الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Economic Evaluation Studies Guidelines

Version 1.1

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Economic Evaluation Studies Guideline

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Saudi Food & Drug Authority

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Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

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What is New in version no. 1.1?

The following table shows the update to the previous version:

Section	Description of change
2.4. Access Agreements	Update
3.3 Exemption criteria from EEs:	Update
4.PHARMACOECONOMICS SUBMISSION FORM:	Update

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1. INTRODUCTION

1.1. Definitions

Economic Evaluations Studies (EES) are the "comparative analysis of alternative courses of action in terms of both their costs and their consequences", with a view for decision making on their added value to the current standard of practice in the healthcare system.

There are two main types of Economic Evaluations Studies.

A. Partial Economic Studies is a sub-discipline of economic evaluation where an analysis of cost or consequence occurred independently e.g.:
   - Budget Impact Analysis (BIA): an economic evaluation that assess the financial impact of the adoption of new intervention that can aid in setting and allocating resources relative to its affordability.

B. Full Economic Studies or Pharmacoeconomics Evaluation Studies (PES) is a sub-discipline of economic evaluation where an analysis of different intervention compared in terms of both their costs and their added value for an outcomes. There are four main types of PESs:
   - Cost Effectiveness Analysis (CEA): is a comparative economic evaluation of two or more alternatives intervention in terms of their relative costs and outcomes, where the later are measured in a natural unit.
   - Cost Minimization Analysis (CMA): is a comparative economic evaluation in which the outcomes of the two or more comparators are assumed to have equivalent health effects.
   - Cost Utility Analysis (CUA): Cost-utility analysis is a type of cost-effectiveness analysis in which the (incremental) cost per quality-adjusted life year (QALY), or some other preference-based valuation of heath outcome, is estimated.
   - Cost Benefit Analysis (CBA): is a comparative economic evaluation, where both the costs and outcomes are expressed in monetary terms.

1.2. Objective

This guidance helps manufacturers, marketing authorization holders, or agents in describing a standard method for performing, submitting, or publishing an EES. These will be evaluated at the Saudi Food and Drug Authority (SFDA) to determine the added value deserved over the current standard of practice utilized in Saudi Arabia's healthcare system.

1.3. Scope

This guidance applies to all human pharmaceutical products undergoing pricing procedures including registration, price re-evaluation, and renewal in SFDA.

1.4. Related guidelines

- The Pharmaceutical Product Pricing Rules
- Data Requirements for Human Drugs Submission

2. GENERAL REQUIREMENTS

2.1. Epidemiological Data

Information on the disease, its prevalence, incidence, targeted population, no. of patients both globally and in Saudi Arabia are required to be documented within the submission file to the SFDA.

2.2. Market Share

Refers to the proportion of the pharmaceutical product sells in volume and value compared to the total number of alternatives used in treating the same condition. Information on the current market share of the product in Saudi Arabia are required to be documented in the submission file to the SFDA. In case of a new product, the estimates of the market share for the upcoming five years are required to be documented.

2.3. Drug Marketing Plan

Drug marketing plan refers to the targeted segment of healthcare in Saudi Arabia that the product is mainly distributed in. Information on the targeted segment should be presented in the submission file to the SFDA. It could be one or more of the following:

Distribution in:	
i.	Tender Item only
ii.	Retail Pharmacy only
iii.	Public (whole market)

Prescription Type:	
i.	Hospital item only
ii.	Restricted
iii.	Controlled
iv.	Over the Counter (OTC)

2.4. Access Agreements

Access agreements defined as arrangements with companies at time of submission to address points supporting the access of medicine. The most common types of agreements:

1. Entry Agreements.
2. Localization.
3. Incentives granted.
4. Breakthrough designation.
5. Patient Supporting Program (PSP)
6. Or any other initiatives to support the access of medicine.

It is worth noting that entry agreements are considered when pricing decisions are made which requires commitment with the agreement by the company, the applicant must clearly state the type of agreement anticipated for Saudi Arabia and present it to the SFDA upon registration. If any changes in the access agreement occur later, the applicant must notify the SFDA at the nearest updated submission or when required.

2.5. List of Published EES's and Health Technology Assessment Decisions

Information on the published EES(s) are required to be documented in the submission file to the SFDA showing the following information (title, disease area, time horizon, method of analysis, model used, comparators, cost measure, outcomes measure, results, and conclusion). In addition, a summary conclusion from the following Health Technology Assessment (HTA) agencies are required to be presented such as The National Institute for Health and Care Excellence (NICE), Institute for Clinical and Economic Review (ICER), Canadian Agency for Drugs and Technologies in Health (CADTH), Haute Autorité de santé (HAS), Pharmaceutical Benefits Advisory Committee (PBAC) …etc.

3. EES's REQUIREMENTS

It is mandatory to provide at least one of the best-suited EES based on product type:

Study options for all types of submissions				
Product type	BIA	CMA	CEA	CUA
New Chemical	✓	x	✓	✓
Biological	✓	x	✓	✓
Generic Chemical	✓	✓	x	x
Biosimilar	✓	✓	x	x

3.1 Full Economic Evaluation:

Below are a summary table of the required information to be included in each EES:

Criteria	Description	CMA	CEA	CUA
Study objective	The study objective(s) should be clearly stated including research questions for each goal.	√		
Targeted population	The specifications of targeted population should be included. Sub-group analyses are encouraged.	√		
Perspective of analysis	The viewpoint of the study should be indicated. A healthcare payer and/or societal perspective should be indicated in EES are sufficient for the evaluation.	√		

Time horizon	The length of the study should include the natural disease history or encapsulate all differences either in cost or outcomes.	2-5 years	Lifetime	
Comparator	The comparator should be included from the current standard of practice. This include the least expensive and the most effective treatments available at least. Inclusion of emerging technologies are encouraged.	√		
The estimated Threshold	The current estimated cost-effectiveness threshold published in Saudi Arabia ranges between SAR 50,000 – 75,000 per QALY. However, consideration will be taken for specific products.	√		
Modeling	The details of the model utilized and justifications for using it should be included. Validation of the model is encourage to be provided. Parameterization should be applied to the global models by changing the main key parameters (i.e. utility values, costing and epidemiological data) to meet SFDA's requirements in case no local economic model is available.	√		
Costs calculations	All relevant costs determined by perspective choice should to be included. The direct healthcare costs are required to be included at least. Intangible costs are encouraged to be provided when adapt societal perspective.	In SAR or USD		
Long-term care and productivity loss costs	The costs resulted from a long period of patient care or inability to work during illness are encouraged to be included in the analysis. The method for calculating these costs is required to be included.	In SAR or USD		
Outcomes measurement	The outcome effectiveness measurement should be stated clearly in the evaluation. Based on the type of analysis, the relevant outcome measure is chosen. Utility	x	Natural units	QALYs

	measurement is required to be included if CUA is submitted.			
Additional benefit in efficacy or safety	The evaluation should highlight the additional benefit in either safety or efficacy of the new health technology. Effectiveness data resulted from Real World Evidence (RWE) are encouraged to be submitted.	x	√	√
Sources of cost or clinical data	All sources of data used in the evaluation should be included. Cost data should be retrieved from Saudi Arabia healthcare system, while clinical data retrieved from Randomized Controlled Trial (RCT) and RWE, and/or Network Meta-Analysis (NMA).	√		
Discounting	This is the monetary value and outcomes depreciation over time. The yearly discount rate is 3% - 5%. It is mandatory to be included for cost calculations at least.	3% - 5%		
Uncertainty and sensitivity analysis	All uncertainties (Parametric, methodological and Structural) in the base-case scenario should be addressed in the sensitivity analyses. Probabilistic Sensitivity Analyses (PSA) is preferred to be used in the evaluation. Deterministic Sensitivity Analysis (DSA) should be provided including one-way sensitivity analysis (preferred) and, multi-way sensitivity analysis with scenario sensitivity analysis (if feasible).	√		
Presentation of results	Results of the base-case should be presented in cost-outcomes increments demonstrated in cost effectiveness plane. For PSA and DSA, the result should be depicted in a cost effectiveness acceptability curve with scatter plot and tornado diagram, respectively. Results of BIA should be presented in table format.	In SAR or USD	ICER	ICUR

Data Source, Equity and generalizability to Saudi Arabia	The data in the evaluation should be applicable to generalize it to Saudi Arabia with all patients having a fair opportunity for participation and for obtaining the expected treatment outcomes. Equity and fairness in distribution should be taken into consideration.	√
Other	Conflicts of interests and funding should be reported if any.	√

3.2 Partial Economic Evaluation.

Below are a summary table of the required information for Budget Impact Analysis:

Criteria	Description
Study objective	The study objective(s) should be clearly stated including research questions for each goal.
Targeted population	The specifications of targeted population should be included. Sub-group analyses are encouraged.
Perspective of analysis	The viewpoint of the study should be healthcare payer perspective for partial economic evaluation. All sources of data used in the evaluation should be included in SAR. Cost data must be collected form Saudi's healthcare system. The direct healthcare costs are required to be included.
Time horizon	The required length of time horizon is 2-5 years.
Comparator	The comparator should be included from the current standard of practice. This include the least expensive and the most effective treatments available at least. Inclusion of emerging technologies are encouraged.
Uncertainty and sensitivity analysis	Scenario analysis should be performed for BIA
Presentation of results	Results of BIA should be presented in table format.
Other	Conflicts of interests and funding should be reported if any.

