الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Pricing rules

Pharmaceutical preparations

Rabi` al-Awwal 1442 AH

Approved pharmaceuticals pricing rules

By the Authority's Board of Directors by Resolution No. (12-26-1442) dated 3/22/1442 AH

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These rules will be effective as of 1/6/1442 AH corresponding to 1/14/2021 AD

(Definitions)

Article 1:

The following words and expressions - wherever they are mentioned in these rules - have the meanings shown before them, unless the

Commission: General Authority for Food and Drug Administration.

Pharmaceutical preparation (medicine): Any product that is manufactured in a pharmaceutical form and contains one or more substances that are used externally or internally in treating humans from diseases or preventing them.

The Commission: Committee for registering pharmaceutical companies and factories and their products.

the rules: The mechanism followed by the authority to determine the price of a drug.

Country of Origin: The country in which the drug is manufactured in its initial pharmaceutical form (such as: tablets, capsules, injection)

Country of Origin: The country from which the Certificate of Pharmaceutical Product-CPP is issued.

Emerging Factory: A factory that obtained an initial factory license from the Authority.

Innovated drug: Preparations that contain a new active ingredient and are put on the market under a brand name by the innovative company.

The generic drug (GenericDrug): Formula equivalent to an innovative product in pharmaceutical form, concentration, mode of administration, quality, efficacy and therapeutic claim.

Biological Drug: It is a drug produced from living sources such as humans, animals, bacteria, viruses or fungi, or manufactured using advanced biotechnology, genetics or cytology.

Biosimilar Drug: It is a biological medicine similar to the reference biological medicine registered with the FDA in terms of the active substance (s) included in the composition, efficacy, purity and safety of use, even if the medically inactive substances included in the composition differ.

Therapeutic alternatives: Medicines that have the same therapeutic effect and are from the same or different treatment groups.

Expensive Drug: Pharmaceutical preparations whose monthly cost exceeds the monthly domestic product per capita (GDP per capita, PPP).

Ex-Factory Price: The price of the drug in the country of manufacture before adding the cost of shipping, insurance, and the profit of the agent a

Export Price ()) Cost, Insurance & Fright (CIF): Factory price plus shipping and insurance costs.

Wholesale price of the drug in the country of origin: The factory price in the country of origin plus the profit of the wholesaler.

Wholesale price in the Kingdom of medicine: The export / factory price plus the profit percentage of the drug trade warehouse.

The price of selling the medicine to the public in the Kingdom (public price): The wholesale price of the medicine plus the profit from the ph

(Pricing of pharmaceuticals)

second subject:

The lotion is priced The pharmacist At an appropriate price, taking into account the following data when pricing:

1. The added therapeutic value of the product.
2. Prices of treatment alternatives registered in the Kingdom.
3. Economic Studies of Drugs (Pharmacoeconomics / Economic Evaluation Studies).
4. The factory price of the preparation in the country of manufacture in its local currency.
5. The wholesale price of the product in the country of origin in its local currency.
6. The proposed price for the Kingdom provided by the company in the currency of the country of origin.
7. Factory price or export to all countries in which the preparation is marketed in its local currency.
8. The selling price of the product to the public in the country of origin and the countries in which it is marketed.
9. Procurement price references approved prices.

(Paragraphs 4 to 8 are attached to the price certificate form (attachment No. 1), provided that no more than six months have passed since the date of issuance of the certificate from the company upon its pricing, and the authority may review the list of reference countries in the price certificate form periodically in accordance with global economic and health variables).

(Innovative and vital products)

Article Three:

The innovative preparation and the biological preparation shall be priced according to the provisions of Article Two, subject to the follo

a. The preparation for which there are no therapeutic alternatives registered and not marketed in any of the reference countries is priced in a

Prices are based on the company's proposed export price, and the committee may consider the possibility of reducing the price after discussing with the company on that.

B. The product is priced based on clinical comparison studies and pharmacological economics studies with registered therapeutic alternatives, provided that the price of the therapeutic alternative does not exceed its equivalent in the event that it is not marketed in any of the countries of reference in the price certificate, and the committee may consider the possibility of adop

C. The preparation for which there are no registered therapeutic alternatives is priced based on the weight of the price in the countries in which the product is marketed, using economic and health factors, and the committee may consider the

Dr.. possibility of considering the price of one of the reference countries in the price certificate. The locally manufactured product under license from international companies and is still in the patent period, and locally produced under the name of the national company, is priced at the same price of the innovative product during the patent period, and after the end of the patent p

e. The preparation submitted for registration with the authority for the first time is priced by a local manufacturer, assuming the price of the innovative product of the company that owns the medicine worldwide and that is still in the patent period, then the local

(Generic preparations)

Article Four:

The price of the innovative product in all its concentrations and packages is reduced by 25% upon registering the first generic product.

