الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Regulatory Framework for Drugs Approval

Version 6.3

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Regulatory Framework for Drugs Approval

Version 6.3

Saudi Food & Drug Authority

Drug Sector

For Inquiries	*SDR.Drug@sfda.gov.sa*
For Comments	*Drug.Comments@sfda.gov.sa*

Please visit SFDA's website at for the latest update

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	15 March 2008	Initial draft for internal consultation
2.0	Licensing department	15 July 2008	Published for comments
3.0	Licensing department	19 January 2009	Revised draft
4.0	Licensing department	5 July 2009	Final version posted
5.0	Regulatory Affairs	16 March 2014	Update
6.0	Executive Directorate of Regulatory Affairs	17 March 2019	Update and published for comments purposes
6.1	Executive Directorate of Regulatory Affairs	1 September 2020	Update
6.2	Executive Directorate of Regulatory Affairs	12 October 2021	Update
6.3	Executive Directorate of Regulatory Affairs	23 February 2022	Update (Next page shows the updated details)

What is New in version no. 6.3?

The following table shows the update to the previous version:

Section	Description of change
Glossary	**<u>Update:</u>** Glossary - Stringent Regulatory Authority (SRA) ➢ **<u>For human products:</u>** USFDA, EMA, MHRA (UK), Swissmedic, Health Canada, TGA (Australia) and PMDA (Japan).

Table of Contents:

Acronyms and Abbreviations

API	Active Pharmaceutical Ingredients
ATC	Anatomical Therapeutic Chemical Classification System
ATC vet	Anatomical Therapeutic Chemical Classification System for veterinary products
BSE	Bovine spongiform encephalopathy
CEO	Chief Executive Officer
COO	Country of Origin
CPP	Certificate of Pharmaceutical Product
CTD	Common Technical Document
EMA	European Medicines Agency
KSA	Kingdom of Saudi Arabia
MA	Marketing Authorization
MAA	Marketing Authorization Application
MAH	Marketing Authorization Holder
MHRA	Medicines and Healthcare products Regulatory Agency
NCE	New Chemical Entity
NPC	National Pharmacovigilance Center
PMDA	Pharmaceuticals and Medical Devices Agency
RA	Regulatory Affairs
SDR	Saudi Drug Registration system
SFDA	Saudi Food and Drug Authority
Swissmedic	Swiss Agency for Therapeutic Products
TGA	Therapeutic Goods Administration
TSE	Transmissible Spongiform Encephalopathy
US FDA	United States Food and Drug Administration

Glossary

Applicant	The company or its representative
Biologics	Medicinal products derived from a variety of natural sources or produced by biotechnology methods and other cutting-edge technologies. They include a wide range of products such as vaccines, blood and blood components, allergenics, advanced therapy medicinal products (ATMPs), recombinant proteins and biosimilars
Biosimilars	Therapeutic proteins produced by recombinant DNA technology or gene expression method following the footsteps of one licensed reference biotechnological product. They are complex and heterogeneous in their nature; hence they are not considered generics, but as closely similar to the innovator's drug as possible
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	Refer to *the SFDA classification guidance*
Herbal product	Any finished labeled medicinal products that contain as active ingredients aerial or underground parts of plants or other plant materials or the combination of them, whether in crude state or plant preparation that is used to treat or prevent diseases or ailments or to promote health and healing. Plant materials include juices, gums, fatty oils and any other substance of this nature
Inquiry	A questions or clarifications posted in SDR system to be responded by the applicant
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.
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	*The Rules for Pharmaceutical Products Pricing* 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)	**For human products:** USFDA, 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), 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).
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	A process of informing SFDA of any minor or major changes in the drug product.
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.

1. INTRODUCTION

The Drug Sector in Saudi Food & Drug Authority (SFDA) has developed this administrative document to provide assistance for stakeholders on how to submit applications for various types of drug products and the procedure to authorize the applications.

Besides the Market Authorization Application (MAA) of various types of drug products, it also describes variations applications and renewal of MAA. Various application forms and time-frame for processing applications to marketing the product in Saudi Arabia are also included in this document.

2. Scope:

This framework applicable to all types of drug product submitted for registration, variation or renewal.

3. NEW MARKETING AUTHORIZATION APPLICATION (MAA) [1]

The MAA of pharmaceutical product will be subjected to the followings processes:

3.1. Submission

The process of submitting a new MAA consists of two steps:

3.1.1. Online submission

1. The applicant shall apply through SDR system to fill the application form and pay the fees.
2. Upload the product file; The components of the file shall follow the requirements and guidelines published on SFDA website.

3.1.2. Validation

The product file will be validated in technical and business bases to ensure the applicant fulfills the requirement. The validation involves two steps:

3.1.2.1. Technical validation

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

3.1.2.2. Business validation

1. The product file will be validated to ensure that all information provided is according to the requirements and guidelines.
2. If any information is missing or incorrect, an electronic inquiry will be forwarded to the applicant through the SDR system. The applicant will be given an opportunity to complete the file within 30 working days.
3. The completed file will proceed to the next steps for Assessment (section 3.2).

[1] Performance targets for every step are provided at the end of this part (section 3.5) for all pathways (Regular, Priority, Verification and Abridged)

The registration request will be rejected in the following cases:

- No response from the applicant within 30 working days.
- Failure to provide acceptable clarifications after the third wave.

