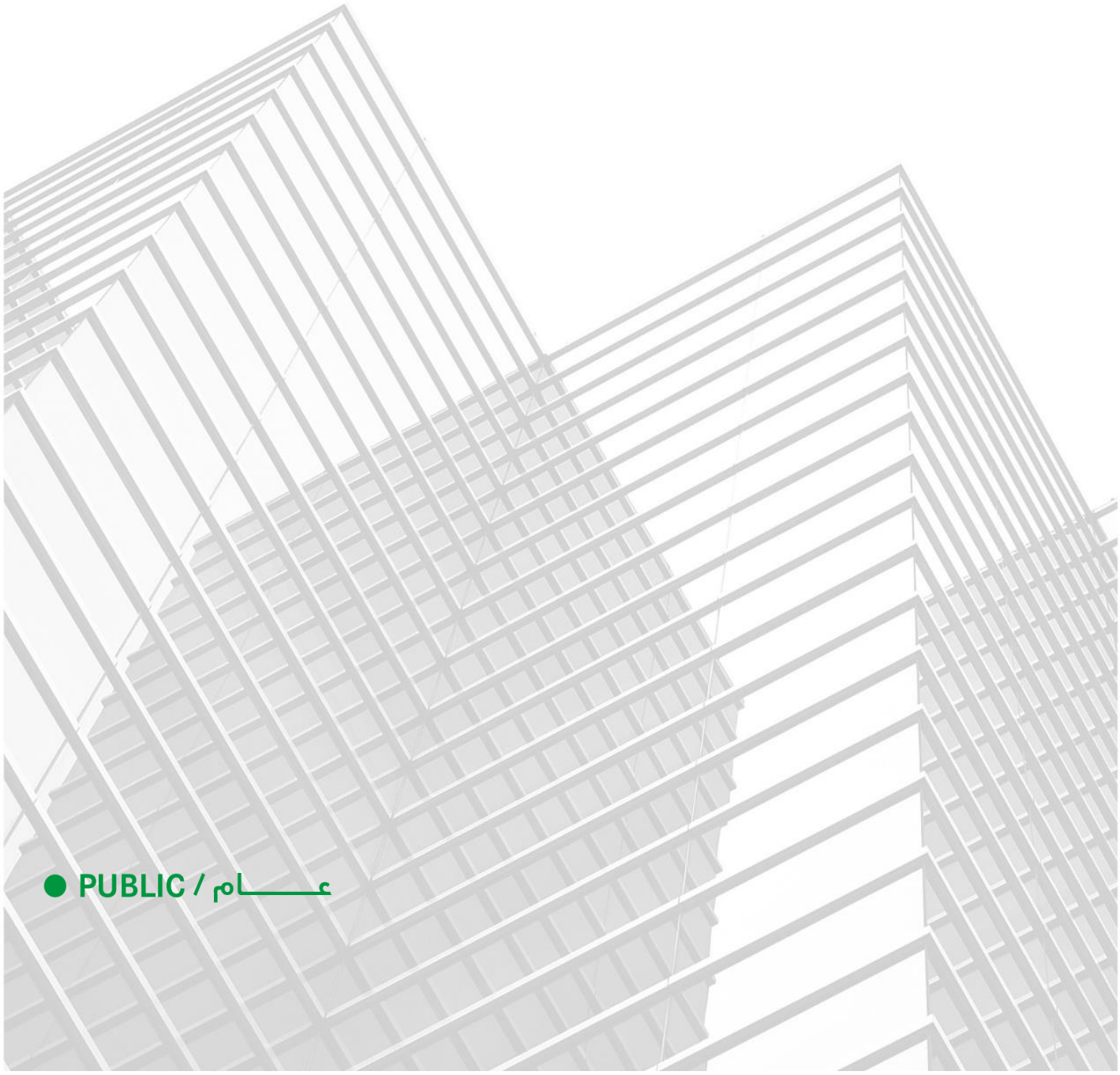
دائـــــرة الـصـــحـــة
DEPARTMENT OF HEALTH

POLICY of Establishing Managed Entry Agreements / Risk Sharing Agreements in the Emirate of Abu Dhabi



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1. Policy Purpose and Brief

The purpose of this policy is to provide directives and to detail the objectives and process involved in entering into Managed Entry agreements (MEAs)/ Risk Sharing Agreements (RSAs) for new technologies including pharmaceuticals in the emirate of Abu Dhabi.
The development of MEAs)/ (RSAs) between regulators, payers and pharmaceutical companies has been increasing lately across the world, as there is a high demand to curb the growth of health expenditures whilst also mitigating the risk of spending on new technologies including pharmaceuticals without full evidence of clinical benefit. The objective of such agreements is to improve patient access to this technology/ pharmaceutical by allowing healthcare program's coverage of either, under certain conditions, using a variety of mechanisms to address uncertainty about the new technology performance, to manage adoptions of such new technology to maximize its effective use, or have a limited impact on budget.

2. Definitions and Abbreviations

No.	Term / Abbreviation	Definition
2.1	Managed Entry Agreements (MEAs)/ Risk Sharing Agreements (RSAs)	Are contracts that can be used for mitigating the uncertainty regarding a medicine's relative effectiveness, cost-effectiveness, or budget impact
2.2	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, Manufacturer funded diagnostics, Manufacturer funded initial treatment, free doses or dose-capping schemes.
2.3	Outcome-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.
2.4	Payer	For the purpose of this policy is the Department of Health (DOH) through its appointed third-party administrator.
2.5	Healthcare Provider / Facility	Government or private healthcare Facilities comprising Hospitals, Medical Centers, Clinics, Laboratories, Diagnostic Centers, pharmacies and other organizations and actors, which are licensed by the DOH to provide healthcare services in the Emirate of Abu Dhabi.
2.6	Third Party Administrator or the TPA	A health insurance claims' administrator licensed or permitted by the DOH to administer a healthcare program & settle associated claims on behalf the DOH. directly associated from the main primary parties involved in agreement or relationship.
2.7	New Pharmaceutical product	A newly developed medication or therapeutic agent that has undergone research, development, and regulatory approvals. It offers novel approach to diagnosing, treating, preventing or managing diseases or medical conditions.

3. Policy Content

3.1 Objective:

3.1.1. The main objectives of an MEA/RSA are to:

3.1.1.1. Enable the swift adoption of innovative technology into the healthcare system with high budget impact while minimizing risk arising from uncertainties related to cost-effectiveness, budget impact or clinical effectiveness.

3.1.1.2. Improve patient access to innovative, patented health technologies.

3.1.1.3. Enhance financial sustainability of the reimbursement system.

3.1.1.4. Increase flexibility of shaping the pricing and reimbursement system.

3.1.1.5. Enable more streamlined discussions with all stakeholders about value, affordability and transactability so that patient access to technologies and medicines is not unnecessarily delayed.

3.1.1.6. To drive more purposeful engagement between regulators, payers, and the pharmaceutical industry when it comes to decisions about new technologies/ pharmaceuticals.

3.1.1.7. To ensure new medications/ technologies are clinically and cost effective for better utilization of resources.

3.1.2. In addition to that, MEA/RSA will allow to identify the risk that needs to be mitigated upon introducing the new technology whether it would be risk associated with its cost-effectiveness, budget impact or real-world effectiveness. This is beneficial to allow choosing the appropriate MEA/RSA design and ensure its success.

3.1.3. The MEA/RSA will provide opportunity to create a mutually beneficial situation for the Payer and the manufacturer minimizing the impact on budget and allowing access to new technologies.

3.2. New technology/pharmaceutical products eligibility criteria:

3.2.1. The selection of a new pharmaceutical product to be a subject matter of an MEA/RSA shall be according to an agreed upon criterion which could be based on high cost or unmet needs. For example, one of the criteria is the affordability of the medicine due to high cost. In that case, a benchmark price should be identified to decide which pharmaceutical product will be considered of high cost and which is not. Other criteria for a product to be considered for MEA/RSA include the unmet clinical need for the selected medicine and its indication. The consideration of clinical need would involve:

3.2.1.1. An assessment of the prevalence and severity of the disease,

3.2.1.2. Whether alternative therapies are available,

3.2.1.3. The extent to which the proposed medicine is expected to meet the residual need.

3.2.2. Potential candidates for MEA/RSA could feature one or more of the following characteristics:

3.2.2.1. Large benefit to patients receiving the technology/ pharmaceutical.

3.2.2.2. Small to moderately-sized targeted patient populations

3.2.2.3. Immature clinical trials data

3.2.2.4. A disease profile where improvements in outcomes are measurable in the short term are particularly valuable.

3.2.2.5. Unaffordability of technology/ pharmaceutical (high cost).

3.2.2.6. If the new pharmaceutical product evaluated or appraised with high uncertainty about its clinical data and cost effectiveness.

3.3. Scope of work:

3.3.1. The DOH to list or define medicines that are under regulatory decision for registration in the UAE that might be suitable for an MEA/RSA scheme. The DOH will establish the need for an MEA/RSA, considering the cost effectiveness, risks associated with decision uncertainty, sources of uncertainty and choice of MEA/RSA scheme.

3.3.2. The DOH shall have the following roles:

3.3.2.1. Assess the eligibility of a new technology/pharmaceutical for an MEA/RSA according to an agreed upon criterion as stated above.

3.3.2.2. MEAs/RSAs may be considered where a pharmaceutical company proposes an enhanced value offer; and/or where there are unusual or unique circumstances that mean launching a product is considered particularly challenging or commercially unviable.

3.3.2.3. The DOH must ensure the availability of all relevant clinical and financial data that will support MEA/RSA development. This includes information and evidence in support of the efficacy of a treatment and the cost effectiveness model data analysis.
3.3.2.4. The DOH will evaluate the cost effectiveness model submitted by the pharmaceutical company and may ask to get more data to complete the evaluation process.
3.3.2.5. The DOH will share the outcome of their decision with all relevant stakeholders.
3.3.2.6. If the DOH concludes the need to establish MEA/RSA for a particular technology, a series of meetings will be conducted with representation from all relevant stakeholders, including the pharmaceutical company.
3.3.2.6. The DOH will be responsible for agreeing the type of MEA/RSA required, and the development of the MEA/RSA document following the five steps outlined in the procedure section of this policy document.
3.3.2.7. Additionally, the DOH to identify long-term objectives for the policy framework that will allow the continuous update of the framework to achieve its long-term objectives.
3.3.2.8. The DOH shall set a pilot phase for the managed entry agreement (MEA)/ Risk sharing agreements (RSA) policy framework to enable the evaluation of outcomes and to assess its success and update the recommendations.
3.3.2.9. It is also recommended to start implementing this policy on a small volume of products as pilot. With the increase in capacity and skills, the depth and scope of technologies can be increased (include medical devices or revise previous MEAs/RSAs).

3.4. **Phases of Development and implementation of MEAs/RSAs**

Pharmaceutical company may submit MEA/RSA proposals to the DOH. The development of MEA/RSA agreements is a multi-step process which could be divided into the following phases:

3.4.2. Phase I: Internal Assessment and collection of Information
3.4.3. Phase II: Setting up the proposal.
3.4.4. Phase III: Stakeholder feedback
3.4.5. Phase IV: Finalization of the proposal
3.4.6. Phase V: Agreement sign off and implementation.

3.4.1. Phase I: Internal Assessment and collection of Information:

The DOH shall gather relevant information on the new technology/ pharmaceutical including the clinical criteria and the specific patient population, analysis of available data, economic evaluation, impact on public, available clinical treatment protocols and clinical experts' opinions-where applicable.

The DOH to conduct several meetings engaging concerned divisions within DOH i.e. Healthcare payers' sector, Finance, Legal, research and innovation and with Payer for taking consensus on the need and feasibility of pursuing a MEA/RSA.

3.4.2. Phase II: Setting up the proposal:

The DOH to conduct several meetings with manufacturers and engage in early discussions to assess the possibility of having a MEA/RSA agreement and mutual interest. Discussions may include targeted patient population, budget impact, defining outcome measures, monitoring and execution strategies.

Pharmaceutical company shall provide the DOH with scientific references and relevant international clinical protocols to set a proposed clinical criteria and targeted patient population.

