الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Pricing Rules for Pharmaceutical Products

Approved by SFDA Board of Directors Resolution No. (12-26-1442) dated 22/03/1442 AH
These Rules will be effective as of 01/06/1442 AH (14/01/2021 AD)

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

DS-REQ-082-V03/210114

(Definitions)

Article One:

The following words and phrases, wherever they appear herein, shall have the same meanings ascribed hereunder, unless the context requires otherwise:

- **SFDA:** Saudi Food and Drug Authority.
- **Pharmaceutical Product (drug):** A pharmaceutically manufactured product containing one substance or more, and used externally or internally in treatment or prevention of human diseases.
- **The Committee:** The Registration Committee for Pharmaceutical Companies, Manufacturers and their Products.
- **The Rules:** The approach followed by SFDA to determine the price of a drug.
- **Manufacturing Country:** The country in which the drug is manufactured in its initial dosage form (such as tablets, capsules, injection)
- **Country of Origin:** The country from which the Certificate of Pharmaceutical Product-CPP has been issued.
- **Growing Manufacturer:** A Manufacturer that obtained an initial Manufacturer license from the SFDA.
- **Innovated Drug:** Products that contain new active ingredient and marketed under a brand name by the innovative company.
- **Generic Drug:** A drug that is equivalent to an innovative product in dosage form, concentration, route of administration, quality, efficacy and therapeutic indication.
- **Biological product:** It is a medicine produced from living sources such as humans, animals, bacteria, viruses or fungus, or produced by using advanced biotechnology
- **Biosimilar product:** a biological product similar to the reference biological medicine registered with the SFDA in terms of the active substance(s) that included in the composition, efficacy, purity and safety of use, even if the medically inactive ingredients included in the composition are different.

- **Therapeutic alternatives:** Medicines that have the same therapeutic effect and are from the same or different therapeutic class.
- **Expensive Drug:** Pharmaceutical products which their monthly cost exceeds the monthly gross 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 freight, insurance, the profit of the agent and the pharmacy.
- **Export Price (Cost, Insurance & Freight (CIF)):** Ex-factory price plus freight and insurance costs.
- **Wholesale price of the drug in the country of origin (Wholesale Price):** The ex-factory price in the country of origin plus the profit of the wholesaler.
- **Wholesale price in the Kingdom:** The export / factory price plus the profit percentage of the drug trade warehouse.
- **The price of selling the drug to the public in the Kingdom (Public Price):** The wholesale price of the drug plus the pharmacy's profit.

(Pricing of Pharmaceutical Products)

Article Two:

The pharmaceutical product is priced fairly, taking into account the following:

1. The added therapeutic value of the product.
2. Prices of therapeutic alternatives, which are registered in the Kingdom.
3. Economic studies of drugs (Pharmacoeconomics / Economic Evaluation Studies).
4. The product ex-factory price in the manufacturing country in its local currency.
5. The product wholesale price in the country of origin in its local currency.
6. The proposed price for the Kingdom's market provided by the company in the currency of the country of origin.
7. Ex-Factory or export price to all countries where the product is marketed in its local currency.
8. The wholesale price of the product in the country of origin and the countries where it is marketed.
9. The product price in the approved prices references.

Points (4 to 8) of article 2 shall be provided within the Price Certificate Form (Attachment No. 1), given that upon product pricing no more than six months have passed since the date of issuance of the certificate from the company. SFDA may review the list of reference countries in the Price Certificate Form periodically in accordance with global economic and health variables).

(Innovative and biological Products)

Article Three:

The innovative and the biological products shall be priced according to the provisions of Article Two, taking into account the following:

A. The product pricing shall be based on the company's proposed export price if there are not any registered therapeutic alternatives, and the product is not marketed in any of the reference countries mentioned in the Prices Certificate. The committee may consider the possibility of reducing the price after holding a discussion with the company.

B. The product pricing is based on clinical comparative studies and pharmacoeconomics studies with registered therapeutic alternatives, and the price of the product shall not exceed its equivalent therapeutic alternative if it is not marketed in any of the reference countries mentioned in the Price Certificate. The Committee may consider the possibility of adopting the price of a similar therapeutic alternative.

C. The product for which there are no registered therapeutic alternatives is priced according to the scale of the price in the countries in which the product is marketed, using economic and health factors to weigh the price, and the Committee may consider the possibility of adopting the price of one of the reference countries in the Price Certificate.

D. The product which is manufactured locally under a license from international companies and still in the patent term, and locally produced under the name of the national company, is priced at the same price as the innovative product during the patent period. The product of the national company shall be treated as a generic product when the patent term expires

E. The product which is submitted for registration with the SFDA for the first time by a local manufacturer shall be priced by assuming the price of the innovative product of the company that owns the medicine globally and that is still in the patent term. Accordingly the local manufacturer shall be given the same price.

(Generic Products)

Article Four:

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

Article Five:

The generic product shall be priced according to the provisions of Article Two, taking into account the following:

A. The first generic product shall be priced without exceeding 70% of the price of the innovative product that registered and marketed in the Kingdom before reducing it due to the registration of the first generic product.
B. The second generic product shall be priced without exceeding 65% of the price of the innovative product that registered and marketed in the Kingdom before reducing its price.
C. The third generic product and beyond shall be priced without exceeding 60% of the price of the innovative product that registered and marketed in the Kingdom before reducing its price.

(Biosimilar Products)

Article Six:

The price of the biological product, in all their concentrations and pack sizes, is reduced by 20% upon the registering of the first biosimilar product.

Article Seven:

The biosimilar product shall be priced according to the provisions of Article Two taking into account the following:

A. The first bio-similar product is priced so that its price does not exceed 75% of the price of the biological product that registered and marketed in the Kingdom before reducing it due to the registration of the first Bio-similar product.
B. The second similar Bio-similar product shall be priced without exceeding 65% of the price of the biological product registered and marketed in the Kingdom before reducing its price.
C. The third similar Bio-similar product and beyond shall be priced without exceeding 55% of the price of the biological product that registered and marketed in the Kingdom before reducing its price.

(Combination Drugs)

Article Eight:

The pharmaceutical product 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 drug registered at the SFDA to other registered drugs for the same company, the pricing of the pharmaceutical product shall not exceed the price of the first drug plus the prices of the other drugs.

B. When adding a drug registered for the company at the SFDA to other registered drugs which are not from the same company, the pricing of the pharmaceutical product shall not exceed the price of the first drug plus the average price of the generic drugs registered from the other added products.

(Re-Pricing of Pharmaceutical Products)

Article Nine:

The pharmaceutical product 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 product's price.

Article Ten:

The Committee may reevaluate the price of the pharmaceutical product within two years of its registration according to the following cases:

A. Expensive products.
B. Products that require proof of their health outcomes.

Article Eleven:

The Committee may reevaluate the price of the pharmaceutical product during its registration period according to the following cases:

A. When reviewing the prices of products within the therapeutic class.
B. Decreasing in product's price in the country of origin or marketed countries.
C. When the company requests to reevaluate the price of the registered and marketed product, in accordance with objective justifications accepted by the Committee.

(Renewal)

Article Twelve:

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

A. Products that the prices of all their packages and concentrations are less than 30 Saudi Riyals will be exempt from the re-pricing upon their renewal.

B. When re-pricing the innovative product upon renewal of its registration for the first time after registering and marketing a generic product, the prices of the registered generic products shall be reviewed in which the difference in the price between the generic products and the innovative product is not less than 10%.

C. When re-pricing a biological product upon renewal of its registration after registering and marketing of biosimilar product, the prices of the registered biosimilar products of the biological product under re-pricing shall be reviewed in which that the difference in prices between biosimilar products and the biological product is not less than 15%.

