الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

The Procedure of Implementing Prices on Pharmaceutical Products

Version No. 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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Version No. 2

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

Version	Author	Date	Comments
Draft	Executive Directorate of Regulatory Affairs	21 June 2021	-
1.0	Executive Directorate of Regulatory Affairs	3 March 2022	Final
2.0	Executive Directorate of Regulatory Affairs	17 November 2026	Final

- **What is new in version no. 2.0?**

The following table shows the updates to the previous version:

Section	Description of change
Introduction	**Update**
GENERAL PROVISIONS	**Update**
Implementing procedures	**Update**

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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:

- Guaranteeing patients' and consumers access to pharmaceuticals in the Kingdom at a fair and suitable price.
- Ensuring the capability of the pharmaceutical supply chain to implement the approved prices.
- Ensuring that pharmaceutical products at pharmacies and retail outlets are not available at the old price.

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.

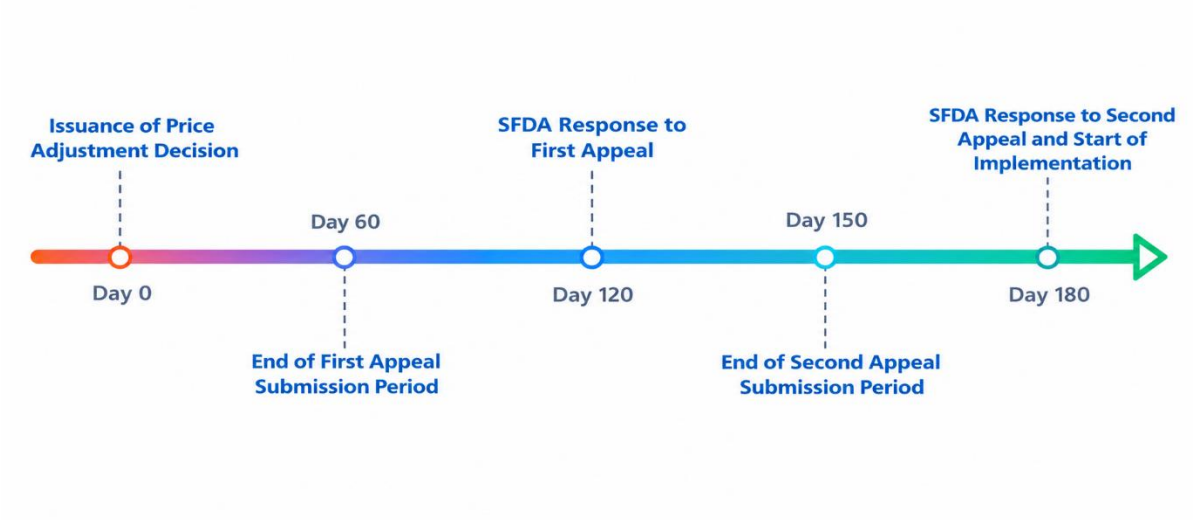
GENERAL PROVISIONS:

- 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 the Authority does not respond to the objection request within the specified timeframe for its review, the issued decision shall be deemed effective, and the company must apply the approved price after the expiry of the implementation deadline
- The Authority has the right to implement the approved price decision within 180 days of its issuance.
- If a decision is made to reduce the price of a pharmaceutical product whose price was adjusted less than two years, the decision shall take effect once the two-year period expires.
- Upon the issuance of a decision to fix the price of a registered innovative or biological pharmaceutical product in accordance with the Pricing Rules for Pharmaceutical Products, the company or its agent shall be notified through official channels of the decision and its duration.

- The company has the right to directly implement the price after the objection or reconsideration request for the pharmaceutical product's price is decided, 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 SFDA issues a decision to change the price of a registered pharmaceutical product, the company or its agent shall be notified of the approved price through official channels.
2. All appeal procedures fall within the original implementation period (180 days). As shown below:



3. Once the implementation timeframe expires, the price will be updated and posted on the Authority's website, along with updating all associated electronic systems.
4. If the company has optionally printed the product’s previous price on the outer packaging, it shall place a non-removable label showing the approved price on all quantities held in the agent's warehouses, pharmacies, and point-of-sale outlets, or comply with the specific regulation regarding price printing in accordance with the circular concerning the removal of drug prices from pharmaceutical packaging.