الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

The Procedure of Implementing Prices on Pharmaceutical Products

Version No. 1

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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

Saudi Food & Drug Authority
Drug Sector

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Please visit SFDA's website 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

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INTRODUCTION

This guideline aims to explain the required procedures and steps followed by the Saudi Food and Drug Authority (SFDA) to implement the prices of the registered pharmaceutical products after modifying the old prices, in order to:

- Limiting the delay of some supply elements in the implementation of prices based on the new packaging of the registered pharmaceuticals.
- Limiting the availability of these products with the old price.
- Guarantee the availability of these products at fair and affordable prices.

RELATED DOCUMENTS

- The Policy of appeal to Drug Sector Decisions.
- Pricing Rules for Pharmaceutical Products.
- Circular on Removing Drug Price Labels from Pharmaceutical Product Packages.

GENERAL PROVISIONS

- The company or its agent may submit an appeal to the decisions issued by Drug Sector, in accordance with The Policy of appeal to Drug Sector Decisions.
- If period for considering the appeal has been passed without receiving a response from SFDA, the issued decision will be implemented and the company must apply the new price.
- The company may directly apply the new price after the appeal is completed. However, a price re-evaluation request could be submitted for a pharmaceutical product, in accordance with the Policy of appeal to Drug Sector Decisions.
- If a price reevaluation is requested for a pharmaceutical product, the company is obligated to sell such product at the price approved by the SFDA until the request is decided.
- The SFDA may extend the period for implementing prices as it deems appropriate.

IMPLEMENTING PROCEDURES

1. When a decision is issued to change the price of a registered pharmaceutical product, the company or its agent is notified by SFDA through a letter (find attached a letter form), containing the following:
    - The new price of the pharmaceutical product.
    - The price implementation period (180 days).
2. All appeal procedures fall within the original implementation period (180 days).
3. Upon expiry of the implementation period, the price is modified on the SFDA website, the IBRCS (Importing, Batch-Release & Clearance System) and Drug Track and Trace System (RSD) are updated accordingly, and no batch can be released at the old price. The company can import at the old price before the price change if obtains the approval of the Import Department. Also, the company should place a non-removable label with the new price (if the old price is printed on the outer package) or following the price printing regulation (Circular on Removing Drug Price Labels from Pharmaceutical Product Packages).
4. Companies must agree to place a non-removable label with the new price for the in-stock quantities at the agent warehouses, pharmacies and retail stores (if the old price is printed on the outer package) or to follow the price printing regulation when the price implementation period expires.

Attachment: The letter of implementing the price

مدير الشؤون التنظيمية بشركة ..... **المحترم**

صورة لمدير التسجيل بشركة ..... **مع التحية**

السلام عليكم ورحمة الله وبركاته

بناء على قرار لجنة تسجيل شركات ومصانع الأدوية ومنتجاتها رقم ../..../sfda/.. عليه نفيدكم بتعديل سعر المستحضر التالي:

رقم التسجيل	الاسم العلمي	الاسم التجاري

بحيث يصبح سعر التصدير الجديد XX ريال سعودي، وسعر الجمهور الجديد XX ريال سعودي حيث تم احتسابه .....

على أن يتم تطبيق السعر الجديد خلال 180 يوم من تاريخ هذا الخطاب.

مع أطيب تحياتي

رئيس قسم دعم تسجيل الأدوية البشرية

Frequently Asked Questions

1. **Does the term "days" mentioned in this procedures mean "business days"?**

   It means regular calendar days, not business days.

2. **What are the procedures for submitting an appeal request?**

   The appeal procedures are according to the "Policy of Appeal to Drug Sector Decisions ".

3. **When can the company submit an appeal?**

   As of the date of issuing the price implementation letter.

4. **Does the price implementation letter include a pricing procedures?**

   Yes, as indicated in the letter form.

- **If the old price is printed on the outer package:**

5. **Is a written approval from the SFDA required to place the new price label after the expiry of the implementation period?**

   No written approval is required to place the new price label.

6. **What are the label specifications?**

   The label must be non-removable and hide the old price.

7. **Is the SFDA inspector required to conduct an inspecting visit after placing the approved label?**

   Yes, the SFDA inspector is required to conduct a checking visit and inspect the quantities before release.