



وزارة الصحة
Ministry of Health

Managed Entry Agreement Policy for Saudi MOH

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1.0 Purpose

This policy manual is an official document that provides directives on the functioning and processes involved in establishing managed entry agreements in the Kingdom of Saudi Arabia.

2.0 Definitions

Managed Entry Agreements (MEAs): Formal arrangement between pharmaceutical companies and payers or regulators to improve access to costly, innovative medicines.¹ They are aimed at sharing the clinical and/or financial risk arising due to the introduction of expensive pharmaceutical technologies.²

- **Financial-based MEAs:** Agreements where the manufacturer contributes to the cost of new medication without linking the reimbursement to health outcomes. These agreements may include one of the following: discounts, price-volume agreements, payback agreement, free doses or dose-capping schemes.
- **Value-based MEAs:** Agreements where the payment terms for medication(s) are tied to clinical outcomes, or measures based on agreed-upon criteria. The agreement may be based on a conditional coverage (i.e. - coverage with evidence development and conditional treatment continuation) or direct performance linked agreements.

3.0 Development and Implementation of MEAs in KSA

3.1 Roles and responsibilities

Stakeholders involved throughout the entire process of development through the implementation of MEAs include:

- Regulator: Deputyship of therapeutic services/ Pharmacy and Therapeutics Committee
- Payer: Deputyship of supply & Engineering affairs
- NUPCO (National Unified Procurement Company)
- Manufacturers
- Providers: Hospitals and healthcare clusters
- Third parties

An overview of the roles and responsibilities of different stakeholders is summarized in Table 1

Table 1: Roles and responsibilities of stakeholders involved in MEAs

Development Phase/stakeholders	MOH		NUPCO	Manufacturers	Providers	Third parties
	Deputyship of therapeutic services	Deputyship of supply & Engineering affairs				
Phase I: Internal Assessment and information gathering						
Information gathering and assessment	R/A	S	S	R/A	S	I
Phase II: Early dialogue						
Pharmacoeconomic analysis	R/A	I	S	I	S	S
MEA design	R/A	I	I	R/A	S	I
Phase III: Formal Negotiation						
Mutual agreement on the MEA design	R/A	S	S	R/A	I	I
Phase IV: MEA Implementation						
MEA signing off	R/A	R/A	I	R/A	I	I
MEA execution	R/A	R/A	I	R/A	R/A	S
Medication procurement	C/I	R/A	R/A	I	I	I
MEA monitoring (clinical endpoints)	R/A	I	I	I	R/A	A
Interim & Final reports generation	R/A	I	I	I	I	S
Interim & Final evaluations	R/A	I	I	I	R/A	S
A- Accountable; C-Consulted; I-Informed; R-Responsible and S- Support						

3.2 Phases of Development and implementation of MEAs

The development of a MEA is a multi-step process categorized into four phases which may overlap or run in parallel. The initiation of these phases begins at the time of considering the evaluation of a drug for formulary inclusion. Listed below are the different phases and an overview of the associated processes.

- **Phase I: Internal Assessment and information gathering**
 - MOH gathers relevant information on the medical intervention and related therapy area including the clinical, economic and societal burden, clinical guidelines and clinical experts' opinions-where applicable.
 - An internal discussion is initiated on the need and feasibility of pursuing a MEA.
 - The adoption of the MEA concept linked to a certain intervention is initiated by the MOH

- **Phase II: Early Dialogue**
 - MOH and manufacturers engage in early, informal discussions to assess the possibility of negotiating a MEA agreement and confirm mutual interest.
 - Discussions may include exchange of views on patient population involved, potential budget impact of the drug, defining outcome measures, monitoring and execution strategies.

