THE LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIENCE

Development of policies to increase headroom for innovation in Egypt and the Kingdom of Saudi Arabia

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Background

Establishing an efficient and sustainable healthcare system is important, balancing high quality care and improvements in the health of the population with efficiency of services while not overburdening national budgets. Uptake of new, innovative pharmaceuticals has been associated with long-term improvements in health outcomes, better quality of life, and benefits for the healthcare system.

Headroom for innovation can be achieved through improving policies for generic pharmaceuticals and investing the resulting resources where need is significant, such as new and potentially innovative pharmaceutical products. Generating healthcare savings and subsequently re-allocating these savings to reward and encourage innovation and promote the use of novel, innovative pharmaceuticals can be an essential part of establishing and maintaining an efficient and sustainable healthcare system.

Objectives

This study considers the potential for creating headroom for innovation in the healthcare systems of Egypt and the Kingdom of Saudi Arabia (KSA), in both of which difficulties in patient access to and delays in the market entry of innovative medicines have been observed.

The specific objectives of the study were as follows:

1. To identify gaps and issues in current generic and biosimilar policies in Egypt and KSA based on best practices from other countries.
2. To propose how to improve generic and biosimilar uptake and suggest potential policy reform to reducing inefficient healthcare spending on these products.
3. To quantify the potential savings associated with optimised spending on generics and biosimilars.
4. To provide recommendations on how to create headroom for innovation by freeing up resources through generic and biosimilar policy change and how to redirect savings to reward innovation using examples of practices from other countries.

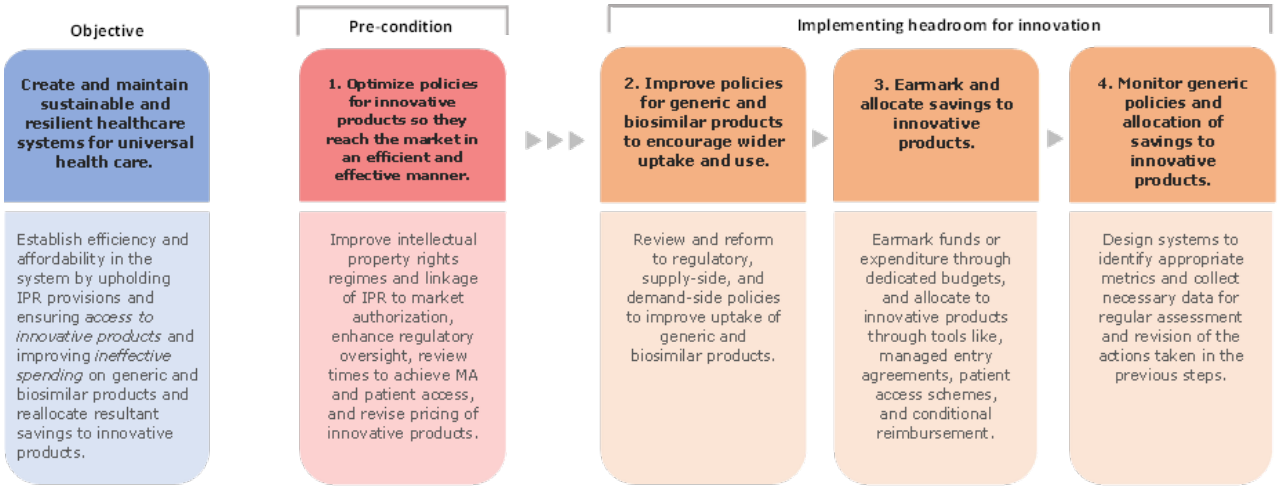
Potential savings in Egypt and KSA

A simulation exercise showed potential savings from optimizing prices and volume market shares in line with comparator countries, leading to significant potential savings in Egypt and KSA.

	Potential savings from optimised purchasing	*Potential savings from reduction in generic prices*	*Potential savings from increase in generic market share*
Egypt	2016: $55 million (26%) 2020: $95 million (34%)	2020: $64 million (23%)	2020: $28 million (10%)
KSA	2016: $602 million (86%) 2020: $634 million (80%)	2020: $529 million (67%)	2020: $115 million (14%)

Steps to achieving headroom for innovation

Figure 1. Four concrete steps in working towards headroom for innovation in Egypt and KSA



Step 1: Optimise policies for innovative products so they reach the market in an efficient and effective manner. Establishing a sustainable landscape for innovative products is a key requirement prior to making other changes to create headroom for innovation. Recommendations on measures to ensure optimal product penetration for innovative medicines reflect on three key issues: (a) recognising and rewarding innovation through intellectual property rights, (b) time to both market and patient access and (c) pricing. For Egypt and KSA, establishing robust IP regulations, such as patent protection, regulatory data protection, and compulsory licensing provisions, is a crucial step. Without appropriate enforcement of these protection periods, innovation is not encouraged nor rewarded, and savings will not be able to be reallocated efficiently.

Step 2: Improve policies for generic and biosimilar products to encourage uptake and use. Generic penetration remains low in both Egypt and KSA compared to other countries. The potential to achieve savings through modulating volume and uptake in cases where further price reductions may not be possible exists, highlighting the potential for Egypt and KSA to review and proceed with changes to supply- and demand-side policies for generics and biosimilars. In addition, processes for smoother transitions for medicines with expiring patents should be established.

Step 3: Earmark and allocate savings to innovative products. Egypt and KSA need to design and implement policies to earmark revenue from improved generic and biosimilar policies and redirect earmarked funds to innovative products. Both countries will need to identify which strategies may function in their local setting and embed these in their healthcare systems. Willingness and commitment from key stakeholders are essential to uphold the pledge to earmark funds for innovative medicines and to ensure the connection between savings and innovation is maintained and protected.

Key features when designing and implementing processes to earmark funds.

- Clear definition of the scope of the fund.
- Incorporate ways to ensure the suitable allocation of funds and limited overspending.
- Use the opportunity to link to other needs, such as data collection.
- Develop funds to recognise country organisation and context, as well as national needs and prioritisation.

Step 4: Monitor generic policies and allocation of savings to innovative products to ensure a sustainable healthcare system. Egypt and KSA should find ways to monitor whether changes to policies are effective and a redirection of savings is achieved.

Metrics for monitoring reform: generic and biosimilar products.

- Drug availability post-patent expiry.
- The speed with which generics/biosimilars launch after expiry of IP protection on innovative products.
- Number of (generic/off-patent) competitors post-patent expiry.
- Price development of originators and generics after loss of exclusivity.
- Evolution of generic volume market share.

Metrics for monitoring reform: innovative products

- Observed changes and reform to policies for innovative products.
- New product uptake.
- Coverage decisions for a new product.
- Time taken between global launches and local launches.
- Time taken for regulatory completion.
- Time taken to achieve reimbursement.

Immediate action

Action should be taken immediately for Step 1, after which activities across all steps should commence simultaneously to ensure systems are ready to support headroom for innovation. Immediate action for both countries across these steps follow. Necessary mid- and long-term efforts have also been identified and are outlined in the full report.

Roadmap for immediate next steps in Egypt

Ensure access to innovative products through IPR, regulatory, and pricing provisions (Step 1)

- Introduce of regulatory data protection provisions.
- Establish of mechanisms which enforce IPR provisions.
- Adhere to TRIPs, particularly for compulsory licensing.
- Establish possibility for patent extension.
- Establish system to provide transparent information on patent expiry.
- Strengthen national court systems to resolve any disputes.
- Seek to shorten market entry timelines for innovative products.
- Improve oversight capabilities of national regulatory agencies and ensure adequate number of suitably trained assessors to review applications.
- Introduce an early market access scheme.
- Seek to delink pricing from marketing authorisation.
- Recalibrate the ERP systems used for innovative products.
- Ensure reimbursement decisions are compliant with value-based assessment.
- Refer innovative products to a negotiation process and MEAs.

Once access to innovative products is improved, action to consider will be:

Improve policies for generic products (Step 2)

- Improve regulatory issues by utilizing abridged approval pathways, reviewing the length of time taken for market authorisation of generics, and enforcing quality of generic and biosimilar products.
- Regulate the supply-side by introducing price reductions for patent-expired originator medicines (once an appropriate patent system is in place), and monitor the newly introduced healthcare system for any continued use of preferential practices.
- Improve demand for generics by encouraging generic prescribing and substitution, and strengthening biosimilar prescribing. This step could be introduced initially by targeting highly generised markets such as proton pump inhibitors or statins.

Allocate savings to innovative products (Step 3)

- Secure commitment from relevant institutional stakeholders.
- Streamline the time taken for P&R processes by ensuring newly approved drugs enter reimbursement negotiations immediately after they are launched and for these negotiations to be completed within a fixed amount of time.
- Use horizon scanning to understand the landscape for innovative medicines.
- Design policies to earmark savings through funds, budgets, or other means which suit the country context. Examples of such policies include earmarked funds or expenditure, conditional reimbursement mechanisms for high uncertainty products, and the use of managed entry agreements and/or patient access schemes.

Monitor actions (Step 4)

- Secure institutional support from relevant bodies for monitoring efforts.
- Design data collection policies with regular collection of relevant data which suit the country context.

Roadmap for immediate next steps in KSA

Ensure access to innovative products through IPR, regulatory, and pricing provisions (Step 1)

- Introduction of regulatory data protection provisions.
- Establishment of mechanisms which enforce IPR provisions.
- Adherence to TRIPs, particularly for compulsory licensing.
- Establish possibility for patent extension.
- Establish system to provide transparent information on patent expiry.
- Strengthen national court systems to resolve any disputes.
- Seek to shorten market entry timelines for innovative products.
- Improve oversight capabilities of national regulatory agencies and ensure adequate number of suitably trained assessors to review applications.
- Seek to delink pricing from marketing authorisation.
- Recalibrate the ERP systems used for innovative products.
- Ensure reimbursement decisions are compliant with value-based assessment.
- Refer innovative products to a negotiation process and MEAs.

Once access to innovative products is improved, action to consider will be:

Improve policies for generic products (Step 2)

- Improve regulatory issues by reviewing the length of time taken for market authorisation of generics and enforcing the quality of generic and biosimilar products.
- Regulate the supply-side by seeking to eliminate phenomena where generic list prices are higher than originator prices and revising the price capping percentage for biosimilar products.
- Improve demand for generics by encouraging generic prescribing and substitution, and strengthening biosimilar prescribing. This step could be introduced initially by targeting highly generised markets such as proton pump inhibitors or statins. KSA should also ensure existing IT systems monitor generic prescribing behaviour.

Allocate savings to innovative products (Step 3)

- Secure commitment from relevant institutional stakeholders.
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