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# Pricing of biosimilars in Saudi Arabia

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Innovation in the pharmaceutical industry is expensive and risk must be rewarded. Some novel pharmaceuticals may be worth their high prices. Yet, high prices may hinder accessibility to novel products. It is paramount for pharmaceutical companies to demonstrate the value of their products in the face of increasingly budget-conscious stakeholders. This paper will provide background on the pricing of biosimilars in Saudi Arabia and explain the system used for pricing these products. Factors influencing pricing of pharmaceuticals in general as well as approaches to pharmaceuticals price control worldwide will be discussed.

**Keywords:** Biosimilar, price, Saudi Arabia

## Introduction: pricing of pharmaceuticals

Pharmaceuticals are one of the vital products that are subject to regulatory control in Saudi Arabia. The reason for regulation is due to the fact that pharmaceuticals are one of the most important elements of many countries' healthcare programme spending and one of the central factors contained in the citizen spending basket, especially for low-income families, which is reflected on the health of the population [1]. A system that installs pharmaceutical prices could be considered as an interference with the economic concept that says that the price of the commodity is determined by supply and demand [2]. It can also be seen as a hindrance to innovation [3]. However, it is not patients who decide what pharmaceutical they will use based on information available to them, whether it is for its properties, advantages, or price. Rather, patients depend on the physician or pharmacist to select the prescribed pharmaceutical based on several factors that direct their choice and affects their decision. Therefore, patients are at the mercy of their doctor or pharmacist [1]. Generally, prices are negotiated by governments to meet policy objectives and by pharmaceuticals manufacturers to attain profitability.

## Factors influencing pricing of pharmaceuticals

Although it is easy to calculate the cost of manufacturing and marketing of a drug,

it is difficult to calculate the total cost of getting a pharmaceutical product to the market. Therefore, the pharmaceutical companies price their products by allocating the cost distribution of all the elements involved in getting products to the market including research and development, production and quality control, administrative expenses, marketing, and distribution and retailing. However, by looking at pharmaceuticals prices and seeing differences in price between countries, one can argue that there are other factors influencing price than the total cost of manufacturing and selling these products. Examples of these factors include:

1. Income per capita [4]
2. Degree of state influence on drug pricing [4]
3. Market size [5]
4. Fluctuations in currency rates [5]
5. The cost of marketing and the possibility of it reaching consumers in the country. For instance, pharmaceutical companies cannot advertise directly to patients in Saudi Arabia, which affects demand
6. The existence of intellectual property protection system in the country [1].

## Approaches to pharmaceuticals price control worldwide

Due to high prices of pharmaceuticals worldwide, which have led to increased economic pressure on countries, countries are trying to control prices through

Biosimilars for Healthcare Professionals regulation and by encouraging commercial competition among pharmaceutical companies by making way for the marketing of generics and biosimilars. In the face of these developments, countries found themselves obliged to intervene to determine the prices of pharmaceuticals in order to adjust public spending on pharmaceuticals and encourage local pharmaceutical industry growth in a way that ensures the availability of effective and safe pharmaceuticals in their markets. Countries have historically controlled prices of pharmaceuticals through one of the following options:

1. *Full Control in the price system.* This is used in Saudi Arabia and several countries in the Middle East and North Africa (MENA) region. In Saudi Arabia, it is mostly applied in the pricing of new chemical entities or innovator products. In Saudi Arabia, the company submits pricing certificates showing the price of its product in the country of origin and its price in the countries where it is marketed (Form 30). A price is set based on ex-factory price. A maximum of 2% is then added for the cost, insurance and freight (CIF price) and 10–15% is added for wholesaler profit, with another 10–20% added for retail profit when it is sold to the public [6]. The percentage depends on ex-factory or CIF price; see Table 1. Despite the difficulties in the application of the system in terms of auditing of certificates and authentication, including outages, it has helped greatly in stabilizing prices in the country and preventing fluctuations. The pricing committee can review prices when there is a change in exchange rates that might affect the availability of products in the Saudi market. In the case of change of price in the country of origin, or in the case that the company asks for a change in price, an appeal against set price is allowed within 60 days of the decision with proper justification [6].
2. *Ceiling price system.* The regulator sets an upper limit on the price of the pharmaceutical to be marketed without committing the company to this price. The company is free to sell its products at any price based on market conditions and marketing policy as long as it is less than ceiling price. One

