

# Regulatory Framework for Drug Approvals

Version 5.0

قطاع الدواء  
Drug Sector 

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# Regulatory Framework for Drug Approvals

## Version 5.0

Drug Sector

Saudi Food & Drug Authority

Kingdome of Saudi Arabia

Please visit SFDA's website at <http://www.sfda.gov.sa/en/drug> for the latest update

## Drug Sector

### Vision & Mission

#### Vision

To be the leading regional Drug Regulatory Authority for pharmaceuticals and safety of cosmetic products, with professional excellence and services that contribute to the protection and advancement of public health in the Kingdom of Saudi Arabia.

#### الرؤية

أن يكون قطاع الدواء رائداً إقليمياً في الرقابة على الأدوية وسلامة مستحضرات التجميل، ويقدم خدماته بمهنية متميزة تسهم في حماية وتعزيز الصحة في المملكة العربية السعودية.

#### Mission

Protecting public health by ensuring safety, quality, efficacy and accessibility of human, veterinary drugs and biological products, and safety of cosmetics, through administration of a national regulatory system which is consistent with international best practice. Through our mission, we also provide accurate and scientific-based information to the public and healthcare professionals.

#### الرسالة

حماية الصحة العامة من خلال ضمان أمان وجودة وفعالية وتوفير الأدوية البشرية والبيطرية والمنتجات الحيوية وسلامة مواد التجميل عبر تطبيق نظام وطني للرقابة متوافق مع أفضل الممارسات الدولية وتقديم المعلومات الدوائية المبنية على أسس علمية للعامة والمهنيين الصحيين.

## Document Control

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## Foreword

The Drug Sector in the Saudi Food & Drug Authority (SFDA) has developed this document, ‘*Regulatory Framework for Drug Approvals*’, to provide assistance for stakeholders on how to submit applications for various types of drug products. This document is an administrative instrument that outlines the requirements of various types of applications to be filled out and submitted to the SFDA.

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

It is important to note that the SFDA reserves the right to request information, material or defined conditions not specifically described in this document, in order to allow the administration to adequately assess the safety, efficacy and quality of drug products. The SFDA is committed to ensuring that such requests are justifiable and decisions are clearly documented.

This document should be read in conjunction with the other relevant and applicable guidance documents. A copy of this document can be found on our website:

[http://www.sfda.gov.sa/en/drug/drug\\_reg/Pages/drug\\_reg.aspx](http://www.sfda.gov.sa/en/drug/drug_reg/Pages/drug_reg.aspx)

The SFDA is fully committed to an orderly process for the review and authorization of pharmaceutical products, and we are working to develop procedures to implement those aspects of the initiative. We are also committed to assuring that stakeholders remain fully informed of our progress as we implement the initiative.

## Glossary

<b>Applicant</b>	The company or its representative.
<b>Biologicals</b>	Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologicals can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologicals are isolated from a variety of natural sources — human, animal, or microorganism — and may be produced by biotechnology methods and other cutting-edge technologies <sup>1</sup> .
<b>Biosimilars</b>	Therapeutic proteins produced by recombinant DNA technology or gene expression method following the footsteps of one licensed reference biotechnological product after the expiration of the innovator's patent. 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.
<b>Common Technical Document (CTD)</b>	An international harmonized format for submissions for approval of pharmaceuticals for human use. The CTD provides a standardization of the presentation of the content.
<b>Dosage form</b>	The finished formulation of a pharmaceutical product, e.g. tablet, capsule, suspension, solution for injection, suppository
<b>Drug</b>	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.
<b>Drug Application</b>	A drug application includes the application form, the product file and the drug samples
<b>Generic (multisource) drug</b>	Approved drugs that are no longer protected by patents and are approved for marketing by companies without the need for clinical trials; generic drugs are bioequivalent to the original approved drugs.
<b>Hard copy - product file</b>	The paper-based submission of the product file.

<sup>1</sup> FDA (Drugs@FDA Glossary of Terms)

<b>Herbal product</b>	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.
<b>Innovator pharmaceutical product</b>	Generally, the innovator pharmaceutical product is that which was first authorized for marketing, on the basis of documentation of quality, safety and efficacy.
<b>Inquiry Form</b>	A form used to collect needed information by the applicant.
<b>Known active substance</b>	A new dosage form, strength, or indication for a new drug already marketed in Saudi Arabia.
<b>New Drug/ New Chemical Entity</b>	A drug molecule that has never been marketed in Saudi Arabia.
<b>Product manager</b>	The SFDA employee responsible for following up all activities related to drug approval process.
<b>Radiopharmaceutical product</b>	A radioactive drug that can be administered safely to humans for diagnostic and therapeutic purposes.
<b>Reference number</b>	Any combination of letters and numbers that is assigned to the transaction in order to follow it.
<b>Renewal of marketing authorization</b>	A process of renewing the marketing authorization license every five years.
<b>SADAD</b>	A system that links between the commercial sector and the local banks; it offers the ability to collect its customer payment electronically through all the banking channels in KSA around the clock.
<b>SFDA's pricing rules</b>	The pricing guideline “ <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.
<b>Soft copy – product file</b>	The electronic version of the product file presented in CDs or DVDs.
<b>Stringent Drug Regulatory Authority (SRA)</b>	An SRA is one the following authorities: US FDA, EMA, MHRA, SwissMedic, Health Canada and TGA.

<b>Vaccines</b>	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.
<b>Validation (Phase I &amp; II)</b>	The process of checking if documents satisfy a certain criterion.
<b>Variation</b>	A process of informing the authority of any minor or major changes in the drug product.
<b>Veterinary drug</b>	Any substance or mixture of substances manufactured, sold or represented for use in: <ul style="list-style-type: none"><li>• the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in animals,</li><li>• restoring, correcting or modifying organic functions in animals</li></ul>

## Registration Rules

Drug sector at SFDA sets the rules for registering different types of drugs. Such rules are developed by examining the current and future competencies of its evaluators. These rules will help the applicants to decide whether to submit their drug applications or not.

The following rules/conditions if met, the submitted drug application will be accepted:

1. **New Drug** and **Biological** (either registered in an SRA or not)
2. **Generic Drug** that is equivalent to the registered innovator in an SRA (the drug shall be registered as “New Drug” because the API is *not registered* in KSA)
3. Biosimilar drug only if it is manufactured locally
4. Biosimilar drug if registered in an SRA
5. Combination products (2 or more API):
  - a. If the API's are registered in KSA as single drugs (with the same strength, dosage form and therapeutic indication), the application is considered Generic
  - b. If one or more of the API's are not registered in KSA, the application is considered New Drug

### Notes:

- Performance targets will differ depending on the type of drug
- Generic drugs that are not equivalent to the innovated product in the *strength*, are considered Generic (as long as the API is registered in KSA)
- Generic drugs that are not equivalent to the innovated product in the *dosage form*, are considered New Drug – Known active substance (as long as the API is registered in KSA)

## Submission Process

The process of submitting a **NEW drug application**<sup>2</sup> to the SFDA consists of three major steps:

1. **Online submission of the APPLICATION FORM,**
2. **The PRODUCT FILE delivered in person,**
3. **DRUG SAMPLES.**

### *Important Note:*

- *All days mentioned throughout this document are **WORKING** days (subject to change).*

### **Step by step procedure:**

1. Applicant shall go to the Saudi Drug Registration system (SDR) website (<http://sdr.sfda.gov.sa/>)
2. Login to apply (each applicant should have a user ID and a password<sup>3</sup>)
3. Choose and complete the appropriate application form:
  - *The application form can be saved partially as the applicant may complete it in several steps.*
4. Then, the applicant has to pay the submission fee (through SADAD Payment System) in order to submit the application form and schedule an appointment to deliver the hard and soft copy of the product file:
  - *Submission fees are mandatory in order to proceed to the next step.*
  - *The applicant can reschedule 3 weeks before the appointment. An automatic reminder will be sent 3 days before the appointment.*
  - *A reference number will be generated, and this number should always be used with regard to any communication with the SFDA.*

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<sup>2</sup> A **drug application** includes the application form, the product file and the drug samples.

<sup>3</sup> The **Drug Establishment National Registry** (DENR) is the source of the user ID and password

5. At the appointment, the applicant will deliver the product file along with the samples.
6. The Regulatory Affairs Pharmacist will validate (Phase I) the following:
  - a. The application form
  - b. The product file (hard and soft copy)
  - c. The samples
  - *If the above are valid, an acknowledgment letter will be generated and given to the applicant. The drug application will enter the queue.*
  - *If some of the above are missing or not satisfactory, an acknowledgment letter will be generated and given to the applicant stating the **deficiencies**. The applicant will have a period of **90** days to complete the requirements and the drug application will not be queued. When the required information is met, an appointment (completion appointment) is requested by email ([sdr.drug@sfda.gov.sa](mailto:sdr.drug@sfda.gov.sa)), and the step no 6 will be repeated again.*

**Notes:**

- Currently for renewal applications, no appointment scheduling is required. And for the variation applications, neither payment nor appointment are required.
- Refer to the ***Guidance for Submission*** for more details on preparing the drug file.

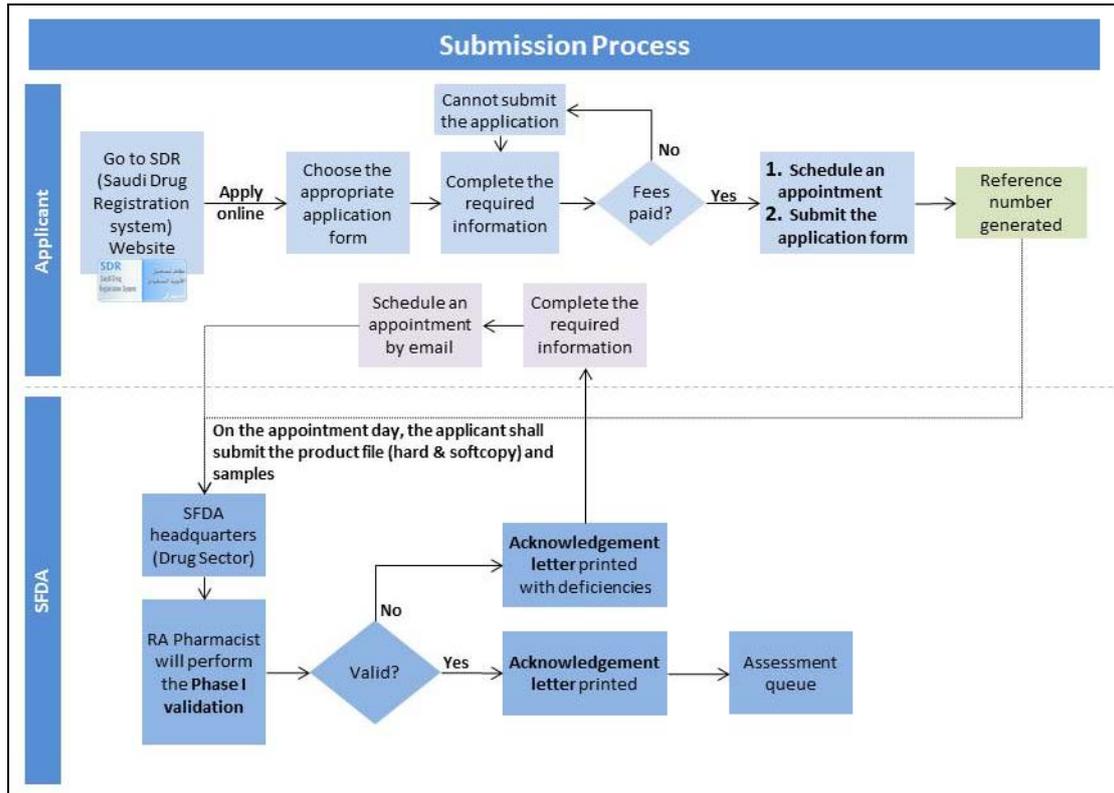


Figure 1 Flow chart of the submission process

## Marketing Authorization Application (MAA)

The Market Authorization Application for the different drug submission types will be subjected to the following processes:

### A. Validation (Phase II):

1. The product file will be validated to ensure that all information provided are according to the requirements and/or guidelines:
  - a. The completed file will proceed to the next steps in parallel – assessment, testing and inspection.
  - b. If any information is missing or incorrect, the applicant will be notified electronically. The applicant will be given an opportunity to complete the file within **90** days. Otherwise, the file will be rejected.
2. *Performance target: 10 days for all drug submission types*

### B. Assessment:

1. The product file will be distributed by the product manager to THREE groups: Quality, Safety and Efficacy.
2. **Quality assessment** will be performed by a quality group. Once completed, a report will be forwarded to the product manager.
3. **Safety assessment** will be performed by a safety group. Once completed, a report will be forwarded to the product manager.
4. **Efficacy assessment** will be performed by an efficacy group. Once completed, a report will be forwarded to the product manager.
5. If a clarification is required, an electronic “**Inquiry Form**” will be forwarded to the applicant through the product manager. The response should be received within **90** days. Otherwise, the application will be rejected.
6. The reports (i.e. recommendation for approval or rejection) will be forwarded to the secretary of the Registration Committee.
7. *Performance target:*
  - a) *Generics: 120 days*
  - b) *New Drugs:*
    - i. *Registered in a Stringent Regulatory Authority (SRA): 245 days*
    - ii. *Not registered in SRA: 370 days*
  - c) *Biologicals:*
    - i. *Registered in SRA: 245 days*
    - ii. *Not registered in SRA: 370 days*
  - d) *Radiopharmaceuticals: 245 days*
  - e) *Veterinary drugs: 150 days*
  - f) *Herbal & Health products: 110 days*

### C. Testing

1. Samples received by SFDA headquarters will be sent to the laboratory.
2. If more information, clarification or additional samples are needed, an electronic “**Inquiry Form**” will be forwarded to the applicant through the product manager. A response should be received within **90** days.
3. The results will be written in a report and forwarded to the product manager.
4. *Performance target: 90 days for all drug submission types*

#### Note:

- *Testing will not delay the registration of a product*
- *The 1<sup>st</sup> batch imported after approval will be tested and the company will be notified of the results within 35 days. However, the company should not distribute the product during this period. After 35 days, the company may distribute the product under their own liability.*

### D. Inspection

1. The product file will be forwarded to the Head of the inspection unit:
  - a. If more information or clarification is required, an electronic “**Inquiry Form**” is forwarded to the applicant through the Inspection unit. A response should be received within **90** days.
2. Inspection department will check the manufacturing line:
  - a. If the manufacturing line has been approved (valid certificate from KSA MoH, SFDA or GCC-DR), the line would not be inspected and the head of the inspection unit will inform the product manager.
  - b. If the manufacturing line is not approved:
    - i. The head of the inspection unit will schedule a visit for inspection (depending on the time available for both inspectors and the company).
    - ii. After the visit, the inspection report will be written and forwarded to the Head of inspection unit.
    - iii. Head of inspection unit will send the inspection report to the company (*please, refer to the Inspection guidance*).
3. The final inspection report will be forwarded to the product manager.
4. *Performance target:*
  - a) *Generics: 120 days*
  - b) *New Drugs: 245 days*
  - c) *Biologicals: 245 days*
  - d) *Radiopharmaceuticals: 245 days*
  - e) *Veterinary drugs: 150 days*
  - f) *Herbal & Health products: 110 days*

**After the Assessment and Inspection reports are completed, the product file will be forwarded to the pricing department.**

## E. Pricing

1. The Pricing department handles pricing requests and ensures that all pricing requirements are met (such as the presence of a valid, updated and authenticated Price Certificate (Form-30) and a product sample in its final pack form). However, if more information or clarification is required, an electronic “**Inquiry Form**” will be forwarded to the applicant through the product manager. A response should be received within **90** days.
2. The Pricing department will calculate the price of each concentration and/or pack size of different product from a pricing & economic perspectives according to the SFDA's pricing rules.
3. The Pricing minute is then prepared to be discussed with the Pricing Committee.
4. If the committee ask for more information or clarification, an electronic “**Inquiry Form**” will be forwarded to the applicant by the pricing department through the product manager. A response should be received within **90** days.
5. The approved price by the committee will be written in a report and forwarded to the product manager.
6. *Performance target: 20 days for all drug submission types<sup>4</sup>*

## F. Product Licensing

1. Product manager will receive all reports from departments and forward them to the secretary of the “Registration Committee”:
  - a. The secretary of the Registration Committee will add the product to the agenda of the next available meeting.
  - b. At the meeting, the Registration Committee will either recommend approval, rejection or ask for further information – if needed.
  - c. *Performance target: 12 days for all drug submission types*
2. The meeting minutes:
  - a. Will be sent to the SFDA CEO for approval.
  - b. Then, the Product Licensing department will issue a marketing authorization.
  - c. *Performance target: 3 days for all drug submission types*

### **Total performance target =**

- a) *Generics: 165 days*
- b) *New Drugs:*
  - i. *Registered in a Stringent Regulatory Authority (SRA): 290 days*

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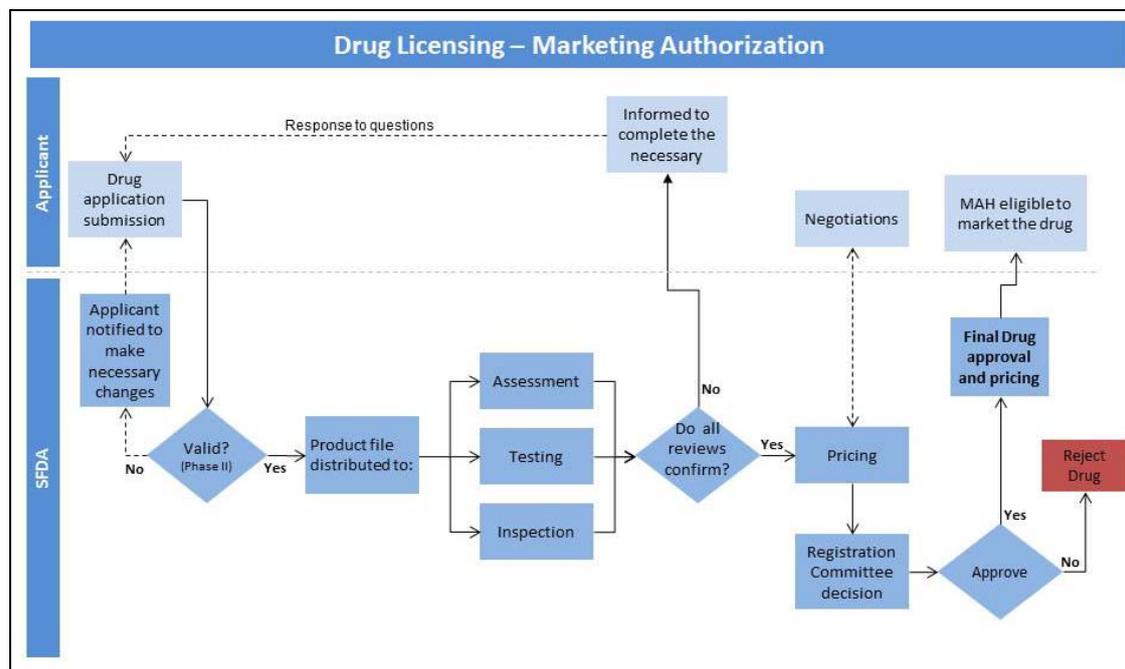
<sup>4</sup> Only for the drug types that require pricing

- ii. *Not registered in SRA: 415 days*
- c) *Biologicals:*
  - i. *Registered in SRA: 290 days*
  - ii. *Not registered in SRA: 415 days*
- d) *Radiopharmaceuticals: 290 days*
- e) *Veterinary drugs: 175 days*
- f) *Herbal & Health products: 155 days*

*Note: the performance target in any step will STOP if a clarification or information is needed from the applicant, and resume after receiving the response.*

**Appeal Process:**

The applicant has the right to appeal against the decision within **60** calendar days by submitting a letter including the scientific justifications supporting the appeal, in addition to fee payment (through SADAD Payment System). However, The Pricing Committee may negotiate the approved price with the company – if needed and upon the request of the applicant.



**Figure 2:** Schematic figure showing the different levels for getting a marketing authorization for Generics, NCE, Biologicals, Radiopharmaceuticals, Veterinary, Herbal and Health products

## Renewal of Marketing Authorization

### Notes:

- *The renewal of marketing authorization should be carried out every 5 years.*
- *The renewal application should be requested 6 months before the expiry date of the registration certificate.*
- *For the renewal requirement, guidelines are published in the SFDA website.*

The Renewal of Marketing Authorization will be subjected to the following processes:

### A. Validation (Phase II):

1. The product file will be validated to ensure that all information provided are according to the requirements and/or guidelines:
  - a. The completed file will proceed to the next steps.
  - b. If any information is missing or incorrect, the applicant will be notified electronically. The applicant will be given an opportunity to complete the file within **90** days. If no response, the file will be rejected.
2. *Performance target: 10 days.*

### B. Assessment:

1. The product file will be distributed by the product manager to **THREE** groups: Quality, Safety and Efficacy.
2. **Quality assessment** will be performed by a quality group. Once completed, a report will be forwarded to the product manager.
3. **Safety assessment** will be performed by a safety group. Once completed, a report will be forwarded to the product manager.
4. **Efficacy assessment** will be performed by a efficacy group. Once completed, a report will be forwarded to the product manager.
5. If a clarification of any group is required, an electronic “**Inquiry Form**” will be forwarded to the applicant through the product manager. The response should be received within **90** days. Otherwise, the application will be rejected.
6. The reports (i.e. recommendation for approval or rejection) will be forwarded to the Director of the Product Licensing department.
7. *Performance target: 50 days.*

### C. Pricing:

1. The Pricing department will **review** the price according to the SFDA's pricing rules.
2. The final price will be written in a report and forwarded to the product manager.

3. *Performance target: 30 days.*

#### **D. Inspection:**

1. Inspection department will check if the manufacturing line is approved before or not:
  - a. If the manufacturing line is approved with a valid inspection report, the line would not be inspected and the head of the inspection unit will inform the product manager.
  - b. If the manufacturing line is not approved:
    - i. The head of the inspection unit will schedule a visit for inspection (depending on the time available for both inspectors and the company). Then inform the product manager to continue the process.
    - ii. After the visit, the inspection report will be written and forwarded to the Head of inspection unit.
    - iii. Head of inspection unit will send the inspection report to the company.
2. The final inspection report will be forwarded to the product manager.
3. *Performance target: 50 days.*

#### **E. Marketing Authorization Renewal:**

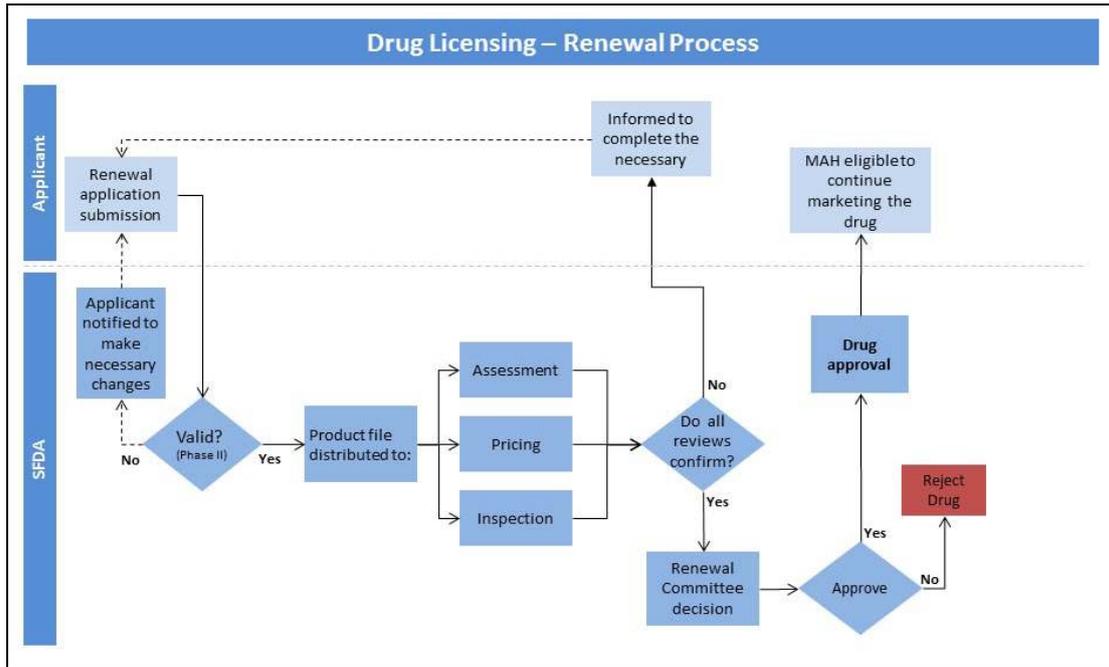
1. The product manager will forward the renewal application to the secretary of the “Renewal Committee”.
2. The Committee will either recommend approval, rejection or ask for further information if needed.
3. The meeting minutes will be sent to the Drug VP for approval.
4. The licensing department will issue the renewal authorization documents.
5. *Performance target: 10 days.*

**Total performance target = 70 days**

*Note: the performance target in any step will STOP if a clarification or information is needed from the applicant, and resume after receiving the response.*

#### **Appeal Process:**

The applicant has the right to appeal within **60** calendar days of the SFDA’s final decision. Please, refer to the relevant guideline (*under development*).



**Figure 3:** Schematic figure showing the renewal process of a marketing authorization

## Variation

The variation or post-marketing changes can be classified into two categories:

### A. Minor changes:

1. **Type IA**: minor variations that does not require prior approval before implementation (“Do and Tell” procedure) but require notification submitted by the marketing authorization holder (MAH) within **60** days after implementation.
2. **Type IB**: minor variations that must be notified to the SFDA by the Marketing Authorization Holder (MAH) before implementation, but do not require a formal approval. However, the MAH must wait a period of **120** days to ensure that the application is deemed acceptable by the SFDA before implementing the change (“Tell, Wait and Do” procedure).

### B. Major variation:

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

The variation will be subjected to the following processes:

### A. Validation (Phase II):

1. The variation file will be validated to ensure that all information provided are according to the requirements and/or guidelines:
  - a. The completed file will proceed to the next steps.
  - b. If any information is missing or incorrect, the applicant will be notified electronically. The applicant will be given an opportunity to complete the file within **90** days. Otherwise, the file will be rejected.
2. *Performance target: 10 days.*

**Depending on the type of variation, one or more department may review the variation application (refer to the latest published guideline).**

### B. Product Licensing:

1. The variation request will be evaluated/reviewed.
2. The necessary action will be taken within the department.
3. If a clarification is required, an electronic “**Inquiry Form**” will be forwarded to the applicant through the product manager. The response should be received within **90** days.
4. *Performance target: 10 days.*

### C. Assessment:

1. The product file will be distributed to THREE groups: quality, safety and efficacy – as needed.
2. **Quality assessment** will be performed by a quality group. Once completed, a report will be forwarded to the product manager.
3. **Safety assessment** will be performed by a safety group. Once completed, a report will be forwarded to the product manager.
4. **Efficacy assessment** will be performed by an efficacy group. Once completed, a report will be forwarded to the product manager.
5. If a clarification is required, an electronic “**Inquiry Form**” will be forwarded to the applicant through the product manager. The response should be received within **90** days. Otherwise, the application will be rejected.
6. The reports (i.e. recommendation for approval or rejection) will be collected by the product manager.
7. The reports will either be forwarded to other department(s) or registration committee depending on the type of variation.
8. *Performance target for:*
  - *Type IA: 45 days*
  - *Type IB: 105 days*
  - *Type II: 120 days*

### D. Testing:

1. Samples received by SFDA headquarters will be sent to the laboratory.
2. If more information, clarification or additional samples are needed, an electronic “**Inquiry Form**” is forwarded to the applicant through the product manager, and a response should be received within **90** days.
3. The results will be written in a report and forwarded to the product manager.
4. *Performance target: 90 days.*

### E. Inspection:

1. Inspection department will review the variation request in addition to the assessment reports – if applicable:
  - a. If the manufacturing line is approved with a valid inspection report, the line would not be inspected and the head of the inspection unit will inform the product manager.
  - c. If the manufacturing line is not approved:
    - iv. The head of the inspection unit will schedule a visit for inspection (depending on the time available for both inspectors and the company). Then inform the product manager to continue the process.
    - v. After the visit, the inspection report will be written and forwarded to the Head of inspection unit.

- vi. Head of inspection unit will send the inspection report to the company.
2. The final inspection report will be forwarded to the product manager.
3. *Performance target:*
  - *Type IA: 45 days*
  - *Type IB: 105 days*
  - *Type II: 120 days*

#### **F. Pricing:**

1. The Pricing department handles all variation requests that require pricing review (according to the guideline) and ensures that all pricing requirements are met. However, if more information or clarification is required, an electronic “**Inquiry Form**” will be forwarded to the applicant through the product manager. A response should be received within **90** days.
2. The Pricing department will re-calculate the price of each concentration and/or pack size of different product according to the SFDA's pricing rules.
3. The Pricing minute is then prepared to be discussed with the Pricing Committee.
4. If the Pricing Committee asks for more information or clarification, an electronic “**Inquiry Form**” will be forwarded to the applicant by the pricing department through the product manager. A response should be received within **90** days.
5. The new approved price by the committee will be written in a report and forwarded to the product manager
6. *Performance target: 20 days.*

#### **G. Variation Approval:**

1. **For type IA:**
  - a. The Licensing Director will approve the final report.
  - b. Notify the applicant.
  - c. *Performance target: 5 days.*
2. **For type IB:**
  - a. The Licensing Director will approve the final report.
  - b. Notify the applicant.
  - c. *Performance target: 5 days.*
3. **For type II:**
  1. Product manager will receive all reports from departments and hand them to the secretary of the “Registration Committee”:
    - a. The secretary of the Registration Committee will add the product to the agenda of the next available meeting.

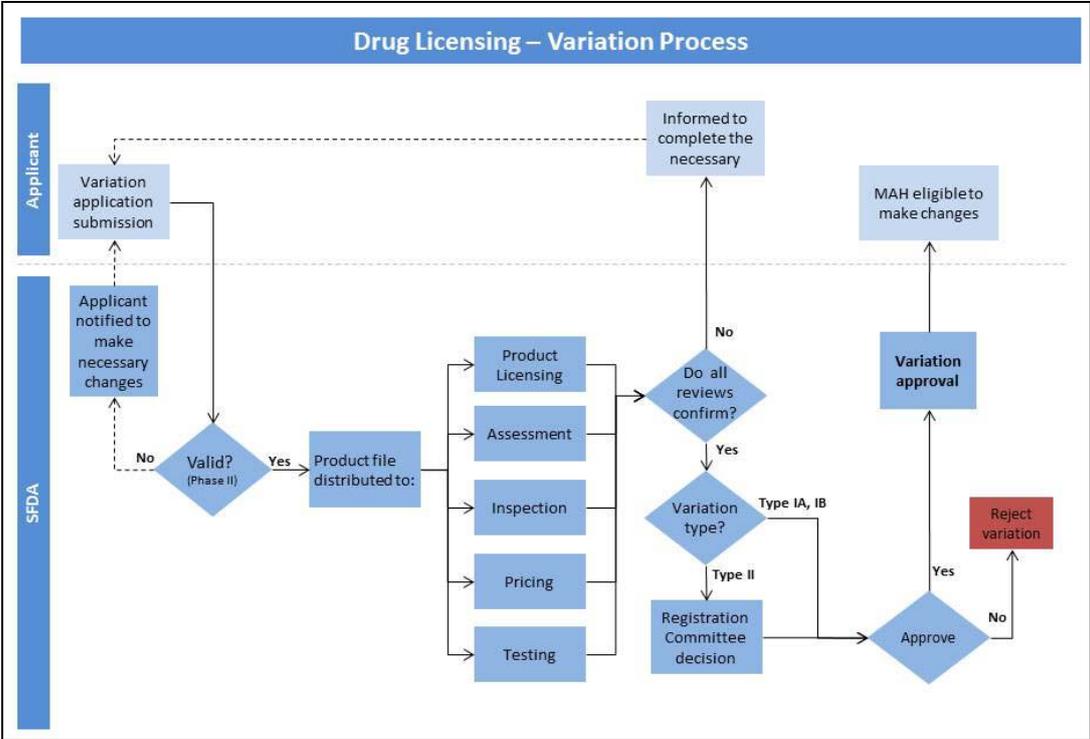
- b. At the meeting, the Registration Committee will either recommend approval, rejection or ask for further information – if needed.
  - c. *Performance target: 12 days*
2. The-meeting minutes:
- a. Will be sent to the SFDA CEO for approval.
  - b. Then, the Product Licensing department will issue a marketing authorization.
  - c. *Performance target: 3 days*

**Total performance target (Type IA) = 60 days**  
**Total performance target (Type IB) = 120 days**  
**Total performance target (Type II) = 145 days**

*Note: the performance target in any step will STOP if a clarification or information is needed from the company, and will be resumed after receiving the response.*

**Appeal Process:**

The applicant has the right to appeal within 60 calendar days of the SFDA’s final decision. Please, refer to the relevant guideline (*under development*).



**Figure 4:** Schematic figure showing the workflow of Variation

## Appendices

## Appendix A: Performance Targets

Process	Total Performance Target <sup>5</sup>
Marketing Authorization Application for Generics	165 days
Marketing Authorization Application for New Drugs	290 days
Marketing Authorization Application for New Drugs not registered in an SRA	415 days
Marketing Authorization Application for Biologicals	290 days
Marketing Authorization Application for Biologicals not registered in an SRA	415 days
Marketing Authorization Application for Radiopharmaceuticals	290 days
Marketing Authorization Application for Veterinary drugs	175 days
Marketing Authorization Application for Herbal & Health products	155 days
Renewal of Marketing Authorization	70 days
Variation to a Marketing Authorization Type IA	60 days
Variation to a Marketing Authorization Type IB	120 days
Variation to a Marketing Authorization Type II	145 days

<sup>5</sup> Working days

## Appendix B: Acronyms and abbreviations

API	Active Pharmaceutical Ingredients
ATC	Anatomical Therapeutic Chemical Classification System
ATCvet	Anatomical Therapeutic Chemical Classification System for veterinary products
BSE	Bovine spongiform encephalopathy
COO	Country of Origin
CPP	Certificate of Pharmaceutical Product
CTD	Common Technical Document
Drug VP	SFDA's Drug Vice President
EMA	European Medicines Agency
GCC-DR	Gulf Cooperation Council Drug Registration
HATC	Herbal Anatomical Therapeutic Chemical Classification System
KSA	Kingdom of Saudi Arabia
MA	Marketing Authorization
MAA	Marketing Authorization Application
MHRA	Medicines and Healthcare products Regulatory Agency
NCE	New Chemical Entity
SFDA	Saudi Food and Drug Authority
SMF	Site Master File
SPC	Summary of Product Characteristics
Swissmedic	Swiss Agency for Therapeutic Products
TGA	Therapeutic Goods Administration
TSE	Transmissible Spongiform Encephalopathy
US FDA	United States of America Food and Drug Administration

## Appendix C: Application Forms

Application form	Page
Marketing Authorization Application of Medicinal Product for Human Use: New Drugs, Generics (Multisource), Biologicals and Radiopharmaceuticals	30
Marketing Authorization Application of Medicinal Product for Veterinary Use	46
Marketing Authorization Application of Herbal Product	61
Application for Variation to a Marketing Authorization	74

## طلب رخصة تسويق مستحضر دوائي

(الأدوية الجديدة والجنيسة والحيوية والمشعة)

# Marketing Authorization Application for Medicinal Product

New Drugs, Generics (Multisource), Biologicals and  
Radiopharmaceuticals

<input type="radio"/> New	<input type="radio"/> Renewal Registration No:
---------------------------	---

<p>This application form is used to apply for a marketing authorization of a medicinal product for human use submitted to Saudi Food &amp; Drug Authority (SFDA).</p> <p><b>A separate application form is needed for <u>each strength, dosage form, and flavor.</u></b></p>	<p>هذه الاستمارة تستخدم لطلب رخصة تسويق لمستحضر طبي للاستخدام البشري، ليتم تقديمها إلى الهيئة العامة للغذاء والدواء.</p> <p>يجب تقديم طلب منفصل لكل تركيز وشكل صيدلاني ونكهة.</p>
--	---

## 1 Type of Application

The following sections should be completed where appropriate.

### 1.1 This application concerns:

- New Drug
- Generic (Multisource)
- Biological
- Radiopharmaceutical

### 1.2 Please provide the following information for the product:

#### 1.2.1 New Drug Application

- Known active substance
- New Chemical Entity (NCE)

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:

## 1.2.2 Generic (Multisource) Drug Application

### 1.2.2.1 Generic drug information:

Is Saudi Arabia the country of origin (COO)?

- Yes (complete part 1.2.2.2)
- 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:

### 1.2.2.2 Reference Product information in KSA:

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

### 1.2.3 Biological 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)

#### 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:

#### 1.2.4 Radiopharmaceutical Application

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 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:

## 2 Marketing Authorization Application Details

### 2.1 Name(s) and ATC code:

2.1.1 Proposed trade name:

2.1.2 List the active substance(s):

Single active substance       Multiple active substances

Name of active substance(s)	Quantity	Unit	Reference/Monograph standard

2.1.3 Pharmacotherapeutic group: *(Please use current ATC code)*

ATC Code	Group

No ATC code has been assigned

2.1.2 List the excipient(s):

Name of excipient(s)	Quantity	Unit	Reference/Monograph standard

### 2.2 Product information:

Manufacturer name:

Manufacturing site: City:

Country:

Dosage form:

Strength/unit:

Package size(s):

Package size	Volume	Unit of Volume

Route of administration:

Administration device (if applicable):

Primary packaging:

Secondary packaging:

Proposed shelf life:

Proposed shelf life after **first opening** container (if applicable):

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

Proposed storage conditions:

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

Reference Pharmacopoeia:

## 2.3 Marketing Authorization Holder/Contact Person(s)/Company Details:

2.3.1 Proposed marketing authorization holder/person legally responsible for placing the product on the market in KSA:

- Company Name:
- Person Name:
  - First name:
  - Middle name:
  - Family/last name:
- Address:

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

2.3.2 Person/Company authorized for communication in KSA on behalf of the applicant:

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

2.3.3 Person/Company authorized for communication between the marketing authorization holder and the SFDA after authorization, if different from 2.3.2 in KSA:

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

2.3.4 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:

## 2.4 Manufacturers:

### 2.4.1 Active Pharmaceutical Ingredient (API) manufacturer:

Name of manufacturer	Name of ingredient	Address <sup>6</sup>	Phone	Fax	Activity	Is it GMP certified?		Certifying Authority	Date of certification (dd/mm/yyyy)
						Yes	No		
						<input type="radio"/>	<input type="radio"/>		
						<input type="radio"/>	<input type="radio"/>		

### 2.4.2 Excipients manufacturer:

Name of manufacturer	Name of excipient	Address <sup>3</sup>	Phone	Fax	Activity	Is it GMP certified?		Certifying Authority	Date of certification (dd/mm/yyyy)
						Yes	No		
						<input type="radio"/>	<input type="radio"/>		
						<input type="radio"/>	<input type="radio"/>		

### 2.4.3 Finished Product manufacturer:

2.4.3.1 Do you have a valid inspection report from the MoH or SFDA in the past 5 years?

- Yes       No (go to 2.4.3.2)

2.4.3.2 What is the appropriate time for the visit?

2.4.3.3 Is this product under-licensed?

---

<sup>6</sup> Full address as Line 1, 2 & 3; Postal/Zip code, City & Country

Yes       No       Not applicable

Name of manufacturer	Address <sup>3</sup>	Phone	Fax	Activity	Is it GMP certified?		Certifying Authority	Date of certification (dd/mm/yyyy)
					Yes	No		
					<input type="radio"/>	<input type="radio"/>		
					<input type="radio"/>	<input type="radio"/>		

## 2.5 Certificate of a Pharmaceutical Product (CPP):

Do you have a CPP?       Yes       No

If not, do you have a marketing authorization (or free sales) certificate from the country of origin (COO)?       Yes       No

## 2.6. 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
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

- 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.

### 3 Scientific Advice

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

Yes

No

If yes:

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

#### 4 Pediatric Development Program

4.1. Is there a pediatric development program for this medicinal product?

Yes

No

If yes, please indicate the relevant section(s) in the dossier.

5 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:

**Declaration:**

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

Company Director/CEO:

Signature:

Date:

## طلب رخصة تسويق مستحضر دوائي للاستخدام البيطري

### Marketing Authorization Application of Medicinal Product for Veterinary Use

<input type="radio"/> New	<input type="radio"/> Renewal Registration No:
---------------------------	---

<p>This application form is used to apply for a marketing authorization of a medicinal product for veterinary use submitted to Saudi Food &amp; Drug Authority (SFDA).</p> <p><b>A separate application form is needed for <u>each strength, dosage form, and flavor.</u></b></p>	<p>هذه الاستمارة تستخدم لطلب رخصة تسويق لمستحضر طبي للاستخدام البيطري، ليتم تقديمها إلى الهيئة العامة للغذاء و الدواء.</p> <p>يجب تقديم طلب منفصل لكل تركيز وشكل صيدلاني ونكهة.</p>
---	---

## 1 Type of Application

The following sections should be completed where appropriate.

### 1.1 This application concerns:

- New Drug
- Generic (Multisource)
- Biological

### 1.2 Please provide the following information for the product:

#### 1.2.1 New Drug Application

- Known active substance
- New Chemical Entity (NCE)

#### Product information in the COO:

- 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:

### 1.2.2 Generic (Multisource) Drug Application

Is Saudi Arabia the country of origin(COO)?

- Yes (complete section 1.2.2.2)
- No (complete section 1.2.2.1)

1.2.2.1 Generic drug information:

- 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:

1.2.2.2 Reference product information in KSA:

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

### 1.2.3 Biologicals Application

- Biosimilar
- Blood product
- Vaccine
- Others (please specify):

Is Saudi Arabia the country of origin(COO)?

- Yes (go to sections 1.3)
- No (complete the following information)

#### Product information in the 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:

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

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

Withdrawal Period/Unit:

## 2 Marketing Authorization Application Details

### 2.1 Name(s) and ATC code:

2.1.1 Proposed trade name:

2.1.2 List the active substance(s):

Single active substance       Multiple active substances

Name of active substance(s)	Quantity	Unit	Reference/Monograph standard

2.1.3 Pharmacotherapeutic group: *(Please use current ATCvet code)*

ATCvet Code	Group

No ATC code has been assigned

2.1.4 List the excipient(s):

Name of excipient(s)	Quantity	Unit	Reference/Monograph standard

### 2.2 Product information:

Manufacturer name:

Manufacturing site: City:

Country:

Dosage form:

Strength/unit:

Package size(s):

Package size	Volume	Unit of Volume

Route of administration:

Administration device (if applicable):

Primary packaging:

Secondary packaging:

Proposed shelf life:

Proposed shelf life after **first opening** container (if applicable):

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

Proposed storage conditions:

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

Reference Pharmacopoeia:

## 2.3 Marketing Authorization Holder/Contact Person(s)/Company Details

2.3.1 Proposed marketing authorization holder/person legally responsible for placing the product on the market in KSA:

- Company Name:
- Person Name:
  - First name:
  - Middle name:
  - Family/last name:
- Address:
  - Line 1:

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

2.3.2 Person/Company authorized for communication in KSA on behalf of the applicant:

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

2.3.3 Person/Company authorized for communication between the marketing authorization holder and the SFDA after authorization, if different from 2.3.2 in KSA:

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

## 2.4 Manufacturers:

2.4.1 Active Pharmaceutical Ingredient (API) manufacturer:

Name of manufacturer	Name of ingredient	Address <sup>7</sup>	Phone	Fax	Activity	Is it GMP certified?		Certifying Authority	Date of certification (dd/mm/yyyy)
						Yes	No		
						<input type="radio"/>	<input type="radio"/>		
						<input type="radio"/>	<input type="radio"/>		

<sup>7</sup> Full address as Line 1, 2 & 3; Postal/Zip code, City & Country

#### 2.4.2 Excipients manufacturer:

Name of manufacturer	Name of excipient	Address <sup>5</sup>	Phone	Fax	Activity	Is it GMP certified?		Certifying Authority	Date of certification (dd/mm/yyyy)
						Yes	No		
						<input type="radio"/>	<input type="radio"/>		
						<input type="radio"/>	<input type="radio"/>		

#### 2.4.3 Finished Product manufacturer:

2.4.3.1 Do you have a valid inspection report from the MoH or SFDA in the past 5 years?

Yes  No (go to 2.4.3.2)

2.4.3.2 What is the appropriate time for the visit?

2.4.3.3 Is this product under-license?

Yes  No  Not applicable

Name of manufacturer	Address <sup>5</sup>	Phone	Fax	Activity	Is it GMP certified?		Certifying Authority	Date of certification (dd/mm/yyyy)
					Yes	No		
					<input type="radio"/>	<input type="radio"/>		
					<input type="radio"/>	<input type="radio"/>		

#### 2.5 Certificate of a Pharmaceutical Product (CPP)

Do you have a CPP?  Yes  No

If not, do you have a marketing authorization (or free sales) certificate from the country of origin (COO)?  Yes  No

#### 2.6. 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
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

- 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.

3 Scientific Advice

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

Yes

No

If yes:

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

#### 4 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:

**Declaration:**

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

Company Director/CEO:

Signature:

Date:

## طلب رخصة تسويق مستحضر عشبي أو صحي

# Marketing Authorization Application for Herbal or Health Product

<input type="radio"/> New	<input type="radio"/> Renewal Registration No:
---------------------------	---

<p>This application form is used to apply for a marketing authorization of a herbal or health product for human use submitted to Saudi Food &amp; Drug Authority (SFDA).</p> <p><b>A separate application form is needed for <u>each strength, dosage form, and flavor.</u></b></p>	<p>هذه الاستمارة تُستخدم لطلب رخصة تسويق لمستحضر عشبي أو صحي للاستخدام البشري، ليتم تقديمها إلى الهيئة العامة للغذاء و الدواء.</p> <p>يجب تقديم طلب منفصل لكل تركيز وشكل صيدلاني ونكهة.</p>
---	---

## 1 Type of Application

The following sections should be completed where appropriate.

### 1.1 This application concerns:

- Herbal product
- Health product

### 1.2 Please provide the following information for the product:

#### 1.2.1 Herbal product:

Is Saudi Arabia the country of origin(COO)?

- Yes (go to section 2)
- No (complete the following information)

#### Product information in the 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:

1.2.2 Health product:

Is Saudi Arabia the country of origin(COO)?

- Yes (go to section 2)
- No (complete the following information)

Product information in the 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:

## 2 Marketing Authorization Application Details

### 2.1 Name(s):

#### 2.1.1 Herbal Products:

2.1.1.1 Proposed trade name:

2.1.1.2 List the active substance(s):

Single active substance  Multiple active substances (max 5)

Name of active substance(s)	Quantity	Unit	Reference/Monograph standard

2.1.1.3 List the excipient(s):

Name of excipient(s)	Quantity	Unit	Reference/Monograph standard

2.1.1.4 Raw plant materials:

2.1.1.4.1 Scientific name, family:

2.1.1.4.2 Traditional or common name (Arabic and/or English)

2.1.1.4.3 Used parts:

### **2.1.2 Health Products:**

2.1.2.1 Proposed trade name:

2.1.2.2 List the active substance(s):

Single active substance     Multiple active substances

Name of active substance(s)	Quantity	Unit	Reference/Monograph standard

2.1.2.3 List the excipient(s):

Name of excipient(s)	Quantity	Unit	Reference/Monograph standard

### **2.2 Product Information:**

Manufacturer name:

Manufacturing site: City:

Country:

Dosage form:

Strength/unit:

Package size(s):

Package size	Volume	Unit of Volume

Route of administration:

Administration device (if applicable):

Primary packaging:

Secondary packaging:

Proposed shelf life:

Proposed shelf life after **first opening** container (if applicable):

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

Proposed storage conditions:

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

Reference Pharmacopoeia:

### 2.3 Legal Status:

Does this product have medical claims?

Yes

No

If yes, please specify:

### 2.4 Marketing Authorization Holder/Contact Person(s)/Company Details:

2.4.1 Proposed marketing authorization holder/person legally responsible for placing the product on the market in KSA:

- Company Name:
- Person Name:
  - First name:
  - Middle name:
  - Family/last name:
- Address:
  - Line 1:

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

2.4.2 Person/Company authorized for communication in KSA on behalf of the applicant:

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

2.4.3 Person/Company authorized for communication between the marketing authorization holder and the SFDA after authorization, if different from 2.3.2 in KSA:

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

## 2.5 Manufacturers:

2.5.1 Active Ingredient manufacturer (raw material manufacturer):

Name of manufacturer	Name of ingredient	Address <sup>8</sup>	Phone	Fax	Activity	Is it GMP certified?		Certifying Authority	Date of certification (dd/mm/yyyy)
						Yes	No		
						<input type="radio"/>	<input type="radio"/>		
						<input type="radio"/>	<input type="radio"/>		

<sup>8</sup> Full address as Line 1, 2 & 3; Postal/Zip code, City & Country

### 2.5.2 Excipients manufacturer:

Name of manufacturer	Name of excipient	Address <sup>6</sup>	Phone	Fax	Activity	Is it GMP certified?		Certifying Authority	Date of certification (dd/mm/yyyy)
						Yes	No		
						<input type="radio"/>	<input type="radio"/>		
						<input type="radio"/>	<input type="radio"/>		

### 2.5.3 Finished Product manufacturer:

2.5.3.1 Do you have a valid inspection report from the MoH or SFDA in the past 5 years?

Yes  No (go to 2.5.3.2)

2.5.3.2 What is the appropriate time for the visit?

2.5.3.3 Is this product under-license?

Yes  No  Not applicable

Name of manufacturer	Address <sup>6</sup>	Phone	Fax	Activity	Is it GMP certified?		Certifying Authority	Date of certification (dd/mm/yyyy)
					Yes	No		
					<input type="radio"/>	<input type="radio"/>		
					<input type="radio"/>	<input type="radio"/>		

### 2.6 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
			<input type="checkbox"/>
			<input type="checkbox"/>
			<input type="checkbox"/>

- 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.

### 3 Scientific Advice

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

Yes

No

If yes:

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

#### 4 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:

**Declaration:**

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

Company Director/CEO:

Signature:

Date:

## طلب تعديل رخصة التسويق

# Application for Variation to a Marketing Authorization

Reference Number<sup>9</sup>:

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<sup>9</sup> The original application will be retrieved automatically from SDR system

**1. This application concerns<sup>10</sup>:**

- Human Drug       Veterinary Drug  
 Herbal Product       Health Product

Trade Name:

Active ingredient(s):

Dosage form:

Strength/unit:

Package size(s):

Route of administration:

Administration device (if applicable):

Primary packaging:

Secondary packaging:

Approved shelf life:

Approved storage conditions:

Reference Pharmacopoeia:

Marketing authorization holder:

Manufacturer name:

Manufacturing site:

City:

Country:

API Manufacturer name:

API Manufacturer site:

City:

Country:

Marketing authorization holder in KSA (Agent):

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<sup>10</sup> All information are retrieved from the original application in SDR

## 2. Type of the variation:

- Type IA
- Type IB
- Type II

## 3. Type(s) of variation(s):

- Copy of the relevant page(s) from the Variation Guidelines for this/these change(s) is attached and the relevant boxes for conditions and documentation.

- Variations included in this application:

Number and title of variation, as per the GCC guidelines for the variation requirements	Procedure Type	Date of Implementation <sup>11</sup>
a) Specific variation applied for, as per the classification guideline	Type	

- Precise scope and background for change (*Include a description and background of all the proposed changes with its proposed classification*)

Current <sup>12,13</sup>	Proposed <sup>10,11</sup>

<sup>11</sup> Date of implementation of Type IA variation should be specified if this variation is implemented prior SFDA approval

<sup>12</sup> Specify the precise present and proposed wording or specification, including dossier section number(s) at the lowest possible level

<sup>13</sup> For SPC, labelling and package leaflet changes, underline or highlight the changed words presented in the table above or provide as a separate Annex

**Declaration:**

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

Company Director/CEO:

Signature:

Date: