISTRATION ACTIVITIES

هذا النموذج يساعد المتقدم على كتابة خطاب تغطية عند تقديم أنشطة تنظيمية بعد التسجيل
This is a template to assist the applicant in writing a cover letter for Post registration activities

سلمه الله

سعادة نائب الرئيس التنفيذي لقطاع الدواء

الهيئة العامة للغذاء والدواء

السلام عليكم ورحمة الله وبركاته

نتقدم إلى سعادتك بطلب الموافقة على نشاط تنظيمي للمستحضر حسب البيانات الموضحة أدناه، علماً بأنه تم إرفاق جميع البيانات والدراسات المطلوبة مع هذا الخطاب:

Sub-Product No.		الرقم المرجعي الفرعي
Request Number		رقم الطلب
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*
Request Type	☐ Renewal ☐ Variation/ Annual report ☐ Cessation	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

سلمه الله

سعادة نائب الرئيس التنفيذي لقطاع الدواء

الهيئة العامة للغذاء والدواء

السلام عليكم ورحمة الله وبركاته

نتقدم إلى سعادتك بالرد على الملاحظات/ النواقص المرسلة لنا على نظام سدر للمستحضر الموضحة بياناته أدناه، علماً 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	☐ Regular pathway ☐ Breakthrough Designation ☐ Orphan ☐ Verification Designation ☐ Abridged Designation ☐ Designation Priority designation ☐ GCC ☐ 2nd Brand
Company Representative	
Email	
Mobile No.	

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

وتقبلوا سعادتك 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 التشغيل
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

Appendix K: Types of application for specific Product:

Specific application categories are required for a marketing authorization submission, based on the nature and characteristics of the product. Applicants must correctly classify their product to ensure they select the appropriate submission.

Note: Incorrect classification may lead to delays in the regulatory review process.

Product	Type of application
Synthetic peptides	Generic Drug
Well -Established Use	New Drug - Known Active Substance