الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

The Policy of Appeal to Drug Sector Decisions

Version No. 1.2

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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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Saudi Food & Drug Authority
Drug Sector

For Inquiries	*Sdr.drug@sfda.gov.sa*
For Comments	*Drug.Comments@sfda.gov.sa*

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Saudi Food and Drug Authority

Vision and Mission

Vision

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

Mission

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

Document control

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INTRODUCTION

This document has been prepared by the drug sector to provide the information for Companies or their agents about the procedures and requirements for submitting an appeal on the decisions issued by the Drug 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:

- Decisions of rejection the registration
- Permanent Cessation
- Pricing decisions

FIRST: GENERAL CONCEPTS

- Appeal: the right of the company or its agent in the Kingdom to submit an appeal to Drug Sector decisions.
- Product Price Reevaluation: is a right for the company or its agent in the Kingdom to submit a repricing request for the registered pharmaceutical product, provided that such request is submitted after two years from the date of issuing the Certificate of Pharmaceutical Product (CPP) and once during its validity period.
- Responsible Department:
    - Products Department: is responsible for following up the requests of product registration and permanent cessation.
    - Pricing and Pharmacoeconomics Department: is responsible for evaluating the pricing and re-pricing of pharmaceutical products by applying pharmaceutical pricing rules and conducting or analyzing economic and clinical studies.

- Submitting an appeal to the SFDA does not relieve the company or its agent from other obligations, such as supplying and monitoring the product in the local market, in accordance with Article (21) of the Law of Pharmaceutical and Herbal Establishments and Products.
- The appeal is deemed to be rejected if the period for studying the request passed without a response from the side of SFDA.

SECOND: APPEAL STEPS

- The company or its agent is allowed to submit two (2) appeals, as follows:
    1- **First Appeal:** to be submitted within sixty (60) days as of the date on which the company or its agent is notified of the decision.
    2- **Second Appeal:** to 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, or if that period has passed without a response.
- The SFDA may extend the above-mentioned periods if it is necessary and subject to the product's priority and availability.

THIRD: THE PROCEDURES OF SUBMITTING FIRST APPEAL

1. Comply with the requirements stated in Section (Five).
2. The appeal must be submitted to the competent department along with all technical requirements, and SFDA will evaluate the appeal during the business validation within five (5) days.
3. In case of deficiency to fulfill the requirements during the business validation period, the applicant will be notified via the Saudi Drug Registration (SDR) System, to complete the requirements and provide the necessary documents within the applicant's appeal period, or no later than five (5) days upon the expiration of the appeal period. The request will be rejected if the requirements are not fulfilled within this period.
4. The appeal will be referred to the competent department for evaluation. In case of incomplete request to submit a proper technical justifications, the competent department may notify the company or its agent that the appeal will not be considered or otherwise request further inquiry, with condition that only one inquiry request will be made. In case the competent department sends

an inquiry or comment, the company or its agent must respond within ten (10) days, otherwise the request is considered rejected.

5. SFDA responds to the appeal request providing the justifications for its decision, within sixty (60) days as of the date on which the appeal is submitted with all its requirements fulfilled.
6. The company or its agent may request a meeting with the SFDA after the appeal is submitted and before the decision is issued.

FOURTH: THE PROCEDURES OF SUBMITTING SECOND APPEAL

1. The appeal fees must be paid as specified for each concentration and package.
2. The rejection decision of the first appeal, if any, must be submitted.
3. Requirements (1), (2), (3) of Third Section must be considered.
4. The competent department evaluates the appeal technically. In case of incomplete request to submit proper technical justifications, the competent department may notify the company or its agent that the appeal will not be considered.
5. SFDA responds to the second appeal request, indicating the justifications of its decision within (30) days as of the date on which the appeal was submitted.
6. The company or its agent may request a meeting with the SFDA before submitting the appeal.