Fifth Article:

The generic preparation is priced according to what is mentioned in Article Two, taking into account the following:

a. The first generic product is priced so that its price does not exceed 70% of the price of the innovative product registered and marketed in t

Before lowering it due to the introduction of the first formulation.

B. The second generic product is priced so that its price does not exceed 65% of the price of the innovative product registered and marketed

Before lowering it.

C. The third generic product and beyond is priced so that its prices do not exceed 60% of the registered innovative product price

And the marketer in the Kingdom before reducing it.

(Similar biological preparations)

Article Six:

The price of the vital product in all its concentrations and packages is reduced by 20% when registering the first similar biological product.

Article Seven:

A similar biological preparation is priced in accordance with the provisions of Article Two, subject to the following:

a. The first similar biological product is priced so that its price does not exceed 75% of the registered and marketed biological product In the Kingdom before it was reduced due to the introduction of the first similar preparation.

B. The second similar biological product is priced so that its price does not exceed 65% of the registered and marketed biological product In the kingdom before it was reduced.

C. The third similar biological product and beyond is priced so as not to exceed 55% of the biological product price Registrar and marketer in the Kingdom before reducing it.

(Combination preparations)

Article Eight:

The pharmaceutical preparation that contains more than one active substance is priced according to what is stated in Article Two of the rules, taking into account the following:

a. When adding a product registered with the authority to other preparations registered from the same company, the preparation is priced so It does not exceed the price of the first preparation plus the prices of the other preparations.

B. When adding a product registered for the company with the authority to other products registered not from the same company, it is priced The preparation, provided that the price of the first product plus the average price of the generic preparations registered from the other added products does not exceed.

(Re-pricing of pharmaceuticals)

Article 9:

The pharmaceutical preparation shall be re-priced in accordance with the provisions of Article Two of these rules, provided that the reduction rate upon re-pricing does not exceed 30% of the price of the preparation.

Article Ten:

The committee may review the price of the pharmaceutical preparation within two years of its registration in the following cases:

a. Lotions are very expensive.

B. Preparations that require proof of health outcomes.

Article Eleven:

The committee may review the price of the pharmaceutical preparation during its registration period in the following cases:

a. When reviewing the prices of preparations in the therapeutic group.

B. In the event of a decrease in the price of the preparation in the country of origin or countries to which it is marketed.

C. When the company requests a review of the registered and marketed price of the product, according to objective justifications accepted b

(Renewal)

Article Twelve:

The committee shall consider re-pricing the pharmaceutical preparation upon renewing its registration in accordance with the provisions of Article Two of the rules, taking into account the following:

a. Exempt from the re-pricing upon renewal of preparations whose prices and concentrations are less than 30 Saudi riyals.

B. When re-pricing the innovative product during its registration renewal for the first time after registering and marketing a generic product for it, the prices of the generic preparations registered for it are reviewed so that the difference between the prices of the generic products and the price of the innovative product is not less than 10%.

C. When re-pricing a biological product during its registration renewal after registering and marketing of similar biological preparations, the prices of similar biological preparations registered for the re-priced biological product are reviewed so that the difference between the prices of similar biological products and the biological product is not less than 15%.

Dr.. When re-pricing the innovative product or biological product during the renewal of their registration after registering and marketing generic preparations or similar biological preparations for them for at least 10 years, the prices of the generic preparations and the bio-similar preparations registered for them are reviewed so that their prices do not exceed the price of the innovative product or biological product, taking into account the inflation rate in the pharmaceutical industry and the volume

(Modifications)

Article Thirteen:

The committee may review the price of the pharmaceutical preparation when the company makes adjustments to the company that owns the mar

Article Fourteen:

The committee may reconsider the price of the pharmaceutical preparation for the emerging factory when it is considered an emerging factory and is not committed to transferring the manufacturing to the Kingdom.

Article Fifteen:

The price of the innovative and vital preparation registered for the foreign company is proven when it fully transfers all manufacturing steps to the Kingdom and begins marketing the product for a period not exceeding seven years.

Article Sixteen:

When adding a new package, concentration, or pharmaceutical form to a registered pharmaceutical preparation, the provisions of Article Two of these rules shall be applied, taking into account the price of the same registered drug.

(General Provisions)

Article seventeen:

Pharmaceutical preparations of different concentrations and packages are priced according to what is stated in Article Two of the rules, taking into account the following:

a. The percentages shown in annex No. (2) shall be applied in the event of different concentrations of packages.

B. The committee has the right to give a flat price for all concentrations of the preparation if the company submits this.

C. If the company provides a group of concentrations at the same time, the price of the lowest concentration unit of the concentrations is calc

On its basis.

Article 18:

When taking the factory price in the countries where the pharmaceutical drug is marketed, or the public price in the country of origin, the shipping and insurance difference is added at a rate not exceeding 2%.

Article Nineteen:

The committee may consider giving a price advantage to pharmaceutical preparations that have specific characteristics that increase the effectiveness or safety of the product, or give it therapeutic or manufacturing advantages, provided that the percentage of this price a

Article Twenty:

The innovative and biological product shall be treated in terms of price, the treatment of the generic product and the similar biological product if they are registered after the registration of the generic product and the similar biological product, subject to the provisions of A

Article twenty-one:

When the company requests to re-register the innovative product or biological product after approval of its cancellation request, it will be priced as a new product presented for the first time in the Kingdom.

Article twenty-two:

The price of the pharmaceutical product is not reduced within two years from the date of the last approved price reduction.

Article twenty-three:

The price stipulated by the committee is considered a higher price ceiling, and the company has the right to downgrade this price to a lower price.

Article twenty-four:

The Committee may exclude pharmaceutical preparations from some of the provisions contained in these rules to ensure their availability in the lo

Article Twenty Five:

The company or its representative has the right to object to the price of the pharmaceutical preparation within sixty days from the date on which the agent or company is notified of the new price, in accordance with the policies followed by the Authority.

Article Twenty-Six:

The company or its representative has the right to apply for the pricing of the pharmaceutical preparation before its registration, accord

- Submit a recent price certificate signed by the authorized person and sealed by the company.
- Fill out the approved form (Attached No. 3) attached with the required studies.
- Provide a sample of the preparation.
- Pay the monetary fee upon approval to submit the application.
- It is not allowed to submit an objection to the proposed price of this service.

The proposed price shall be considered approved by the Authority in the event that the product is registered within nine months from the date of informing the company or its representative.

(Attachments)

Attachment No. (1):

Price Certificate Form (20 Country Form)

Form (Form 20) Certificate Price

	Dosage Form		**Strength**		**Product Name**
	Pack Size		**Nationality**		**Company Name**

Currency	**Public Price** In Country of Origin's currency	**Currency**	**Wholesale Price** In Country of Origin's currency	**Currency**	**Ex-Factory Price** In Country of Origin's currency
Note		(By Units) **Consumptions** In Country of Origin		**Currency**	**Proposed CIF to KSA** In Country of Origin's currency

Notes	**Consumptions (By Units)**		**Public Price**		**CIF Price**		**Ex-Factory Price**	**Packing**	**Country**	**NO.**
									Australia	. 1
									Austria	. 2
									Belgium	. 3
									Brazil	. 4
									Canada	. 5
									France	. 6
			Currency		**Currency**		**Currency**		**Hungary**	. 7
									Ireland	. 8
									Italy	. 9
									Japan	. 10
									Jordan	. 11
									Lebanon	. 12
									Netherlands	. 13
									Portugal	. 14
									South Korea	. 15
									South Africa	. 16
									Sweden	. 17
									Switzerland	. 18
									UAE	. 19
									UK.	. 20

Company attest:		We:
All prices stated on this form are correct		Certify That all prices in this form are correct and accurate

The name of the person authorized to sign for the company	Name of the person authorized to sign on behalf of the company
Company seal owner of marketing rights Marketing authorization Holder Stamp	

If there is more than one marketed package, the price of each package and the countries in which it is marketed shall be mentioned in a separate form sealed with the company's seal.

In case of registering multiple package sizes, each packmust have a separate stamped form.