D. When re-pricing the innovative or biological product upon the renewal of their registration after registering and marketing their generic products or biosimilar products for not less than 10 years, the prices of the generic and biosimilar products registered for them shall be reviewed in which that their prices do not exceed the price of the innovative or biological product, taking into account the inflation rate in the pharmaceutical industry and the volume of consumption of the innovative or biological product.

(Variations)

Article Thirteen:

The Committee may reevaluate the price of the pharmaceutical product when the company makes changes to the marketing authorization holder.

Article Fourteen:

The Committee may reevaluate the price of the pharmaceutical product for the growing manufacturer when it is no longer considered emerging and fail to meet the obligation of manufacturing transfer to the Kingdom.

Article Fifteen:

The price of the innovative and biological product which are registered for a foreign company shall be fixed for a period not exceeding seven years when all the manufacturing phases of the product are fully transferred to the Kingdom and begins marketing the product to the market.

Article Sixteen:

The provisions of Article Two of these Rules shall be applied when adding a new pack size, concentration, or dosage form to a registered pharmaceutical product, taking into account the price of the same registered product.

(General Provisions)

Article Seventeen:

Pharmaceutical products of different concentrations and pack sizes are priced according to what is stated in Article Two of the Rules, taking into account the following:

A. The percentages stated in Attachment No. (2) shall be applied in the event of different concentrations of the same pack size.
B. The committee has the right to give a flat price for all concentrations of the product if requested by the company.
C. If the company submits more than one concentration at the same time, the price of the lower concentration shall be considered, and other concentration will be priced accordingly to it.

Article Eighteen:

The freight and insurance expenses are added at a rate not exceeding 2% when considering the manufacturer price in the countries where the pharmaceutical product is marketed or the public price in the country of origin.

Article Nineteen:

The Committee may consider giving price premium to pharmaceutical products that have specific characteristics that increase the effectiveness or safety of the product, or adding therapeutic or manufacturing advantages, provided that the percentage of this premium shall not exceed 20%.

Article Twenty:

The innovative and biological products shall be treated, in terms of price, as generic and biosimilar products if they were registered after the registration of the generic and biosimilar products, taking to consideration Article Two of the Rules.

Article Twenty One:

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

Article Twenty Two:

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

Article Twenty Three:

The price which is determined by the Committee is considered a maximum price, and the company has the right to reduce it to a lower price.

Article Twenty Four:

The Committee may exempt pharmaceutical products from some of the provisions stated in these Rules to ensure their availability in the local market.

Article Twenty Five:

The company or its representative has the right to appeal the price of the pharmaceutical product within sixty days from the date on which the agent or company was notified about the new price, in accordance with the policies followed by the SFDA.

Article Twenty Six:

The company or its representative has the right to submit a pricing application for its pharmaceutical products before its registration, according to the following:

- Submit a recent price certificate signed by the authorized person and stamped by the company.
- Fill in the approved form (Attached No. 3) attached with the required studies.
- Provide a sample of the product.
- Pay the financial fees upon approval to submit the application.
- It is not allowed to submit an appeal to the proposed price from this service.

The proposed price shall be approved by the SFDA if the product is registered within nine months from the date of informing the company or its representative of the proposed price.

(Attachments)

Attachment No. (1): Price Certificate Form (Form 16)

Date			التاريخ
Separate forms must be filled for each pack or strength		يتم تعبئة نموذج مستقل لكل عبوة أو تركيز	

	حجم العبوة Pack Size		الشكل الصيدلاني Dosage Form		التركيز Strength		اسم المستحضر Product Name
	الجنسية Nationality		اسم المصنع Manufacturer		الجنسية Nationality		اسم الشركة المسوقة MAH Name

عملة بلد الشركة المسوقة MAH Country Currency	سعر التصدير المقترح Proposed CIF	سعر الجمهور Public Price	سعر الجملة Wholesale Price	سعر المصنع Ex-Factory Price