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## Biosimilars for Healthcare Professionals

**Table 1: Differences in wholesaler and retail profits based on ex-factory or CIF price [7]**

| Retail profit | Wholesaler profit | Ex-factory or CIF price         |
|---------------|-------------------|---------------------------------|
| 20%           | 15%               | Saudi Riyals 50 or cheaper      |
| 15%           | 10%               | Between Saudi Riyals 50 and 200 |
| 10%           | 10%               | More than Saudi Riyals 200      |

CIF: cost, insurance and freight.

of the main benefits of this system is that it opens the field to competition between companies and pharmacies and increases the sales of generic drug products [8]. The success of this system, however, requires an effective regulatory system and the presence of generic drugs industry with an accompanying advanced system and strict sanctions on companies, pharmacies and health practitioners who engage in the unethical marketing of products [8].

3. *Open pricing system.* Pricing is left to pharmaceutical companies and retail pharmacies to sell pharmaceuticals at a price that will bring them a reasonable profit without interference from a regulator, allowing market forces to determine the price. This system is applied in the US, and it is noted that the prices of pharmaceuticals in the US are one of the highest in the world [9].
4. *Reference pricing.* This is applied mostly to generic drug products in Saudi Arabia. Generics are priced based on the price given to innovator products or new chemical entities. The reference product's price is reduced by 20% at the license of the first generic drug, which is priced 35% cheaper than the reference product before a reduction in the reference product price; every subsequent generic drug is 10% cheaper, until the fourth generic drug. The reduction in price then stops. For example, if a reference product is priced at Saudi Riyals 100, when the first generic is registered, the price will be reduced to Saudi Riyals 80, the first generic will be Saudi Riyals 65, and subsequent generics 10% cheaper, till the fourth generic. An appeal against set price in Saudi Arabia can be lodged within 60 days of the decision with proper justification.

### Evolution of pharmaceuticals pricing in Saudi Arabia

In 1935, the law of pharmaceuticals use was issued by the Royal Decree No. 157/1/18 [10]. The law regulated the practice of pharmacy and the opening of retail pharmacies in

Saudi Arabia. The system for pricing of pharmaceuticals was first issued by Royal Decree No. 12 on 1953, which required the determination of pharmaceuticals prices and set a 15% profit for each of

the wholesaler and retail pharmacies. Royal Decree No. M/37 on 1961 was then issued which raised the proportion of profits allowed for the sale of pharmaceuticals by retail pharmacies to 17% of the value of their purchase from the wholesaler. Profits specified for wholesalers remained the same without any increase or decrease of 15% of the value of the imported pharmaceuticals. Royal Decree No. M/37 also required wholesalers to put pricing stickers on every imported pharmaceutical [11].

This continued until 1977 when the Ministerial Decree No. 7 issued the regulations for the registration and pricing of pharmaceuticals [12]. Registration and pricing of pharmaceuticals were entrusted for the first time to the Registration Committee at the Ministry of Health. The committee was to use the following when estimating the price:

1. The price of pharmaceuticals to the public in the country of origin
2. The price of pharmaceuticals in other countries
3. The price is not to exceed export prices to Saudi Arabia for wholesale selling prices in the exporting country.

Regulations also required to provide a number of reference pricing certificates when filing for registration such as certificates describing the selling price to the public in the country certified by the source of the concerned governmental authorities and from the Saudi embassy there or its substitute [12].