Attachment No. (2):

Calculating the prices of medicine packages when the concentration differs and the package size is fixed

Pharmaceutical forms	Differences between concentrations	Price change ratio
Solid lotions (Tablets, capsules, sachets)	2: 1 3: 1 4: 1 5: 1 6: 1 etc.	- 18% -% 24 30% 30% 30%
Liquid formulations (Oral syrups and liquids)	2: 1 3: 1 4: 1 5: 1 6: 1 etc.	- %15 -% 20 30% 30% 30%
Suppositories and topical treatments	2: 1 3: 1 4: 1 5: 1 6: 1 etc.	-% 20 25% 30% 30% 30%
Ampoules and vials	2: 1 3: 1 4: 1 5: 1 6: 1 etc.	-% 14 -% 20 25% 25% 25%

Attachment No. (3):

Pricing form before registration Pricing before Registration Form

14 / /	Date		Product Name
20 / /			
	SADAD invoice		Letter No.

1. Product Information:

	Strength / Unit or Conc.		Active Ingredient
	Route (s) of administration		Dosage form
	Therapeutic class		Pack size
			MAH
			Agent
			Manufacturer
			Country of Manufacturer

2. Price Information:

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

3. Prevalence (References):

Retail Item □		al Item Hospit □			Product Type
	KSA Prevalence		KSA Incidence		KSANo. of Patient
	Global Prevalence		Global Incidence		Global No. of Patient

4. Attachments (Hard or Soft Copy):

3- SADAD Bill.	**1- Clinical Data:**
4- Economic Studies.	Approved indication. •
Pharmacoecnomics studies. •	Place in therapy. •
Budget impact studies. •	Guidelines. •
5- Registered alternative products at SFDA.	Clinical studies. •
6- Sample.	**2- Price certificate:**
7- Other information.	Authorized & updated •

You can fill this form by using Adobe Acrobat Reader

Attachment No. (4):

The new pricing model New Pricing Form

14 / /	Date		Product Name
20 / /			Reference No.

1. Product Information:

	Strength / Unit or Conc.		Active Ingredient
	Route (s) of administration		Dosage form
	Therapeutic class		Pack size
			MAH
			Agent
			Manufacturer
			Country of Manufacturer

2. Price Information:

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

3. Prevalence (References):

Retail Item □		al Item Hospit □			Product Type
	KSA Prevalence		KSA Incidence		KSANo. of Patient
	Global Prevalence		Global Incidence		Global No. of Patient

4. Attachments (Hard or Soft Copy):

3- Economic Studies. Pharmacoecnomics studies. • Budget impact studies. • **4- Registered alternative products at SFDA.** **5- Sample.** **6- Other information.**	**1- Clinical Data:** Approved indication. • Place in therapy. • Guidelines. • Clinical studies. • **2- Price certificate:** Authorized & updated •

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Attachment No. (5):

Re-quote form upon renewal of registration Price Revision at Renewal Form

14 / /	Date		Product Name
20 / /			Registration No.

1. Product Information:

	Strength / Unit or Conc.		Active Ingredient
	Route (s) of administration		Dosage form
	Therapeutic class		Pack size
			MAH
			Agent
			Manufacturer
			Country of Manufacturer

2. Price Information:

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

3. Prevalence (References):

Retail Item □		al Item Hospit □			Product Type
	KSA Prevalence		KSA Incidence		KSANo. of Patient
	Global Prevalence		Global Incidence		Global No. of Patient

4. Consumption & Market Share:

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

5. Attachments (Hard or Soft Copy):

1- Clinical Data: Approved indication. • Place in therapy. • Guidelines. • Clinical studies. • **2- Price certificate:** Authorized & updated •	**3- Economic Studies.** Pharmacoecnomics studies. • Budget impact studies. • **4- Registered alternative products at SFDA.** **5- Sample.** **6- Other information.**

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Attachment No. (6):

Objection submission form Price Appeal Form

Price Revision ☐ New Registration ☐

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

1. Product Information:

	Reference No.		Registration No.
	Strength / Unit or Conc.		Active Ingredient
	Route (s) of administration		Dosage form
	Therapeutic class		Pack size
	Agent		Manufacturer

2. Price Information:

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

Retail Item ☐ Hospital Item ☐

3. Prevalence (References):

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

4. Consumption & Market Share (Only for Price Revision Appeal):

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

5. Attachments required (CD):

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

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Attachment No. (7):

A re-examination request form

Price Reevaluation Request Form

Price Revision ☐ **New Registration ☐**

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

1. Product Information:

	Reference No.		Registration No.
	Strength / Unit or Conc.		Active Ingredient
	Route (s) of administration		Dosage form
	Therapeutic class		Pack size
	Agent		Manufacturer

2. Price Information:

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

Retail Item ☐ Hospital Item ☐

(References): Prevalence 3

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

4. Consumption & Market Share:

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

5. Attachments required (CD):

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

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