Kingdom of Saudi Arabia
Saudi Food & Drug Authority

SFDA Experience in Developing a Value Framework to Determine New Drugs Price Premium Using Multi-criteria Decision Analysis Approach

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Importance

New drug with added value is eligible for a price premium over comparators in proportion to its additional value. Pharmaceuticals Pricing Rules published by Saudi Food and Drug Authority (SFDA) states that the committee has the right to give a product with added value (i.e. therapeutic, safety, manufacturing advantages) a 20% price premium with no specifications.
The aim of this study is to analyze SFDA price premium decisions and develop a multidimensional value framework for price premium of a drug over comparators using Multi-criteria Decision Analysis (MCDA).

Methods

An analysis of historical price premium decisions was made to determine criteria and magnitude of price premium given for a drug. Then, a literature search was conducted to determine value elements to incorporate in the price premium framework. MCDA approach was used to build the framework. Then, experts were consulted to determine magnitude of price premium, weight, and scoring system for each value element.

Findings

The analysis showed price premium decisions were made for drugs with therapeutic advantages (n=106); drugs with superior efficacy and\or superior dosage form, manufacturing advantages (n=97); drugs offering new packaging or dosage form, combined drugs, and\or addition of new substance, and\or marketing advantages (n=1); a brand product.
Before MCDA, value elements and premium magnitude was not specified; some products received 130% premium. Then, value elements considered for the price premium framework were therapeutic, safety, manufacturing, and novel value elements.
Using MCDA methodology, multi-dimensional sub-criteria and sub-sub-criteria were incorporated into the framework under each value element. Experts advised each value element should not exceed 20% as a price premium, and therapeutic advantages should hold the largest magnitude of price premium and the magnitude of each value element determined case-by-case (Tables).

Name of the criterion and definition		Levels
Therapeutic advantages		***%10***
1. Efficacy/Effectiveness		
•Expected clinical benefit or actual clinical benefit compared with alternatives in the framework of clinical trials or real word settings. •A treatment intent may be curative and has a significant impact on survival. It could be to stabilize the diseases and prevent further deterioration or disabilities. It could improve quality of life. Or it may be intended only to be used in palliative or symptomatic care. •Real world evidence is complementary to clinical trials.	**Clinical benefit**	superior benefit
		similar benefit
	Treatment intent	curative or significant increase in survival
		stabilization of the disease or improvement in quality of life
		palliative or symptomatic
2. Health-related quality of life		
•Improvement in patient's HRQoL (physical, psychological, or social aspects) due to the new treatment compared to no or minimal changes with alternatives		Improved
		No or minimal improvement
3. Quality of evidence		
•Credibility and robustness of evidence using assessment tools such as GRADE. •Other appropriate tools (such as CONSORT, STROBE, etc.) should be used with specific study designs or considerations.		High
		Moderate
		Weak
4. Extended population or Age of targeted population		
•The approved indication is extended over the current SoC; vulnerable population: pediatric or pregnant, liver impairment, renal impairment ...etc. •Or the treatment target disease at the beginning of the disease.		Yes
		No
Safety		***6%***
5. Serious AEs		
•Serious AEs caused by the new treatment that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a birth defect.		No serious event
		Low/Moderate frequency of serious event (>0-30%)
		High frequency of serious events (>30%)
6. Severity		
•Severity of AE is the degree of AE symptoms significance and to what extent it prevents normal daily activities.		Mild / Moderate
		Sever
		Life-threating/ Death
7. Discontinuation		
•The rates of any discontinuation due to drug-related adverse effects.		Low frequency (>0-20%)
		Moderate frequency (>20%-50%)
		High frequency (>50%)
Manufacturing Advantages		***4%***
8. Innovation (First in class)		
•First-in-class drugs use a unique mechanism of action and can be the first drug receiving indication approval in cetin diseases.		Yes
		No
9. Superior Dosage form / Convenience		
•Superior dosage forms in terms of acceptability, convenience, safety of administration and sometimes expected drug bioavailability... etc.		Yes
		No
10. Quality Attributes		
•The quality attributes of a drug product may include identity, assay, content uniformity, degradation products, residual solvents, drug release or dissolution, moisture content, microbial limits, and physical attributes such as color, shape, size, odor, score configuration, and friability.		Yes
		No
11. Superior Formulation and Novel delivery system		
•Superior formulations, technologies, and systems for transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effects.		Yes
		No

Regulatory Implication

Transparency on how the added value of product is converted into a premium price is important. Advancing the evaluation process and using different approaches such as MCDA enables inclusive value assessment. Price Premium enables the pharma investor empowerment for sustainability and allows companies to invest, grow and brining innovative products to Saudi Arabia market.