Note: The Company or its agent must comply with the decision of the second appeal. If the product is registered and the company needs to terminate its registration, the company can submit a request for Permanent Cessation of Marketing of Medicinal Product Form (attachment No. 1).

FIFTH: REQUIREMENTS OF THE FIRST AND SECOND APPEAL

After referring to the relevant guidelines depending on the type of each appeal, the company or its agent must submit justifications to support the appeal, as follows:

A. For registration decisions:

1. Attaching the response file as per eCTD/CTD/ VNeeS requirements.
2. Attaching the decision, along with justifications in "the Response to Question" section.

B. For pharmaceutical product pricing decisions:

The agent or the scientific office must submit Authenticated Price Appeal Form (Attachment No. 2), attaching a cover letter along with necessary scientific justifications, containing the following:

1. Attaching the response file as per eCTD/CTD/ VNeeS requirements
2. Attaching the last decision, along with the Price Appeal Form in "the Response to Question" section.
3. An updated price certificate ~~with~~ a new suggested price.
4. A scientific, economic, or logistic justifications for rejecting the price must be added in the "additional-data" section in the technical file, containing the following:

   - Clinical Practice Guideline.
   - Comparative studies on product safety and efficacy against registered alternatives
   - Comparative economic studies for the product under registration to the registered alternatives.
   - Disease prevalence and incidence rate in the Kingdom and the number of patients targeted for treatment with the product
   - Data on product availability during the past five (5) years (for previously registered products)
   - Market share of the product during the past two (2) years (for previously registered products)

In case of unavailability of above mentioned requirements, the company must submit the appropriate justifications.

SIXTH: PRICE REEVALUATION REQUEST

The company or its agent may submit a price reevaluation request for a pharmaceutical product, as follows:

1- Paying the appeal fees specified each concentration and package.
2- The agent or the scientific office must submit the Price Reevaluation Request Form (Attachment No. 3), and attaching a cover letter along with scientific justifications mentioned in fifth Section requirement (B).

The SFDA will take a decision on the price reevaluation request, along with justifications of such decision, within (90) days as of the date on which the request is submitted, fulfilling all requirements. If a decision for a new price is issued, the company has the right to appeal to such decision in accordance with Second Section.

Attachments:

Attachment No. (1):

Permanent Cessation of Marketing of Medicinal Product form

Product Information			
Trade Name		**Reg. no.**	
Active Ingredient(s)			
Route(s) of Administration		**Dosage Form**	
Package Size and Type		**Strength/Unit**	
Marketing Authorization Holder (MAH)		**Price**	
Name and Site of Manufacturer		**Agent**	

Reason(s) for cessation	
□ **Production line shutdown**	□ **Product have not been marketed since first registration**
□ **Low price** **Have you submitted an appeal?** ☐ **Yes** ☐ **No** **no. of appeals:**	□ **Product have not been marketed since ……**
□ **Increased production expenses**	□ **Problems in manufacturing**
□ **MAH changed (resourced)**	□ **Reported adverse events**
□ **Low demand of the product**	□**Availability of another pack size of the product, specify**
□ **Manufacturer changed, specify with address**	□**Availability of another concentration of the product, specify**
□ **Contract termination with the licensor company**	□**Availability of another dosage form of the product, specify**
□ **MAH changed, specify with address**	□**Availability of other alternatives marketed by other MAH, specify**
Other:	

Did you attach an official letter from MAH with all required information (The letter should contain a justification for cessation request) **If not, a justification for not attaching should be provided:**	**Yes** **No**

Consumption (for the last four years)				
Year	**20..**	**20..**	**20..**	**20..**
Amount				

List of countries that the product is still marketed in	
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	

List of countries that ceased the product with dates and reasons for cessation			
Country		**Date**	**Reasons**
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

Declaration:

- I hereby certify that the submitted information is true and accurate.

Title:

Name:

Signature:

Date:

Company stamp:

Attachment no. (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	
Phone No.	
Signature	

Stamp

Attachment No. (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		**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	
Phone No.	
Signature	

Stamp