Market Overview 2016

Kuwait

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1. Market Synopsis and Trends

Business Environment

- Oil production is expected to increase up to 4 million barrels per day by 2020, as planned by Kuwait officials. Petroleum accounts for more than half of the country's GDP, 94% of export revenues, and 90% of government income
- Although the GDP per capita is expected to reach 37,855.54 USD$ in 2020 (growth of 5% compared to 2015), the GDP in Kuwait is expected to be the lowest vs. other GCC countries based on 2016 data
- A significant budget deficit was recorded by the country in 2015-2016 (estimated to be around 16.5-19.8 billion USD$) and it is projected that a significant budget deficit for the fiscal year 2016-2017 will follow due to the sliding price of oil
- The Kuwaiti government has decided to reform its finance model which will provide better oversight and discipline to the budget planning and execution processes, and would also build momentum to strengthen capital investment planning and prioritization towards high-growth sectors

Healthcare Provision

- The next five years will witness rapid growth in the healthcare sector, reflecting heavy investment in the country's healthcare infrastructure. This will allow the Kuwaiti government to act early to tackle the projected future healthcare requirements. The budget forecast of the Ministry of Health (MoH) for 2015-2016 is expected to be close to 2 billion KD (6.6 million USD$), which has doubled in the past five years
- The country's new healthcare authority is expected to increase private sector investment improving the overall quality of healthcare services
- The MoH envisions the private sector to be instrumental in the overall development of the medical sector. The private healthcare market in Kuwait is estimated to grow by 15-20% in the coming years
- Several new private hospitals are expected to open in the next few years adding 1,800 hospital beds
- There are currently 20 large-scale mega healthcare projects in the pipeline for Kuwait, worth 3.5 billion KD (12 billion USD$) with an approximate 11,200 additional hospital beds
- The government also plans to expand public healthcare provisions to meet public demand, including advanced new hospitals and specialist medical centers
- The Kuwait Health Assurance Company (KHAC) aims to refinance the healthcare costs of the expatriate population of Kuwait and the Private Health Insurance Initiative for Kuwaiti Retirees is aimed at addressing the healthcare finance needs of the national population
- There continues to be a strong need to create an independent healthcare regulatory authority that will lead the policy development, licensing, quality assurance and the overseas healthcare functions in Kuwait
- The new Public-Private Partnership (PPP) law will provide the foundation for a more investor-friendly and streamlined PPP landscape to flourish in Kuwait

Pricing and Reimbursement

- International referencing will limit new drug prices. However, Kuwaiti drug prices remain among the highest in the Gulf, rising more rapidly than the price of consumer goods
- Drugs on the "Circular 365" list are fully reimbursed for Kuwaiti nationals. According to some estimates, unaffordable medicines are a major barrier to adequate healthcare for approximately one-third of the population (mainly expatriates)
- Universal health insurance covers the cost of drugs, but high-cost specialist treatments have limited availability
- The country provides limited legal protection for pharmaceutical product patents

Pharmaceutical Business Environment

- The market is dominated by foreign multinational players, which capture up to 90% of the total market in value
- It is expected that the availability of generic products will increase due to cost containment measures, reduction in healthcare budget and prescribers being encouraged to adopt more rational prescription patterns by private insurers This will drive local manufacturers business though they will eventually face competition from overseas generic specialists
- Price harmonization across GCC might further lead to substantial reduction in prices of several products across therapy areas

2. Business Environment

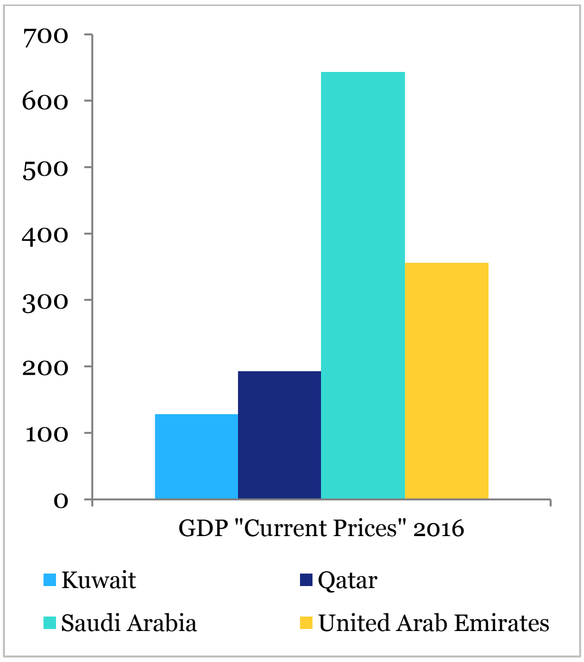
2.1. Economic Environment

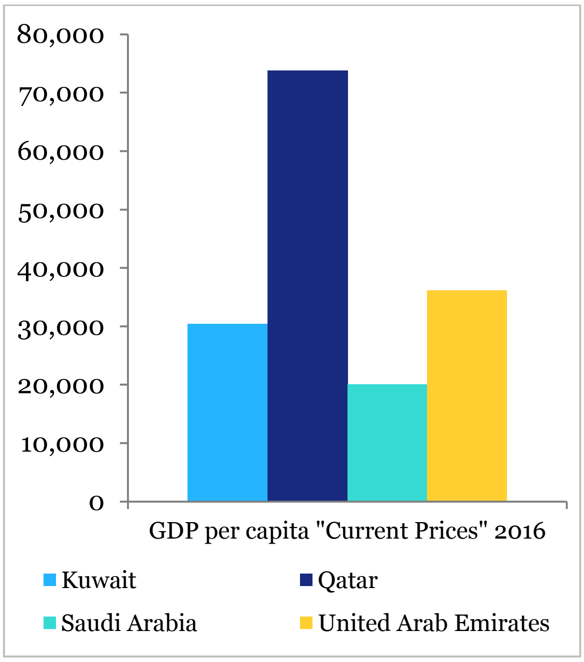
Economic Growth

Kuwait is geographically small (17,818 sq km) but enjoys a wealthy, relatively open economy with crude oil reserves of about 102 billion barrels - more than 6% of world reserves. Kuwaiti officials plan to increase oil production to 4 million barrels per day by 2020. Petroleum accounts for over half of the GDP, 94% of export revenues, and 90% of government income.

Subject Descriptor	Units	Scale	2015	2016	2017	2018	2019	2020
GDP current prices	U.S. dollars	Billions	123.228	128.538	141.776	155.529	167.562	178.517
GDP per capita, current prices	U.S. dollars	Units	29,982.63	30,426.36	32,649.62	34,845.40	36,523.04	37,855.54
GDP (PPP) valuation of country GDP	Current internationa l dollar	Billions	288.763	299.555	313.067	328.203	345.165	362.971
GDP (PPP) per capita GDP	Current internationa l dollar	Units	70,258.72	70,907.75	72,096.22	73,531.93	75,234.78	76,970.03

Kuwait's GDP is expected to be the lowest vs. other GCC countries based on 2016 data.





Population

Kuwait's population is expanding at an average of 2.9% per year; rising from 3.99 million in 2014 to an expected 4.58 million in 2019. According to European System of Accounts (ESA), nearly 98% of the population in Kuwait is urbanized, and about 83% of the total population resides in the capital, Kuwait City.

According to Central Intelligence Agency (CIA) data, the middle-aged group (25-54) represents the biggest proportion of the total population (52.32%) and only 2.33% are 60+.

Exchange Rate

On 16th June 2007, the Kuwaiti Dinar (KD) was re-pegged to a basket of currencies and is now worth about 3.33 USD$.

Foreign Trade and Current Account

The International Monetary Fund (IMF) forecasts that the current account balance will increase to 12.5 billion in 2017, with an average 2.8% of GDP percent change over the period 2017-2019.