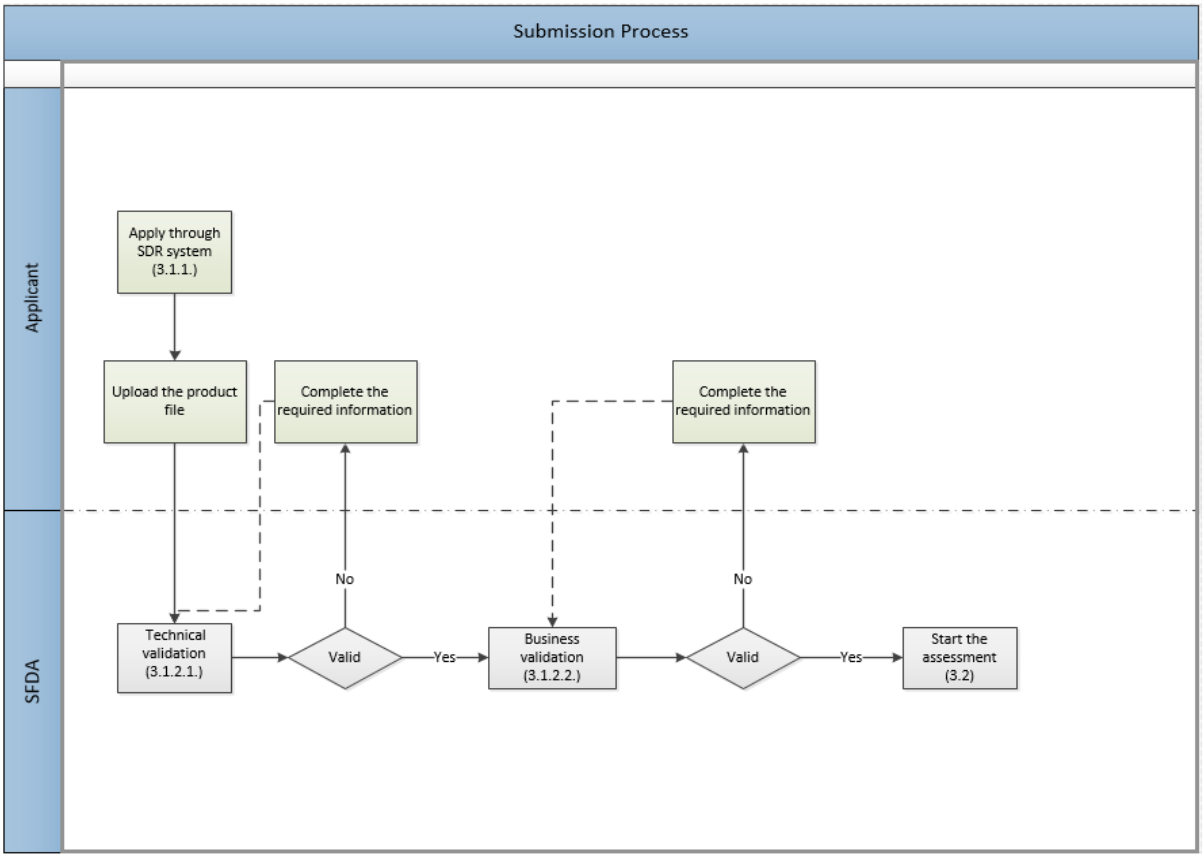

Figure 1 Schematic chart of the submission process (section 3.1)

3.2. Assessment

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

3.2.1. Evaluation / Inspection

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

- Visit will be scheduled for inspection depending on the time available for both inspectors and the company.
- After the visit, the inspection report will be sent to the company (please, refer to *the Good Manufacturing Practice for Medicinal product*).

2. If more information or clarification is required, an electronic inquiry will be posted through SDR system as one wave for evaluation and inspection. A response should be received within 60 working days.
3. Once the evaluation and inspection are completed, the registration request will be forwarded to Pricing (section 3.3)

3.2.2. Testing

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

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

3.3. Pricing

1. The Pricing Department will review product's price according to the "*SFDA's pricing rules*".
2. If more information or clarification is required, an electronic inquiry will be posted through SDR system. A response should be received within 60 working days.
3. The product's price will be forwarded to Registration Committee (section 3.4).

The registration request will be rejected in the following cases:

- No response from the applicant within 60 working days.
- Failure to provide acceptable clarifications after the 4th wave.

Important Note:

The applicant will have a total of four (4) waves for Evaluation / inspection and Pricing.

3.4. Product licensing

1. The Registration Committee will review the registration request for approval, rejection or ask for further information (if needed).
2. The SFDA CEO will approve the meeting minutes.
3. For approved registration request, the applicant will be notified through SDR system to issue the MA.

Appeal Process:

The applicant has the right to appeal against any decision within **60** calendar days, for more information refer to *Guidance for Submission*.

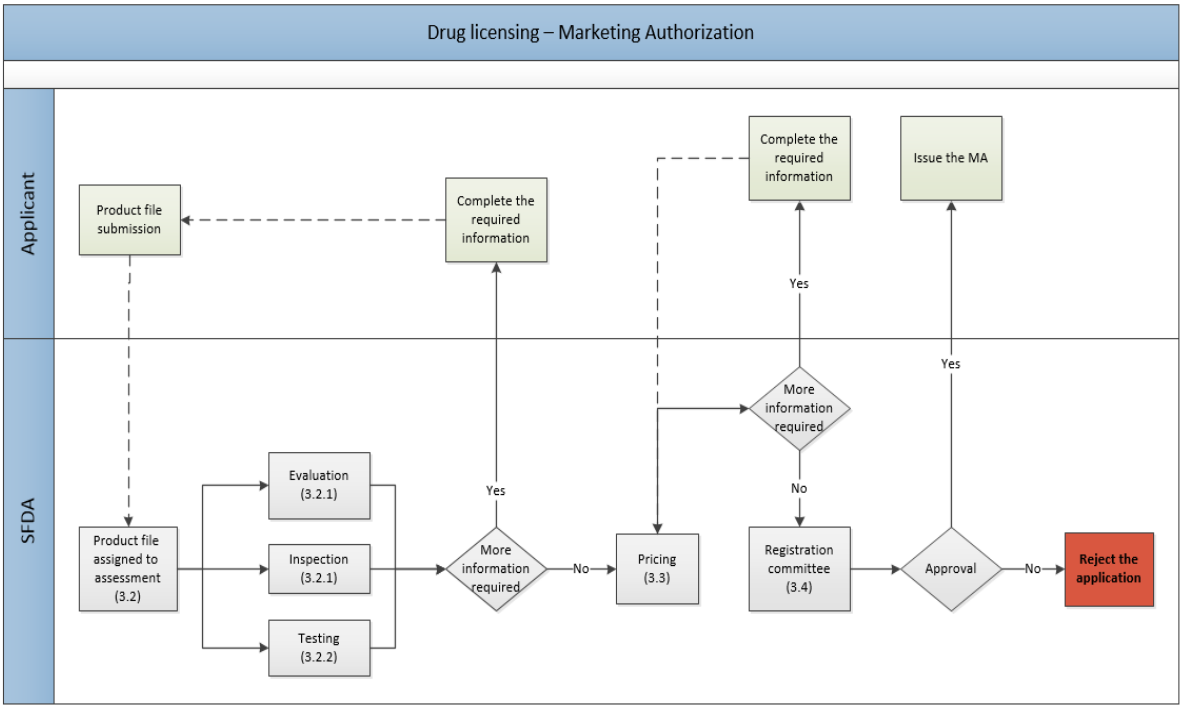

Figure 2 schematic figure showing the different levels for getting a marketing authorization (section 3.2, 3.3 and 3.4)

