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Pharmaceutical pricing policies in Qatar and Lebanon: narrative review and document analysis

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Abstract

Objectives This study aimed at reviewing and analysing the pharmaceutical pricing policies implemented in two middle-east countries.

Methods Official documents related to national pharmaceutical pricing policies were reviewed, and meetings with key informants in the registration and pricing departments in the Qatari and Lebanese ministries of public health were conducted.

Key findings As of April 2017, the laws currently in effect in Qatar and Lebanon are based on the latest versions of decrees enacted in 2011 and 2005 respectively. Both countries have implemented similar pharmaceutical pricing policies which apply only to the private sectors in both countries. Landing price in Lebanon is either free-on-board (FOB) or cost-insurance-freight (CIF) while it is only CIF in Qatar. External reference pricing and mark-up regulations were two of the common policies identified in both countries. For external reference pricing, the basket of countries considered and the price adopted were different. Mark-ups were applied with different schemes along the pharmaceutical supply chain in each country with Qatar imposing an overall higher mark-up margin. Moreover, Qatar utilized health technology assessment whenever such economic evaluation studies were available at the time of medicine registration. These pricing strategies applied to both public and private sectors in Lebanon, while they only applied to the private sector in Qatar.

Conclusions The pharmaceutical pricing policies implemented in Qatar and Lebanon are reflective of both the advancements in the human capital and financial resources of the nations and are in line with the World Health Organization-recommended pricing policies for developing countries.

Keywords external reference pricing; health technology assessment; mark-up; pharmaceutical; price; pricing policy

Introduction

Access to medicines is a human right and some countries incorporate it in their national constitution.^[1–3] Achieving and fulfilling this right enhances the quality of an individual's life and sustains an adequate standard of health. Poor access is not always related to technical issues. Other factors influencing access include social beliefs or values, economic interests and political process.^[4] World Health Organization (WHO) identifies several barriers to access including high medicine prices, availability and affordability.^[5–7]

Governments can control different stages in the pharmaceutical supply chain. WHO has provided governments with the following recommended methods to influence the prices set by the manufacturers^[8]:

- 1 Price controls on the manufacturer;
- 2 Profit controls on the manufacturer;
- 3 Reference pricing and brand premiums;
- 4 Comparing pricing controls (international benchmarking);
- 5 Eliminating tariffs and taxes;
- 6 Fixed margins;
- 7 Digressive mark-ups and
- 8 Capitation systems

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In general, countries adopt varying strategies to manage the pharmaceutical market. Some have minimal interventions while other countries get fully engaged and intervene by either subsidizing medicines or offering them for free to their population. The latter case is what is encountered in industrialized countries which are members of the Organization of Economic and Co-operation and Development (OECD).^[9]

The final retail price at which patient buy the pharmaceutical is the result of various cumulative price components added throughout the pharmaceutical value chain. These factors vary widely among countries, and they include^[4]:

- 1 Basis for setting the original prices;
- 2 Shipping cost;
- 3 Distribution cost;
- 4 Import duties;
- 5 Taxes;
- 6 Product registration cost and
- 7 Transfer price

Usually, the ex-factory price or manufacturer selling price (MSP) of a medicine is only an initial starting component of the final retail price at which a patient purchases the medicine.^[4,7]

Inadequate access to medicines is most pronounced in poor countries where people face difficulties due to medicine price and availability whether in the public or private sector.

While the right to be treated should be a basic right for people around the world, this is not the case in low- and middle-income countries (LMICs). In these countries, people are purchasing medicine out of pocket (OOP) because of the lack of a comprehensive health insurance system and inadequate publicly subsidized pharmaceutical services.^[10] Therefore, strategies to ameliorate access should take into account improving affordability.^[6] A close inspection of the disparity in access across the world sheds light on poor pharmaceutical policies and strategies. This is due to discrepancy in medicine needs and challenges of each individual country. A financial burden on households is usually accompanied with social and psychological burdens. Such burdens can lead people to forgo their medical treatment in favour of other living expenses.^[11]

In order to assess the general situation in the developing countries, Abdel Rida *et al.*^[12] conducted a systematic literature search to identify government strategies or guidelines used to control the pharmaceutical pricing and to explore their effects on the adopting nations. These strategies were also assessed in view of WHO pricing policy guidelines.^[6]

The WHO-recommended pricing policies as per the ‘WHO Guideline on Country Pharmaceutical Pricing Policy’^[6] were identified in the reviewed studies as represented in Figure 1 below:

The data confirmed a scarcity of pharmaceutical pricing evaluative studies in developing countries as compared to developed countries.^[6,13,14] No significant relationship between income level and types of policies implemented was identified.