Inflation

The IMF expects a 3.3% consumer price growth in 2016.

Fiscal Policy

Kuwait recorded a significant budget deficit in 2015-2016 (estimated to be around 16.5-19.8 billion USD$) and is projecting a significant budget deficit for the fiscal year 2016-2017 due to the sliding price of oil.

The government has decided to reform its finance model which will provide better oversight and discipline to the budget planning and execution processes, and would also build momentum to strengthen capital investment planning and prioritization towards high-growth sectors.

2.2. Political Environment

Political Institutions and Current Government

Kuwait is an independent sovereign Arab State. The religion of the State is Islam, and Islamic Sharia is the main source of legislation. Kuwait is a constitutional monarchy, governed by the al-Sabah family.

International Relations

The United States (U.S.) established diplomatic relations with Kuwait in 1961 following its full independence from the United Kingdom. The U.S. shares a long history of friendship and cooperation with Kuwait, rooted in shared values, democratic traditions, and institutions.

In 1990, Iraq invaded Kuwait. Military forces of the U.S. and a multinational coalition expelled Iraq in 1991. Kuwait is part of the anti-Houthi coalition in Yemen, led by Saudi Arabia, which wants to bring back to power ousted President Abd Rabbuh Mansur Hadi, who fled from the Shiite insurgents in January 2015.

3. Healthcare Environment

The healthcare system in Kuwait will be the subject to heavy investment in the coming years.

Kuwait's public healthcare sector accounts for more than 80% of healthcare spending in country. Currently, Kuwait's MoH is the owner, operator, regulator, and financer of the vast majority of healthcare services rendered, pharmaceuticals purchased, and medical equipment acquired in the country. It operates 15 general and specialized hospitals.

The private sector is expected to grow moderately in the coming years, with private firms estimated to account for 15-20% of healthcare spending.

The country has a well-established primary care network (polyclinics), which provides a local clinic in every residential district of Kuwait. Non-resident patients may visit any of these public clinics, whereas residents may only visit the public clinics located at their neighborhood of residence. 19 new government polyclinics are projected to open in the next two years.

According to the MoH, the private sector will be instrumental in the overall development of the medical sector. The private healthcare market is estimated to grow by 15-20% in the coming years. Currently, a total of 12 private hospitals (totaling 1,038 hospital beds) provide private medical services in Kuwait. Several new private hospitals are expected to open in the next few years, adding 1,800 hospital beds.

Although the government offers free healthcare services, patients are willing to pay a premium for private treatment in order to reduce waiting times and treatment schedules. In certain fields such as obstetrics and gynecology, local patients pay a premium for high-end services offered by private hospitals.

3.1. Healthcare System

Healthcare/MoH Structure and Budget

Kuwait's public health system is divided into six 'health regions', each with a general hospital and several polyclinics. Primary care is provided through a system of local clinics, which can be found in community centers, while secondary care is provided by the six major hospitals: Sabah Hospital, Amiri Hospital, Adan Hospital, Farwaniya Hospital, Mubarak Al-Kabeer Hospital and Jahra Hospital. All of these hospitals include a health centre, specialized clinics and dispensaries.

The private sector consists of a growing number of private hospitals and clinics, as well as more than 200 private retail pharmacies. Around 20% of pharmacies are chain stores, with the majority of the remainder operating independently.

Kuwaitis and expatriates (65% of the population) are covered by a universal health scheme, with more extensive coverage for nationals.

- Kuwaiti nationals: Free health services and drugs on the "Circular 365" list
- Expatriates: Pay fees for non-emergency health services and state-subsidized drugs from a limited list

65% of the population has private health cover; majority of these are expatriates who receive limited benefit from the government scheme. Expatriates mostly purchase medicines from the private sector, because it gives them access to drugs not available in the public sector. Kuwaiti nationals also use the private sector to avoid crowded public facilities or to obtain drugs with limited availability.

The Kuwaiti government is planning to expand public healthcare provision to meet public demand, including advanced new hospitals and specialist medical centers.

The budget forecast for 2015-2016 is expected to be close to 2 billion KD (6.6 million USD$), meaning that the MoH budget will most likely be double of that of the past five years. Furthermore, the percentage of healthcare spending by the MoH as a percentage of overall government expenditure has stayed relatively stable at around 7%.

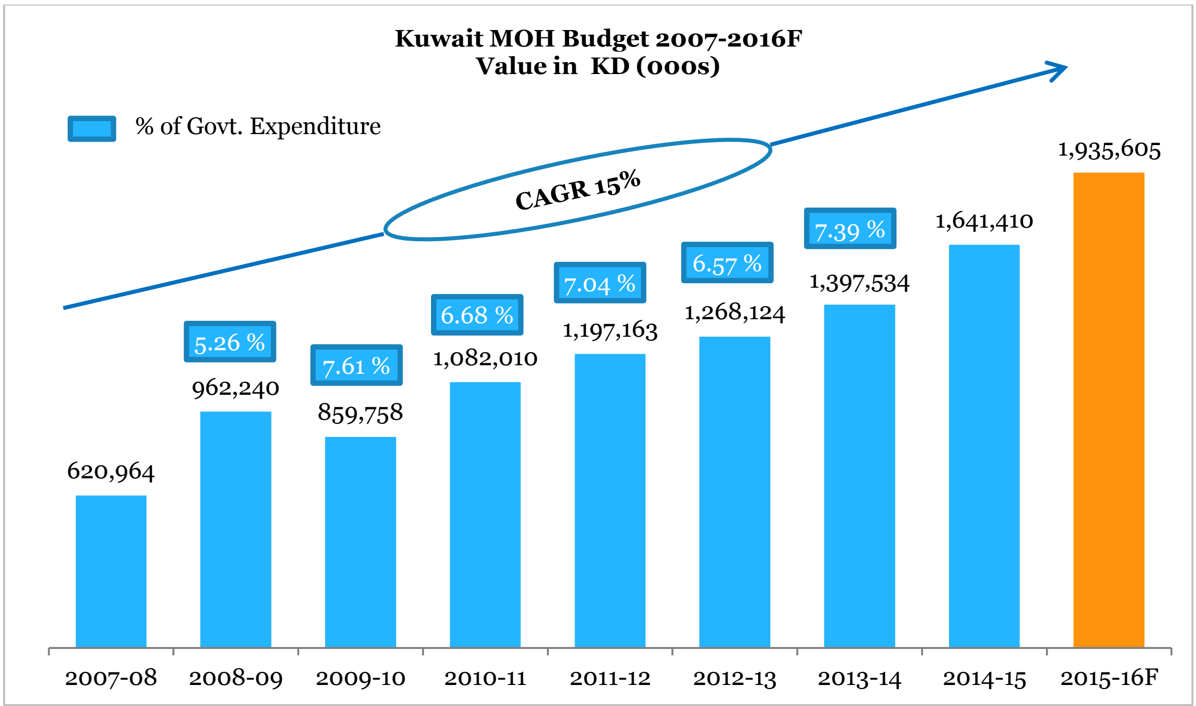


Figure: Ministry of Health Budget 2007 to 2016

However, these figures do not take into account the amount spent by the other eight government-related entities such as the Ministries of Defense (MoD) and Interior (MoI) or the Kuwait Oil Company, that make up between 10 to 20% of the healthcare sector in Kuwait.

There are currently 20 large-scale mega healthcare projects in the pipeline for Kuwait, worth 3.5 billion KD (12 billion USD$) with an approximate 11,200 additional hospital beds.