The DOH will identify the potential outcomes from using the technology/ pharmaceutical that are to be linked to payment. The outcomes need to be important to patients and clinicians and need to be clearly affected by the technology, rather than by other or exogenous factors.

As part of any MEAs/RSAs between regulator, payer and pharmaceutical companies, specific metrics should be included to measure the technology's effects on patients, considering the following four types of outcomes as standard:

3.4.2.1. Survival
3.4.2.2. Disease progression, relapse or recurrence
3.4.2.3. Long-term side effects
3.4.2.4. Return to normal activities

A mapping exercise should be undertaken to ascertain the appropriate data sources and identify "gaps" in the capacity to collect data on the "standard" outcomes. This review should involve healthcare providers, regulator and the pharmaceutical company.

The DOH must consider the practicalities of collecting data for an outcome-based scheme, when applicable.

Each outcome must have a metric for which data can be collected, but also agreement as to when to measure those outcomes.

The DOH should ensure resources are available to monitor and analyze data in a timely manner.

Agree on how to link the price to the measured outcome.

3.4.3. Phase III: Stakeholder feedback:

The DOH to obtain stakeholders feedback on the proposed clinical criteria and targeted population. Further discussion on the financial model with finance team and healthcare Payer team.

Based on the discussion and all stakeholder engagement decision to be made on the most appropriate type of MEA/RSA to be applied.

The DOH legal and information security shall review the full proposal ensuring it is in line with applicable UAE laws and regulations.

3.4.4. Phase IV: Finalization of the proposal

Formal discussion on the terms and conditions of a MEA/RSA with manufacturers and further negotiation in order to finalize all terms of agreement with the purpose of establishing a written agreement. The DOH to complete the MEA/RSA document, outlining key responsibilities and ensuring the commercial access agreement and data capture agreement are included.

MEA/RSA agreements are not intended for purchase of medications. Procurement of medications & pharmaceutical technologies will be made by other concerned entities.

3.4.5. Phase V: Agreement sign off and implementation

- The DOH as the Payer and the manufacturer to officially sign a MEA/RSA with defined terms and conditions stipulated in the agreement after review by legal entities in the relevant parties ensuring confidentiality of such agreements.
- All data is owned by the DOH and access to be granted to the TPA for audit purposes.
- Regular monitoring and follow up on the implementation shall be conducted by the DOH and the TPA at defined intervals with agreed upon roles and responsibilities.
- Pharmaceutical company has no access to patient confidential data and audit of reports shall be conducted by a hired third-party company (whenever applicable).
- Clinical audit can be also conducted by the hired third party (whenever applicable) to ensure proper implementation and ensure patient eligibility criteria as per terms and conditions and assess the performance of the drug and clinical outcomes.

3.5. **MEA/RSA Structure:**

The MEA/RSA document is a legal agreement, that must address data collection agreement and commercial access agreement. Any managed entry/risk sharing agreements developed between regulator, TPA and the pharmaceutical company, must include the following sections and is to be signed off by commissioners/ decision makers in the three entities i.e. regulator, payer and pharmaceutical company:

3.5.1. Agreement terms and conditions

3.4. 3.5.2. Main terms & condition of the agreement includes without limitation:

3.5.2.1. Clinical criteria and Protocol
3.5.2.2. Technology/ pharmaceutical product information, Patient selection/eligibility criteria,
3.5.2.3. Financial scheme i.e. cost sharing scheme
3.5.2.4. Expected outcome, evaluation of clinical efficacy
3.5.2.5. Governance and process including engaging third party if any
3.5.2.6. Data collection
3.5.2.7. Roles and responsibilities of involved stakeholders

3.5.3. Date of agreement and validity duration

3.5.4. Confidentiality

3.5.5. Assignments and Subcontracting

3.5.6. Governing Law and Jurisdiction

3.5.7. Termination clause, governing law & jurisdiction

3.5.8. Liability

Each agreement should contain a clear flow of the process with detailed timelines and clear payment mechanism. A simple process with less administrative complexity is needed to ensure success.

MEA/RSA agreement should have transparency for all parties that should be maintained in the context of confidentiality.

A defined process is required for resolving disputes between stakeholders to ensure that the agreement is implemented fairly and that all stakeholders are treated equally.

The governing law of the agreement shall be the United Arab Emirate Federal laws & the Abu Dhabi courts shall have exclusive jurisdiction to hear disputes that may arisen between the parties to the agreement (s).

3.6. **Types of MEA/RSA:**

3.6.1. Financial-based MEAs/RSAs are structured in such a way as to mitigate the risks associated with assumptions of real-world utilization or volume for a given technology/pharmaceutical product:

3.6.1.1. Population Level: Hepatitis C medications are an example of products for which population-level financial-based RSAs. In these cases, a budget cap or a price-volume agreement could be prudent solutions.

3.6.1.2. Patient Level: agreements to cover medications that are with highly variable dosing i.e. immunotherapies. Risks associated cause uncertainty for payers with regard to the cost per patient. Patient-level utilization caps or partial manufacturer funding of initial or excess dosing could accommodate mutual risk sharing.

3.6.1.3. Performance based MEAs/RSAs: When there is uncertainty or unclear value related to the benefits provided by a medical technology/pharmaceutical product. Include a program of data collection, typically initiated during the time period following the regulatory approval. In such an agreement, the price, reimbursement, and/or revenue for the product are linked to the outcome of the program. For outcome-based agreements, outcomes measures should be simple and objective with the following characteristics e.g., they can be easily measured, either a hard or surrogate endpoint that can be measured or provides short-term outcomes so they could be captured.

3.6.2.1. Types of outcome performance based RSAs:

3.6.2.1.1. Conditional Coverage: Coverage is granted conditionally at the initiation of a program of data collection. Thereafter, the data will be reviewed to support the continued, expanded, or withdrawn coverage for a medical technology. The use of medical technology within the context of clinical trial is an example and may be done alongside a trial to help inform future use.

3.6.2.1.2. Performance linked reimbursement: It ties the actual reimbursement to a formula relating to pre-specified measures of clinical outcomes in the real-world setting. This might include guarantees of outcomes such as safety or efficacy, response rates and tolerability in newly initiated patients.

Based on the risk that should be mitigated, a calculation model should be created to show if the implementation of a specific proposed agreement will effectively reduce the risk. This helps in choosing the appropriate type of risk sharing agreement to be applied.

The proposed agreement should be clearly defined and should have clear forecasted outcomes. This could be done through applying the proposed agreement to the cost-effectiveness or budget impact model. This allows decision makers to see the numerical effect of applying the agreement, and therefore take a decision easily.

The proposed agreement should preferably be provided in several adjustable scenarios. This could be done in the cost-effectiveness or budget impact model to show the effect of changing several inputs, like the duration of contract, the discount, the number of patients…. etc., and choosing a suitable scenario based on the results.

4. Policy Roles and Responsibilities

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

Stakeholder name	Stakeholder Key Role
Regulator: Department of Health Abu Dhabi.	Collection of Information and assessment
	Pharmacoeconomic analysis
	Design of MEA/ RSA
	MEA/ RSA Sign off and execution
	MEA/ RSA monitoring
	Final report generation and evaluation
	Audit and report validation
Insurance TPA: National Health insurance company.	Support in Mutual agreement on the MEA design (throughout the different phases)
	Support in gathering information and assessment
	Perform audit and support in final report review and validation
Procurement entity (Unified Procurement Company for governmental sector)	Support in information gathering and assessment
	Support in MEA sign off and execution
	Medication procurement
Manufacturers	Collection of Information and assessment
	Pharmacoeconomic modelling
	Design of MEA/ RSA
	MEA/ RSA Sign off and execution
Providers: Hospitals and other healthcare facilities	Support in collection of Information and assessment
	Design of MEA/ RSA
	MEA Execution and monitoring
	Final report generation and evaluation
Third parties	Support in Pharmacoeconomic analysis
	Support in MEA/RSA execution and monitoring
	Support in final report review and validation

4.1. Exact roles and responsibilities for each party to be defined during the development phases of the MEA/RSA.
4.2. MEAs/RSAs could be initiated by concerned stakeholders however, it is also recommended to allow pharmaceutical companies to initiate a request for MEAs/RSAs.
4.3. All administrative requirements will be handled by the DOH. This includes but not limited to drafting the agreement, revision by relevant internal the DOH divisions, clinical expert review, management of clear and timely communication among parties involved in agreements implementation (manufacturers, providers, payers and third party).

5. Policy Scope of Implementation

This Policy applies to the evaluation of /pharmaceutical technologies & products used by THIQA, basic and ABM members eligible for coverage. It applies to newly introduced innovative products and selected products that has highest impact on budget. Coverage will be provided after setting the appropriate clinical criteria for use and defining the right agreement type with pharmaceutical companies with reimbursement mechanism.

6. Exempted from Policy Scope

Any other products that do not fall within the criteria detailed in the policy content under technology/pharmaceutical products eligibility criteria section.

7. Enforcement and Compliance (Consequences/sanction of not applying policy by related stakeholder)

DOH-licensed healthcare service providers and TPAs must comply with the terms and requirements of this Policy. The DOH may impose sanctions in relation to any breach of requirements under this Policy in accordance with the the Healthcare Sector Diciplinary Regulation.

8. Monitoring and Evaluation (Key success factors)

Monitoring the success of MEA/RSA implementation would be assessed via evaluation of its saving impact on Thiqa, basic and ABM budget. Suggested KPIs:

8.1. Number of risks sharing agreements on top drugs identified with high spent.

8.2. Reduce in pharmaceutical spent for Thiqa, basic and ABM patients for high-cost innovative products

* Critical success factors: engagement and cooperation between different parties i.e. regulator, insurer, providers and pharma companies.

9. Relevant Reference Documents

No.	Reference Date	Reference Name	Relation Explanation / Coding / Publication Links
1	Dec 2022	Goncalves et al. Risk-sharing agreements, present and future. 10th April 2018. eCancer 2018, 12:823	https://doi.org/10.3332/ecancer.2018.823
2	April 2023	Fasseeh, A. N., Adel, R., Elezbawy, B., Abouelmaged, E., Abaza, S., & Kaló, Z. (2020). PNS55. Managed Entry Agreements in Egypt: Current Practices and Future Preferences. Value in Health, 23, S652-S653.	https://secure.jbs.elsevierhealth.com/action/getSharedSiteSession?redirect=https%3A%2F%2Fwww.valueinhealthjournal.com%2Farticle%2FS1098-3015%2820%2933755-4%2Fpdf&rc=0&__cf_chl_tk=TLp2eOoOLfRJ4gY5c0DVpewRW2pUot1QteFDCvbDdYg-1690263367-0-gaNycGzNDPs
3	March 2023	Managed Entry Agreement Policy for Saudi MOH	https://www.moh.gov.sa/Ministry/MediaCenter/Publications/Documents/Managed-Entry-Agreeement-Policy-MEA.pdf
4	April 2023	Wonder, M., Backhouse, M. E., & Sullivan, S. D. (2012). Australian managed entry scheme: a new manageable process for the reimbursement of new medicines. Value in health, 15(3), 586-590	https://app.amanote.com/v4.0.44/research/note-taking?resourceId=cJ8S3nMBKQvf0BhiS1Pi
5	April 2023	Carlson, J. J., Sullivan, S. D., Garrison, L. P., Neumann, P. J., & Veenstra, D. L. (2010). Linking payment to health outcomes: a taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health policy, 96(3), 179-190.	https://pubmed.ncbi.nlm.nih.gov/20226559/
6	March 2023	Klemp, M., Frønsdal, K. B., & Facey, K. (2011). What principles should govern the use of managed entry agreements. International journal of technology assessment in health care, 27(1), 77-83.	https://www.researchgate.net/publication/49780871_What_principles_should_govern_the_use_of_managed_entry_agreements/link/542963030cf26120b7b6a22f/download
7	Aug 2023	Bouvy, J.C., Sapède, C. and Garner, S. (2018). Managed Entry Agreements for Pharmaceuticals in the Context of Adaptive Pathways in Europe. Frontiers in Pharmacology, [online] 9. doi:	https://doi.org/10.3389/fphar.2018.00280.