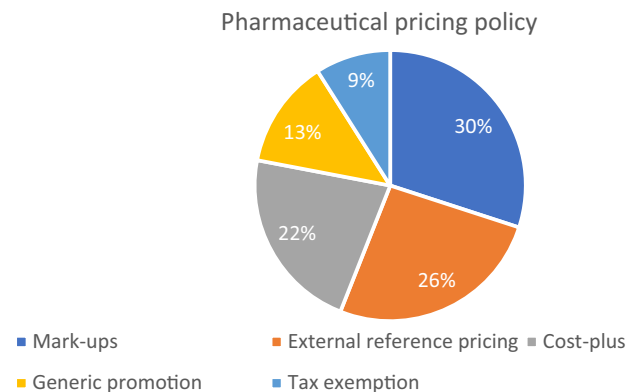


Figure 1 Identified World Health Organization policies in reviewed articles Source: Abdel Rida, Nada, & Mohamed Ibrahim, M. Izham (2018). Medicines pricing policy and strategies in developing countries: A review. In M. Izham Mohamed Ibrahim, A. I. Wertheimer, & Z. -U. Din Babar (Eds.), *Social and administrative aspects of pharmacy in low- and middle-income countries: present challenges and future solutions*. Elsevier: Academic Press, 111–128.

Although developing countries are implementing policies as recommended by WHO guidelines, such policies have not always been successful as reported in China^[15] and Indonesia.^[16] Accordingly, each country should assess its own health care and pharmaceutical situation and consequently implement adequate policies and interventions.

After reviewing the impact of policies and the reality of the pharmaceutical sector status in developing countries to the extent permitted by the reviewed studies, robust research targeting the analysis of pharmaceutical and pricing policy in the developing countries should be conducted, taking into consideration policy reform and adoption. With regard to two developing countries, Qatar and Lebanon, a single study by Kaló *et al.*^[17] was identified. However, it did not reflect the actual pricing policies implemented nor measure the direct effect of these policies on the availability and affordability of medicines in these two countries. The study only identified and assessed ERP by comparing the price corridor of pharmaceuticals that are subject to ERP versus non-pharmaceuticals.

Both Qatar and Lebanon are Arab countries in the MENA region and therefore fall under EMRO, the Eastern Mediterranean Regional Office of the WHO. They differ in terms of economic indicators due to the differences in income levels (Table 1). While Qatar is a high-income country, Lebanon is an upper-middle-income country.

A closer look demonstrated that both Qatar and Lebanon reveal the absence of an established national pharmaceutical policy^[18]; however, both countries have put enormous efforts to control the pharmaceutical sector^[5] and to curb the high prevalence of diseases especially the non-communicable disease (NCD) such as cardiovascular diseases ranked first and second cause of death in Lebanon and Qatar respectively.^[19] Ensuring equitable access to medicines treating such diseases is a cornerstone in the chronic disease’s pharmaceutical management. The price of medicines and the overall cost of therapy are financial burdens and are key factors of medication

Table 1 Qatar and Lebanon economic indicators and demographics

	Qatar	Lebanon
GDP (\$ bn)	164.64	47.08
Population (mn)	2.58 [†]	6.24 [‡]
Citizens (mn)	0.313 [§]	4.751 [‡]
GDP per capita (\$)	73 653	8047
Health expenditure (\$ bn)	4.82	3.34
Public health expenditure (\$ bn)	4.10	1.59
Private health expenditure (\$ bn)	0.72	1.75
Pharmaceutical sales (\$ bn)	0.52	1.64
Pharmaceutical sales, % of health expenditure	10.90	49.00
Per capita spending on pharmaceuticals (\$)	234	280
Spending on originator pharmaceuticals (\$ mn)	360.0	800.0
Spending on generic pharmaceuticals (\$ mn)	110.0	490.0

Source: (1) World Bank. Data, Indicators: The World Bank Group; 2016 [Available from: <http://data.worldbank.org/indicator>]; (2) Business Monitor International (BMI). Lebanon pharmaceuticals & healthcare report Q3 2016: BMI Research, FitchGroup; 2016 [Available from: www.bmi-research.com]. (3) Business Monitor International. Qatar Pharmaceuticals & healthcare report Q3 2016: BMI Research, FitchGroup; 2016 [Available from: www.bmi-research.com].

bn, billion; GDP, gross domestic product; mn, million.

[†]Ministry of Development Planning and Statistics (MDPS). Qatar population number: Ministry of Development Planning and Statistics; 2017 [Available from: <http://www.mdps.gov.qa/en/Pages/default.aspx>].

[‡]Central Intelligence Agency (CIA). The World Factbook – Library: Central Intelligence Agency; 2017 [Available from: <https://www.cia.gov/library/publications/the-world-factbook/geos/le.html>].

[§]Snoj J. Population of Qatar by nationality report 2017 [Available from: <http://priyadsouza.com/population-of-qatar-by-nationality-in-2017/>].

adherence, with lifelong payment for CVD medication is also considered a barrier for adherence.^[20]

Several non-governmental organizations (NGO) and WHO acknowledge that in order to improve the availability and the affordability of essential medicines, evidence-based national policies and programmes must be developed. In the same context, an editorial published in the British Medical Journal (BMJ) after the World Health Assembly in 2000 drew attention to existing problems discussed in the WHO/HAI report related to chronic disease management.^[21] According to BMJ: ‘the report’s findings make explicit what has long been recognized: that the cost of medical care impoverishes or is simply beyond the reach of many people in developing countries. Amid the gloom, however, there is some light. Simply collecting data and presenting it to governments can stimulate action’.^[4] Moreover, to develop a suitable strategy for price control, it is imperative to understand factors involved in medicine price setting. Therefore, an in-depth review and analysis of pricing policies implemented are vital to the endeavours undertaken by the respective governments.

In this study, we aimed to comparatively review and analyse the latest pharmaceutical pricing strategies adopted in Qatar and Lebanon, and to compile our analysis in a concise and accessible reference document.

Methods

Study design

A thorough review and reporting of the official government documents (e.g. decrees, decisions and laws) related to pharmaceutical policies in Qatar and Lebanon were conducted. Moreover, meeting and discussions with active key informants with knowledge of pharmaceutical pricing mechanisms, regulation and supply chain were held at a central level (e.g. ministries). The discussions covered the pricing mechanism of pharmaceuticals and delved into the various price components throughout the different stages of the medicine distribution chain. It was followed by official documents review and reporting.

Ethics

The authors obtained an exemption from Qatar University Institutional Review Board institution.

Study location, setting and timeline

Location

The study is comparative and carried out in two Asian middle-eastern countries: Qatar and Lebanon.

Setting

To collect central level data, public entities involved in the pharmaceutical pricing policies’ implementation and monitoring were visited. In Qatar, meetings were organized with the Pharmacy and Drug Control Department (PDCD) at the MOPH and the Drug Supply Department at Hamad Medical Corporation (HMC) to investigate the retail price composition. These departments regulate the private and public sectors’ medicine procurement processes respectively.

A similar process was followed in Lebanon, where meetings were conducted with the Import/Export & Drug Registration Department at the Lebanese MoPH to investigate the pricing mechanism. In addition, we also reviewed the results of the WHO/HAI study conducted in 2013 to ascertain compliance with pricing regulations.

Timeline

Research and review of documents and the meetings with the key informants were conducted between December 2016 and April 2017. Any amendments to the guidelines and policies during this period would have been reflected; however, there were no such amendments.

Population and sampling

Based on the geographical and centralization of government bodies in the capitals of both countries, the investigational component of the survey was conducted centrally at the respective ministries of public health and related supply departments. The selection of key informants was purposive and followed a snowball sampling process. In total, four personnel were met, one in Lebanon and three in Qatar.

Information and data collection procedure

Data collected from ministries websites and publications were consolidated with the information gathered from individuals met at the respective ministries.

The data gathered regarding the price components and the pharmaceutical pricing policies implemented in Qatar and Lebanon were compared and illustrated using Microsoft Word and Excel.

Results

Two official documents were reviewed in Qatar^[22,23] and three in Lebanon^[18,24,25] (Table 2). These documents were posted on the respective ministries websites and were confirmed to be the only documents to rely on for our study as per the informants met at the ministries. While the pharmaceutical pricing guideline available in Lebanon was comprehensive, the Qatari pharmaceutical pricing guideline issued for all GCC lacked the additional information about one of the pharmaceutical pricing policies identified. The mark-up scheme is different in each gulf country. Further information was collected from the Ministry of Public Health in Qatar.

Registration price

The laws currently in effect in Qatar and Lebanon are based on the latest versions of decrees enacted in 2011 and 2005 respectively.^[22,24] Over the years, the governments have been revising the regulations governing medicine prices either nationally as in Lebanon^[4] or regionally in Qatar in line with other members of the GCC.^[23] Both Qatar and Lebanon have implemented similar pharmaceutical pricing policies. In 2012, cost-insurance-freight (CIF) was adopted as the landed price for pharmaceutical registration in the private sector in all GCC member states.^[23] To set a price for registration, Qatar is mainly relying on the ex-factory and selling price of the medicines in the country of origin, as well as the CIF price in up to 30 countries to which the medicines were exported and sold.^[22] As for Lebanon, the landing price could be either CIF or free-on-board (FOB) price depending on the purchase and shipping agreement between buyers and sellers.^[25]

Pharmaceutical pricing policies

Our review of the price components as per national decrees and pricing guidelines was limited to the add-ons to the agreed-upon landed price for registration.

The pharmaceutical pricing policies in Lebanon apply to all sectors except the primary health centres (PHC) where medicines are procured through the Young Men's Christian Association (YMCA) and are dispensed for free.