The following entities are involved in the aforementioned projects:

- **Ministry of Health (MoH):** Adding approximately 4,600 beds, 150 operating rooms and 500 outpatient clinics across 8 different hospital projects
- **Amiri Diwan:** New Al Jahra Hospital (1,117 beds)
- **Ministry of Public Works:** Two new hospitals (approx. 1,500 beds) in the new urban areas

in Kuwait, in addition to Jaber Hospital (1,200 beds)

- **Kuwait Health Assurance Company (KHAC):** A Public Private Partnership (PPP) between the Ministry of Finance (MoH), Ministry of Finance (MoF), the Kuwait Investment Authority (KIA) and the private sector to establish a health maintenance organization, with three 250-bed hospitals, 10 clinics and one day-surgery center
- **Kuwait University (KU):** New KU Academic Medical Center (600 beds)
- **Public Institute for Social Security (PIFSS):** New Medical City for Retirees (500 beds)
- **Ministry of Interior (MoI):** New Police Hospital (500 beds). Initially planned for 300 beds, this new facility entered the design phase in 2014
- **Kuwait Oil Company (KOC):** New KOC Hospital (350 beds)
- **Ministry of Defense (MoD):** 1.7 billion USD$ sale of services agreement contract requested by the Government of Kuwait for the possible sale for the design, construction, procurement of medical, non-medical, and information technology equipment, and operation and maintenance for the Kuwait Armed Forces Hospital

With both the KHAC and the Private Health Insurance Initiative for Kuwaiti Retiress aiming to refinance their healthcare costs, the Government of Kuwait is sending strong signals of cooperation to the private sector in an attempt to curb the exponential increases in public healthcare spending.

3.2. Healthcare Financing and Expenditure

According to World Health Organization (WHO), Kuwait is a high-income country with one of the most modern healthcare infrastructures in the region. An overwhelming share of health services is provided by the public sector, but there is growing private sector involvement in health services. With increasing government commitment to the sector, growth in healthcare spending will be witnessed over the next five years.

Structure of National Healthcare Expenditure

Product	2010	2011	2012	2013
National health spend as % of GDP	2.8	2.6	2.6	2.9
Government share of national health spend (%)	80.7	82.4	82.8	82.6
Health spend as % of total government spend	5.2	5.8	5.8	5.8
Private share of national health spend (%)	19.3	17.6	17.2	17.4
Insurance as % of private health spend	9.6	9.6	9.6	9.6
Out-of-pocket payments as % of private health spend	90.4	90.4	90.4	90.4
Out-of-pocket payments as % of total health spend	17.5	15.9	15.6	15.7

Source: WHO

However, due to the country's persistent political deadlock, only modest rates of 2.9% (2013) was expressed in national spending on healthcare as a proportion of GDP.

The out-of-pocket payments in private healthcare spend continues to remain high.

3.3. Provider landscape

A. Overview

The Government of Kuwait operates 15 general and specialized hospitals. The country has a well-established primary care network (polyclinics), which provides a local clinic in every residential district of Kuwait. 19 new government polyclinics are projected to open in the next two years.

According to the MoH, the private sector will be instrumental in the overall development of the medical sector. The private healthcare market is estimated to grow by 15-20% in the coming years. Currently, a total of 12 private hospitals (totaling 1,038 hospital beds) provide private medical services in Kuwait. Several new private hospitals are expected to open in the next few years, adding 1800 hospital beds.

B. Medical Tourism

There are seven different government entities that send patients abroad for medical tourism in Kuwait. These include:

- The Amiri Diwan
- The Diwan of the Crown Prince
- The Diwan of the Prime Minister
- The Ministry of Health
- The Kuwait Oil Company
- The Ministry of Defense (including Army, National Guard, Air Force, Navy)
- The Ministry of Interior (Police)

There is a pressing need to create an independent healthcare regulatory authority in Kuwait. The advent of a new Kuwait Health Authority will help guide the Kuwaiti healthcare system away from segregation of care, as currently there are seven government entities involved in building/contracting and operating hospitals in Kuwait. A decision to unify the overseas healthcare tourism process needs to be taken in tandem with the development of a unified Kuwaiti Health Authority.

Kuwait also does not have a unified overseas treatment abroad process. It is yet to adopt a single International Patient Office or an International Patient Committee.

There is a lot of scope in developing a relationship with the existing international insurance or third party administrators (TPA's) to ensure a smoother and more economical overseas medical tourism experience for the Kuwaiti patient and their families.

A decree was issued by the MoH on 17th September 2014 in order to curb the stipends issued for overseas medical care after wide-spread public criticism and alleged abuse by both patients and their accompanying chaperones.

Initially, the approved daily stipend for each patient was 100 KD and a further 100 KD for one chaperone (patients under the age of 18 or over the age of 65, were allowed a maximum of two chaperones). This resulted in the government providing up to 300 KD per day for a patient sent abroad which, when extrapolated, results in up to 110,000 KD (375,000 USD$) per year. This amount was in addition to the amount spent on the medical care of the patient and the airline ticket.

As of 1st October 2014, the MoH has reduced the daily stipend to 75 KD for the patient and 50 KD for only one chaperone. If a second chaperone is needed, the MoH would provide the airfare alone.

C. Public/Private Partnerships Initiatives

As per the new PPP Law passed in mid-2014, the Partnerships Technical Bureau (PTB), which was the main body responsible for implementation of PPP projects, has been replaced by Kuwait Authority for Partnership Projects (KAPP). KAPP is expected to have greater autonomy and authority than its predecessor. It will be supervised by and attached to the MoF and overseen by the PPP Higher Committee.

It is often misconstrued that the Kuwaiti constitution guarantees its citizens free healthcare (Article 15 of the 1962 Kuwaiti Constitution states that “the State cares for public health and for means of prevention and treatment of diseases and epidemics”), however, with regards to the Privatization Law of 2010, the Kuwaiti Parliament decreed that the sectors of healthcare and education were not be fully privatized. The privatization law dictates that any government entity/asset/corporation must be ‘privatized’ according to the following framework:

- 50% will be offered to the public by means of a public joint stock holding company listed on the Kuwait Stock Exchange (KSE)
- 26% (golden operating share) will be offered to a private (technical/financial) partner/consortium. Strong preference is given to Kuwaiti companies, particularly those already publically listed. The consortium is also encouraged to involve international technical partners and investors with exemplary track records
- 24% is retained by the State of Kuwait through the state-owned investment vehicle, the Kuwait Investment Authority (KIA) which will own 19% and the Public Institute for Social Security (PIFSS) which will own 5%

Ongoing Projects or Procurements

The new PPP Law provides that projects already signed under the old law can continue under the existing regime; however, there is no interim legal framework for PPP projects that are already in the procurement stage but not yet signed. The procurement of PPP projects where the procurement process has already commenced but not been concluded should therefore recommence and secure the approval of the PPP Higher Committee. This may result in the redrafting and rerelease of some procurement developed under the old regime documentation.

It is expected that the new regime will open the door for the procurement, development and implementation of a greatly increased flow of PPP projects in Kuwait. There are a number of ambitious projects in the pipeline that have been announced by KAPP, including the following:

1. Kuwait Health Assurance Company (KHAC) - Hospital for Expatriates

The project is valued at 230 million KD (765 million USD$) as of 1st December 2014. It is one of the leading PPP projects in Kuwait, whereby four board seats will be retained by the private sector consortium, and one board seat will be allocated to each of the MoH, the Kuwait Investment Authority (KIA) and the Public Institute for Social Security.

The project is expected to deliver three 250-bed hospitals and 10 primary care clinics (at least one clinic in each of the six governorates of Kuwait) in 36 months, as well as one day-surgery center. The Government of Kuwait has also guaranteed the following benefits specifically for KHAC:

- Unique designation of a Health System (only license in Kuwait) for 10 years
- Grace period for licensing and implementation
- Immediate patient flow (1.2 - 1.7 million expats)
- Sharing of existing MoH medical records
- Staff designation before entry into Kuwait
- Free transfer of clinical staff within the system
- Use of generic prescriptions
- Unit Dose System
- Option for Group purchasing with the MoH
- Preapproved assurance plan premiums with inflation considerations
- Preapproved co-payments for primary care and emergency visits
- Heavily subsidized tertiary care for 5% of pre-approved government premium

The target market for KHAC is the growing expatriate population of Kuwait. It is yet unclear whether it would be mandatory for expatriates to enroll in KHAC. Kuwaiti citizens will also be able to enroll, however it is not clear whether or not the Kuwaiti government would subsidize/take full ownership of the fees. It is believed that Kuwaiti citizens would have to pay out-of-pocket since the MoH would still operate 5-7 government general hospitals.

Furthermore, it remains unclear what exactly will be covered by the proposed 130 KD assurance premium outlined in the KIA study, which is a 260% increase when compared to the current 50 KD government assurance plan which must be covered for every expatriate living in Kuwait.

2. Ministry Of Health (MoH) - Physical Medicine & Rehabilitation Hospital

The MoH initiated the New Physical Medicine and Rehabilitation Hospital (NPMRH) project under a PPP scheme. It is expected to be a 500-bed Hospital located in the Al Andalus area in Kuwait.

D. Expansion of MoH hospitals

The MoH is planning for the expansion of the country's healthcare infrastructure over the next 10 years. Currently there are eight major expansion projects taking place at the following hospitals:

- Kuwait Cancer Center
- Amiri General Hospital
- Al Razi Orthopaedic Hospital
- Sabah General Hospital
- Farwaniya General Hospital
- Infectious Disease Hospital
- Al Adan General Hospital
- Ibn Sina Specialized Hospital

Hospital Project Name	No. of Beds	Build up Area (sqm)	No. of Floors	Budget (KD million)	Main Contractor	Project Status	Completion Status in %	Completion Date
Amiri	415	141,501		93	ASCO/Al Essa/Pizarotti	UC*	9.0	4Q2017
Kuwait Cancer Center	618	200,000	1+12	173	Al Ghanim National	UC	5.4	4Q2017
New Al Sabah	731	230,166		173	Shapourgi Balonji	UC	8.3	3Q2018
Farwaniya	955	406,330		285	Behbehani	UC	5.9	2Q2019
Al Adan	638	286,280		232	Behbehani	UC	2.9	2Q2019
Infectious Diseases	224	54,034		54	Bayan/Ozgi/ Limac	UC	3.8	3Q2017
Ibn Sina	427	145,000		120	Not Awarded	Initial	Concept Design	4Q2017

*UC-Under Construction

With the increased focus on programs of expanding hospital services in both public and private sector, both through direct infrastructure construction and attracting human resource, the government of Kuwait is aiming to develop a more efficient healthcare system in near future.

The Ministry of Public Works (MoPW) - Jaber Hospital

The MoPW is approaching the completion of Kuwait's largest single hospital building – the 1,168-bed Jaber Hospital project located in the South Surra area; Kuwait's largest hospital to date.

The project is expected to be complete by September 2016, according to the parliamentary priorities committee who recently met with MoH officials in December 2015 to follow up the ministry's agenda and match it to the country's general plan.

New Hospital Inaugurations

Al-Razi Hospital

The Al-Razi hospital was inaugurated by His Highness the Prime Minister Sheikh Jaber Al-Mubarak Al-Hamad Al-Sabah in the Al-Sabah area on 12th October 2015. The ceremony was attended by a number of ministers and high-ranking state officials from the PM's diwan and the MoH.

Health Minister Dr. Ali Al-Obaidi stated that the hospital increased by 80% in bed capacity to reach 540 after the project's completion, noting that the costs had amounted to 31.4 million KD (103 million USD$). The total built up area reached 28,000 sqm, via an addition of 10 wings each with 24 beds.

Chest Diseases Hospital

Late Shaikhan Al-Farsi ward at the Chest Diseases Hospital was inaugurated on 18th October 2015. The new ward will serve male cardiac disease, cardiac catharsis and cardiac failure patients. The new ward includes 27 beds and is built according to the latest and most up-to-date international specifications in terms of privacy, patient safety and infection prevention.

Shaikhan Al-Faresi and Sharifa Al-Awadhi Health Center

The center will offer integrated healthcare service to a total of 364,760 residents in the Surra area in general medicine, family medicine, diabetes, pediatrics, psychiatric counselling, dentistry, breast cancer early detection, and chronic diseases.

New Hospital Projects Under Consideration/Planning

New Jahra Hospital in Jahra

The New Jahra Hospital (NJH) is a full-service general secondary care hospital, offering a selection of specialized services along with the infrastructure to accommodate select tertiary care capabilities. The facility is planned to support approximately 1,100 inpatient beds, as well as a free-standing multi-specialty dental centre accommodating approximately 100 clinics with their respective procedure and support areas. The construction of hospital is intended to be carried out with a fast-track execution method in a period of approximately two years.

New (South) Al-Sabah Hospital

The MoH was allocated a land of 81,000 square meters to establish the 7,000-bed hospital in the Sabah Al-Ahamd City in the South of Kuwait.

E. Patient Satisfaction

The MoH took the decision to separate the outpatient clinic appointment timings for its residents; mornings for citizens and evenings for expatriates. The decision took effect at the beginning of December 2015 in Al-Adan Hospital and has since drawn mixed reactions as people believe it has failed to serve its purpose and that many of the public health facilities are still crowded. Those against the idea have pointed out that it is impossible to make this kind of separation between the citizens and expatriates, indicating the decision even delayed appointments and did not stop the long queues in public health facilities. Meanwhile, those in favour of the decision believe it is for the public benefit as it guarantees the provision of treatment to everyone.

F. Major Updates to Emergency Care

Air Ambulance Aviation services were initiated in Kuwait on January 2015, providing air ambulance services in domestic and international sectors at all ICU facilities. The air ambulance service by the MoH has been well received by the Kuwaiti public.

Kuwait has also recently upgraded its fleet of road ambulances, by adding a further 54 digital and online enabled ambulances to its current fleet. These ambulances will be linked to hospital emergency care departments and other ambulances via the internet.

In addition, the recently introduced scooter ambulances has helped medical personnel provide first aid to patients in crowded areas at a record time in-keeping with internationally recognized standards.

3.4. Private Health Insurance

Private Health Insurance Initiative for Kuwaiti Retirees

The initiative sponsored by His Excellency the Minister of Health, Dr. Ali Al Obaidi, is aimed at the 105,000-107,000 retirees recognized as family patriarchs of Kuwaiti nationality (usually male and above the age of 55). The initiative has been budgeted at around 100 million KD (342 million USD$) and expected to be effective from 2016.

This initiative is radically different from previous efforts by the Government of Kuwait to introduce private health insurance within its population. In August 2011, the Council of Ministers highlighted the government's intention to corporatize healthcare insurance for Kuwaiti nationals by creating a Kuwait-domiciled company that will be 50% owned by the public (with the shares most probably set to be equally distributed among the (at the time) 1.15 million Kuwaiti citizens as was done for Kuwaiti Islamic Bank – Warba Bank (formerly known as Bank Jaber), with the remaining 50% offered to a private sector consortium with a strong preference for a consortium that includes an international technical partner with a proven track-record in delivering health insurance products and solutions both regionally and internationally.

Kuwait's central tenders committee launched a tender to provide health insurance to retired citizens in accordance with law No. 114 of the MoH in 2014. Seven companies accepted the government's invitation, including Al Ahleia Insurance, Gulf Insurance Company, Kuwait Insurance, Enaya Insurance, Wethaq Takaful Insurance, Warba Insurance, and Gulf Takaful Insurance Company.

The tender was awarded to Gulf Insurance Company with the lowest outbid of 82.48 million KD (272 million USD$) on September 2015, therefore the health insurance program for retirees is expected to be effective sometime in 2016. As per the Assistant Undersecretary for Legal Affairs at the MoH, Dr. Mahmoud Al Abdul Hadi, the yearly limit of coverage for each member of the plan is 17,000 KD (57,000 USD$) and will cover non-cosmetic primary, secondary and tertiary care within Kuwait without any co-payments.

Another important trend to mention when it comes to private health insurance adoption in Kuwait is that many public entities are already procuring private health insurance on behalf of their employees. This is exemplified by the Kuwaiti Fire Departments two-year, 2.97 million KD (10 million USD$) contract to cover the 3,900 Kuwait Fire Department employees (with an option to extend coverage to their families and dependents) with Ta'azur Takaful Insurance company.

3.5. Future Landscape of the Kuwaiti Healthcare System

The healthcare landscape of Kuwait is as dynamic as the political landscape. There continues to be a strong need to create an independent healthcare regulatory authority that will spearhead the policy development, licensing, quality assurance and the overseas healthcare functions in Kuwait.

It is hoped that the advent of a new Kuwait Health Authority will help guide the Kuwaiti healthcare system away from segregation of care as currently there are seven government entities involved in building/contracting and operating hospitals in Kuwait including the Kuwait Oil Company, the Ministries of Interior, Defense, Public Works, Health, the Public Institute for Social Security, and the Amiri Diwan

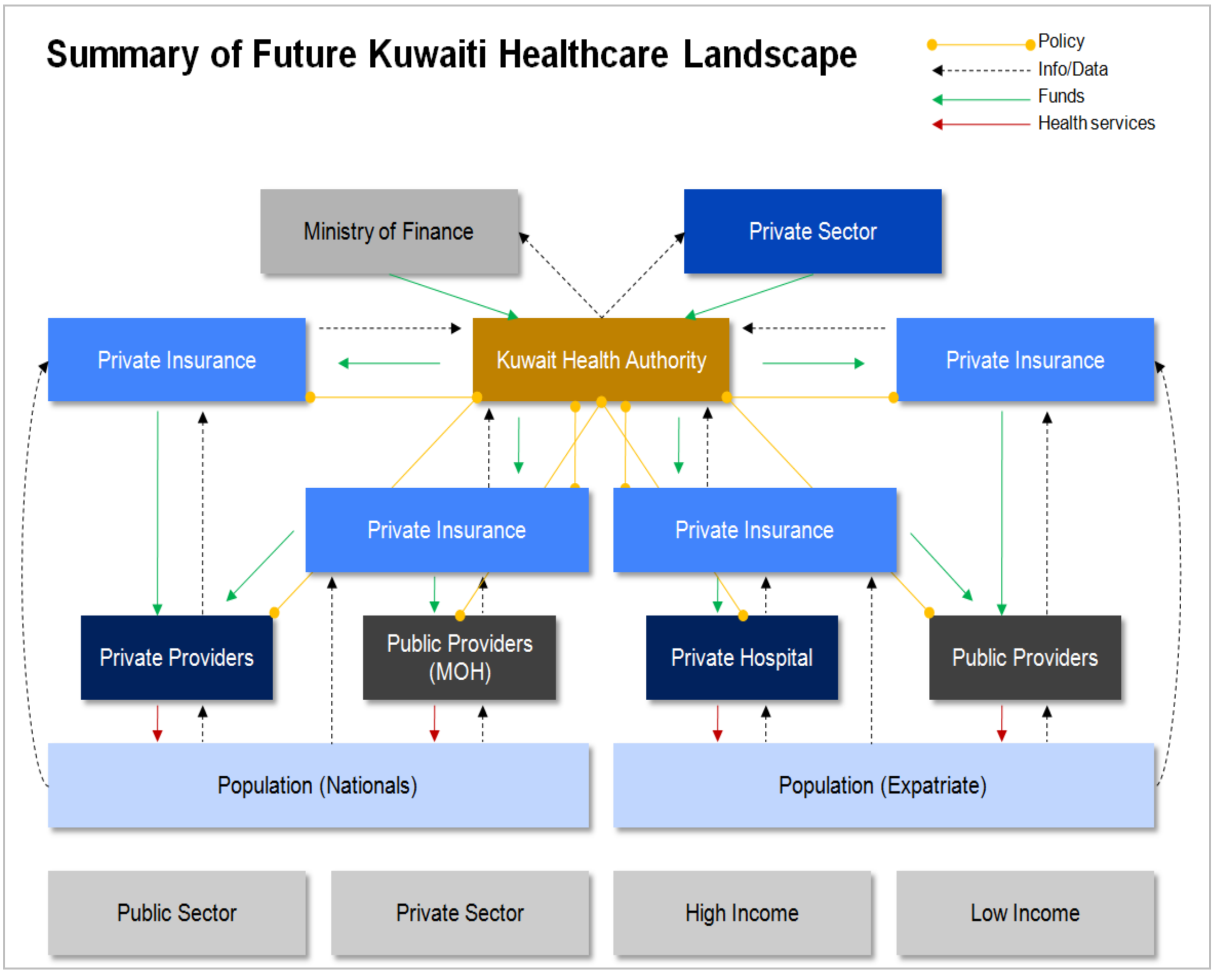


Figure: Future Kuwaiti Healthcare Landscape

The new healthcare authority is expected to increase private sectors investment in Kuwaiti healthcare, thereby improving the overall quality of healthcare services.

4. Pharmaceutical Business Environment

In 2015, the total pharmaceutical market value was LC$ 958.4 million; accounted majorly by institutions. Only 21.4% of the sales were contributed by the retail channel.

MNC players dominate the market by capturing 89.6% of the market share by sales value. The market is majorly dominated by original products while generic products (branded and unbranded) contribute only about 12.3% to the sales and 21.6% to the total volume of the drugs.

The Kuwait Food and Drug Authority (KuFDA) is the head regulatory agency. Manufacturers submit their drug application to MoH for market authorization; decisions are released in 6 to 24 months.

Free-market, competition-based pricing is not allowed in Kuwait; instead the government operates a system of price and profit controls.

For nationals, all the drugs on “Circular 365” list are completely reimbursed. States have limited lists for subsidies for expatriates. Universal insurance covers the cost of drugs, but high-cost, specialist treatments have limited availability.

As per the Law No. 4 of 1962, the country doesn’t provide any effective legal protection for pharmaceutical product patents.

4.1. Pharmaceutical Operating Environment

The overall pharmaceutical sales in Kuwait has grown in the past five years with a CAGR of 6.5% and is valued at LC$983.35 million in 2015. The therapy classes generating maximum sales are cardiovascular, anti-infectives, insulins and anti-TNFs.

The market is dominated by MNC players with top 3 players Pfizer, Novartis and GSK together capturing around 28.6% of the total market.

Local and regional corporations contribute only 9.5% to the total pharmaceutical sales in the country. Among local players, Julphar is the leading corporation contributing 1.7% to the total market and capturing 17.7% of the local pharmaceutical sales.

A. Leading Corporations

The market is dominated by MNC players with only few regional players such as Julphar Spimaco, Tabuk and Hikma in the top 20 list. The market is concentrated, with top five corporations capturing almost 41.5% of the market. Pfizer is the leading corporation in the country and captures 10.3% market share. Novartis and GSK are also among leading corporations, each capturing 9.4% and 9.0% of market share respectively, with their extensive portfolios.

However, a drop in sales for leading corporations over previous year has been observed. Pfizer has been affected due to the loss of patent for its arthritis drug, Celebrex (December 2014) and there is a decline in sales of its top two products Lipitor and Enbrel, both together contributing 50.2% of the company's sales in Kuwait. Similarly, Novartis and GSK observed a decline in the sales of their top products; Diovan (contributing 12.3% to Novartis portfolio) and Augmentin (contributing 15.2% to GSK's portfolio) respectively.

Companies like AstraZeneca and Merck KGAA have seen an overall increase in the sales over previous year. AstraZeneca's top two products have grown more than 75% over last year (Pulmicort: 75.5% and Meronem: 99.1%) and together contribute 30.5% to the company's sales value. Merck KGAA's growth over last year, is reflective of more than 100% growth of many important products like Glucophage, Neurobion, Erbitux etc.

Sales of Top 20 Corporations (2015), at Ex-Manufacturer Prices

Rank	Company	LC $ (million)	Market Share (%)	YoY Growth (%) (2015 vs. 2014)	CAGR (2013-2015)
1	Pfizer	98.4	10.3%	-0.4%	-7.7%
2	Novartis	89.8	9.4%	-18.1%	13.2%
3	GSK	86.3	9.0%	-6.9%	-7.4%
4	Sanofi	67.0	7.0%	-9.8%	3.9%
5	AstraZeneca	56.0	5.8%	23.2%	-0.8%
6	MSD	49.4	5.2%	-46.6%	-29.3%
7	AbbVie	48.4	5.1%	-13.9%	-12.9%
8	Abbott	47.9	5.0%	24.2%	11.5%
9	Roche	40.8	4.3%	-14.9%	67.6%
10	Novo Nordisk	35.4	3.7%	-16.3%	5.3%
11	Merck Kgaa	28.9	3.0%	98.6%	16.5%
12	Bayer	27.9	2.9%	-27.1%	-6.4%
13	J&J	25.0	2.6%	57.2%	8.8%
14	Julphar	16.1	1.7%	-36.5%	-31.2%
15	Spimaco	14.3	1.5%	35.2%	-2.1%
16	Acino Pharma	14.1	1.5%	-14.2%	-30.0%
17	Servier	13.6	1.4%	1.3%	-37.1%
18	Tabuk	13.5	1.4%	72.4%	79.7%
19	BI	13.3	1.4%	-4.5%	-6.0%
20	Hikma Pharma	13.0	1.4%	47.8%	15.5%

Source: IMS Health

B. Local and Foreign Industry

The pharma industry is dominated by foreign corporations. The regional/local industry comprise of players such as Julpar, Spimaco, Tabuk, Hikma etc.

Value Share of MNC v/s Local (2015), (at Ex-Manufacturer Prices)

Corporation	Value (2014)	Value (2015)	Volume (2014)	Volume (2015)
MNC	90.6%	89.6%	75.8%	76.9%
Local	8.6%	9.5%	22.4%	21.3%
Others*	0.8%	0.9%	1.8%	1.7%

Source: IMS Health

Notes:*Others include companies which country of origin is not clear

C. Leading Products

Sales of the Top 20 products in the pharmaceutical market in Kuwait capture 17.5% of the total market. Most of these drugs are used in treating lifestyle diseases, infections and chronic ailments like cancer. For example, cardiovascular (Lipitor, Zocor,Co-Diovan etc.), auto-immune diseases (Humira, Enbrel), cancer (Glivec), diabetes (Lantus, glucophage etc.)

AbbVie's Humira, a drug to treat autoimmune diseases, leads the market by capturing 4.8% of the total market. **Sales of Top 20 Products (2015), (at Ex-Manufacturer Prices)**

Product	Molecule	Manufacturer	LC$ (million)	Annual Growth (%)
Humira	Adalimumab	AbbVie	46.5	-5.4%
Lipitor	Atorvastatin	Pfizer	41.7	-9.8%
Zocor	Simvastatin	MSD	30.2	-31.1%
Lantus	Insulin Glargine	Sanofi	26.7	67.3%
Klacid	Clarithromycin	Abbott	22.6	16.7%
Glucophage	Metformin	Merck KGAA	14.9	143.2%
Seretide	Fluticasone#Salmeterol	GSK	14.7	88.5%
Augmentin	Amoxicillin#Clavulanic Acid	GSK	13.1	-38.7%
Co-Diovan	Hydrochlorothiazide#Valsartan	Novartis	13.0	22.8%
Diovan	Valsartan	Novartis	11.1	-46.5%
Glivec	Imatinib	Novartis	9.5	316.2%
Pulmicort	Budesonide	AstraZeneca	9.3	75.5%
Ventolin	Salbutamol	GSK	9.1	188.4%
Amaryl	Glimepiride	Sanofi	8.5	-15.4%
Norditropin Nordil	Somatropin	Novo Nordisk	8.0	-37.0%
Meronem	Meropenem	AstraZeneca	7.8	99.1%
Remicade	Infliximab	J&J	7.7	190.0%
Enbrel	Etanercept	Pfizer	7.7	-10.2%
Gasec	Omeprazole	Acino Pharma	7.6	-11.5%
Kiovig	Immunoglobulin Base	Baxter	7.5	8143.1%

Source: IMS Health

D. Generics Market

Generic products (branded and unbranded) contribute about 12.3% of the sales and 21.6% to the total volume of the drugs in Kuwait.

The brand-conscious nature of prescribers and patients has traditionally enabled multinationals to continue selling original brands profitably, long after their patents have expired. It has also mitigated against the emergence of a significant market for unbranded generics.

The total sales of generic products (branded and unbranded) is majorly accounted for by institutional sales (65.2%).

Branded and patented drugs are popular due to the relative wealth of the population and expatriate workers.

A limited policy of generic substitution exists in the public sector. If a generic is present in the pharmacy and the prescribed branded drug is not, the generic should be dispensed. While there are no incentives for generic prescribing or dispensing in general, the government has been encouraged to support greater generic procurement as a means of cutting health expenditure in the future.

Presently, generic products are not widely available in the private sector and tend to be priced highly, but this is likely to change as private health insurance schemes put pressure on prescribers to adopt more rational prescription patterns.

Value & Volume Share of Product Categories (2015), (at Ex-Manufacturer Prices)

Product Category	Value (2014)	Value (2015)	Volume (2014)	Volume (2015)
Original	78.2%	76.4%	51.4%	51.1%
Branded Generic	10.6%	11.8%	19.9%	20.5%
Unbranded generic*	0.3%	0.5%	0.4%	1.1%
Other Products**	10.9%	11.3%	28.3%	27.3%

Source: IMS Health

Notes: *Unbranded generics are manufactured by local pharmaceuticals as under molecule name.

**Other products include medical devices and OTC products.

4.2. Pharmaceutical Regulatory and PMA Environment

The Kuwait Food and Drug Authority (KuFDA) is the head regulatory agency, which follows the ministerial decree 302/80 to register pharmaceutical products.

Manufacturers submit their drug application to Kuwaiti MoH for market authorization; decisions are released in 6 to 24 months. The MoH also provides a streamlined review process for lifesaving products or products with U.S., EU, or Japanese approval. Prices are reviewed every six months.

The law requires that multinational companies register at the price of the exporting country. Nevertheless, Kuwaiti drug prices remain among the highest in the Gulf, rising more rapidly than prices of consumer goods.

A. Regulatory Landscape for Registration and Trends

Regulation of medicines in Kuwait is done on the basis of quality, safety and efficacy standards, price control, and patent protection. The country has 40 years of experience of a regulatory system and plays a prominent role in the GCC's regulatory environment.

The Kuwaiti review process ensures that (a) the product is registered and marketed in countries with recognized and competent regulatory authorities for at least 12 months, (b) that the product meets the desired, internationally recognized, quality standards to ensure that the product was manufactured for its intended use, (c) that the product is stable for the entire proposed shelf life and for six months under the stressed conditions of 40°C/75% relative humidity, and (d) the product price must be reasonable and affordable for local patients.

The regulatory process has three phases (a) **the submission phase:** the local agent (or the sponsor) submits the registration dossier along with a covering letter to the director of Kuwait Drug and Food Control (KDFC) officially requesting the registration of the pharmaceutical product (b**) the evaluation phase:** the reviewer evaluates the Chemical and Manufacturing Control (CMC) data focusing on data related to product safety and quality (c) **the authorisation phase:** after the successful completion of full assessment, the final approval decision is made by the Drug Registration and Release Superintendent (DRRS) which is officially endorsed by the director of the authority.

B. Pricing System and Trends

Free-market, competition-based pricing is not allowed in Kuwait. Instead, the government operates a system of price and profit controls, as well as a fixed margin for wholesalers and retailers, however, mark-ups are high (E.g. at over 3,000% for some products in early 2010).

Multinational companies have to register at the price of the exporting country. The drug prices in Kuwait are rising rapidly and remain the highest in the Gulf.

In April 2010, Kuwait's Minister of Health announced that medicine prices for 5,000 essential drugs would be reduced by 5%.

Changes to Price Setting: In January 2012, the GCC announced the formation of a unified drug-pricing unit for the region. This unit would be responsible for setting pharmaceutical prices for branded drugs across all countries so the maximum profit margins for distributors and retailers combined would not exceed 45% of the CIF import prices.

For a select specialty drug market basket, Kuwait prices are 34.8% lower than U.S. and 10.6% higher than average of EU5.

C. Reimbursement System and Trends

Drugs on the "Circular 365" list are completely reimbursed for Kuwaiti nationals. This list comprises about 70 active ingredients and includes some biologic drugs. The MoH and Central Medical Stores (CMS) determine listing, though the Therapeutic Committee will become more involved.

States have limited lists for subsidies for expatriates.

According to some estimates, unaffordable medicines are a major barrier to adequate healthcare for approximately one-third of the population. Universal insurance covers the cost of drugs, but high-cost, specialist treatments have limited availability.

The timeline to formal reimbursement is yet not transparent. While price and reimbursement in other countries currently drives listing, pharmacoeconomics, local trial data, and KOL opinion will become key access drivers in the future.

4.3. Intellectual Property

As per the Law No. 4 of 1962 relating to Patents, Designs and Industrial Models in Kuwait; *"a patent of invention shall not be granted…to pharmaceutical compositions unless such products are produced by special chemical methods or processes, in which case the patent shall not be in respect of the products per se, but of the process of manufacture."*

Hence the country does not provide any effective legal protection for pharmaceutical product patents.

In 1998, Kuwait was upgraded on the "Special 301" to "Priority Watch" in response to a lack of tangible progress on intellectual property rights, including software, videos, and adequate and effective patent protection for pharmaceuticals.

The amendments proposed to the patent law were rejected by the parliament, hence the major challenges of pipeline protection and data exclusivity remained.

5. Market Trends

- Rapid growth in healthcare spending will be witnessed over the next five years, reflecting heavy investment in the healthcare infrastructure. This will aid Kuwaiti government in acting early to tackle the country's projected future healthcare requirements
- The new PPP Law and the implementation of its regulations are a positive step for Kuwaiti PPPs and resolve a number of the challenges that were present under the previous regime. The new law will provide the foundation for a more investor-friendly and streamlined PPP landscape to flourish in Kuwait
- The availability of generic products will increase as private health insurance schemes are encouraging prescribers to adopt more rational prescription patterns. Pharmaceutical market in Kuwait is expecting to grow at a CAGR of 8% between 2015-2019
- Price harmonization across GCC can further led to substantial reduction in the prices of majority of products across therapy areas

6. Predictive Analytics

Volume of Potential Customers of Predictive Analytics in Kuwait

The following is a compilation of the Total Addressable Market (TAM) of potential customers within each of the subsectors in the State of Kuwait.

Kuwaiti Healthcare Economy		
Healthcare regulator(s)	**Total**	**1**
Healthcare providers	**Total**	**813**
Hospitals	**Total**	**30**
	Govt.	18
	Pvt.	12
Primary Healthcare centers	**Total**	**96**
	Govt.	96
	Pvt.	0
Clinics	**Total**	**687**
	Govt.	337
	Pvt.	350
Pharmacies	**Total**	**500**
Payers	**Total**	**39**
Health insurance companies		34
Third party administrator(TPA)		5
Medical device distributors	**Total**	**54**
Pharmaceutical distributors	**Total**	**55**
Pharmaceutical manufacturers	**Total**	**1**

Value of Potential Customers of Predictive Analytics in Kuwait

The report follows the same logic as in the case for Saudi Arabia when calculating the value of potential customers of predictive analytics by multiplying the total volume by the pricing model and by the immediate customers that could be readily accessed maintaining a fairly conservative value.

Again, the report does not to include any potential employer contracts or any large-scale public contracts. Instead, the report aims to be as conservative as possible and limit the focus with respect to the departmental level within each of the potential subsectors. The report also, once again, applies market-penetration rates based on international best practices.

Value for Customized Consultation and Data Analysis

- Regulators – it is anticipated that the single regulating body in Kuwait would not be interested in procuring customized predictive analytical services
- Health Service Providers – it is anticipated that at least three hospitals from the private sector space would be interested in procuring customized predictive analytical services. Based on international best practices, each contract will be priced on average at 50,000 USD$. Total value: 150,000 USD$
- Payers – it is anticipated that at least three insurance companies out of the total 39 payer entities in Kuwait would be interested in customized predictive analytics services. Based on international best practices, each contract will be priced on average at around 100,000 USD$. Total value: 300,000 USD%
- Medical Supply Companies – it is anticipated that at least two of the 55 known medical supply companies in the market would be interested in customized predictive services. Each contract will be priced on average at 50,000 USD$. Total value: 100,000 USD$

Total Value from Customized Consultation: 550,000 USD$ per year

Value for Standardized Data Analysis Tools

Once again, within the below table, the first number quoted is the number of potential clients and the second number is the total value of contracts per year. Due to the limited potential from recurring revenue from the supplier subsector, the report excludes the subsector from these calculations. The report also takes into consideration the fact that the potential for standardized data analysis tools will be strongly influenced by initial contact made with clients for customized consultation and data analysis engagements.

Total Value from Standardized Analytics: 1,920,000 USD$ per year

	Kuwait Value Calculations	Regulator	Provider	Payer	Subtotal
1	Drug Development	-	-	-	N/A
2	Patient Reported Outcomes		3x60	2x120	420
3	Time to Market	-	1X60	-	60
4	Access and Allocation	Limited	3x60	2x60	300
5	High Risk Patients	Limited	1x60	1X120	180
6	Reduce Readmission	-	Limited	1x60	60
7	Preventative Health	-	Limited	Limited	-
8	Reimbursement Models	-	10x60	3x60	780
9	Disease Management	-	Limited	1x120	120

Total Value for Predictive Analytics Market in Kuwait:

550,000 USD$ (Customized) + 1,980,000 USD$ (Standardized) = 2,550,000 USD$

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7. Appendix

7.1. Glossary

1	**CAGR**	Compound Annual Growth Rate
2	**CIA**	Central Intelligence Agency
3	**CIF**	Cost, Insurance and freight
4	**CMC**	Chemical and Manufacturing Control
5	**CMS**	Central Medical Stores
6	**DRRS**	Drug Registration and Release Superintendent
7	**ESA**	European System of Accounts
8	**EU**	European Union
9	**GCC**	Gulf Cooperation Council
10	**GDP**	Gross Domestic Product
11	**GSK**	GlaxoSmithKline
12	**ICU**	Intensive Care Unit
13	**J&J**	Johnson & Johnson
14	**KAPP**	Kuwait Authority for Partnership Projects
15	**KD**	Kuwaiti Dinar
16	**KDFC**	Kuwait Drug and Food Control
17	**KHAC**	Kuwait Health Assurance Company
18	**KIA**	Kuwait Investment Authority
19	**KOC**	Kuwait Oil Company
20	**KSE**	Kuwait Stock Exchange
21	**KU**	Kuwait University
22	**KuFDA**	Kuwait food and drug authority
23	**LC**	Local Currency
24	**IMF**	The International Monetary Fun
25	**MNC**	Multinational Corporation
26	**MoF**	Ministry of Finance
27	**MoH**	Ministry of Health
28	**MoPW**	Ministry of Public Works
29	**NJH**	New Jahra Hospital
30	**NPMRH**	New Physical Medicine and Rehabilitation Hospital
31	**OTC**	Over the Counter
32	**PIFSS**	Public Institute for Social Security
33	**PPP**	Public Private Partnership
34	**PTB**	Partnerships Technical Bureau
35	**TAM**	Total Addressable Market
36	**TNFs**	Tumor Necrosis Factors
37	**TPA**	Third Party Administrators
38	**USD**	United States Dollar

7.2. Sources and Methods

Market Segmentation

Total market sales are divided into the following three categories:

- Non-generics: Sales of "protected", "no longer protected" and "never protected" products, excluding generics
- Generics: Sales of generic products
- Other: Sales of OTC, non-categorized and other products

These segments are defined according to IMS MIDAS Market Segmentation data as follows:

Definition of Categories According to Market Segmentation

	Rx/OTC *	Market Segmentation	Protection Status**	Final Classification
1	Rx	Non Generic Products	Protected	Non-generics
2	Rx	Non Generic Products	No Longer Protected	
3	Rx	Non Generic Products	Never Protected	
4	Rx	Generic Products	Never Protected	Generics
5	Rx	Generic Products	No Longer Protected	
6	Rx	Generic Products	Protected	
7	Rx	Non Categorized Products	Prot Not Covered	Other
8	Rx	Non Categorized Products	Prot Unknown	
9	Rx	Non Categorized Products	Prot Under Investigation	
10	Rx	Non Categorized Products	Never Protected	
11	Rx	Other Products	Never Protected	Other
12	OTC	Non Generic Products	Protected	
13	OTC	Non Generic Products	No Longer Protected	
14	OTC	Non Generic Products	Never Protected	
15	OTC	Generic Products	Never Protected	
16	OTC	Generic Products	No Longer Protected	
17	OTC	Generic Products	Protected	
18	OTC	Non Categorized Products	Prot Not Covered	
19	OTC	Non Categorized Products	Prot Unknown	
20	OTC	Non Categorized Products	Prot Under Investigation	
21	OTC	Non Categorized Products	Never Protected	
22	OTC	Other Products	Never Protected	

Source: IMS Health

Sources

- World Health Organization
- Embassy of United states – Kuwait City
- National Center for Biotechnology Information
- World Journal Of Pharmacy And Pharmaceutical Sciences
- World Intellectual Property Organization
- UAE Interact
- Fierce Pharma
- BBC
- Kuwait E-Gate News Feed Search
- Oxford Business Group
- The International Monetary Fund
- Central Intelligence Agency
- European System of Accounts
- Arabian business
- U.S Department of State

Useful Definitions

Compound Annual Growth Rate

The CAGR is the compound annual growth rate required for the first value to grow to the level of the second value – if the growth rate is the same each year. In reality, the growth rates may have been higher in some years, and lower in others, but the CAGR is a measure of the overall growth rate. For instance, suppose you have a sector of a market, which is 100. To make the calculations easy, imagine that the first year's growth rate is 15% and 0% in the second year. At the end of two years, you have 115. In statistics, the first year is called the base period or the reference period, and the second year is called the given period. The CAGR is calculated using the formula:

((value in given year)/(value in base/reference year))^(1/(number of years different))

In the example the formula would be:

(115/100)^(1/2) = 1.0724

or a CAGR of 7.24%.

So, an annual growth rate of 7.24% in each of the two years would give the same final increase of 15%.

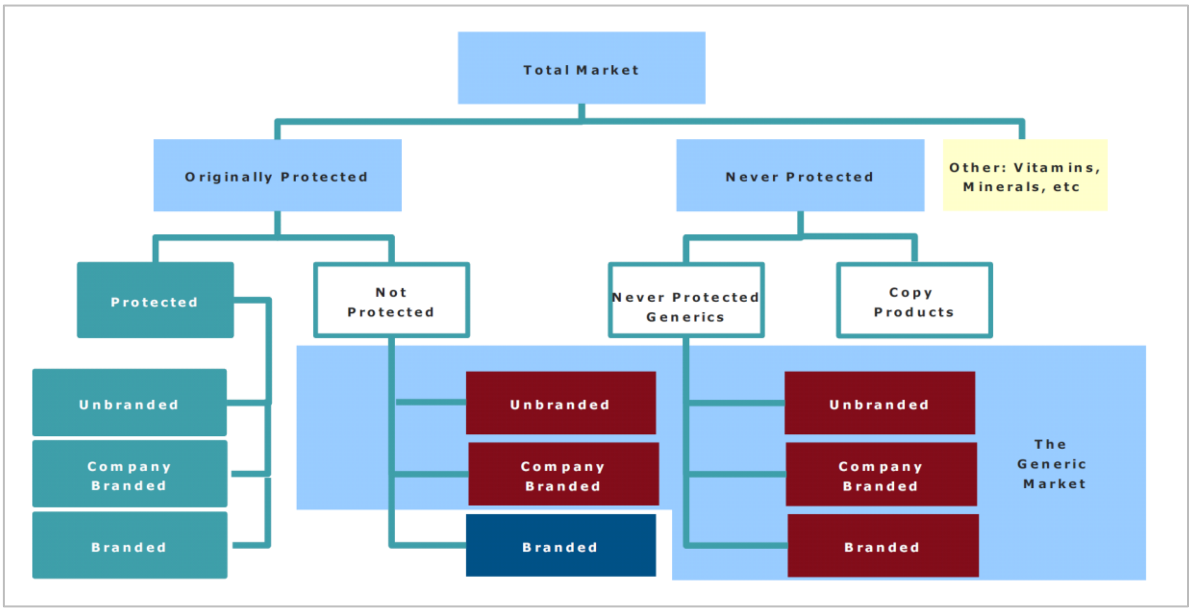
Generic Definition Using The IMS MIDAS Market Segmentation Feature

For countries for which the IMS MIDAS Market Segmentation feature is available, IMS Market Prognosis uses the product status categories defined in the feature. It includes the following categories:

- **Non-Generic Products:** This category includes rx-bound products that are currently under patent protection, original products that are no longer under patent protection, and line extensions
- **Generic Products:** This category includes rx-bound unbranded products sold under their international non-proprietary name, company branded products and branded generics (where these products have never been under patent protection, were launched after the protection expired on the original product and are subsequently launched products)
- **Non-Categorized Products:** This category includes rx-bound products out of scope of the IMS Market Segmentation feature, products for which the product status is unknown and products which are under investigation
- **Other Products:** This category includes rx-bound products that have never been under patent protection and were launched before the protection expired on the original product (copy products)

OTC products are excluded from the above described categorisation to form a separate category.

Generic Definition Using the IMS MIDAS Market Segmentation Feature



Source: IMS Health