3.5. Registration performance targets

- The performance target in any step will STOP if a clarification or information is needed from the applicant, and resume after receiving the response.
- All days are considered as working days.
- Total Performance Target calculated without the Business Validation for all pathways

3.5.1. Regular review pathway

Registration phases	Technical Validation	Business Validation	Evaluation / Inspection	Pricing	Product licensing	Total Performance Target
	section 3.1.2.1	section 3.1.2.2	section 3.2.1	section 3.3	section 3.4	
No. of Waves	-	3	4		-	
Human Generic	-	10	120	20	15	**155**
Human New Drugs registered in SRA	-	10	245	20	15	**280**
Human New Drugs not registered in SRA	-	10	370	20	15	**405**
Human Biologics registered in SRA	-	10	245	20	15	**280**
Human Biologics not registered in SRA	-	10	370	20	15	**405**
Radiopharmaceuticals	-	10	245	20	15	**280**
Veterinary Generics	-	10	150	-	15	**165**
Veterinary New Drugs registered in SRA	-	10	245	-	15	**260**
Veterinary New Drugs not registered in SRA	-	10	370	-	15	**385**
Veterinary Biologics registered in SRA	-	10	245	-	15	**260**
Veterinary Biologics not registered in SRA	-	10	370	-	15	**385**
Herbal & health products	-	10	120	20	15	**155**

3.5.2. Priority review pathway (40% reduction)[2]:

Registration phases	Technical Validation	Business Validation	Evaluation / Inspection	Pricing	Product licensing	Total Performance target
	section 3.1.2.1	section 3.1.2.2	section 3.2.1	section 3.3	section 3.4	
No. of Waves	-	3	4		-	
Human Generic	-	10	72	12	9	**93**
Human New Drugs registered in SRA	-	10	147	12	9	**168**
Human New Drugs not registered in SRA	-	10	222	12	9	**243**
Human Biologics registered in SRA	-	10	147	12	9	**168**
Human Biologics not registered in SRA	-	10	222	12	9	**243**
Radiopharmaceuticals	-	10	147	12	9	**168**

3.5.3. Verification & abridged pathway[3]:

Registration phases	Technical validation	Business validation	Evaluation / Inspection	Pricing	Product licensing	Total Performance target
	section 3.1.2.1	section 3.1.2.2	section 3.2.1	section 3.3	section 3.4	
No. of Waves	-	3	4		-	
Verification	-	5	15	5	10	**30**
Abridged	-	5	40	10	10	**60**

[2] Refer to the *Guidance for Priority Review of Product Registration*
[3] Refer to the *Registration According to Verification and Abridged*

4. VARIATION OF MARKETING AUTHORIZATION[4]

Any changes on a registered product has to be submitted to the SFDA as a Variation of MAA. The variations are classified into two main categories[5]:

A. Minor variations

- **Type IA:** Such minor variations do not require prior approval before implementation ("**Do and Tell" procedure**). Type IA_{IN} 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.

The variation request subjects to the following process:

4.1. Submission

The process of submitting a variation of MAA consists of two steps**:**

4.1.1. Online submission

1. The applicant shall apply through SDR system to fill the application form and pay the fees.
2. Upload the product file; The components of the file shall follow the requirements and guidelines published on SFDA website

[4] Performance targets for each step are provided at the end of this part (section 4.5)
[5] Refer to *the GCC Guidelines for Variation Requirements*

For applications made via the new SDR system, three parallel variation applications can be submitted at a time, each includes administrative, quality or safety variations. Each category of variations will be assigned to the related departments.

4.1.2. Business Validation

1. The product file will be validated to ensure that all information provided is according to the requirements and/or guidelines.
2. If any information is missing or incorrect, an electronic inquiry will be forwarded to the applicant through the SDR system. The applicant will be given an opportunity to complete the file within 30 working days.
3. The completed file will proceed to the next step for Assessment (section 4.2).

The variation request will be rejected in the following cases:

- No response from the applicant within 30 working days.
- Failure to provide acceptable clarifications after the second wave.

4.2. Assessment

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

4.2.1. Evaluation / Inspection:

1. The variation request will be distributed to the relevant related department – as needed;
    - For the inspection related requests: the department will check the approval of manufacturing line, if not approved:
        - Visit will be scheduled for inspection depending on the time available for both inspectors and the company.
        - After the visit, the inspection report will be sent to the company (please, refer to the guidance of Good Manufacturing Practice for Medicinal product).
2. If more information or clarification is required, an electronic inquiry will be posted through SDR system. The response should be received within 60 working days.

3. Reports (recommendation for approval or rejection) will be collected by the RA.
4. The reports will be forwarded (if needed) to pricing (section 4.3) and registration committee (section 4.4) depending on the type of variation.

4.3. Pricing

1. The Pricing Department handles all variation requests that require pricing review according to "*SFDA's pricing rules*".
2. If more information or clarification is required, an electronic Inquiry will be posted through SDR system. A response should be received within 60 working days.
3. The approved price will be forwarded to the Registration Committee (section 4.4).

The variation request will be rejected in the following cases:

- No response from the applicant within 60 working days.
- Failure to provide acceptable clarifications after the third wave.

Important Note:

The applicant will have a total of three (3) waves for Assessment and Pricing

4.4. Product Licensing

- For all variation types except variation affecting product price:
    1. The RA will approve the final report.
    2. Notify the applicant through SDR system.
- For variation affecting product price:
    1. The Registration Committee will review the variation request for approval, rejection or ask for further information (if needed).
    2. The SFDA CEO will approve the meeting minutes.
    3. For approved variation request, the applicant will be notified through SDR system.

General variation notes:

- For applications made via the new SDR system; after the completion of an application of a particular category (by approval or rejection), another application of the same category can be submitted.
- For application includes more than one type of variation, the longest duration in total performance target will be considered. For example: application includes type 1B and type II, the total performance target for the application is 100 working days.

Appeal Process:

The applicant has the right to appeal within 60 calendar days of the SFDA's final decision, for more information refer to Guidance for submission.