In Qatar, the public and private sectors have distinct procurement and pricing mechanisms. The public sector is massively subsidized. The medicines are procured through different channels, mostly through GCC bulk procurement, in addition to other agreements directly with manufacturers, local agents or from local manufacturing. The pricing mechanism in the public sector is not disclosed; however, prices

of medicine were observed to be much lower than the private sector. The low prices are mainly due to the bulk procurement and public tendering processes and low total cumulative mark-up margin. The range of mark-up schemes varies from 2 to 10% on the purchased price.

External reference pricing (ERP) is one of the pricing policies adopted by both countries, albeit with different baskets of reference countries. This pricing policy is used to price originator brands and thereafter for most of the newly launched on-patent medicines in the country. The basket of countries to which the prices in each country are benchmarked varies. In Lebanon, prices are benchmarked against three sets of prices with the lowest price adopted: ex-factory and patient selling price of medicines in the country of origin; basket 1 which is composed of seven European countries; and basket 2 comprised of neighbouring Arab countries including Qatar.^[25] Regardless of the landed price at registration and the pricing strategy used to set a registration price for a pharmaceutical, mark-ups are applied with different schemes along the pharmaceutical supply chain in both countries. While a decree detailing all the different mark-up schemes is available to the public in Lebanon,^[18] such detailed scheme is not available in Qatar. In Lebanon, the MoPH decision 306/1 of 2005 was continuously reviewed with the latest update being decision 796/1 in 2014, adopting the lowest price out of any of the price comparisons considered for registration (Table 2). The different CIF and free-on-board (FOB) tranches were lately updated as well in decision 1131/1 in 2014 by the addition of a new tranche for expensive in-patient medicines.^[26] Table 3 demonstrates the various regressive and cumulative mark-up add-ons to medicines in Lebanon based on FOB and CIF price. As mentioned above, tranche E represents mainly in-patient formulation where specialized skills are required for the preparation. For this tranche, a new decision 1131/1 enacted in 2014 has allowed the addition of 8% as dispensing fees followed by \$86 as a fixed mark-up.^[25]

Some imported medicines are exempt from taxes. These include medicines manufactured in Arab countries or medicines imported under EUR1 trade agreement. Such details are withheld within the Ministry of Finance. Table 4 shows some government encouragement of local manufacturer efforts. In Qatar, the maximum mark-up allowed in the GCC was set at 45% and Qatar adopted a uniform cumulative mark-ups' scheme of 44% (Figure 2). Although pricing mechanism is not disclosed, HMC applies a mark-up ranging from 2 to 10% on the landing price. In Qatar, the add-on cost in the private sector is defined and linear. All MSP prices are CIF based in USD. Figure 2 below illustrates these mark-up schemes. Given that the mark-up in Lebanon is variable and regressive depending on the CIF or FOB price and whether the medicine is exempted from taxes or not, we compared the different mark-up ranges added to medicines registered under the same condition in Lebanon as in Qatar. Figure 3 illustrates medicines that were imported as CIF and exempt from taxation in Lebanon as compared to all medicines imported in the private sector in Qatar. Only the medicines with CIF up to 10.70\$ and 52.52 \$ have cumulative mark-up schemes higher and equal, respectively, to those added to medicines registered in

Table 2 Primary features and characteristics of the pharmaceutical pricing policies and regulation in Qatar and Lebanon