3.3 Exemption criteria from EEs:

Medicinal products will be exempted from submitting EEs if they met the following criteria:

- Product classifies as generic or biosimilar.
- Innovative and biological products with generic or biosimilar alternatives registered.
- Product classified as OTC.

4. PHARMACOECONOMICS SUBMISSION FORM:

All the information mentioned in this guidance must be summited as full text with references and summarized as part of the eCTD section 1.8.2 (Other documents related) in the following forms:

- Form (A) for General Requirement.
- Form (B) for Full Economic Evaluation.
- From (C) for Partial Economic Evaluation.
- The applicant must provide justifications for not submitting any required data.

5. APPENDIX

General requirements Submission Form (A – 1/2)

Product type	☐ New chemical ☐ Biological ☐ Generic ☐ Biosimilar	Date	
		Separate forms must be filled for each pack or strength	

Product Name		Strength	
Dosage Form		Pack Size	
MAH Name		Nationality	
Manufacturer		Nationality	

General requirements:						
Epidemiology data	Global No. of Patient	KSA No. of Patient	Global Incidence	KSA Incidence	Global Prevalence	KSA Prevalence
Expected Market Share	Type of Consumption	Expected Consumption for the upcoming five years				
		20	20	20	20	20
	Volume					
	Market share					
	Value					
Drug marketing plan	What entities do you plan for launching in Saudi Arabia? What obstacles do you for see entering the market?					
Access Agreements	☐ No ☐ Yes	Type of agreement:				
Distribution in	☐ Tender Item only	☐ Retail Pharmacy only	☐ Public (whole market)			
Prescription Type	☐ Hospital item only	☐ Restricted	☐ Controlled	☐ Over the Counter (OTC)		

General requirements Submission Form (A – 2/2)

HTA recommendations	
NICE	
HAS	
SMC	
CADTH	
ICER	
PBAC	
TLV	
Other	

Pharmacoeconomics Submission Form (B)

Summary of Pharmacoeconomics Study: *(Please Attach the Full Study as appendix)*			
Title			
Method of Analysis	☐ Cost-Effectiveness Analysis (CEA)		☐ Cost-Utility analysis (CUA)
	☐ Cost-Minimization Analysis (CMA)		☐ Cost-Benefit analysis (CBA)
Target Population			
Type of Comparator			
Type of Perspective	☐ Societal Perspective	☐ Payer Perspective	☐ Other:
Type of Cost	☐ Direct	☐ In-Direct	☐ Other:
Source of Cost			
Time Horizon	☐ Short-Term: No. of Years ( )		☐ Long-Term: No. of Years ( )
Discount rate			
Productivity loss costs			
Measured Outcomes			
Results			
Sensitivity Analysis	☐ Deterministic Sensitivity Analysis (DSA): ☐ One-way Sensitivity Analysis: - Presentation the results in Tornado Diagram ☐ Yes ☐ No ☐ Multi-way Sensitivity Analysis.		☐ Probabilistic Sensitivity Analysis (PSA) - Presentation the results in Cost-Effectiveness Acceptability Curve (CEAC) ☐ Yes ☐ No - Presentation the results in scatter plot. ☐ Yes ☐ No
Result of Sensitivity Analysis			
Generalizability of the result to KSA jurisdiction			

Budget Impact Analysis Submission Form (C)

Summary of Budget Impact Analysis Study: *(Please Attach the Full Study as appendix)*		
Title		
Target Population		
Type of Comparator		
Type of Perspective	☐ Payer Perspective	
Type of Cost	☐ Direct	
Source of Cost		
Time Horizon	☐ Short-Term: No. of Years ( )	
Results		
Sensitivity Analysis	- Scenario analysis ☐ Yes ☐ No - Presentation the results in table format ☐ Yes ☐ No	
Result of Sensitivity Analysis		
Budget Impact Analysis	☐ Yes No. of Years ( ) *Attach the Full Analysis as appendix*	☐ No

6. REFERENCES

- WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies.
- Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Statement: Updated Reporting Guidance for Health Economic Evaluations.
- The Pharmaceutical Pricing and Reimbursement Information (PPRI) networks.
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