PT46

Development of Economic Evaluation Studies (EEs) in Saudi Arabia

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Introduction

The Saudi Food and Drug Authority (SFDA) is responsible for pharmaceuticals' pricing, governed by transparent pricing regulations that clarify the rationale behind pricing decisions. The SFDA utilizes two main methodologies for price determination:

- Internal Reference Pricing (IRP) which involve in-depth evaluation of safety and clinical efficacy, clinical effectiveness as well as associated costs between the registered medication and its alternatives
- External Reference Pricing (ERP) focus on benchmarking the price across 16 countries in the basket.

In Saudi Arabia, the healthcare infrastructure operates within a decentralized framework facilitating unrestricted access to medications within the public healthcare sector. The national health transformation within 2030 vision mandate shifting from volume to value-based healthcare models. This transition necessitates the adoption of value-based pricing, procurement, and services. The introduction of Economic Evaluation Studies (EEs) guidelines serves as an additional and vital tool for setting fair prices of medicine based on its value and consider as a complement of existing pricing methodologies.

This poster will illustrate the experience of In-house development the EEs in Saudi Arabia.

Methodology

This methodology was developed to assess the compliance of EEs with global benchmark and applicability with stakeholders in the Saudi's healthcare system in order to establish the first unified EEs guideline in Saudi Arabia.

1. **Global Benchmark:**

   The EEs guideline was developed using a scientific approach and an assessment for parameters compliance with benchmarked countries where conducted for global harmonization. The countries include Australia, United Kingdom, United States, France, Germany, and Japan.

2. **Stakeholders Engagement:**

   The initial draft was published for public consultation to collect scientific comments from all professionals, healthcare institutions, governmental agencies, and pharmaceutical companies. Furthermore; several workshops planned with multiple healthcare institutions and private sector in Saudi Arabia to collect their feedback about the expected outcomes and customization of the EEs to Saudi Arabia.

Furthermore, we conducted descriptive statistical analysis of the compliance and comments received from stakeholders on various sections of the EEs guideline.

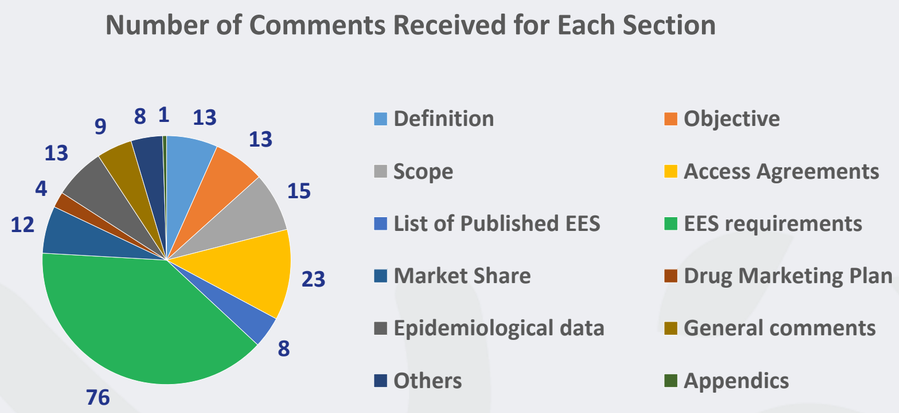
Results

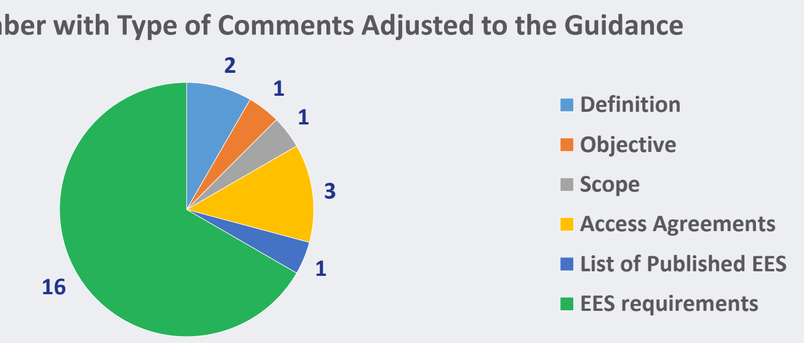
Assessment for compliance with benchmarked countries explained below:

Table 1: Global Benchmark Parameters for EEs requirements	% Compliance
Perspective, time horizon, choice of comparator, preferred analytical technique, discounting on costs and outcomes, preferred outcome measure, sensitivity analysis methods, results with incremental ratio (costs vs effectiveness).	100%*

* Country specific parameters were modified to fit Saudi Arabia

In February 2023, SFDA published the first draft of the EEs guideline and the descriptive statistical analysis is illustrated as below:





Discussions

- In terms of global benchmark, six countries were selected because they share a common commitment to a value-based healthcare system model despite differences in healthcare system structure, reimbursement, and pricing processes.
- The EEs guideline is aligned with international standards; however, a few modifications have been applied to the parameters for example, Implication of EEs decisions and access agreement to fit for Saudi context.
- SFDA held multiple workshops with relevant healthcare institutions in order to establish a clear objective for EEs and compliment current studies required by institutions without overlapping with their internal procedures.
- Following several workshops with healthcare institutions in which they were aligned with SFDA, two additional workshops with pharmaceutical companies were conducted to ensure alignment and address challenges related to EE implementation.
- Based on the insights gained in workshops, adjustments were made to the EEs guideline draft. Pharmaceutical companies responded to the EEs under the assumption that they would influence reimbursement decisions. However, the SFDA clarified that the EEs will be utilized to determine medicine pricing based on their value primarily, not to influence formulary management, tendering, nor reimbursement decisions.
- Majority of comments were not considered, as they pertained to formulary management, tendering, and reimbursement processes, which falls outside SFDA's scope.
- The EEs introduced a new concept termed "Access Agreement" defined as arrangements with companies at time of submission to address points supporting the access of medicine, including: entry agreements, localization, incentives granted, breakthrough designation, patient supporting program, or any other initiative to support the access of medicine.
- To facilitate the process of implementing the EEs in Saudi Arabia, SFDA provided a choice for the pharmaceutical companies to perform "Parameterization" which is an option to adapt a global health economic model and adjust the parameters to meet SFDA requirements.
- SFDA suggested implementing EEs gradually, with voluntary submissions allowed for one year. After July 2025, submission of EEs will be required.

Conclusion

This represents the first unified guidelines for EEs in Saudi Arabia, playing a crucial role in setting fair prices of medicine based on its value that facilitate transitioning the healthcare sector from a volume-based to a value-based system. Global benchmark and stakeholders engagement were involved in the preparation process to ensure alignment and harmonization. To overcome the challenges related to the implementation of EEs, SFDA has proposed the gradual implementation of EEs in the upcoming years.

EEs Guideline