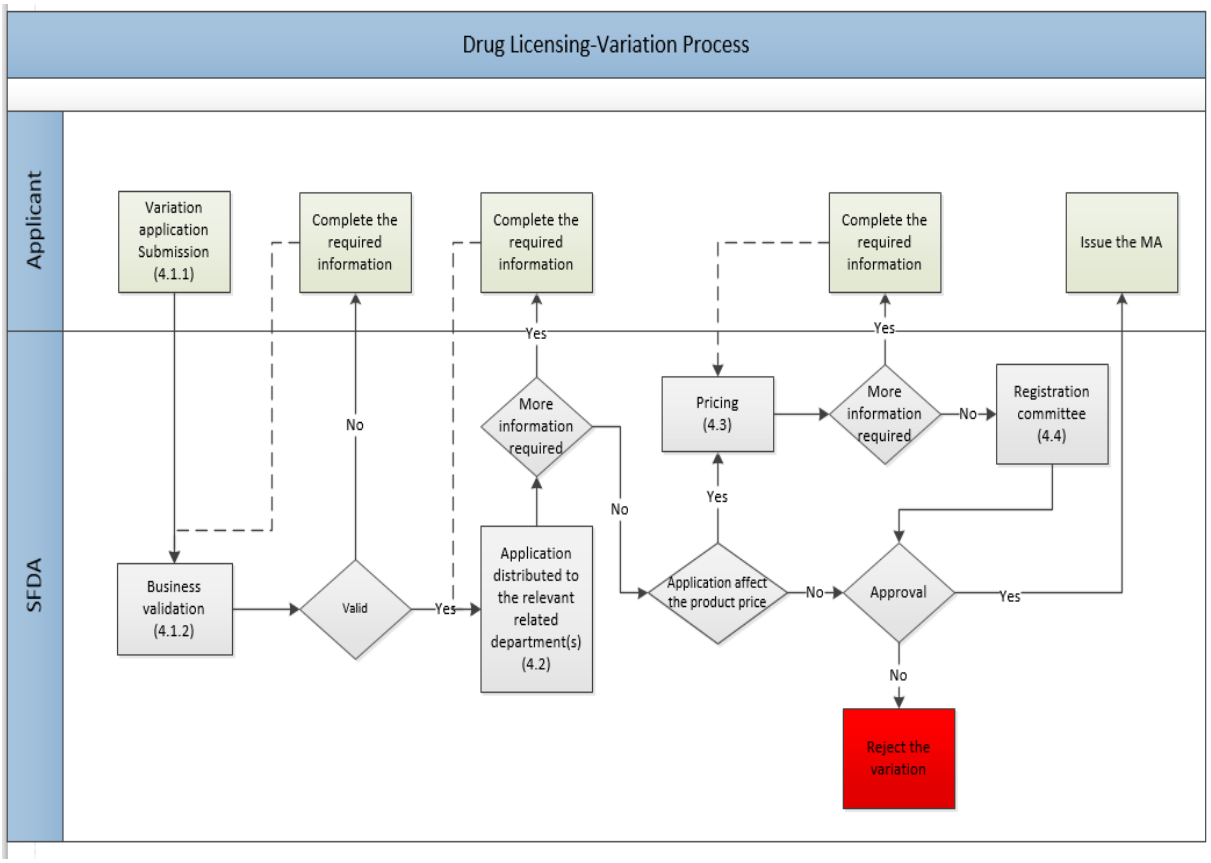

Figure 3 Schematic figure showing the workflow of Variation

4.5. Variation performance targets:

- The performance target in any step will STOP if a clarification or information is needed from the applicant, and resume after receiving the response.
- All days below are considered as working days.
- Total Performance Target calculated without the Business Validation for all types of variations.

Phases	Business Validation	Assessment	Pricing	Product licensing	Total Performance target
	section 4.1.2	section 4.2	section 4.3	section 4.4	
No. of Waves	2	3		-	
Type IA	5	20	-	10	**30**
Type IB	5	40	10	10	**60**
Type II	5	80	10	10	**100**

5. RENEWAL OF MARKETING AUTHORIZATION[6]

An applicant shall submit a renewal request every five years[7]. It is possible to request for renewal within six months of the certificate expiry.

As most of the registered drugs have went through at least one renewal process or have been registered through SDR system; therefore, the renewal process is shorter as follows:

5.1. Submission

The process of submitting a renewal of MA consists of two steps:

5.1.1. Online submission:

1. The applicant shall apply through SDR system to fill the application form and pay the fees.
2. Upload the renewal file; The components of the file shall follow the requirements and guidelines published on SFDA website.

5.1.2. Business Validation:

1. The product file will be validated to ensure that all information provided are according to the requirements and/or guidelines.
2. If any information is missing or incorrect, an electronic Inquiry will be forwarded to the applicant through SDR system. The applicant will be given an opportunity to complete the file within 30 working days.
3. The completed file will proceed to the Pricing Department (section 5.2).

The renewal request will be rejected in the following cases:

- No response from the applicant within 30 working days.
- Failure to provide acceptable clarifications after the first wave

[6] Performance targets for each step are provided at the end of this part (section 5.4)

[7] For Human Medicinal products refer to the *GCC Data Requirements for the Renewal of MA, For* Veterinary Medicinal products refer to the *Data Requirements for Renewal the MA of Veterinary Medicinal Products*

5.2. Pricing

1. The Pricing Department will review the price according to the “SFDA's pricing rules”.
2. If more information or clarification is required, an electronic inquiry will be posted through SDR system. A response should be received within 60 working days.
3. The approved price will be forwarded to the product licensing (section 5.3).

The renewal request will be rejected in the following cases:

- No response from the applicant within 60 working days.
- Failure to provide acceptable clarifications after the first wave.

5.3. Product Licensing

1. The RA will issue the renewal of MA.
2. The applicant will be notified through SDR system.

Important Note:

The rejected renewal applications obligate the applicant to submit a new one.

Appeal Process:

The applicant has the right to appeal within 60 calendar days of the SFDA's final decision, for more information refer to Guidance for submission.

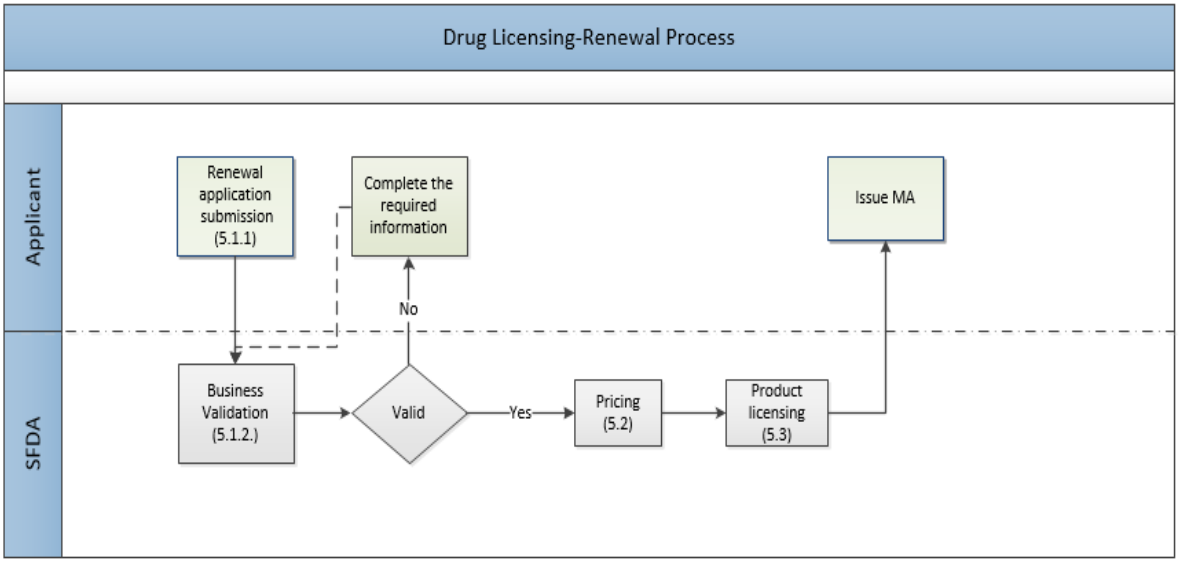

Figure 4 Schematic figure showing the renewal process of a marketing authorization

5.4. Renewal performance targets:

- The performance target in any step will STOP if a clarification or information is needed from the applicant, and resume after receiving the response.
- All days below are considered as working days.
- Total Performance Target calculated without the Business Validation.

Phases of Renewal	No. of Waves	Total Performance target
Business validation (section 5.1.2)	1	5
Pricing (section 5.2)	1	30
Product licensing (section 5.3)	-	10
		Total performance target: 40

6. APPENDIX

6.1. Application Forms

Note:

- **The application forms are available electronically in SDR system. These forms are only for viewing and preparing the required information before starting the process of submission.**

طلب رخصة تسويق مستحضر دوائي

Marketing Authorization Application for Pharmaceutical Product

1 Type of Application

The following sections should be completed where appropriate.

This application concerns:

❍ Human medicinal product

❍ Herbal product

❍ Veterinary product

1.1 Please choose the type of product:

Human medicinal product

❍ New Drug (1.2.1.1)

❍ Biological Drug (1.2.1.2)

❍ Radiopharmaceutical Drug (1.2.1.3)

❍ Generic (Multisource) Drug (1.2.1.4)

❍ Health product (1.2.1.5)

Veterinary product

❍ New Drug (1.2.3.1)

❍ Biological Drug (1.2.3.2)

❍ Generic (Multisource) Drug (1.2.3.3)

❍ Health product (1.2.3.4)

❍ Herbal product (1.2.3.5)

1.2 Please provide the following information for the product:

1.2.1 Human medicinal product

1.2.1.1 **New Drug Application**

❍ New Chemical Entity (NCE)

❍ Known active substance

1.2.1.1.1 Is Saudi Arabia the country of origin (COO)?

❍ Yes (go to section 2)

❍ No (complete the following information)

Product information in COO:

- Trade name:
- Product strength/unit:
- Dosage form:
- Marketing Authorization holder:
    - Name:
    - Address :
        - Line 1:
        - Line 2:
        - Line 3:
        - Postal/Zip code:
        - City:
        - Country:
    - Certifying Authority:
    - Date of authorization (dd/mm/yyyy):
    - Country:

1.2.1.1.2 Is the product registered in GCC?

❍ Yes, please specify the following

- Registration number:
- Trade name:
- Committee meeting number:

❍ No

1.2.1.1.3 Is this product registered in SRA?

❍ Yes, please specify the SRA:

❍ No

1.2.1.1.4 Is this product under-license?

❍ Yes, please specify the MAH:

❍ No

1.2.1.1.5 Is this product from the SFDA exemption list?

❍ Yes, please choose the product:

❍ No

1.2.1.1.6 This product is candidate for:

❍ Abridge registration process

❍ Verification registration process

❍ Priority review process, please specify the SFDA letter number:

❍ None of the above

1.2.1.2 Biological Drug Application

❍ Biological

❍ Biosimilar

❍ Blood product

❍ Vaccine

❍ Others, please specify:

1.2.1.2.1 Is Saudi Arabia the country of origin (COO)?

❍ Yes (go to section 2)

❍ No (complete the following information)

<u>Product information in COO:</u>

- Trade name:
- Product strength/unit:
- Dosage form:
- Marketing authorization holder:
    - Name:
    - Address :
        - Line 1:
        - Line 2:
        - Line 3:
        - Postal/Zip code:
        - City:
        - Country:
- Certifying Authority:
- Date of authorization (dd/mm/yyyy):
- Country:

1.2.1.2.2 Is the product registered in GCC?

❍ Yes, please specify the following

- Registration number:
- Trade name:
- Committee meeting number:

❍ No

1.2.1.2.3 Is this product registered in SRA?

❍ Yes, please specify the SRA:

❍ No

1.2.1.2.4 Is this product under-license?

❍ Yes, please specify the MAH:

❍ No

1.2.1.2.5 Is this product from the SFDA exemption list?

❍ Yes, please choose the product:

❍ No

1.2.1.2.6 This product is candidate for:

❍ Abridge registration process

❍ Verification registration process

❍ Priority review process, please specify the SFDA letter number:

❍ None of the above

1.2.1.3 Radiopharmaceutical Drug Application

1.2.1.3.1 Is Saudi Arabia the country of origin(COO)?

❍ Yes (go to section 2)

❍ No (complete the following information)

<u>Product information in COO:</u>

- Trade name:
- Product strength/unit:
- Dosage form:
- Marketing authorization holder information in COO:
    - Name:
    - Address :
        - Line 1:
        - Line 2:
        - Line 3:
        - Postal/Zip code:
        - City:
        - Country:

- Date of authorization (dd/mm/yyyy):
- Certifying Authority:
- Country:

1.2.1.3.2 Is the product registered in GCC?

❍ Yes, please specify the following

- Registration number:
- Trade name:
- Committee meeting number:

❍ No

1.2.1.3.3 Is this product registered in SRA?

❍ Yes, please specify the SRA:

❍ No

1.2.1.3.4 Is this product under-license?

❍ Yes, please specify the MAH:

❍ No

1.2.1.3.5 Is this product from the SFDA exemption list?

❍ Yes, please choose the product:

❍ No

1.2.1.3.6 This product is candidate for:

❍ Abridge registration process

❍ Verification registration process

❍ Priority review process, please specify the SFDA letter number:

❍ None of the above

1.2.1.4 Generic (Multisource) Drug Application

1.2.1.4.1 Is Saudi Arabia the country of origin (COO)?

❍ Yes (complete part 1.2.1.4.2)

❍ No (complete the following information):

Product information:

- Trade name:
- Product strength/unit:
- Dosage form:
- Marketing Authorization holder:
    - Name:
    - Address :
        - Line 1:
        - Line 2:
        - Line 3:
        - Postal/Zip code:
        - City:
        - Country:
    - Date of authorization (dd/mm/yyyy):
    - Certifying Authority:
    - Country:

1.2.1.4.2 Reference Product Information:

- Trade name:
- Product strength/unit:
- Dosage form:

1.2.1.4.3 Is the product registered in GCC?

❍ Yes, please specify the following

- Registration number:
- Trade name:

- Committee meeting number:

❍ No

1.2.1.4.4 Is the product a 1st or 2nd Generic?

❍ Yes, please choose:

❍ 1st Generic

❍ 2nd Generic

❍ No

1.2.1.4.5 Is this product a 2nd Brand?

❍ Yes, please choose the Innovator product from the list:

❍ No

1.2.1.4.6 Is this product under-license?

❍ Yes, please specify the MAH:

❍ No

1.2.1.4.7 Is this product from the SFDA exemption list?

❍ Yes, please choose the product:

❍ No

1.2.1.4.8 Is this product candidate for Priority Review process?

❍ Yes, please specify the SFDA letter number:

❍ No

1.2.1.5 Health product Application

1.2.1.5.1 Is Saudi Arabia the country of origin (COO)?

❍ Yes (complete section 2)

❍ No (complete the following information)

<u>Product information:</u>

- Trade name:

- Product strength/unit:
- Dosage form:
- Marketing Authorization holder:
    - Name:
    - Address :
        - Line 1:
        - Line 2:
        - Line 3:
        - Postal/Zip code:
        - City:
        - Country:
    - Date of authorization (dd/mm/yyyy):
    - Certifying Authority:
    - Country:

1.2.1.5.2 Is this product under-license?

❍ Yes, please specify the MAH:

❍ No

1.2.2 Herbal product

Is Saudi Arabia the country of origin(COO)?

❍ Yes (go to section 2)

❍ No (complete the following information)

<u>Product information in COO:</u>

- Trade name:
- Product strength/unit:

- Dosage form:
- Marketing authorization holder information in COO:
    - Name:
    - Address :
        - Line 1:
        - Line 2:
        - Line 3:
        - Postal/Zip code:
        - City:
        - Country:
    - Date of authorization (dd/mm/yyyy):
    - Certifying Authority:
    - Country:

1.2.2.1.1 Is this product under-license?

❍ Yes, please specify the MAH:

❍ No

1.2.3 Veterinary product

1.2.3.1 **New Drug Application**

❍ New Chemical Entity (NCE)

❍ Known active substance

1.2.3.1.1 Is Saudi Arabia the country of origin (COO)?

❍ Yes (go to section 2)

❍ No (complete the following information)

Product information in COO:

- Trade name:

- Product strength/unit:
- Dosage form:
- Marketing Authorization holder:
    - Name:
    - Address :
        - Line 1:
        - Line 2:
        - Line 3:
        - Postal/Zip code:
        - City:
        - Country:
    - Certifying Authority:
    - Date of authorization (dd/mm/yyyy):
    - Country:

1.2.3.1.2 Is the product registered in GCC?

❍ Yes, please specify the following

- Registration number:
- Trade name:
- Committee meeting number:

❍ No

1.2.3.1.3 Is this product registered in SRA?

❍ Yes, please specify the SRA:

❍ No

1.2.3.1.4 Is this product under-license?

❍ Yes, please specify the MAH:

❍ No

1.2.3.1.5 Is this product from the SFDA exemption list?

❍ Yes, please choose the product:

❍ No

1.2.3.1.6 This product is candidate for:

❍ Abridge registration process

❍ Verification registration process

❍ Priority review process, please specify the SFDA letter number:

❍ None of the above

1.2.3.2 Biological Drug Application

❍ Biological

❍ Biosimilar

❍ Blood product

❍ Vaccine

❍ Others (please specify):

Is Saudi Arabia the country of origin (COO)?

❍ Yes (go to section 2)

❍ No (complete the following information)

<u>Product information in COO:</u>

- Trade name:
- Product strength/unit:
- Dosage form:
- Marketing authorization holder:
  - Name:
  - Address :
    - Line 1:

- Line 2:
- Line 3:
- Postal/Zip code:
- City:
- Country:

- Certifying Authority:
- Date of authorization (dd/mm/yyyy):
- Country:

1.2.3.2.1 Is the product registered in GCC?

❍ Yes, please specify the following

- Registration number:
- Trade name:
- Committee meeting number:

❍ No

1.2.3.2.2 Is this product registered in SRA?

❍ Yes, please specify the SRA:

❍ No

1.2.3.2.3 Is this product under-license?

❍ Yes, please specify the MAH:

❍ No

1.2.3.2.4 Is this product from the SFDA exemption list?

❍ Yes, please choose the product:

❍ No

1.2.3.2.5 This product is candidate for:

❍ Abridge registration process

❍ Verification registration process

❍ Priority review process, please specify the SFDA letter number:

❍ None of the above

1.2.3.3 Generic (Multisource) Drug Application

1.2.3.3.1 Is Saudi Arabia the country of origin (COO)?

❍ Yes (complete part 1.3.3.3.2)

