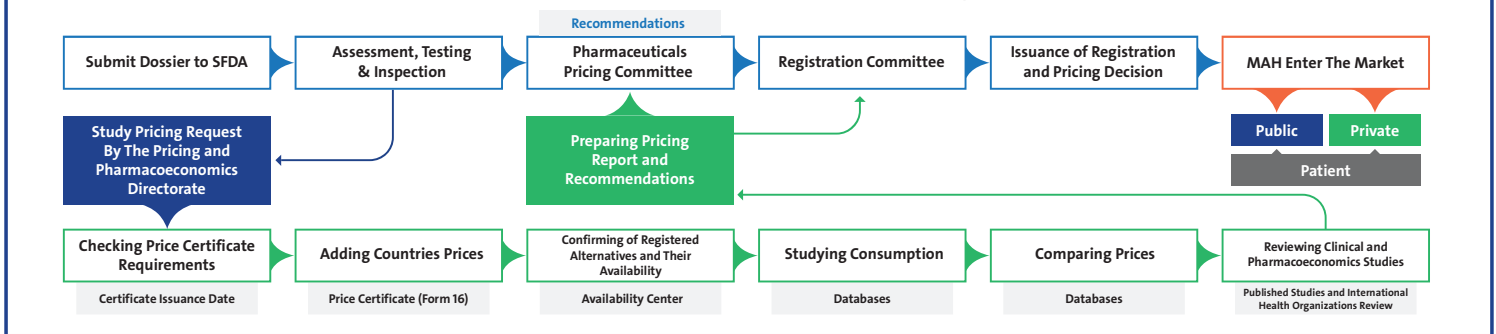




Healthcare System and Pharmaceutical Pricing in Saudi Arabia

Saudi healthcare system is overseen by several entities including: the Saudi Food and Drug Authority (SFDA), the Ministry of Health (MOH), the Saudi Health Council, and the Council of Cooperative Health Insurance (CCHI). Most of Saudi citizens and residents have access to healthcare through the MOH's care centers, The Ministry of Defense Affairs (MODA) hospitals, the National Guard (NG) hospital, or by health insurance given by employers.

Medication Access and Pricing Process



Pharmaceutical Pricing Rules

Promoting Pricing Transparency

Following WHO Guideline on Country Pharmaceutical Pricing Policies

SFDA clearly describe innovative products pricing approaches through a hybrid methodology where a full analysis incorporating clinical and economic data. This include an Internal Reference Pricing (IRP) with comparable registered alternatives based on clinical studies, External Reference Pricing (ERP) list containing 16 referenced countries to increase the transparency and predictability:

		Therapeutically equivalent alternative marketed?	
		Yes	No
Marketed in referenced countries?	Yes	Based on the direct or indirect comparative safety and efficacy with the best alternative compared to the price in the marketed countries and the economic studies	Based on the price in the marketed country and the economic studies
	No	Based on the direct or indirect comparative safety and efficacy with the best alternative and the economic studies	Based on proposed price by company (after discussion with the company)

Profit margins for wholesalers and pharmacies selling pharmaceutical and herbal drugs should be calculated as follow:

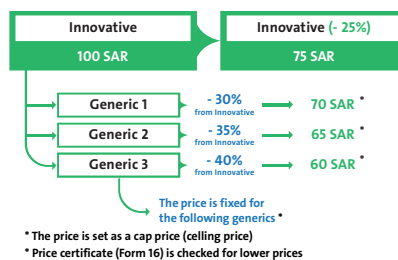
Ex-factory / CIF Price (SAR)	Wholesale Margin	Pharmacy Margin
50 or below	15%	20%
Above 50 to 200	10%	15%
Above 200	10%	10%

- The maximum price reduction per product cycle (every 5 years) not exceeding 30% of original price.
- The given prices are not subject to further discount unless after 2 years post marketing.
- The triggers for repricing have been determined (e.g. therapeutic class review, renewal, CCC price unification and change of marketing authorization holder).
- Sharing the net transaction prices of pharmaceutical products to relevant stakeholders (Internally: NUPCO and CCHI, Externally: GCC & Middle East countries and PPRI network).
- Communicating pricing decisions to the public through SFDA website and smartphone application (Tameni app).

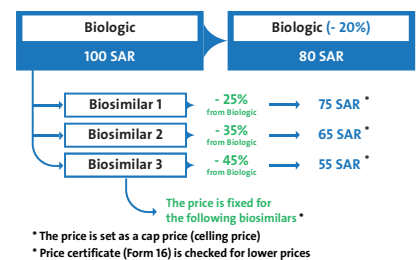


- Promoting Technology Transfer & Localization Plans:** Price fixation upon technology transfer and full localization plan achieved of the innovative product for period not more than 7 years.
- Increasing the Availability of Products:** Products facing shortage are allowed to price revisiting once per product lifecycle. Price re-evaluation requests are allowed to company through appeal process within 60 days of decision informed.
- Introducing Biosimilar Pricing Methodology.**
- Publishing Pharmacoeconomic Studies Guidelines.**
- Price Adjustment Based on The Differences in Several Factors:**
Economic: GDP/PPP/Capita.
Health: Prevalence, Incidence & consumption.
- Developing Selection Criteria for Countries Basket (Form 16).**
- VAT**
Currently the pharmaceutical product's tax is \$ 0.

Pricing of Innovative and Generics



Pricing of Biologics and Biosimilar



Pharmaceutical Reimbursement and Tendering

Reimbursement

- For Governmental Sector:** Medications are reimbursed in each hospital through mostly positive open formulary. The Pharmacy and Therapeutics (P&T) Committee in the light of a pre-specified budget set inclusion criteria in each financial year.
- For Private Sector:** Medication approved by SFDA can be reimbursed depends on the copayment percentage and the policy of health insurance companies and prescriber's behavior, the whole process is under controlled by the Council of Cooperative Health Insurance (CCHI).

Tendering

- Group purchasing at national level (for both governmental & Private sectors) is processed through National Unified Procurement Company for Medical Supplies (NUPCO).
- The Cost, Insurance & Fright (CIF) price (price without profit margin) determined by SFDA is the ceiling price for tendering and considered the starting point of negotiation for further reduction.