	Qatar	Lebanon
National decree and law	<ul style="list-style-type: none"> Decree number (1-10-1432) in 2011 	<ul style="list-style-type: none"> Decision 1/306 in 2005 Amendment decision 1/796 in 2014
Pricing mechanism	<ul style="list-style-type: none"> Ex-factory price and retail price in the country of origin Price in countries where the medicine is marketed Proposed cost Pharmacoeconomic considerations may be considered if available Therapeutic significance Price benchmarking to several countries: country of origin and other importing countries CIF price to KSA and thereafter Qatar imposes 44% OB price is reduced by 20% upon registration of first generic 	<ul style="list-style-type: none"> Ex-factory price and retail price in the country of origin Review of shipping certificate (CIF or FOB) to either: Jordan, KSA, Kuwait, Oman, UAE, Bahrain and Qatar or France, UK, Belgium, Switzerland, Italy, Spain and Portugal Adopt the lowest MSP, and the lowest FOB among neighbouring and basket countries (796/1) Repricing every 5 years
Generic pricing mechanism	<ul style="list-style-type: none"> First generic is 35% less than OB Second generic is 10% less than first generic Third generic is 10% less than second generic All subsequent generics are 10% less than third generic 	<ul style="list-style-type: none"> Generic is priced on the same mechanism as OB, and price to consumer is at least 30% less than OB (1/728 in 2013) If no OB is registered, prices are reviewed 3 months after third generic is registered and average price is adopted If the OB price was changed, the generics price should be changed in a rate that halves that of OB
Locally manufactured/Packed pricing mechanism	<ul style="list-style-type: none"> Locally manufactured generic: same pricing mechanism as generic If generics were already registered, then existing price applies Generic package under license: same pricing mechanism as generic OB manufacturing and packaging under license: same pricing mechanism as OB 	<ul style="list-style-type: none"> Locally manufactured: adopt ex-factory price Packaged under license: adopt ex-factory price in country of origin If generic, price must be at least 30% lower than OB
Basket of countries	<ul style="list-style-type: none"> Country of origin Other GCC countries All other countries where medicine is exported 	<ul style="list-style-type: none"> Country of origin Neighbouring countries France, UK, Belgium, Switzerland, Italy, Spain and Portugal
Pharmaceutical pricing policy	<ul style="list-style-type: none"> ERP Mark-up regulation HTA Promotion of the use of generics 	<ul style="list-style-type: none"> ERP Mark-up regulation Promotion of the use of generics
Importing currency	<ul style="list-style-type: none"> USD 	<ul style="list-style-type: none"> Several currencies according to exporting country and purchase currency
Price adjustments for exchange rate Fluctuations	<ul style="list-style-type: none"> Occasionally (QAR is pegged to USD) 	<ul style="list-style-type: none"> Updated every 2 weeks
Shipping agreement	<ul style="list-style-type: none"> Private: CIF Public: various agreement 	<ul style="list-style-type: none"> Public and private: CIF or FOB
Mark-up	<ul style="list-style-type: none"> Public: variable depending on the shipping agreement Private: uniform 	<ul style="list-style-type: none"> Private: digressive mark-up
Price tag in the private sector	<ul style="list-style-type: none"> Set by the PDCD in MOPH 	<ul style="list-style-type: none"> Set by wholesaler, adjusted by pharmacist in case of variation in price indices (exchange rate)

CIF, cost-insurance-freight; FOB, free-on-board; HMC, Hamad Medical Corporation; KSA, Saudi Arabia; LPG, lowest-price generic; MOPH, Ministry of Public Health; OB, originator brand; MSP, manufacturer selling price; PDCD, Pharmaceutical and Drug Control Department; QAR, Qatari riyal; UAE, United Arab Emirates; USD, US dollar.

Table 3 Different pharmaceutical mark-up schemes in percentage (%) applied to medicines in Lebanon

1 Tranche [†]	2 Cost of freight and insurance (only if FOB)	3 Custom clearance, import tax and others		4 Importer and wholesaler mark-up	5 Pharmacist mark-up	6 Base/100
		Without custom	With custom			
A	7.00	6.00	11.00	10.00	30.00	143.00
B	5.00	5.00	10.00	10.00	30.00	143.00
C	4.00	3.00	8.00	9.00	27.00	138.43
D	3.00	2.50	7.50	8.00	24.00	133.92
E	1.50	1.50	6.50	6.50	\$86.00	\$86+106.50

FOB, free-on-board.

Source: Ministry of Public Health (MoPH). Decision 796/1 Beirut: Ministry of Public Health; 2014 [Available from: <http://www.moph.gov.lb/en/laws#/Laws/view/19>].

[†]Wider range for locally manufactured medicines.

Table 4 Tranches divisions per FOB and CIF prices in Lebanon

Tranche	FOB price \$	CIF price \$	Local product price \$
A	0–10	0–10.70	0–11.34
B	10–50	10.70–52.50	11.34–55.13
C	50–100	52.5–104	55.13–107.12
D	100–300	104–309	107.12–316.72
E	300–and above	309–and above	316.72–and above

CIF, cost-insurance-freight; FOB, free-on-board.

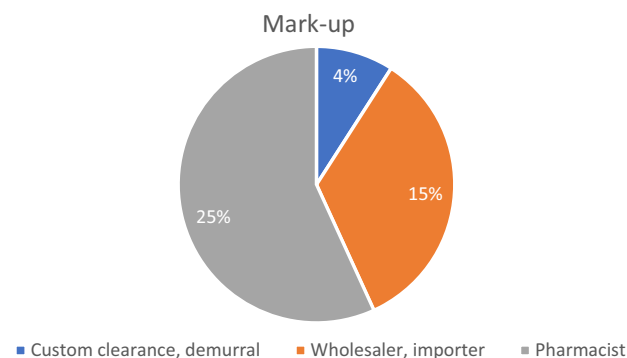
Source: Ministry of Public Health (MoPH). Decision 796/1 Beirut: Ministry of Public Health; 2014 [Available from: <http://www.moph.gov.lb/en/laws#/Laws/view/19>].

Inclusion of FOB/CIF to any tranche is related to the exchange indices.

Qatar. At all time, the wholesaler mark-up in Qatar is higher than any CIF price range in Lebanon.

Additionally, Qatar may consider the economic evaluation of a medicine to set the price if such evaluation or health technology assessment (HTA) is available at the time of registration.^[22] As such, relevant information was gathered directly from the public entities in charge of the process. Table 2 below summarizes the details pertinent to our study aim.

Both Qatar and Lebanon are promoting the use of generic medicines by setting their prices lower than the originator brand. In the private sector, the price of the first generic registered in Qatar is 35% less than the originator. With each new generic registered, the price is set at 10% less than the preceding generic until the fourth one. Upon the registration of the first generic in the Qatari pharmaceutical market, the price of the originator brand is reduced by 20% automatically.^[22] For the few generics found in the public sector in Qatar, no price difference was reported compared to the originator brands as per the ministry. Based on discussions with HMC personnel, the HMC allocates a weighted average to the active ingredient price depending on the overall stock in use in various facilities with minimal impact to the end user price. As for Lebanon where the

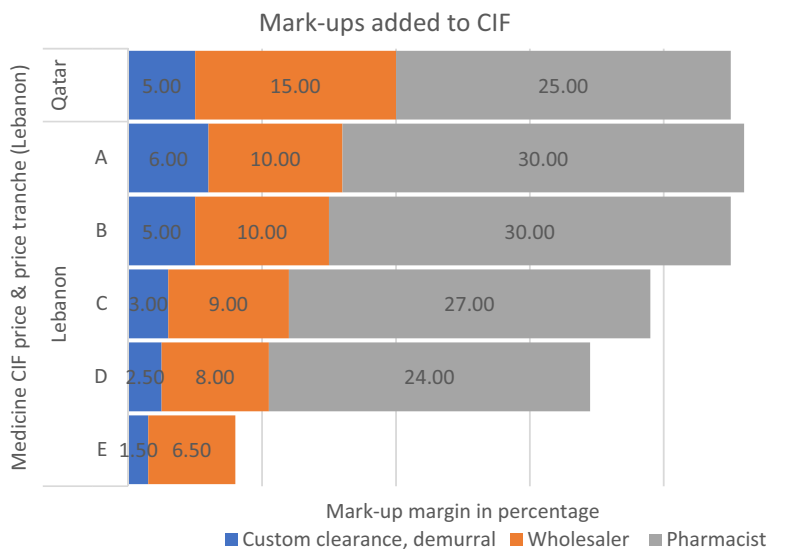
**Figure 2** Different cumulative mark-up schemes applied uniformly to all medicines in the private sector in Qatar.

market for generics is active, the price of generic medicines is at least 30% less than their comparative originator.^[25] The price of generics of the same active ingredient is revised and reduced once five different generics brands are registered in the country. If no originator brand is registered, the price of generics is reviewed once three generics are available in the market and average price is adopted. Generally, the price of generic brands is pegged to the originator; this results in price review for both originator and generic brands every 5 years. Hence, any change in the OB price is translated in a change of the generic brand at a rate that equals half that of the originator. The MOPH in Lebanon is also promoting the use of generics by supporting the local packaging and manufacturing of pharmaceutical as expressed by a higher profit margin (higher mark-up schemes) applied to local manufactured generics as per Table 4.

Discussion

The aim was to review the pharmaceutical pricing policies nationwide and across nations. By reviewing governmental

Figure 3 Comparison of mark-up schemes added to cost-insurance-freight in Qatar and Lebanon.



documents and interviewing stakeholders, our results provided a clearer understanding of the pharmaceutical situation in Qatar and Lebanon.

The pharmaceutical sector is a major subset of the health sector especially with spending on pharmaceuticals constituting a high percentage of the total health expenditure.^[6,27,28] In Lebanon, almost half of the health expenditure is attributed to purchase of pharmaceuticals.^[29]

Unethical behaviours such as substandard/falsified medicines, price gouging and medicines misuse along the supply chain and utilization can have a negative impact on patient health and well-being. It can also waste public resources and can be impoverishing for patients.^[30-32] Close monitoring, auditing and increased transparency of the pharmaceutical supply chain from the seller or manufacturer until it reaches the patients are necessary regardless of the pharmaceutical and economic status of the country.^[32] Undeniably, constant monitoring and review of the prices of pharmaceutical or health expenditure is a common practice worldwide.^[33] Different actions taken by stakeholders that are controlling the medicine supply chain result in a complex interplay whereby some governments may not be fully aware of the cumulative price components. The regulation of these components has a considerable impact on the public price (retail price) and improves access.^[34] Whether or not a government should intervene in product pricing is debatable in most cases, unless the product in question can determine quality of life and survival. The documented periodic review and adjustment of the original regulations in both Qatar and Lebanon have generally resulted in beneficial effects for the patients. For instance, the WHO/HAI survey on prices, availability and affordability of medicines, was conducted twice in Lebanon in 2003 and 2013 after which several laws were amended.^[4,24] Another example of such periodic reviews is China where the pharmaceutical pricing policy had been subject to several updates and adjustments between 2004 and 2015.^[15,35-37]

Manufacturer selling price is the agreed-upon medicine price before shipping to the buyer. This agreed-upon price

can be set based on the pricing policy adopted for a specific drug. The shipping fees can be either CIF (Qatar and Lebanon) or FOB (in Lebanon only), which results in the landed price. The price of originator brand is set based on either benchmarking with a predefined basket of countries or decided based on the economic evaluation or therapeutic value of the drug. As for the generic brand drug, the price is usually determined as a predefined percentage discount to their comparative originators and/or in relation to the price of other pre-existing generic brands in the market.^[22,25] Thereafter, the landed price is generally subject to additive and cumulative price components that can increase the final price from 30% to more than 100% in some countries.^[8] While MSP is related to the procurement type and channels and the negotiation power and market volume of a nation, the price components added to landed price are a good indication of the effectiveness of a national pharmaceutical pricing policy, the pharmaceutical sector structure and regulation.^[4,8,38] While some of the incremental costs mentioned above are indispensable, others can be waived or should not be included in the final price. Some governments decide to exempt essential medicines from taxes as in the case of Qatar, and in general, patients should not be charged for the drug registration fees.^[4]

WHO/HAI separates the medicines' price components in up to five stages. MSP and the shipping cost are the first stage of this cascade. The comprehension of the price escalation at each stage helps understanding the pharmaceutical value chain and therefore empowers advocates and governments to take the appropriate actions towards supplying public with affordable drugs.

Use of external reference pricing

Qatar and Lebanon apply different pricing mechanisms for medicine registration. For medicines priced based on external reference pricing (ERP), three main approaches exist for allowed price setting. Lebanon is assigning the lowest prices available^[18,25] similar to Portugal and Iran,^[39] while Qatar

and Ireland are using the average price,^[22] and Italy is adopting the weighted average price.^[40] The four pharmaceutical pricing policies identified in our study are among the six recommended by the WHO for developing countries. The pharmaceutical pricing in Qatar and Lebanon is mainly based on ERP and mark-up regulations. In addition, Qatar may consider the economic evaluation and therapeutic importance of a medicine to set the price if such evaluation is available at the time of registration.^[41] Furthermore, ERP and mark-up regulation were the most adopted in developing countries as per Abdel Rida *et al.*^[12] Most of the industrialized countries are endeavouring to apply aggressive strategies to control pharmaceutical expenditures.^[42] ERP is widely implemented for on-patent medicines.^[43,44] As of 2011, 24 out of the 27 European Union countries (EU) covered in the RAND report used ERP with the exception of Sweden, the UK and Denmark.^[45] As previously mentioned, ERP is a dynamic process to price on-patent and prescription only medicines including reimbursable medicines.^[44,45] Moreover, the trend is towards including countries of similar income levels as the country applying the policy.^[43] The supply chain remuneration (mark-ups) is also relatively regulated in these countries through either a fixed fee, a fixed percentage or a fee-for-service.^[34,44,46] To set a price for registration, Qatar and Saudi Arabia are mainly relying on the ex-factory and selling price of the medicines in the country of origin, as well as the CIF price in up to 30 countries to which the medicines are exported and sold. In selecting a basket of countries, most common practice in Europe is usually to include up to 10 countries in the basket,^[43] and to use either the lowest price, the average price or the weighted average price as a reference.^[40] Recently, studies were reporting that the Chinese government has been considering to use ERP, and are seeking to identify a basket of reference countries that adhere to Chinese financial and social values.^[47]

Regulation of mark-ups in the pharmaceutical supply distribution chain

Moreover, the mark-up schemes applied in both countries are also different. These different policy implementation mechanisms validate the conclusions of international organizations that: ‘there is no one-size solution’ that fits all.^[6] For the mark-up regulation, it is recommended that once established, the government should progress to regressive mark-up schemes.^[6] Lebanon and Saudi Arabia^[25,48,49] are already applying it, while Qatar still has a uniform mark-up of 44% to all medicines registered and sold in the private sector regardless of the registered CIF price.

Use of health technology assessment

Although some countries attempt to use health technology assessment (HTA) to price medicines, its implementation is challenging for developing economies due to demanding human capital and financial needs.^[6,50,51] In some countries where HTA was being considered and implemented, economic evaluation studies revealed poor practices and fewer

methodological flaws in the low- and middle-income countries (LMICs)^[52] as well as in Saudi Arabia,^[53] Iran^[54] and Thailand.^[51] South Korea, an OECD country, has switched from the use of cost-plus and ERP to implementing HTA since 2007.^[55,56] No negative feedback has been reported from the country. This may be due to South Korea having the required human capital and financial resources to best adopt HTA.

Promotion of the use of generic medicines

To promote the use of generic medicines, two approaches are essential: supply-side and demand-side strategies.^[6,57] Qatar and Lebanon had been implementing supply-side strategies by ensuring the market entry and setting competitive prices for generic medicines compared to the originator brands.^[22,25] Moreover, Lebanon is encouraging the local manufacturing of medicines mainly by providing manufacturers, distributors and pharmacists a higher margin of profit by applying a higher mark-up scheme compared to imported medicines within the same price tranche. Qatar has recently realized the importance of domesticating the production of generic medicines; therefore, measures had been taken to encourage local manufacturing of medicines by accelerating their licensing and registration, subsidizing the establishment of manufacturing plants as well financial and commercial support. Most industrialized countries have implemented policy tools to increase the market share and volume of generics.^[13] This resulted in increased affordability of medicines and substantial savings in healthcare expenditure.^[58,59] For instance, the United Kingdom (UK) is strictly prohibiting the use of brand names in the prescriptions.^[13] Bangladesh and Iran are two developing countries that undertook strategies to promote the use of generic medicines since 1980s by adopting supply-side strategy initiatives including promotion of local manufacturing and ensuring availability of generic medicines, which has resulted in continuous growth of the generic medicines’ market.^[60,61] With regard to the demand-side strategy options, the public sector in Lebanon is mostly procuring and dispensing generic medicines^[48] while the public dispensing outlets in Qatar rarely dispense generic brands. This could be related to the varying economic status and distinct national subsidy vision of the healthcare systems in these two countries.^[62] In the private sector, the Lebanese pharmaceutical market is more open for generic medicine, regulations are already in place to encourage generic prescription and substitutions, and patients tend to buy generics for financial reasons.^[63,64] The Qatari population prefers originator brands and shows resistance for generic medicines’ uptakes.^[65] With the public sector being the major provider of pharmaceuticals in Qatar where there is no price difference between medicine types, patients are not incentivized to seek generic over originator brands. Similarly, most patients visiting the private sector are insured and the market is lightly penetrated by generic brands. Moreover, the pharmacists in Qatar do not have the authority to substitute a generic for an originator brand and do not have access to national formulary of substitution options.

Limitations

This study relied on core elements that strengthen its outcomes. This is the first study to document and compare the pharmaceutical pricing policies in two Arab middle-eastern countries and to emphasize the different implementation approaches of the same pricing strategies. Such studies provide valuable advocacy messages for policymakers, pharmaceutical industry, regulators, prescribers and patients if it is shared and delivered in a timely manner. However, several limitations existed that may have impacted the findings. Due to time limitations and lack of institutional support, the price components of medicines were not surveyed. This could have helped in providing more in-depth of medicine price composition. Moreover, the study was limited to the official pharmaceutical pricing policies' documents published by the governments due to the lack of available literature. As such, the findings and analysis provided in this article deliver advocative and informative message to different stakeholders and establish a foundation for other scholars to elaborate on the subject.

Recommendation

Based on what have been presented in this study, the Ministry of Public Health in Qatar is recommended to publish an updated pharmaceutical pricing policy that is inclusive and encompasses the new government vision in terms of healthcare sustainability goal. We recommend Qatari government to switch to regressive mark-up on pharmaceuticals and to reconsider the wholesaler mark-up margin. Also, there should be a thoughtful consideration of local manufacturing of generic medicines for local consumption and export. Implementing a pro-generic policy by promoting generic medicines as a substitute and educating physicians, pharmacists and patients about the benefits of generics would be useful. Moreover, legally enabling pharmacists to offer and provide generic substitutes is highly recommended. As for Lebanon, given the rare incidence of falsified and substandard medicines reported, it is recommended to test and ensure the quality of generics available in the private pharmaceutical market. Lastly, the Lebanese government is encouraged to exempt essential medicines from taxes.

This study revealed several issues that need further analysis and review. To better understand the pharmaceutical supply chain, a detailed analysis of the public procurement system is required.

Conclusion

This study demonstrated that both countries were using multiple internationally recognized pharmaceutical pricing policies simultaneously.

The pharmaceutical pricing policies implemented in Qatar and Lebanon are reflective of both the advancements in the human capital and financial resources of the nations and are in line with the WHO-recommended pharmaceutical pricing policies for developing countries. However, more tailoring of these policies to the local environment is

required for greater benefit to the populations given the substantially high prices of medicines especially in the private sectors and their low availability in various sectors. One area of focus should be the optimization and implementation of various supply and demand strategies for the promotion of generic medicines' availability and affordability.

Declarations

Conflict of interest

The Author(s) declare(s) that they have no conflicts of interest to disclose.

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Authors' contributions

NA, MI and ZUD conceived the study. NA and MI selected the data collection sources and sites. MI coordinated with stakeholders for data collection. NA gathered the official documents, met with the key informants for validation and drafted the manuscript. MI and ZUD reviewed the data collected. All authors read and approved the final manuscript. All Authors state that they had complete access to the study data that support the publication.

Availability of data and materials

This study is part of Masters' graduate project that will be published in ProQuest. Until then, more data can be requested from the corresponding author.

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