❍ No (complete the following information)

Product information:

- Trade name:
- Product strength/unit:
- Dosage form:
- Marketing Authorization holder:
    - Name:
    - Address :
        - Line 1:
        - Line 2:
        - Line 3:
        - Postal/Zip code:
        - City:
        - Country:
    - Date of authorization (dd/mm/yyyy):
    - Certifying Authority:
    - Country:

1.2.3.3.2 Reference Product Information:

- Trade name:
- Product strength/unit:

- Dosage form:

1.2.3.3.3 Is the product registered in GCC?

❍ Yes, please specify the following

- Registration number:
- Trade name:
- Committee meeting number:

❍ No

1.2.3.3.4 Is the product a 1st or 2nd Generic?

❍ Yes, please choose:

❍ 1st Generic

❍ 2nd Generic

❍ No

1.2.3.3.5 Is this product a 2nd Brand?

❍ Yes, please choose the Innovator product from the list:

❍ No

1.2.3.3.6 Is this product under-license?

❍ Yes, please specify the MAH:

❍ No

1.2.3.3.7 Is this product from the SFDA exemption list?

❍ Yes, please choose the product:

❍ No

1.2.3.3.8 Is this product candidate for Priority Review process?

❍ Yes, please specify the SFDA letter number:

❍ No

1.2.3.4 Health product Application

Is Saudi Arabia the country of origin (COO)?

- ❍ Yes (complete section 2)
- ❍ No (complete the following information)

Product information:

- Trade name:
- Product strength/unit:
- Dosage form:
- Marketing Authorization holder:
  - Name:
  - Address :
    - Line 1:
    - Line 2:
    - Line 3:
    - Postal/Zip code:
    - City:
    - Country:
  - Date of authorization (dd/mm/yyyy):
  - Certifying Authority:
  - Country:

1.2.3.4.1 Is this product under-license?

- ❍ Yes, please specify the MAH:
- ❍ No

1.2.3.5 Herbal product Application

Is Saudi Arabia the country of origin (COO)?

- ❍ Yes (complete section 2)
- ❍ No (complete the following information)

Product information:

- Trade name:
- Product strength/unit:
- Dosage form:
- Marketing Authorization holder:
  - Name:
  - Address :
    - Line 1:
    - Line 2:
    - Line 3:
    - Postal/Zip code:
    - City:
    - Country:
  - Date of authorization (dd/mm/yyyy):
  - Certifying Authority:
  - Country:

1.2.3.5.1 Is this product under-license?

- ❍ Yes, please specify the MAH:
- ❍ No

2 Product Information Details

The following sections should be completed where appropriate.

2.1 Product information:

2.1.1 Proposed trade name in English:

2.1.2 Proposed trade name in Arabic:

2.1.3 Product number 1:

2.1.3.1 List the active substance(s):

❍ Single active substance

❍ Multiple active substances

Name of active substance(s)	Operator[8]	Quantity	Unit	Reference/ Monograph standard

2.1.3.2 List the excipient(s):

Name of excipient(s)	Operator[9]	Quantity	Unit	Reference/ Monograph standard

2.1.3.3 Pharmaco-therapeutic group: (Please use current ATC code)

ATC Code	Group

[8] Quantity operator: equal to, less than, more than, less than or equal to, more than or equal to, equivalent to, approximately equal to, range

☐ No ATC code has been assigned

2.1.3.4 Raw plant materials: (for Herbal products only)

2.1.3.5 Scientific name, family: (for Herbal products only)

2.1.3.6 Traditional or common name (Arabic and/or English): (for Herbal products only)

2.1.3.7 Used parts: (for Herbal products only)

2.1.3.8 Dosage form:

2.1.3.9 Strength

2.1.3.10 Unit of strength:

2.1.3.11 Package size: *1 value only*

Package size	Volume	Unit of Volume

2.1.3.12 Route of administration:

2.1.3.13 Administration device (if applicable):

2.1.3.14 Primary packaging:

2.1.3.15 Secondary packaging:

2.1.3.16 Is a GTIN assigned for this pack?

❍ Yes, please specify the value:

❍ No

2.1.3.17 Proposed shelf life:

2.1.3.18 Proposed shelf life after first opening (if applicable):

2.1.3.19 Proposed shelf life after reconstitution or dilution (if applicable):

2.1.3.20 Proposed storage conditions:

2.1.3.21 Proposed storage conditions after first opening (if applicable):

2.1.3.22 Reference Pharmacopoeia:

2.1.3.23 Do you have a Certificate of a Pharmaceutical Product (CPP)?

❍ Yes

❍ No

If not, do you have a marketing authorization (or free sales) certificate from the country of origin (COO)?

❍ Yes

❍ No

2.1.3.24 List and specify any material of animal source contained in any component of the product, if applicable:

Material	Animal	Animal part	Free from BSE/TSE
			☐
			☐
			☐

- Please note that any pork content has to be clearly specified.
- It should be noted that all material used must be free from BSE/TSE. If a certificate confirming that the product is free from BSE/TSE is available, it should be provided.

2.1.3.25 Maximum Residual Limit (MRL) Status: (only for food producing species)

Substance(s)	Species	Target tissue(s)	MRL	Remarks

2.1.3.26 Withdrawal Period:

2.1.3.27 Withdrawal Period Unit:

3 Manufacturers Details:

The following sections should be completed where appropriate.

3.1 Active Pharmaceutical Ingredient (API) manufacturers:

Name of manufacturer	Name of ingredient	Address[9]	Phone	Fax	Activity [10]	Is it GMP certified? Yes	No	Certifying Authority	Date of certification (dd/mm/yyyy)
						❍	❍		
						❍	❍		

3.2 Excipients manufacturers:

Name of manufacturer	Name of excipient	Address[10]	Phone	Fax	Activity[10]	Is it GMP certified? Yes	No	Certifying Authority	Date of certification (dd/mm/yyyy)
						❍	❍		
						❍	❍		

3.3 Finished Product manufacturers:

Name of manufacturer	Address[10]	Phone	Fax	Activity[10]	Is it GMP certified? Yes	No	Certifying Authority	Date of certification (dd/mm/yyyy)
					❍	❍		
					❍	❍		

[9] Full address as Line 1, 2 & 3; Postal/Zip code, City & Country

4 Marketing Authorization Details

The following sections should be completed where appropriate.

