SYMPOSIUM

How can value assessment principles be applied to support access to innovative medicines in Middle East and North Africa (MENA) region?

Pharmaceutical Pricing and Reimbursement in the MENA region

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Outline

- Current methods of value assessment and coverage of innovative pharmaceuticals in the MENA region
- The dominance of ERP and its impact in the region and more broadly; is ERP optimally implemented?
- Transitioning from command and control systems of pharmaceutical pricing (e.g. ERP) to value assessment systems
- Explicitly implementing value based assessment in MENA countries: requirements, pathways and timing

Current methods of value assessment and coverage of innovative pharmaceuticals in the MENA region

Pricing policies for in-patent pharmaceuticals

	Price in country of origin	Price of similar pharmaceuti-cals on the market – IRP[5]	Prices found in official references or publications[2]	Therapeutic Significance	Pharmaco-economic studies/ Cost-Effectiveness Evidence[3]	ERP	Price in Saudi Arabia	Proposed price by the manufacturer
Algeria	-	-	-	-	-	✓	-	-
Bahrain	✓	✓	✓	✓	✓	✓	-	-
Egypt	-	-	-	-	-[6]	✓	-	-
Jordan	✓	(✓)[4]	-	-	✓	✓	✓	✓
Kuwait	-	-	-	-	-	✓	-	-
Lebanon	✓	-	-	-	-	✓	-	-
Morocco	-	-	-	-	-	✓	-	-
Oman	✓	✓	✓	-	-	✓	-	-
Qatar	-	-	-	-	-	✓	-	-
Saudi Arabia	✓	-	✓	✓	✓	✓	-	✓
UAE	✓	-	✓	-	-	✓	-	✓

Notes:[1] Combining primary and secondary evidence, the latter not necessarily from 2018.

[2] Refers to prices found in official publications and in addition to those from reference countries. For example, the British National Formulary (BNF) is such a source and constitutes an additional criterion for pricing.

[3] Pharmacoeconomic analysis is not an explicit requirement for the countries shown on this column and, in most cases, it is used in selected conditions only.

[4] If the pharmaceutical is only available in the country of origin.

[5] Internal reference pricing, which practically signals that reimbursed prices subscribe to a ceiling imposed by the competent authority.

[6] Although there is no evidence that this is used in practice in Egypt, there is some infrastructure/expertise on the subject at MoH level.

Key: '✓' = Yes/used.
'-' = No evidence that this is used in practice.

Sources: Kanavos et al, 2018.

Reimbursement & Procurement of in-patent pharmaceuticals

	IRP (molecular)	IRP (therapeutic)	IRP (managed competition)	ERP	HTA[1]	RSA[2]	Tendering	Formulary management	CCBA[3]	Negotia-tion	Budget Impact
Algeria	×	×	×	✓-	×	✓	✓[4]	✓[4]	✓	✓	✓
Bahrain	-	-	-	-	×	-	-	-	-	-	-
Egypt	×	×	×	×	×[5]	✓	✓	✓[4]	✓	✓	-
Jordan	-	-	-	-	✓-	×	✓	-	-	-	-
Kuwait	×	×	✓-	✓	×	×	✓	×	×	×	×
Lebanon	×	×	×	×	×	✓	✓	✓	×	✓	-
Morocco	×	×	×	✓-	×	×	✓	×	✓	✓	-
Oman	-	-	-	-	×	-	-	-	-	-	-
Qatar	×	×	×	✓-	✓[1]	×	✓	✓	×	×	×
Saudi Arabia	×	×	×	✓	×[5]	×	✓	✓	×	✓	-
UAE	×	×	×	×	×	×	×	✓	×	✓	-

Notes:* Applies to all medicines whether outpatient or in-patient; if relevant to out- or in-patient, a qualification is made where appropriate.
[1] The application of HTA is inconsistent and not systematic. It may be the case that national (pricing) guidelines specify that it may be necessary for countries to submit pharmacoeconomic evidence, but it is unclear whether this it taken into account or how.
[2] Primary data collection from a few settings suggested that RSA was being *considered* but this was likely to be relating to the future application of any RSA arrangements. Current legislative frameworks in the study countries do not allow RSA strategies to be implemented, particularly those of outcome-based RSAs.
[3] Comparative clinical benefit assessment. Although it has been mentioned that CCBA is applied as part of national legislation, it is unclear how robustly this is taking place and based on what methodology.
[4] Only used in hospitals, not at outpatient level.
[5] Not currently using but HTA planned to be implemented in due course based on passed legislation or current government initiative.