Note	مبررات احتساب السعر المقترح Rational behind the proposed CIF price	الاستهلاك في بلد المنشأ لآخر ثلاث سنوات (بالوحدة) Consumption In the COO for the last three years (By Units)	
			20
			20
			20
All prices above must be in MAH country currency		جميع الأسعار أعلاه توضع بعملة بلد الشركة المسوقة	

#	الدولة Country	حجم العبوة Packing	سعر المصنع Ex-Factory Price	العملة Currency	سعر التصدير CIF Price	العملة Currency	سعر الجمهور Public Price	العملة Currency	الاستهلاك (بالوحدة / آخر سنة) Consumptions (By Units / Last year)	Notes
1	أستراليا Australia									
2	النمسا Austria									
3	بلجيكا Belgium									
4	كندا Canada									
5	فرنسا France									
6	ألمانيا Germany									
7	المجر Hungary									
8	إيطاليا Italy									
9	اليابان Japan									
10	هولندا Netherlands									
11	بولندا Poland									
12	البرتغال Portugal									
13	كوريا الجنوبية South Korea									
14	إسبانيا Spain									
15	السويد Sweden									
16	المملكة المتحدة United Kingdom									
يتم ذكر المبررات في حال عدم وضع أسعار أحد الدول أعلاه										Justifications must be provided in case of not including prices for any of the countries above

تشهد شركة:		We:
أن جميع الأسعار الواردة في هذا النموذج صحيحة		Certify That all prices in this form are correct and accurate

اسم الشخص المفوض بالتوقيع عن الشركة	Name of the person authorized to sign on behalf of the company
ختم الشركة مالكة حقوق التسويق Marketing authorization Holder Stamp	

In case of registering multiple package sizes, each pack must 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 products (Tablets, capsules, sachets)	2:1 3:1 4:1 5:1 6:1 etc.	- 18% - 24% - 30% - 30% - 30%
Liquid products (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 before Registration Form

Product Name		**Date:**	**00/00/14--** **00/00/20--**
Letter No.		**SADAD invoice**	

1. Product Information:

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

2. Price Information:

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

3. Prevalence (References):

Product Type	☐ **Hospital Item**		☐ **Retail Item**		
KSA No. of Patient		**KSA Incidence**		**KSA Prevalence**	
Global No. of Patient		**Global Incidence**		**Global Prevalence**	

4. Attachments (Hard or Soft Copy):

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

You can fill this form by using Adobe Acrobat Reader

Attachment No. (4):

New Pricing Form

Product Name		**Date:**	**00/00/14--**
Reference No.			**00/00/20--**

1. Product Information:

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

2. Price Information:

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

3. Prevalence (References):

Product Type	☐ **Hospital Item**		☐ **Retail Item**		
KSA No. of Patient		**KSA Incidence**		**KSA Prevalence**	
Global No. of Patient		**Global Incidence**		**Global Prevalence**	

4. Attachments (Hard or Soft Copy):

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

You can fill this form by using Adobe Acrobat Reader

Attachment No. (5):

Price Revision at Renewal Form

Product Name		Date:	00/00/14--
Registration No.			00/00/20--

1. Product Information:

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

2. Price Information:

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

3. Prevalence (References):

Product Type	☐ 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 (Hard or Soft Copy):

1- Clinical Data:
- Approved indication.
- Place in therapy.
- Guidelines.
- Clinical studies.

2- Price certificate:
- Authorized & updated

3- Economic Studies.
- Pharmacogenomics studies.
- Budget impact studies.4

4- Registered alternative products at SFDA.

5- Sample.

6- Other information.

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Attachment No. (6):

Price Appeal Form

☐ New Registration ☐ Price Revision

Product Name		Date:	00/000/14-- 00/000/20--
MAH		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		Agent	

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 (Only for Price Revision Appeal):

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.

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Attachment No. (7):

Price Reevaluation Request Form

☐ New Registration ☐ Price Revision

Product Name		Date:	00/000/14-- 00/000/20--
MAH		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		Agent	

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.

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