- **Phase III: Formal Negotiation**
 - MOH and manufacturers formally discuss the terms and conditions of a MEA with the purpose of establishing a written agreement.
 - The basic MEA structure formulated during the formal negotiation phase should include the following key sections:
 1. Agreement objective(s)
 2. Product information
 3. Patient selection/eligibility criteria
 4. Agreement duration
 5. Cost sharing scheme, if any
 6. Rebates management
 7. Outcome measures/ clinical efficacy evaluation
 8. Governance and process
 - a. Data collection
 - b. Evaluation timepoints
 9. Stakeholders' obligations
 10. Termination clause(s)
 11. Liability and insurance

- **Phase IV: Contract implementation**
 - MOH and manufacturer should officially sign a MEA and begin execution of the terms and activities stipulated in the contract after clearance by legal entities in both parties
 - Implementation will include procurement of the drug, enrollment of the patients into the MEA program, regular follow up of enrolled patients at defined intervals, systematic gathering and recording of clinical data and outcomes into data collection platforms.
 - The performance of the drug will be reviewed periodically to evaluate clinical response & outcomes
 - Interim & final reports will be extracted from data platforms and shared regularly with manufacturers.
 - All data is owned by MOH.

3.3 Administrative requirements for MEAs

All MEAs administrative requirements will be handled by the deputyship of therapeutic services. This includes but not limited to management of clear and timely communication among parties involved in MEAs implementation (manufacturers, providers, NUPCO and third party).

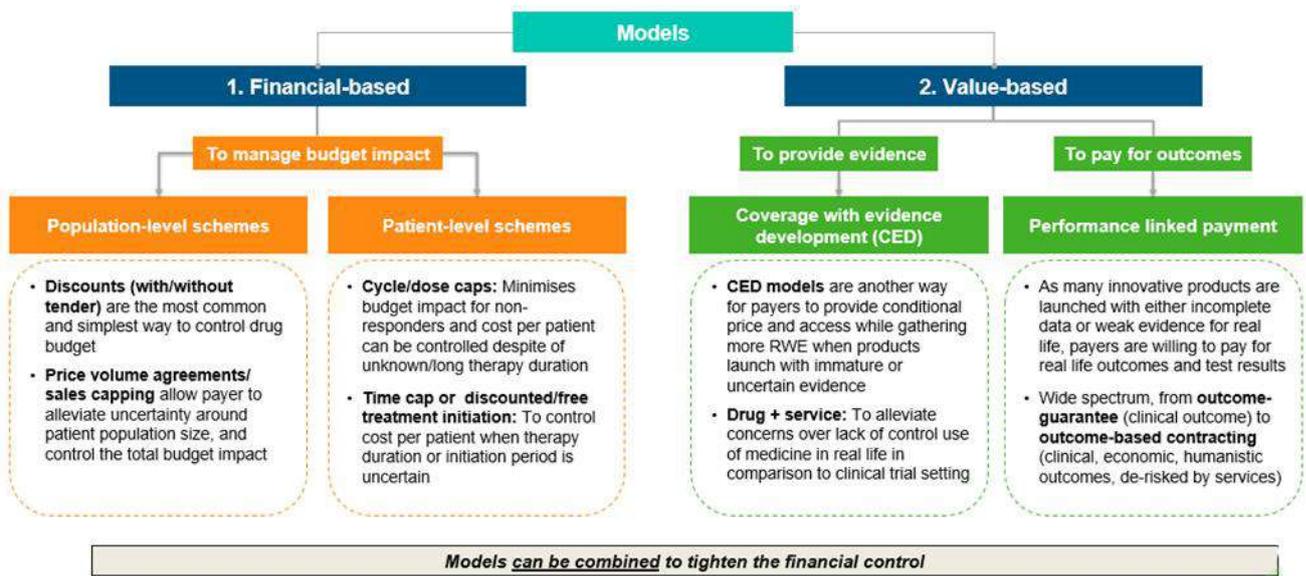
4.0 References

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5.0 Appendix

5.1 MEA Taxonomy

These arrangements are generally classified as financial-based agreements or value-based agreements, but they could as well be a combination of both agreements. The value-based agreements (VBA) can be further classified as outcome-based or evidence-based agreements. Overall, MEAs are classified based on their objectives and illustrated in Figure 1.^{2,3}



Adapted from ISPOR Garrison et al. 2013⁴

Figure 1: Taxonomy for managed entry agreements