Key: '✓' = yes / used
'×' = no / not used
'-' = no evidence
'✓-' = Used as a reference price/guide and/or not necessarily in a systematic way.

Source: Kanavos et al, 2018.

Summary of key trends: Pharmaceutical Markets (2)

- **Fragmented systems** ➔ often little consistency, high OOP payments & access gaps
- **Dominance of ERP**: cost minimization tool in MENA by benchmarking against the lowest list prices in large baskets ➔ prices converge downwards over time
- No account of **value of innovation** ➔ need for local data and capacity building
- Large **ERP baskets** and repetitive referencing lead to complex ERP administration ➔ delay in new product launching and reduced availability
- Absence of **formal value assessment** ➔ need for a) transparent criteria and b) clear implementation mechanisms
- Use of unrealistic and volatile **exchange rates** further lowering prices and availability ➔ need for fixed exchange rates or moving averages
- **Patent Status** issues: using IRP + ERP coupled with differences in IP ➔ price distortions
- Long **registration and pricing processes** ➔ need for streamlined pricing process
- **Interest** in HTA, MEA, CEA ➔ lack of understanding of requirements/prior actions

Consequences of ERP dominance

- Availability issues
  - **Pricing policy**: low prices lead to delays in launching (even not launching) and withdrawal of products in/from the market
  - **Pricing system inflexibility**: highly regulated markets not accommodating external factors, or not considering inflation
  - **Protracted price negotiation and approval**: causes delay in market entry
- Spillover effects, case of small markets and/or limited spending
- International implications
- Value of innovation not explicitly assessed

The dominance of ERP and its impact in the region and more broadly; is ERP optimally implemented?

Is ERP optimally implemented: The 14 principles framework

An analytical framework studying whether national ERP systems adhere to best practice comprising 14 principles (Sullivan, Kanavos & Kalo, 2015) and endeavouring to showcase the performance of national ERP systems based on these principles

No.	ERP best practice principle framework
1	The objectives of ERP systems should be clear and align with health system objectives
2	ERP systems should focus on in-patent products considered for the purposes of coverage, pricing and reimbursement decisions
3	Prices developed via ERP do not over-ride HTA conclusions or VBP approaches
4	The ERP system should have administrative simplicity and transparency
5	Stakeholders should participate in design and review of ERP system
6	Stakeholders are able to appeal regulator decisions
7	Reference countries should be selected based on similarities in economic status and health system objectives
8	International implications of ERP implementation should be considered
9	Publicly available ex-factory prices should form the basis of the ERP system
10	The mean of prices in reference countries should be used
11	ERP system respects patent status of products it covers based on provision of IP that prevail in reference country
12	ERP formula should avoid the impact of exchange rate volatility
13	Price revisions should be kept to a minimum and should be carried out consistently to avoid the perception of opportunistic behaviour
14	ERP-based prices should be aligned with other tools used when negotiating reimbursement

MENA ERP vs. The 14 Best Practice Principles in ERP

ERP best practice is not fully followed in the study countries: failure to use basket mean prices, a simple and transparent system that involves stakeholders, or a system that accounts for the international implications; some countries have made significant progress towards meeting a number of best practice principles: USE, KSA & Jordan

	GDP per capita, 2017 adjusted for PPP$	Clear objectives aligning with policy goals	Focus on in-patent drugs only	ERP prices do not override HTA decisions	Admini-stratively simple and transparent	Stakeholder participation	Possibility to appeal	Appropriate country selection	Consideration of international implications	Use of ex-factory prices	Use of mean prices	Respect of patent status	Avoid impact of exchange rate	Price revisions to a minimum	Alignment with nego-tiation tools
Algeria	15,050	✓	×	N/A	×	×	×[1]	×[1]	×[1,2]	✓	×	×[1]	×	×	×
Bahrain	42,930	×	✓	N/A	✓	×	✓	✓	×	✓	×	✓	×[1]	×	×
Egypt	11,360	×	×	N/A	×	×[1]	×[1]	×	×	×	×	×[1]	×[1]	×	✓
Jordan	9,110	✓	~✓	N/A	✓	~✓	✓	×	×	✓	✓	×	✓	×	×
Kuwait	83,310	×	-	N/A	✓	✓	✓	×	×	×	×	-	×	×	×
Lebanon	14,690	✓	×	N/A	✓	×	✓	×	×[1,2]	×	×	✓	✓	×	×
Morocco	8,063	✓	×	N/A	✓	✓	✓	✓	×	✓	×	✓	✓	×	✓
Oman	40,240	-	×	N/A	✓	-	-	×[1]	-	✓	×	-	-	×	×
Qatar	128,060	×	✓	N/A	✓	×	✓	✓	×	×	×	✓	✓	×	×
Saudi Arabia	54,770	×	✓	N/A	×	×	✓	×	×	✓	×	✓	✓	✓	×
UAE	74,410	×	~✓	N/A	✓	×	✓	✓	×	✓	✓[2]	✓	✓	✓	×

Notes:
[1] Primary and secondary data collection and triangulation with multiple sources suggest this criterion is not met.
[2] While it has been mentioned that local decision-makers consider the international implications, it is unclear how this is applied in practice.
[3] Median price.

Key:
'✓' = satisfies.
'×' = does not satisfy.
'~✓' = partially satisfies.
'-' = no evidence

Source: LSE interpretation based on primary and secondary data collection and further triangulation with stakeholders. GDP per capita data from World Bank, 2018.

Transitioning from command and control systems of pharmaceutical pricing (e.g. ERP) to value assessment systems

A Path to Medium- and Long-Term *Pricing Policy Strategy* in MENA countries

MEDIUM-TERM:

OPTIMISING CURRENT STATE AND CURRENT USE OF ERP

Medium-term pricing policy state

- Administratively simple and transparent
- Possibility to appeal
- Appropriate country selection
- Consideration of international implications
- Use of ex-factory prices
- Use of mean prices
- Avoid impact of exchange rate fluctuations
- Price revisions to the minimum
- *Consider HTA as an option*

Source: Kanavos et al, 2018.

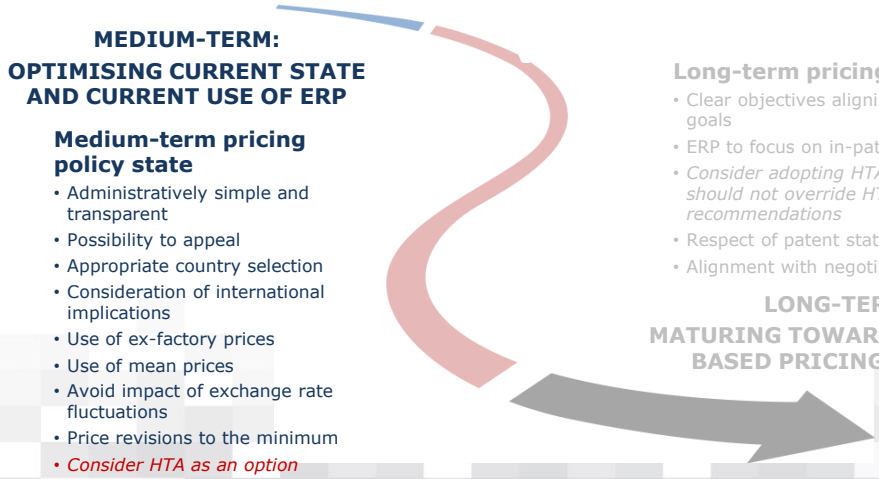
Long-term pricing policy state

- Clear objectives aligning with policy goals
- ERP to focus on in-patent drugs only
- *Consider adopting HTA; ERP prices should not override HTA recommendations*
- Respect of patent status
- Alignment with negotiation tools

LONG-TERM:

MATURING TOWARDS A VALUE-BASED PRICING SYSTEM

The ***Medium-Term*** in MENA Pricing and Value Assessment



Source: Kanavos et al, 2018.