4.1 Marketing authorization holder legally responsible for placing the product on the market in KSA[11]:

- Company Name:
- Address:
  - Line 1:
  - Line 2:
  - Line 3:
  - Postal/Zip code:
  - City:
  - Country:
- Phone:
- Fax:
- E-Mail:

4.2 Person authorized for communication in KSA on behalf of the applicant:

- Person Name:
  - First name:
  - Middle name:
  - Family/last name:
- Company Name[12]:

[11] A drop-down menu (transferred from DENR or Re-engineered system after normalization)
[12] A drop-down menu (transferred from DENR or Re-engineered system after normalization)

- Address:
    - Line 1:
    - Line 2:
    - Line 3:
    - Postal/Zip code:
    - City:
    - Country:
- Phone:
- Fax:
- E-Mail:

4.3 Person/Company authorized for communication between the marketing authorization holder and the SFDA after authorization, if different from 3.2 in KSA:

- Person Name:
    - First name:
    - Middle name:
    - Family/last name:
- Company Name[13]:
- Address:
    - Line 1:
    - Line 2:
    - Line 3:
    - Postal/Zip code:

[13] A drop-down menu (transferred from DENR or Re-engineered system after normalization)

- City:
- Country:

- Phone:
- Fax:
- E-Mail:

4.4 Person qualified for Pharmacovigilance in KSA:

- Name:
  - First name:
  - Middle name:
  - Family/last name:
- Address:
  - Line 1:
  - Line 2:
  - Line 3:
  - Postal/Zip code:
  - City:
  - Country:
- Phone:
- Fax:
- E-Mail:

5 Scientific Advice

5.1 Was there any formal scientific advice given by the SFDA for this medicinal product?

❍ Yes, please complete the following:

- Date (*dd/mm/yyyy*):
- Reference number of the scientific advice letter:

❍ No

6 Pediatric Development Program

6.1 Is there a pediatric development program for this medicinal product?

❍ Yes, please indicate the relevant section(s) in the dossier:

❍ No

7 Legal Status of the Product

The following sections should be completed where appropriate.

7.1 Proposed dispensing classification:

- ❍ Subject to medical prescription:
  - ❍ By a licensed doctor in the KSA:
    - ❍ Consultant
    - ❍ Senior Assistant
    - ❍ Assistant
    - ❍ GP
  - ❍ Restricted prescription
  - ❍ Special distribution program
  - ❍ Hospital-only item
- ❍ Not subject to medical prescription:
  - ❍ By a licensed Pharmacist – Behind the counter (BTC)
  - ❍ Over the counter (OTC)

8 Status of the application in other regulatory agencies

Tick the appropriate box and fill the information.

☐ Authorized

List all countries where the product is authorized for marketing:

Country	Trade name	Product strength/unit	Dosage form	Marketing authorization holder	Date of authorization (dd/mm/yyyy)

☐ Pending

List all countries where the product application is pending:

Country	Trade name	Product strength/unit	Dosage form	Date of submission (dd/mm/yyyy)

☐ Refused

List all countries where the product has been refused for marketing:

Country	Trade name	Product strength/unit	Dosage form	Reason for refusal	Date of refusal (dd/mm/yyyy)

☐ Withdrawn (by applicant **after** authorization)

List all countries where the product has been withdrawn after authorization:

Country	Trade name	Product strength/unit	Dosage form	Date of withdrawal (dd/mm/yyyy)	Reason for withdrawal

☐ Suspended/revoked (by competent authority)

List all countries where the product has been suspended or revoked:

Country	Trade name	Product strength/unit	Dosage form	Date of suspension/revocation (dd/mm/yyyy)	Reason for suspension/ revocation:

9 Price Certificate Form

The following sections should be completed where appropriate.

9.1 Ex-Factory Price:

9.1.1 Country of Origin's currency

9.2 Wholesale Price

9.2.1 Country of Origin's currency

9.3 Public price

9.3.1 Country of Origin's currency

9.4 Proposed CIF to KSA

9.4.1 Currency

9.5 The other price in countries where the product is marketed:

No	Country Name	Pack Size	Ex-Factory Price	Currency	CIF Price	Currency	Public price	Currency	notes
1	Algeria								
2	Australia								
3	Argentina								
4	Bahrain								
5	Belgium								
6	Canada								
7	Cyprus								
8	Denmark								
9	Egypt								
10	France								

No	Country Name	Pack Size	Ex-Factory Price	Currency	CIF Price	Currency	Public price	Currency	notes
11	Germany								
12	Greece								
13	Holland								
14	Hungary								
15	Ireland								
16	Italy								
17	Jordan								
18	Kuwait								
19	New Zealand								
20	Oman								
21	Portugal								
22	Lebanon								
23	Japan								
24	South Korea								
25	Spain								
26	Sweden								
27	Switzerland								
28	Turkey								
29	UAE								
30	UK								
31	Others								

Declaration:

I hereby certify that the submitted information is true and accurate and changes will not be made until they are approved by SFDA.

Title:

Name:

Signature:

Date:

Company stamp:

طلب تعديل رخصة التسويق

Application for Variation to a Marketing Authorization

1 Request type

1.1 This application concerns:

- ❍ Administrative Changes
- ❍ Quality Changes
- ❍ Safety, Efficacy, or Pharmacovigilance Changes

2 Type(s) of variation(s):

2.1 Variations included in this application:

Number and title of variation, as per the guideline[14]	Procedure Type	Date of Implementation

2.2 Precise scope and background for change (Include a description and background of all the proposed changes with its proposed Classification)

Current	Proposed

2.3 Does this change affect the last updated drug application form?

❍ Yes, which part? Please specify to the lowest level and state the new value:

☐ Section 2 - Product Information Details: Please choose the field(s) and type the new value

☐ Section 3 - Manufacturers Details: Please choose the field(s) and type the new value

[14] Choose from the drop-down menu of all variations in the GCC variation guideline

☐ Section 4 - Marketing Authorization Details: Please choose the field(s) and type the new value

☐ Section 7 - Legal Status of the Product: Please choose the field(s) and type the new value

☐ Section 9 - Price Certificate Form: Please choose the field(s) and type the new value

❍ No

Declaration:

I hereby certify that the submitted information is true and accurate and changes will not be made until they are approved by SFDA.

Title:

Name:

Signature:

Date:

Company stamp: