الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

The Policy of Appeal to Drug Sector Decisions

Version 1.3

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Only the Arabic version of this Regulation is authentic and it is applicable when there are differences with this translation

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Version No. 1.3

Saudi Food & Drug Authority
Drug Sector

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Saudi Food and Drug Authority

Vision and Mission

Vision

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

Mission

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

Document Control

Version	Author	Date	Comments
Draft	Executive Department of Regulatory Affairs	21 June 2021	-
1.0	Executive Department of Regulatory Affairs	03 March 2022	Final version
1.1	Executive Department of Regulatory Affairs	09 August 2022	update
1.2	Executive Department of Regulatory Affairs	16 October 2022	update
1.3	Executive Department of Regulatory Affairs	15 December 2024	update

What is New in version no. 1.3?

The following table shows the update to the previous version

Section	Description of change
Scope	**Update:** This policy applies to pharmaceutical, herbal and veterinary plants and their products in the following actions: • Registration rejections. • Deregister decisions (Deregistration). • Pricing decisions. • Clinical studies decisions.
Definitions	**Update:** • Appeal • Reconsidering the product's price. • **Added**: Price-based decision
General Concepts	**Update:** Updating and adding some paragraphs in general concepts.
Annexes	**Update:** Update and add some annexes

Table of Contents

Introduction:

The Drug Sector has prepared this document to provide the necessary information for companies or their agents with the procedures and requirements to submit an appeal to the decisions issued by the Sector, as well as the procedures and requirements to submit a price reevaluation request for the pharmaceutical products.

Scope:

This policy applies to pharmaceutical, herbal and veterinary manufacturers and their products, as follows:

- Registration decisions.
- Deregister decisions (Deregistration).
- Pricing decisions.
- Clinical studies decisions.

First: Definitions:

- Appeal: The right of the company or its agent in the Kingdom to submit an appeal to Drug Sector decisions. The company or its agent is allowed to submit two appeals as follows:
  1- First appeal: It shall be within 60 days from the date of informing the company or its agent of the decision. The application shall be studied within 60 days of its completion.
  2- Second appeal: it shall be submitted after deciding upon the first appeal, within thirty 30 days as of the date on which the company or its agent is notified of the decision on the first appeal. The appeal will studied within 30 days of its completion and is not allowed to submit requests for reconsideration.
- Reconsideration of the product's price: It is the right of the company or its agent in the Kingdom to submit a request to reconsider the price of the registered pharmaceutical product 3 years after the last decision based on the price and the request will be evaluated within 90 days of its completion.

- Price-based decision: It is the decision issued by the Authority's registration committees and it is either to increase, decrease or continue on the approved price

Second: General Concepts:

- In accordance with Article Twenty-One of the Pharmaceutical and Herbal Facilities Law, submitting a request to appeal or reconsider the price with the Authority does not mean that the company or its agent is not responsible for other obligations such as providing the product and following it up in the local market.
- The appeal request shall not be accepted unless it is supported by documents and evidences.
- The evaluation of the appeal application shall not be accepted if it complements the deficiencies during the registration evaluation process.
- The appeal or reconsideration request will be evaluated technically. If the company or its agent does not provide sufficient technical justifications, the authority has the right to inform the company or its agent not to complete the procedure or issue an inquiry, provided that the opportunity to respond to the inquiry does not exceed one time.
- If an appeal or reconsideration request concerns the price of a product that is standardized in the Gulf region, the company must submit the request to the Gulf Health Council. In the event that the price changes, a new request shall be submitted to the Authority accompanied by the decision issued by the Gulf Health Council, taking into account the requirements and conditions mentioned in this policy.
- The Authority has the right to exclude from the requirements of the Guideline and to amend the number of appeals that can be submitted according to the importance of the product and according to the justifications provided by the company.
- The company can submit meeting request to the Authority after submitting the appeal request. The Authority will review the request and respond to it.
- When submitting a request to reconsider the price of a product with multiple pharmaceutical forms, the Company shall submit each specific pharmaceutical form in a separate request. Different concentrations and packs are allowed to be submitted in one application.

- The Company may submit an extension request to complete the response to the appeal if there are acceptable justifications to the Authority before the end appeal specified period.

Third: Regulatory Requirements:

The company or its agent shall submit the justifications supporting the appeal or reconsideration request based on the relevant guidelines for each request as follows:

A- Regarding the registration process decisions:

- Attach response file according to the eCTD/CTD/VNeeS requirements.
- Include the issued decision with justifications in the Responses to questions field.
- Fill out the Appeal (on technical decision) Request form (Appendix No. 1).

B- Regarding the price of the pharmaceutical product decision.

- Attach response file according to the eCTD/CTD/VNeeS requirements
- Include the following in the Responses to question filed:
    1. Cover Letter.
    2. Include the recent decision regarding the product's price.
    3. Updated price certificate and new proposed price.
    4. Submit price Appeal/Reconsideration form, (Appendix No. 2 or 3) and certified (signed and stamped) by the agent or scientific office.
    5. Include the scientific, economic, or logistical justifications for not accepting the price with other documents that are related in the technical file containing the following:
        - Clinical Guideline.
        - Comparative studies of the product's safety and efficacy with registered substitutes.
        - Economic studies: the economic impact of the product compared to the registered alternatives.
        - The extent of the disease in the Kingdom and the number of patients targeted for treatment with the drug.

- Data on the availability of the product during the past five years (for previously registered products).
- Product's market share during the past two years (for previously registered products).
- Pay the financial fee for the appeal or reconsideration study for each registered package.

C- Regarding the decision to not register or cancel a clinical study registration:

- Attach a cover letter and document (certify) it (signed and stamped).
- Include the issued decision with the request justification.
- Fill out the Clinical Trial Rejection/Revoke of Registration Appeal form (Appendix No. 4).

D- Regarding the appeal to the result of the approved inspection visit report:

- Attach a cover letter and certify it (signed and stamped).
- Include the decision with the issued report and the request justifications.
- Fill out the inspection appeal form (Appendix No.5)

The applicant must provide a clarification if one of the requirements is not provided.

Fourth: Appeal /Reconsideration Steps:

- The appeal shall be submitted to the Authority with all technical requirements and its validity (Business Validation) will be verified within 5 days.
- If the requirements are not met during the Business Validation phase, a letter will be sent to the applicant to complete the requirements and deficiencies within the appeal or reconsideration remaining period, or not later than 5 days in the event that the regular period for appeal or reconsideration expires. The application will be rejected if the requirements are unmet within this period.
- If there any inquires or observations during the study phase, the company or its agent must respond within 10 days, otherwise the request is considered rejected.

Annexes:

Annex (1)

Appeal (on technical decision) Request Form

Product Information			
Trade Name		Reg. no.	
Active Ingredient(s)		Name and Site of Manufacturer	
Route(s) of Administration		Dosage Form	
Package Size and Type		Strength/Unit	
Marketing Authorization Holder (MAH)		Agent	
Appeal information			
Reason(s) behind the SFDA's decision			
Reason(s) why the SFDA's decision is invalid from the company's perspective			
List of documents that support the company's perspective			

Email		Stamp
Phone No.		
Signature		

Annex (2):

Price Appeal Form

Product Name		Date	/ /14 / /20
MAH - Nationality		Letter No.	
		SADAD invoice	

1. Product Information:

Registration No.		Reference No.	
Active Ingredient		Strength/Unit or Conc.	
Dosage form		Route(s) of administration	
Pack size		Therapeutic class	
Manufacturer - Nationality		Appeal Number	☐ 1 ☐ 2

2. Price Information:

Current Price		Cost	Per Unit	
CIF			Per Month	
Public			Per Course	
Proposed Price by Company		Cost	Per Unit	
CIF			Per Month	
Public			Per Course	

3. Prevalence (References): ☐ **Hospital Item** ☐ **Retail Item**

KSA No. of Patient		KSA Incidence		KSA Prevalence	
Global No. of Patient		Global Incidence		Global Prevalence	

4. Consumption & Market Share:

Consumption (for the last five years)					
Type of Consumption	20	20	20	20	20
Volume					
Market share					
Value					

5. Attachments required (CD):

1- Clinical Data	☐ Approved indication ☐ Place in therapy ☐ Guidelines	2- Company's Appeal Justifications.	3- SADAD Bill.

6. Authentication:

Email		**Stamp**
Phone No.		
Signature		

Annex (3)

Price Reevaluation Request Form

Product Name		Date	/ /14 / /20
MAH - Nationality		Letter No.	
		SADAD invoice	

1. Product Information:

Registration No.		Reference No.	
Active Ingredient		Strength/Unit or Conc.	
Dosage form		Route(s) of administration	
Pack size		Therapeutic class	
Manufacturer - Nationality		Last Price Update	/ /14 - / /20

2. Price Information:

Current Price (by Saudi Riyal)		Cost	Per Unit		GCC Unified CIF Price (USD)
CIF			Per Month		
Public			Per Course		
Proposed Price by Company (In Country of Origin's Currency)		Cost	Per Unit		
CIF			Per Month		
Public			Per Course		

3. Prevalence (References): ☐ Hospital Item ☐ Retail Item

KSA No. of Patient		KSA Incidence		KSA Prevalence	
Global No. of Patient		Global Incidence		Global Prevalence	

4. Consumption & Market Share:

Consumption (for the last five years)					
Type of Consumption	20	20	20	20	20
Volume					
Market share					
Value					

5. Attachments required:

1- Clinical Data	☐ Approved indication ☐ Place in therapy ☐ Guidelines	2- Company's Appeal Justifications.	3- SADAD Bill.

6. Authentication:

Email		Stamp
Phone No.		
Signature		

Annex (4)

Clinical Trial Rejection/Revoke of Registration Appeal Form

General Information:

Study Title			
SCTR Number		Sponsor	
Protocol Number		CRO (If Applicable)	
Total number of study recruited subject (s) within KSA		Study Site (s)	

Appeal Details:

SFDA remarks to be appealed (1):	…… ……
Applicant Justification:	…… ……
SFDA Decision:	Satisfactory or Not Satisfactory …… ……

SFDA remarks to be appealed (2):	…… ……
Applicant Justification:	…… ……
SFDA Decision:	Satisfactory or Not Satisfactory …… ……

SFDA remarks to be appealed (3):	…… ……

Applicant Justification:	…… ……
SFDA Decision:	Satisfactory or Not Satisfactory …… ……

Attachments required (CD):

1- Cover letter	2- Supportive Documents

SFDA Final Decision

Appeal Approval	☐
Appeal Rejection	☐

Annex (5)

Inspection Appeal Form

General Information:

Type of Objections	☐ Observations ☐ Conclusion		
SCTR Number (If Applicable)		Sponsor	
Inspection Report Number		CRO (If Applicable)	
Inspected Site		Principle Investigator at the inspected site	

Appeal Details:

SFDA remarks to be appealed (1):	……
Applicant Justification:	……
SFDA Decision:	Satisfactory or Not Satisfactory ……

SFDA remarks to be appealed (2):	……
Applicant Justification:	……
SFDA Decision:	Satisfactory or Not Satisfactory ……

SFDA remarks to be appealed (3):	.....
Applicant Justification:	.....
SFDA Decision:	Satisfactory or Not Satisfactory .....

Attachments required (CD):

1- Cover letter	2- Supportive Documents

SFDA Final Decision

Appeal Approval	☐
Appeal Rejection	☐