Interventions in the medium-term (1)

Administrative Simplicity and Transparency

- Reduce size of basket & revision frequency
- Retain ERP with small basket (between 5-7) at launch

Appeals Process

- Stakeholders should be able to appeal in a timely fashion (3-4 weeks) to avoid delays in access

Selection of Reference Countries

- Basket countries could be selected on basis of similar GDP levels and/ or market size
- Wealth adjustment could be used in order to ensure that MENA countries do not overpay relative to some of the basket countries

Choice of Price based on ERP Principles

- By selecting the mean, rather that the lowest price, MENA countries avoid pressure from manufacturers about the spill over effects of the price to other settings.
- Country selection including countries with much higher incomes, may require wealth adjustment in order to arrive at "affordable" prices for some MENA countries.

International Implications of ERP Implementation

- List price levels should remain at the level that manufacturers are still encouraged to launch effective products in the MENA region.
- Considering a smaller and more flexible basket of reference countries, wealth adjustment can be used to ensure that list prices in MENA countries are affordable based on each country's income.
- The reimbursement system and the negotiation of reimbursement prices should be used as the main lever to produce savings on the pharmaceutical budget by reducing the cost of new medicine, whilst leaving list prices unaffected.

Use of Publicly available Ex-factory Prices and deal with exchange rate fluctuations

- Use in the basket countries that report ex-factory prices.
- Ensure that list prices extracted from other countries are relevant to the subject matter of ERP. i.e. setting list price primarily for the retail market
- Publicly available data sources should be used to extract ex-factory prices from basket countries; for transparency purposes discounted prices can be taken as a reference if they are published and are verifiable
- To manage exchange rate fluctuations, use moving average

Explicitly implementing value based assessment in MENA countries: requirements, pathways and timing

The ***Long-Term*** in MENA Pricing and Value Assessment

MEDIUM-TERM:

OPTIMISING CURRENT STATE AND CURRENT USE OF ERP

Medium-term pricing policy state

- Administratively simple and transparent
- Possibility to appeal
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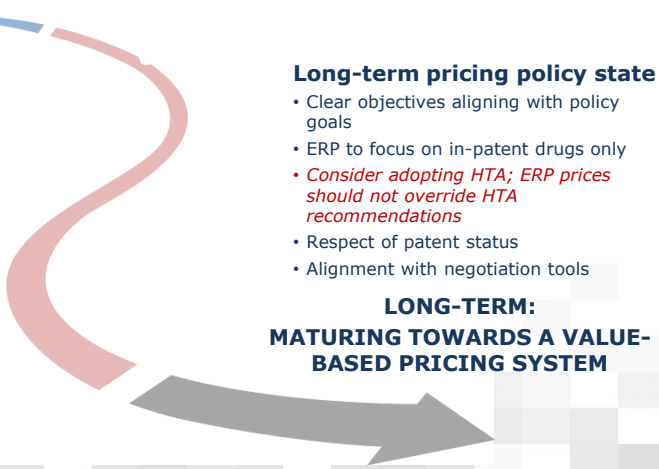
- *Consider HTA as an option*



Long-term pricing policy state

- Clear objectives aligning with policy goals
- ERP to focus on in-patent drugs only
- *Consider adopting HTA; ERP prices should not override HTA recommendations*
- Respect of patent status
- Alignment with negotiation tools

LONG-TERM:

MATURING TOWARDS A VALUE-BASED PRICING SYSTEM

Source: Kanavos et al, 2018.

Interventions in the long – term (1)

Focus ERP on In-Patent Products

- Continue the current mix of ERP with price reductions, but ensure that over time there will be a process of gradual de-linking from ERP principles for off-patent drugs in this space.
- Move away completely from ERP principles and implement a significant one-off price reduction post patent expiry.
- Move away completely from ERP principles and consider a combination of sufficient reductions post patent expiry with tenders in out and in patient markets.

ERP and other Methods to determine Reimbursement

- Include in the basket countries that use HTA but do not override their conclusions in favor of a lower price.
- Consider both HTA and ERP countries but the price function becomes advisory and therefore less important in the process of pricing and reimbursement.

Respecting Patent Status

- Expiry of the patent in the domestic market is a pre-condition for subjecting the price of the originator product to generic price competition from other settings (as well as price competition from domestic generics)

Alignment of ERP to other Tools – cont.

- List prices are set at Launch and will form the basis of negotiations to set reimbursement levels. Negotiations will lead to prices which are favourable for national payers on condition that these remain confidential.
- Tools such as Risk Sharing Agreements and Value assessment, through some form of HTA can be used to inform negotiations.
- The role of re-pricing in informing reimbursement will – in the majority of the cases – be marginal as reimbursement will be based on negotiation rather that a process of re-pricing in order to achieve price reduction over time.

The role of ERP in the Context of Pharmaceutical Policy

- ERP is a supplement to a range of tools that are used to arrive at affordability, including an explicit value assessment process and the implementation of RSA.
- ERP should in principle be the first stage for negotiations regarding the admission of a new product into a national benefit catalogue by enabling the collection of prices from other settings at launch only.

ERP and Innovative/ Niche Products

- If a separate pathway of negotiation and value assessment has been set up for certain products, it would be desirable to exclude these products from inclusion into an ERP updates.

Interventions in the long – term (2)

Transitioning from ERP to a VBP system

- International evidence suggests that transition from ERP to a) the establishment of a robust criteria for value based assessment on clinical and/ or economic grounds, b) a form of HTA, c) the consideration of additional criteria being costs and effects, which capture the importance of local context and local data such as burden of disease, incidence, prevalence and severity, d) the use of negotiation principles to arrive to a reasonable and affordable and e) the more extensive use of risk sharing principles to inform local coverage decisions.
- Transitioning towards a more explicit system of value assessment requires a) institution-building to address practical challenges in value assessment, b) investment in human capital, and c) data generation processes to support evidence based decision making.

Is there a role for HTA in value assessment?

- Before even considering HTA adoption, a set of **prior actions** are needed
- Interested countries should think how it will be incorporated in their decision making process, including the interaction with other policy tools, such as ERP
- A decision to adopt HTA should be followed by investment in human and physical infrastructure as well as data systems to support implementation; a period of learning is also desirable.
- If HTA is established, it needs to be separated from the registration process and should not impact registration based on efficacy or safety.
- The implementation of HTA principles requires a gradual shift in policy making towards an environment which is more transparent, collaborative, consultative and is supportive of innovation and investment.
- Interested countries should carefully consider all available options around an **HTA system** and select one that satisfies their interest before deciding to adopt one.
- Interested countries should carefully consider all available options around **HTA model**, before deciding to adopt one.
- The principle of HTA should ultimately be applied across a wide range of medical interventions, rather than medicines only.

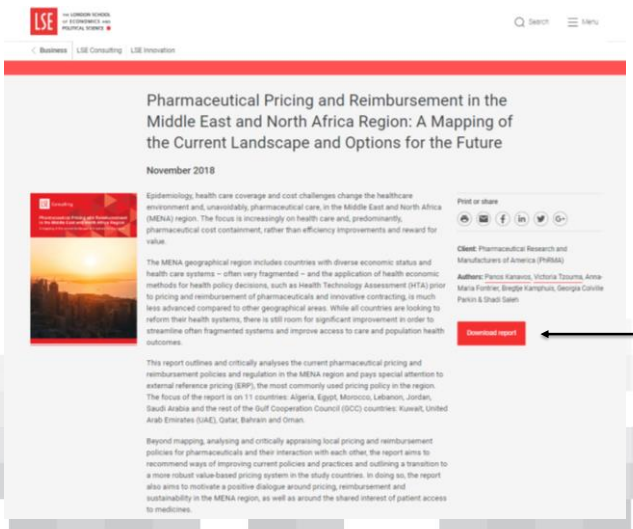
Interventions in the long – term (3)

Re-thinking Universal Coverage and Reimbursement

- ✓ It would be highly desirable to give due consideration to improving coverage substantially and reducing the OOP cost of health care, including medicines; having a single coverage or reimbursement system could be one way forward
- ✓ In the broader context of health care reforms, national pharmaceutical policies will need to address the issue of financing and its sustainability, a balanced industrial policy, the regulation of distribution chain, and the strengthening of regulatory standards

The LSE report on MENA Pharmaceutical Pricing

Available for download on the LSE Consulting website:
http://www.lse.ac.uk/business-and-consultancy/consulting/consulting-reports/pharmaceutical-pricing-and-reimbursement-in-the-middle-east-and-north-africa-region



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