



The Rising Burden of Medication in KSA

A Pragmatic Approach to Minimize It

Director's Note



Dr. Ayman Al-Sulaimani **Medical Director**

Dr. Ayman is a Cardiothoracic & Vascular Surgery Consultant with 24 years of experience in clinical field studies. He has over five years of experience in medical insurance, including medical governance for clinical medicine in medical insurance.

“One of the objectives of the National Transformation Program is increasing private healthcare expenditure from 25% to 35% by 2020. The Ministry of Health (MoH) plans to spend more than SAR 23 billion on new initiatives over the next five years. MoH is expected to spend over SAR 70 billion.

Implementing a generic medicine framework can help save SAR 10 billion annually on medication costs which can be redirected to other healthcare initiatives. Note that the idea of generic medicine is to provide the same quality with the ability to provide savings in order to treat more people for the same amount.”



Alshereef Hamideddin **Marketing Director**

Alshereef is the Marketing Director for Bupa Arabia. Equipped with over 15 years of experience, he is in charge of overseeing Product Development, R&D, Segments and Marketing. He has previously served in Geneva with Procter & Gamble where he had regional responsibility of MEA.

“Vision 2030 highly emphasizes the importance of healthcare and improving the lifestyle and well-being of Saudis. Digitization / e-health, privatization, and corporatization are among Vision 2030’s main pillars, and as a private health insurance company, we aim to contribute to the Saudi Vision. For this reason, we have identified an initiative worth over SAR 10+ billion.

Adopting a generic medicine framework will not only bring savings to SAR 10+ billion annually, it can also augment manufacturing of pharmaceutical products locally, thus boosting Saudi employment level.”

Contributors



Nadeem Shahzad
Sr. Manager Research & Innovation

Nadeem is the head of the Research & Innovation function in Bupa Arabia, with over 18 years of experience in Marketing research & analytics. He holds MSc. in Statistics and a post graduate diploma in Management Information System from Punjab University Pakistan.

“After analyzing the global market in terms of generic medicine, a potential of SAR 10 Billion annual savings for Saudi Arabia was identified.”



Dr. Fadia AlMahdi
Sr. Manager Pharmaceutical Care

Dr. Fadia leads the Pharmaceutical Care and Management unit (PCMU) at Bupa. She received her master’s degree in Clinical Pharmacy from the Jordan University of Science & Technology. She is a Board Certified Pharmacotherapy Specialist (BCPS) from the American Pharmacists Association.

Dr. Fadia has analyzed the Medication & drug data to formulate educated assumptions on medication expenditure.



Dr. Ahmed Ibrahim
Manager Pharmaceutical Care

Dr. Ahmed is the manager of Pharmaceutical Care in Bupa. Dr. Ahmed earned his bachelor’s degree from Alexandria University. He is a Board Certified Pharmacotherapy Specialist from the American Pharmacists Association. He passed the Australian Pharmacy Council assessment of Pharmaceutical Science (KAPS). He has conducted pricing analyses of top/generic brands in Saudi Arabia.

Overview

HEALTHCARE

Global healthcare expenditure in 2017 was estimated at \$ 7.7 trillion¹. It is expected to grow at an annual rate of 5.4% between 2017–2022.

Saudi Arabia is the largest spender on healthcare across the Middle East with over \$37 billion (~SAR 139 billion) in spending between the private and semi-government sectors, the Ministry of Health, and out of pocket expenditures. ²

The global spending on healthcare (excluding the US) is \$677 per capita, whereas healthcare spending in Saudi Arabia is over \$1,120 per capita; that is 66% higher than global spending. In KSA, higher prevalence of lifestyle-related diseases is one of the major causes behind the higher spending on healthcare.

MEDICATIONS & PHARMACEUTICALS

According to a study conducted by the IQVIA Institute for Human Data Science, the global spending on pharmaceuticals reached to a staggering amount of US\$1.2 trillion in 2018 and is expected to exceed US\$1.5 trillion by 2023.²

In a different study specific to the Middle East & Africa (MEA), IQVIA notes that the value of the pharmaceutical market in MEA has reached US\$25 billion in 2018.³ With approximately \$8.2 billion (~SAR 31 billion), up from US\$7.5 billion in 2017 (9% increase)⁴. The estimates for the Saudi pharmaceutical expenditures is close to US\$8 billion.

Implementing a generic medicine framework, which promotes dispensing generic medicines when available, could increase savings to over US\$2.67 billion (~SAR 10+ billion) in Saudi Arabia (details on page #8).

SAUDI ARABIA

The Kingdom has one of the highest prevalence rates of lifestyle diseases in the world. 18.5% of the population over the age of 20 have diabetes, 35% have obesity and over 23% suffer from hypertension.

Non-communicable diseases accounted for 68% of deaths in Saudi in 2018. Cardiovascular diseases, diabetes, urogenital, blood and endocrine system diseases and cancer are currently the leading causes of death in Saudi Arabia.

Medication utilization is affected by the prevalence of many diseases especially chronic conditions. In addition to the spread of chronic diseases, the increase in the numbers of lifestyle diseases in Saudi Arabia poses a major threat as it puts pressure on the healthcare system by increasing pharmaceutical expenditures and medication costs. Public spending on the healthcare sector is largely channeled towards new initiatives, such as increasing life expectancy, reducing obesity and localizing pharmaceutical manufacturing.

Generic medicines, which have similar therapeutic effects as their brand-name equivalents, have been used in most developed countries to counter the increase in healthcare expenditures and medication burden.

Abu Dhabi took a giant leap last year through a regulatory route by implementing a generic medicine framework as a quick win to bring on an estimated saving of 60% on medication expenditure by 2020 (details on page #7).

Localizing the pharmaceutical industry is a key priority for the Saudi government as part of Vision 2030. Today, only 30% of pharmaceuticals are manufactured locally. Implementing a generic medicine framework can boost local manufacturing; thus, contributing to the Vision.

KSA's healthcare burden has risen at a rapid rate in recent years & is expected to grow further!

SAR +10 billion

Annual savings in KSA are possible by implementing a generic medicine framework.

What is a Generic Medicine?

The term 'generic drug' or 'generic medicine', as defined by the World Health Organization (WHO) is "a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights".⁵

In the USA, the Food and Drug Administration (FDA) states that, "A generic drug is identical—or bio-equivalent—to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use".⁶

The European Medicines Agency (EMA), the main regulatory body for pharmaceutical products in the European Union (EU), defines a generic medicinal product as a "product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bio-equivalence with the reference medicinal product has been demonstrated by appropriate bio-availability studies". A generic medicine works in the same way and provides the same clinical benefit as its brand-name counterpart; as the active ingredients are the same and the excipients (inactive ingredients) may differ. This only makes a difference in rare cases where the patient is allergic or sensitive to one of the excipients. The product may also be slightly different in color, shape, or markings.

In order to get the FDA's stamp of approval, a generic medicine must be "bio-equivalent" to its brand-name counterpart. As per FDA's limitations, manufacturers are allowed 20% variation in the active ingredients from that original formula. However, the observed variation is much smaller with less than 4%.

The Hatch Waxman Act, introduced in the US in 1984, provided the legal structure for producing generic medicine around the world. It states:

"The Drug Price Competition and Patent Term Restoration Act - better known as the Hatch-Waxman Act, is a comprehensive legal framework enacted by Congress in 1984 to streamline the process for generic pharmaceutical approvals and preserve incentives for innovation, including the creation of a procedure for patent litigation involving generic pharmaceuticals. The Hatch-Waxman Act established the legal and economic foundation for today's generic pharmaceutical industry"



Perceptions regarding Generic Medicine

General perceptions regarding generic medicine ⁷

The terms “generic medicine” and “generic drugs” come to patients’ minds and, to a lesser extent, to physicians with mistrust. This mistrust about generic medicine is mainly due to the following factors:

1. Substantially lower prices of generic medicine compared to brand-name medicines which is often interpreted by patients and the public as counterfeit medication;
2. The lack of awareness around generic medicine in terms of its quality, safety and bio-equivalency;

The reality of generic medicine is far different from the prevalent perception. They are safe with similar quality and bio-equivalency to patent medicines and undergo vigorous quality assurance processes.

In order to change the prevailing misperception about generics, the following steps are vital:

1. Launching awareness campaigns about generic medicine addressing key concerns around cheaper cost and quality among the general public;
2. Engaging physicians to advocate generic medicine; as patients highly trust their opinion.

Why Generics are cheaper than their equivalent brands?

Generic medicines tend to cost less than their brand-name counterparts because they do not have to repeat the animal and clinical (human) studies that were required from brand-name medicines to demonstrate safety and effectiveness, which often costs millions of dollars.

A survey administered in the US in 2014 among 1,442 patients revealed that most respondents considered generic medicines to be as effective (87 %) and safe (88 %) as their brand-name counterparts, and that they have the same side effects (80 %) and active ingredients (84 %). This shows that awareness campaigns and usage in the US has transformed the perception into a positive one, which in fact is the reality of generic medicines. ⁸

**Generic drugs also
undergo FDA approval**

**Generic drugs are substantially
cheaper with similar quality**
as generic drugs and manufacturer don't
have to bear Research & Development
and Marketing Cost

Generic Drugs - USA Market Trends

In the United States, 90% of prescribed medicines in 2018 were generic brands. Generic medicines account for 22% of all medication spending in USA.

Healthcare spending varies greatly by country, but in most, if not all countries, generic drugs play an important role in the healthcare ecosystem.

Due to a significant difference in price, and having similar therapeutic impact, generic drugs have brought benefits to patients, governments, insurers and others within the healthcare system.

The US generic drug market has witnessed a transformation after implementing the Hatch Waxman Act.

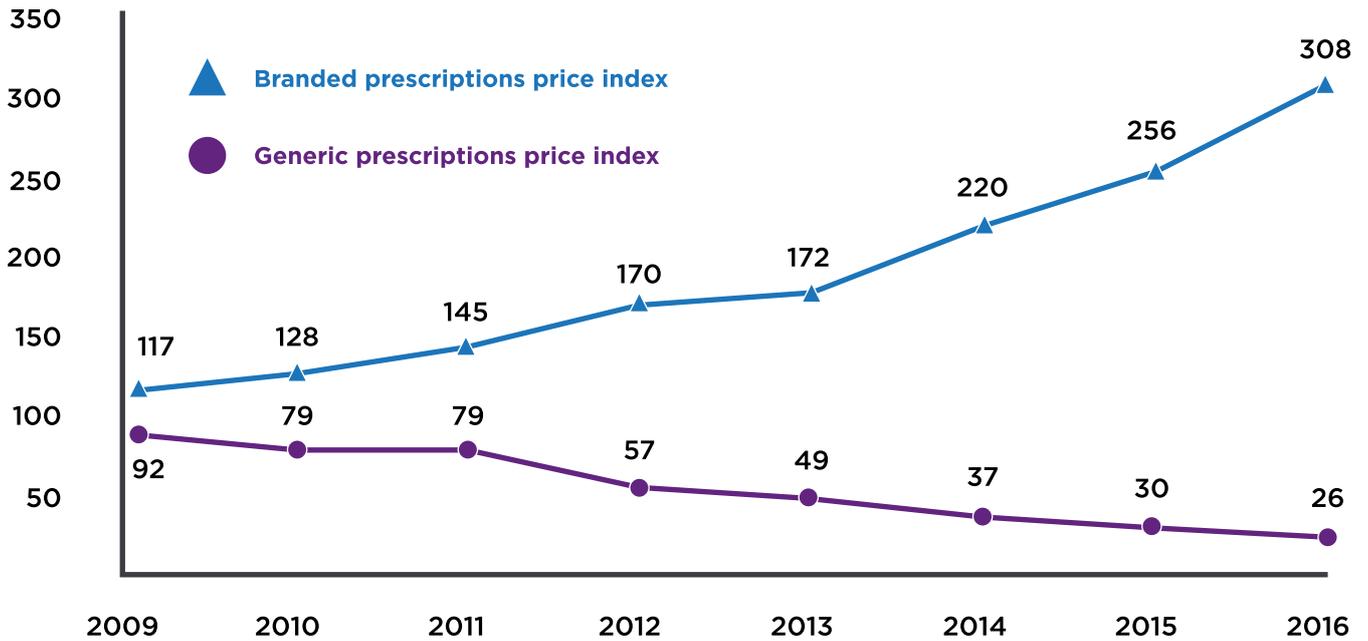
In the past 10 years, the use of generic drugs has saved the US healthcare system nearly \$2 trillion, with greater savings every year.

A price increase in brand-name drugs has impacted almost all countries with a similar magnitude. Generic medicine was the solution for such a grave problem in the countries which adopted a generic medicine strategy.

While the brand-name drug prices, as an index, have been increasing three times in the US market in the past 10 years, contrarily the average price index of generic drugs has decreased significantly. ^{9 10}

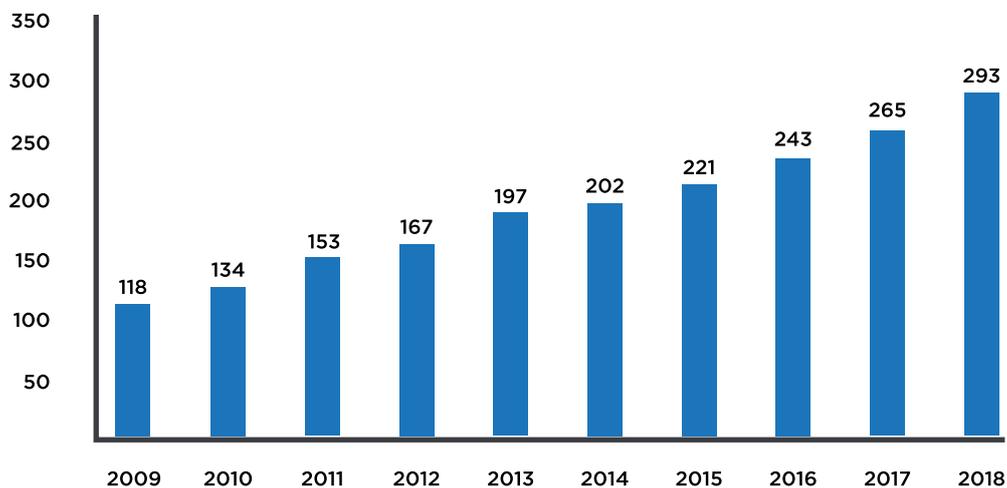


US Market Price Trends ¹¹



Source: IQVIA Institute / Health System Tracker

US Market Annual Savings (in billions) ¹²



Source: Association for accessible medicine

\$2 Trillion savings

is reported in USA market
in the past 10 years



Generic Drugs US Price Impact ¹²

In 2016, the top 10 generic equivalents alone brought a saving of over \$75 billion to the US market. Other generic equivalents brought another \$178 billion in the same year. On average, generic drugs are more than 60% cheaper than brand-name drugs.

For example, Lipitor, a famous drug for cholesterol, was priced at \$3.29 per unit in the US. Once its exclusive rights were lapsed in 2011, its generic equivalent was launched at a price of \$0.11 per unit, which provided 97% saving per unit.

Price / Savings in US - Top 10¹²

Branded Drug name	Generic Equivalent	Branded Drug Price	Generic Drug Price	Generic / Branded Price (Savings %)	Savings US\$ Billions	2016 Dispensed RXs (Million)
Lipitor	Atorvastatin	\$ 3.29	\$ 0.11	97%	\$ 14.40	106.3
Prilosec	Omeprazole	\$ 3.31	\$ 0.08	98%	\$ 11.10	76.3
Zofran	Ondansetron	\$ 21.67	\$ 0.20	99%	\$ 10.00	23.2
Cymbalta	Duloxetine	\$ 4.61	\$ 0.45	90%	\$ 8.20	49
Zocor	Simvastatin	\$ 2.62	\$ 0.03	99%	\$ 6.90	60.4
Neurontin	Gabapentin	\$ 1.02	\$ 0.09	91%	\$ 5.80	60.2
Norvasc	Amiodipine	\$ 1.054	\$ 0.02	99%	\$ 5.60	87.4
Singulair	Montelukast	\$ 3.74	\$ 0.17	95%	\$ 4.70	39
Abilify	Aripiprazole	\$ 21.68	\$ 3.62	83%	\$ 4.60	9.8
Seroquel	Quetiapine	\$ 6.00	\$ 0.29	95%	\$ 4.50	20.6

Abu Dhabi Took the Lead - Case Study

Case Study ¹³

Abu Dhabi took a giant leap last year through a regulatory route by implementing a generic medicine framework; which, as per the Ministry of Health, will bring more than 60% savings on medicine spending annually by 2020.

National demand for pharmaceuticals was around \$2.6 billion in 2016, which is estimated to increase to \$5.9 billion by 2025. In order to meet such high demand, the Health Authority - Abu Dhabi (HAAD) introduced a new policy in September 2018 encouraging the use of generic drugs to reduce healthcare costs in Abu Dhabi.

Under reforms that came into effect on September 1, 2018, patients in the Emirates are now able to access generic treatments through their pharmacies, and medical professionals can use generic products in health facilities, thereby cutting retail and wholesale costs.

The change, announced by HAAD in a circular issued on July 23, 2018 means that patients can now choose between brand-name drugs or generics ones. Health insurance only covers the cost of generic drugs, and if patients choose to buy brand-name drugs, they have to pay the difference.

60%

saving in pharma cost

By implementing a generic medicine framework; where prescriptions will be for generic drugs. Patients have the choice to buy brand-name or generic, however, insurance will cover the cost of generic drugs only.

In a subsequent statement on July 31, 2018, HAAD said the increased use of generics would not only improve access to healthcare but will also create new opportunities for domestic drug manufacturing.

According to estimates from pharmaceuticals players, the switch from brand-name to generic products could result in cost savings of up to 60%. Locally manufactured generic drugs would bring even greater benefits, allowing for substantially lower logistics costs and more control over the supply of vital treatments.

Generic medicine reforms in Abu Dhabi will bring an estimated saving of \$4.4 billion by 2020 – that is 60% of current pharmaceutical spending.

Over 5,000¹⁴ brand-name drugs are now available in generic forms as per HAAD generic drug listing. HAAD's decision to promote the use of generics has been largely welcomed by industry stakeholders.¹⁴

The Current Situation in Saudi Arabia

The Ministry of Health (MOH) and the Saudi Food and Drug Authority (SFDA) are responsible for the overall administration of the healthcare industry in KSA, while the healthcare insurance industry is regulated by the Council of Cooperative Health Insurance (CCHI).

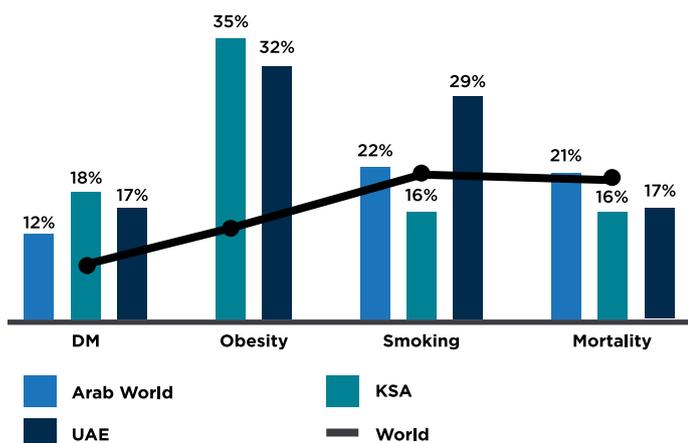
The quality of generic drugs is controlled by the SFDA. MOH law supports dispensing generics; however, CCHI has not passed any regulation to support promoting generic drugs.

SFDA conducts inspections on manufacturing plants on a regular basis to ensure compliance with the Authority's regulations and standards.

Moreover, the SFDA regularly monitors the quality of all pharmaceutical products to ensure their safety and efficacy. Generic drugs must meet high standards to receive SFDA approval. Approved generic drugs are generally only sold after patents and exclusivities protecting the brand-name counterpart end.

1. Globally, Saudi Arabia ranked as the top 4th country for obesity among adult population – over 20 years old.
2. KSA tops Arab countries in terms of diabetes prevalence rates reaching 17.8% of the adult population.
3. KSA has high death rates of cancer, chronic renal, and cardiovascular diseases.
4. Smoking rates in Saudi Arabia are also as high as 16% among the adult population and is rapidly growing.

Prevalence of Diseases ¹²



“Lifestyle related diseases are time bomb for Saudi!”

If not curtailed, this will cripple the economy and create social burdens of illness in KSA

Saudi Arabia spends the largest proportion of its health-care budget (24%) on diabetes alone

Medication Cost & Saving Potential

The healthcare sector has three major players in Saudi Arabia - Ministry of Health, government & semi-government organizations and health insurance companies.

MoH and semi-government healthcare providers are serving around 22 million residents - mainly Saudis. Whereas the private health providers in Saudi are serving 11.5 million-- two third expats-- as mandated by CCHI.

It is important to note that citizens as well as residents of Saudi Arabia also spend from their own pockets either on deductibles or by directly purchasing medications from pharmacies for seasonal diseases.

As per the Intercontinental Medical Statistics, Saudi Arabia medication expenditure for 2018 was \$8.2 billion (~SAR 30.8 billion). Bupa Arabia has analyzed its medication utilization and found that diabetes treatments has the highest spending. Furthermore, we observed that in some cases generic drugs are not available or don't have a significant price difference compared to its brand-name equivalent. In other cases, generics were available and were much cheaper than brand-name drugs, following global norms.

We estimate a saving between 35%-40% of the current medication spending if a generic medicine framework is implemented across public and private sectors in Saudi Arabia. That is around SAR 10+ billion of annual savings.

We estimate annual saving of SAR10+ Billion can be achieved through Generic Medication framework implementation in Saudi Arabia.					
Name of Active ingredient	Brand Name	Average Cost	Generic Name	Average Cost	Savings / Opportunity
Vildagliptin/Metformin	Galvus-Met	165 SR	Jalra M	165 SR	Cost of Brand= Cost of Generic (No saving)
Insulin Glargine	Lantus	306.1 SR	Vivaro;Basaglar	223.8 SR	23%- 34%
Sitagliptin/Metformin	Janu-Met	149.35 SR	Gliptamet	149.35	Cost of Brand= Cost of Generic (No saving)
Liraglutide	Victoza	397 SR	No Generic	No Generic	No Generic
Sitagliptin/Metformin	Gliptamet (Generic)	149.35 SR	Janu-Met (Brand)	149.35	Cost of Brand= Cost of Generic (No saving)
Insulin Aspart	Novorapid	178.8 SR	No Generic	No Generic	No Generic
Insulin Aspart/Insulin Aspart Protamine	Novomix	178.8 SR	No Generic	No Generic	No Generic
Metformin	Glucophage	26.55 SR *	Dialon-Formit-Glucare-Metfor-Riyadhformin-Dimeter-Glymet	12.6 SR	52%- 68% *
Glimepiride	Amaryl	52.35 SR	Glide-Glim-Glimaryl-Glitra-Glorion-Glusafe-Glypride-PiramyI-G-Pride-AmAGLIME-Glumine-Glemax-Glimephan	26.9 SR	49%- 59% **
Gliclazide	Diamicon	25.6 SR	Only Diamicon 30 has Generic (Claz Mr 30 Mg)while 60 Has not	21.75 SR	15%
Linagliptin	Trajenta	113.4	No Generic	No Generic	No Generic

Note : saving is calculated based on switching to either the lowest Generic or the average of all available Generics

* = Based on conc. 850 mg

**= Based on conc. 3 mg

Summary

- Health is a fundamental aspect for the quality of life, and governments across the world have given tremendous focus on improving healthcare for the masses.
- Due to many factors, healthcare expenditures have risen across the world and continue to claim a larger share of national resources.
- Healthcare continues to be a top priority for the government in the Kingdom of Saudi Arabia and it has announced a number of initiatives to improve healthcare services as a part of Vision 2030. Introducing a generic medicine framework can boost local manufacturing of drugs, which not only provides employment opportunities for Saudis but also reduces the medication burden in the country.
- Compared to global norms, medication expenditures in KSA are much higher and are expected to grow further due to high prevalence of diabetes, obesity, hypertension, smoking, and chronic diseases.
- Many countries have adopted a generic medicine framework after the American Hatch-Waxman legislation to benefit from substantially low prices of generic drugs with bio-equivalent active ingredients as a way to redirect funding to other important healthcare initiatives.
- Generic medicines in many countries have an overall less favorable reputation due to substantially lower prices. However, the reality of generic medicine is far different from the prevailing perception, which has to be addressed through awareness campaigns.

Recommendations

The Saudi government is introducing a number of initiatives to improve healthcare services for the public. The implementation of a generic medicine framework is an obvious first step, which can bring benefits to all stakeholders - government, insurance, patients and the healthcare community. For the successful implementation of this framework in Saudi Arabia, we recommend the following:

- Regulators shall prepare a comprehensive National Drug List (NDL) based on utilization / volumes both in public and private sectors. This list should include expired patent drug names as well as near expiry (4-5 years) drugs. SDFA, MOH and CCHI are to ensure that NDL shall be used for prescription and dispensation at all pharmacies both in public and private sectors.
- The government shall create / open “Saudi Drug Cities / Zones” for international generic drug manufacturers to set up local production units offering them tax holidays / other incentives (with one window operation to facilitate them). As Saudi Arabia has a huge population base / consumption volume, it has the potential to become a hub of affordable generic drug production for MENA. Thus, enticing & facilitating international drug manufacturers to set up manufacturing units in “Saudi Drug Cities / Zone”. This will not only help in creating employment for Saudis but also will help meeting Vision 2030 healthcare objectives.
- Registration of 3-5 bio-equivalent generic drugs per NDL patent drug through a vigorous & scientific mechanism ensuring quality, safety, bio-equivalency and lower prices.
- Communication and Engagement with Healthcare professionals: Healthcare professionals play a critical role in dispelling misconception about quality of generic drugs. It is critically important to develop a comprehensive communication and engagement program for healthcare professionals (Physicians, Pharmacist, and Nursing staff) about generic drug regulation, usage, efficacy, safety etc. Incentive programs for healthcare professionals to propagate, and promote/ prescribe generic drugs shall also be considered.
- Generic Medicine Awareness/ Perception Building Campaigns: A comprehensive Awareness & Promotional campaigns to be developed for masses to address misconception about generic drugs and to build trust on quality, efficacy and safety of generic drugs.
- Patients, as observed in the Abu Dhabi case study, shall be given a right to buy branded drugs by paying the difference between the branded & recommended generic drug. This will ensure that generic drugs become more mainstream at a national level.

References

1. Deloitte The Economic Intelligence Unit, Data August 2018 (Page7#)
2. the-global-use-of-medicine-in-2019-and-outlook-to2023- (By IQVIA) (Page2#)
3. mea-pharmaceutical-market-quarterly-report, IQVIA 2019 (Page2#)
4. <https://apps.who.int/medicinedocs/en/m/abstract/Js21608en/> (extract)
5. <https://www.fda.gov/drugs/generic-drugs/generic-drug-facts>
6. https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Fact-Sheet_What-is-Hatch-Waxman_June2018-
7. <https://apps.who.int/medicinedocs/documents/s21608en/s21608en.pdf>
8. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4870419/>
9. The Case for Competition 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report (Association of Accessible Medicine) (page8#) <https://accessiblemeds.org/sites/default/files/09-2019/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf>
10. The Case for Competition 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report (Association of Accessible Medicine) (page10#) <https://accessiblemeds.org/sites/default/files/09-2019/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf>
11. us-generics-market-evolution-of-indian-players (page5#) (<https://www.iqvia.com/-/media/iqvia/pdfs/ap-location-site/india/us-generics-market-evolution-of-indian-players.pdf>)
12. The Case for Competition 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report (Association of Accessible Medicine) (page20#) <https://accessiblemeds.org/sites/default/files/09-2019/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf>
13. Generics-set-transform-abu-dhabi's-pharmaceuticals-market <https://oxfordbusinessgroup.com/news>
14. <https://www.haad.ae/> , <https://www.haad.ae/haad/tabid/1328/Default.aspx>
15. Kingdom of Saudi Arabia Healthcare Overview 2018 (Collier