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Early perspectives on health technology assessment in the Kingdom of Saudi Arabia: exploratory survey into market access implications

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Introduction

- In July 2025, the Kingdom of Saudi Arabia (KSA) enacted health technology assessment (HTA) requirements mandating economic evaluations in Saudi Food and Drug Authority (SFDA) submissions.[1]
- This shifts pricing and reimbursement (P&R) decisions from clinical/comparative efficacy to economic value.
- Key operational elements (e.g., willingness-to-pay thresholds, role of international HTA decisions) are still evolving, creating uncertainty overall and for rare diseases.
- This exploratory study describes early stakeholder perspectives on the impact of KSA's evolving HTA.

Objective

To assess stakeholder expectations of KSA's new HTA for P&R/formulary decisions and its implications for rare diseases.

Methods

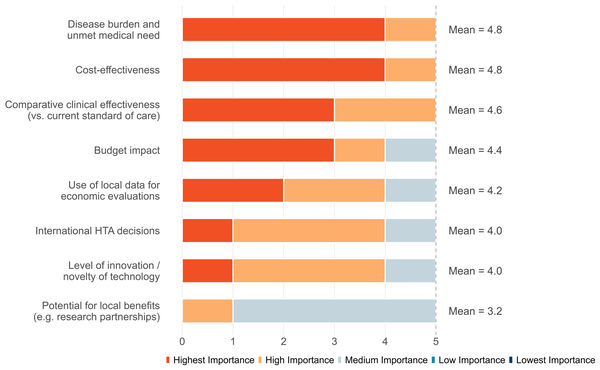
- Five formulary decision makers from the KSA (three national payers, two hospital pharmacists) completed a web-based survey administered via the Rapid Payer Response (RPR^{TM}) platform by Genesis Research Group.
- Respondents were asked Likert-style (1=low; 5=high) and open-ended questions to assess early perceptions on the anticipated impact of the KSA's evolving HTA process, including
  - P&R decision drivers under the new HTA
  - Role of international, established HTA outputs (e.g., NICE, CADTH, HAS) in KSA's process
  - Anticipated changes to local decision-making
  - Impact on manufacturers and anticipated challenges
  - Expected special considerations for rare diseases
  - Economic evaluation barriers for rare diseases products
  - Expected effect of the new HTA process on access
- Quantitative responses were summarized using descriptive statistics (counts, percentages). Open-ended responses were described.
- Participation was voluntary and anonymous. No respondent-level data were collected.

Results

Overall

- Respondents identified cost-effectiveness and disease burden/unmet need (mean score = 4.8 for both) as key anticipated drivers of pricing and reimbursement decisions (**Figure 1**).

Figure 1. Within the new HTA, how important are the following decision drivers for pricing and reimbursement decisions?

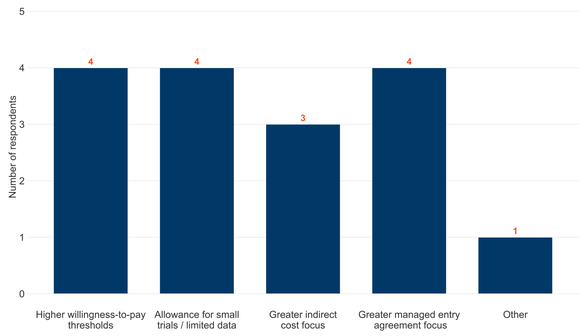


- All respondents (5/5) expected international HTA outputs to be used for benchmarking/validation and methodological guidance. One (1/5) expected use to inform willingness-to-pay thresholds. One (1/5) cited other uses (i.e., informing clinical practice and data requirements).
- Anticipated near-term impact on manufacturers was mixed: 2/5 negative, 2/5 neutral, 1/5 very positive.
- Expected challenges for manufacturers included greater evidence/data requirements (3/5), pricing pressure (3/5), limited access for high-cost products (3/5), longer timelines (3/5), and limited local expertise (1/5).
- Most (3/5) anticipated the new HTA process to shift decisions toward centralized, value-based approaches, with prices linked to cost-effectiveness and budget impact.
  - Several (2/5) expected a phased rollout (initially Ministry of Health/ high-cost technologies); one (1/5) felt private/military/university sectors may retain early flexibility. One (1/5) expected better decision quality and increased formulary inclusion as methods mature. Several anticipated long-term benefits as value rules become clearer and more standardized.

Rare Diseases

- Before the new HTA, respondents described a fragmented approach to rare-diseases:
  - Prices were anchored to external reference pricing with flexibly via case-by-case managed entry and risk-sharing agreements;
  - SFDA incentives (e.g., orphan designation, priority/fast-track review, market exclusivity, scientific consultation) facilitate registration.
- Pre-HTA, three (3/5) noted that high per-patient costs posed a significant barrier to favorable pricing and reimbursement for rare disease products. Two (2/5) cited difficulty demonstrating cost-effectiveness. None selected limited clinical trial data / sample size or lack of local epidemiology data / other data as a significant barrier.
- Respondents anticipated rare disease-specific allowances under the new HTA (**Figure 2**).

Figure 2. Which special considerations do you expect will be given to rare disease therapies being reviewed under the new HTA system?



- For rare diseases, three (3/5) respondents anticipated improved access after the HTA (**Figure 3**), though one caveated that this only applies to therapies that can demonstrate cost-effectiveness; access may be restricted for others.

Figure 3. Do you anticipate the new HTA process to promote or restrict patient access to new rare disease therapies?

Limitations

- This study used a small, purposive sample (n=5) in an early-stage policy environment.
- Views reflect anticipated near-term effects.

Conclusions

- **The KSA's new HTA process is expected to shift decision-making toward a more centralized, transparent, and value-based framework.**
- **International HTA decisions will likely serve as a methodological reference, but local evidence is expected to remain important for decision-making.**
- **For manufacturers, the new HTA process may increase evidence requirements, pricing pressure, and overall market access complexity.**
- **For rare diseases, some flexibility is anticipated in evidentiary and decision thresholds, supported by greater use of managed entry agreements.**
- **Overall, the anticipated effect on rare disease access is cautiously optimistic, with the ultimate impact likely to depend on how flexibly the framework is implemented in practice.**

Disclosures

This study was conducted and funded by Genesis Research Group. Amie Devlin, Darrin Benjumea, and Tijana Ignjatovic are employed by Genesis Research. Lynn Okamoto was employed by Genesis Research Group at the time of this study.

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Presented at ISPOR 2026 (May 17-20, 2026; Philadelphia, USA)