In 2004, the law of pharmaceutical products and establishments was issued. It determined in Article XIII the proportion of profit is calculated for retail and wholesalers according to Table 1. One of the objectives of this law was to encourage the marketing of cheaper pharmaceuticals with smaller packages by giving higher margins for

products at Saudi Riyals 50 or cheaper [13]. In 2008, the responsibility for licensing and pricing of pharmaceuticals was transferred from the Ministry of Health to the Saudi Food and Drug Authority (SFDA). The pricing system was then reviewed by the Registration Committee. A draft executive regulation for the law for pharmaceutical establishments and products was issued and approved by SFDA's Board of Directors in 2011 and is still in effect [14]. The new system included rules for the first time that allow for lowering innovative pharmaceuticals price by 20% when SFDA license its first generic pharmaceutical. The new system also encouraged the marketing of generic pharmaceuticals and the transfer of manufacturing to the Kingdom. It also gives permissions to the Registration Committee to take required measures to ensure the availability of pharmaceuticals in the Saudi market.

### Pricing of biosimilars

A Full Control in the price system is applied to biosimilars in Saudi Arabia. Based on regulatory pricing requirements, the manufacturer is to provide a prices certificate certified by the competent authority in the country of origin and authenticated by the Saudi Embassy that contains information on the following:

1. Ex-factory Price
2. Wholesaler Price, in the country of origin
3. Retail Price, a wholesale price plus expenses, and retail pharmacy profit, which is the final price paid by the patient
4. The proposed export price of the company's product to the Kingdom
5. Form 30, which shows the price in 30 different countries, in case it is registered in these countries. Table 2 shows a list of these countries.

**Table 2: List of countries in Form 30 [6]**

|                 |             |                 |
|-----------------|-------------|-----------------|
| 1. Algeria      | 2. France   | 3. Oman         |
| 4. Australia    | 5. Germany  | 6. Portugal     |
| 7. Argentina    | 8. Greece   | 9. Lebanon      |
| 10. Bahrain     | 11. Holland | 12. Japan       |
| 13. Belgium     | 14. Hungary | 15. South Korea |
| 16. Canada      | 17. Ireland | 18. Spain       |
| 19. Cyprus      | 20. Italy   | 21. Sweden      |
| 22. Denmark     | 23. Jordan  | 24. Switzerland |
| 25. Egypt       | 26. Kuwait  | 27. Turkey      |
| 28. New Zealand | 29. UAE     | 30. UK          |

UAE: United Arab Emirates; UK: United Kingdom.

We will use Remsima, a biosimilar for Remicade (Infliximab), as an example. The company submitted pricing certificates showing the ex-factory price at Saudi Riyals 1,126.029. The cost of insurance and freight was added. Since the ex-factory price is more than Saudi Riyals 200, only 10% is added for the wholesaler profit, and another 10% is added for the retail profit when it is sold to the public. The final price is Saudi Riyals 1,362.50.

## Conclusion

Factors influencing pricing of pharmaceuticals in general as well as approaches to pharmaceuticals price control worldwide were discussed in this paper. Pricing of biosimilars in Saudi Arabia and the system used for pricing these products was presented. Remsima was used as an example to illustrate the pricing system. Biosimilars are priced using the Full Control in the price system. Remsima was the first biosimilar registered in Saudi Arabia for Infliximab. The reference product, Remicade, is priced at Saudi Riyals 2,127.95 whilst Remsima is priced at Saudi Riyals 1,362.50, which is about 36% cheaper than Remicade. Applying this pricing system should reduce the price of biosimilars in Saudi Arabia when compared to innovator reference products, allowing for more patient accessibility and affordability. However, it may put pressure on biosimilars manufacturers due to the high costs associated with their development. Hopefully in the long term, this can be negated with more manufacturers entering this niche market. In

addition, there is clarity now compared to a few years ago when the regulatory pathways worldwide were not clear regarding data requirements for biosimilars. Now the requirements are clear and some of these products are well characterized. Still, I think we will yet have a Hatch-Waxman moment for biosimilars where the regulatory requirements are streamlined allowing for more competition between manufacturers and for more investments. As it stands, biosimilars are still a high-risk investment.

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