Current Market Overview and Outlook

MENA region's potential

- **Pharmaceutical market** in MENA estimated to be worth **$27.6 billion** in 2014 (accounting for 4% of the global pharma market), and forecast to grow at a CAGR of 10% until 2020 vs. overall world pharmaceutical market of 4% to 6%
- Largest pharmaceutical markets in the Middle East are **Saudi Arabia**, the **UAE** and **Iran.**
- Largest pharmaceutical markets in North Africa are **Algeria** and **Egypt** (both of which are second only to Saudi Arabia in broader MENA region)
- Except for Egypt & Iran, **all MENA countries are high importers of branded drugs**; approximately **85%** of pharmaceuticals are imported from other regions. There is a dominance of patented drugs in general (with generics having approx. 5%-6% market share) in the GCC (Gulf Cooperation Council) pharmaceutical market
- Key drivers in the region include **growing population**, greater investment / spending in **healthcare from government**, **western lifestyle** (smoking, poor diet) and **chronic diseases** (e.g. diabetes, cardiovascular disease, oncology)
- Strong governments' investments in infrastructure include: implementation of **health insurance and privatisation systems**, development of **medical tourism infrastructures**, development of **domestic manufacturing**, access to **innovative drugs** (possible via tie ups between foreign pharmaceutical companies and local manufacturers / distributors)

- **Innovative drugs** include all the new drugs that are coming on the market; treatments for **hepatitis C**, **lung cancer**, **multiple sclerosis**, **melanoma**, **diabetes** and **leukaemia** .

- **New innovative drugs** to come on the UAE / MENA market will be related to **obesity** and **hypertension** .

- The regional supports a **strong opportunity** for producing drugs for **orphan** and **rare diseases.**
- **New drug registrations** take from **1 – 3 years for approval**; **Saudi Arabia** and **Jordan** seem to be the only countries with an **independent Food & Drug Administration** (modelled on US FDA) to handle pharmaceutical affairs. **Other countries** are supported by a specialized department in the **Ministries of Health**

- **Pricing policy affect market access;** substantial price reductions across multiple therapeutic areas are to be expected, and the process could even potentially **impact drug prices of other non- markets** i.e. a first generic, practiced around the world, is priced at around **20% less than the originator** due to the region's pricing policy

- **Price harmonisation** introduced to **standardise drug prices in the GCC** in 2014; aiming to harmonise prices by aligning the Cost, Insurance and Freight (CIF) price of all products marketed in GCC countries

A new product in theory would launch first in Bahrain, not Saudi Arabia, due to the registration process timelines (respectively 18 and 24 months)

If a product is launched in Bahrain at a CIF price of €20 and 6 months later the same product is launched in Saudi Arabia at €10, the CIF price in Bahrain would be reduced to £10 due to the Price Harmonization Process

The Price Harmonization Process would mean a re-alignment of prices not only in Bahrain but in any CGG countries where the price is higher than €10

- MENA wide, **local manufacturing is not able to meet the growing demand,** resulting in significant opportunities for **growth and expansion for foreign manufacturers.**

- As there is a **very complex legislation for foreign manufacturers** to penetrate the ME&A region, the implementation of **free zone**, are a **key path to develop a pharma businesses** in the UAE, and other ME&A countries.

Free zones (example)
- Saudi Arabia, the United Arab Emirates and Qatar all have free zones
- DuBiotech was set up as a free zone to attract foreign companies and investors (e.g. laboratory, business centre or logistics warehouse) – now 125 pharma companies
- Typically free zones offer 2 types of service:

✓ 'Delivering Partners': also connecting companies which need each others or partners such as distributors, investors, bankers, etc.

✓ Providing regulatory advice to facilitate the initial stages of their operations

In focus –

UAE is characterised by:

- The UAE **Pharma** market value was **$2.8bn in 2015,** expected to reach $3.8bn by 2020 (CAGR of 6.3%)
- The UAE **Healthcare** market value was **$14.6bn in 2014**, with $29.3bn expected by 2026 (CAGR of 6.2%), of which 28% will be driven by private spend
- Domestic production is focused on **generic drugs**, with very stiff competition from **nutraceuticals** (herbal products) trade

- There is a **strong reliance on imports of pharma products** (primarily the US, Germany, Switzerland, France and the UK); with 30% of the domestic drug market being in the hands of local manufacturers
- It's characterised by **strong amount of M&As to take advantage of innovative new practices**, reaching $520bn in 2015, up by 47% compared to 2014
- The **UAE is used as a hub to re-export in the MENA region**; 12.6% of the pharma products imported by the UAE were re-exported in 2015; this was the case of 42.7% in 2014
- With the domestic production still focused on basic medicines, **UAE imports tend to focus on high-tech prescriptions and medical technology**. Whilst no information is available online on the type of products imported, the acquisition of Globalpharma by Sanofi in 2014/2015 seems to indicate that Sanofi positions in the UAE market (and the region) on products such as **antibiotics**, **cardiovascular medicines**, **painkillers**, **food supplements**, **vitamins** and **anti-allergic formulations** among others.
- UAE is considered **the fastest adopter of innovation in the Middle East;** with **registration processes taking as little as 3-4 months**. This has led some companies to designate the **UAE as a priority launch country** ahead of any other emerging market
- Most Big Pharma used to operate in the region through local distributors (sometimes at high price levels). From 2010, **Big Pharma** started to establish dedicated sales & marketing offices throughout the region, and are now **increasingly perceived as healthcare partners** by local authorities on how to serve better the needs of the country using their expertise
- **UAE Vision 2021** (over 2017-2021) of AED 248bn ($67.5bn), with focus on:
  - **Reduction of cardiovascular diseases**, **cancer** and **diabetes**, providing opportunities for pharmaceutical companies with products in these therapeutic areas
  - Private sector: growing focus towards the construction of **specialised hospitals** and **day surgery centres**
  - Public sector: growing focus towards **non-communicable diseases** and **changing lifestyles** to bring down the incidence of diabetes and obesity

Saudi Arabia is characterised by:

- **Largest manufacturing production** in the Middle East region but **primarily for export markets**
- **Domestic production accounts for approx. 15%** of the overall supply of pharmaceuticals in the market – the **remaining 85% is imported**
- Domestic production's **focus on generic drugs**; less than 20% of the Saudi Arabian pharmaceutical market
- Government's focus is on promoting local production of generic medication in order to curtail the increasing healthcare spending and alleviate unemployment among the citizens
- Government encourages establishment of more locally-grown drug manufacturers through measures such as facilitating faster entry of locally-manufactured medicines into the market and requiring only imported pharmaceuticals to be tested before registration
- Leading local players in the kingdom include **SPIMACO**, **Jamjoom Pharma**, **Tabuk Pharmaceutical Manufacturing** and **Jazeera Pharmaceutical Industries**

- Whist Saudi Arabia promoted local value chains by encouraging joint ventures and sponsoring non-tariff barriers in the form of price control mechanisms, **domestic players face two main imminent challenges** i.e. the presence of **global pharma giants into Saudi Arabia**, as well as **growing popularity of generics** produced in low-cost countries
- Saudi Arabia is likely to become a bi-polar market dominated by branded patented drugs on one hand and low-cost generics on the other

Egypt is characterised by:

- **Most populated country** in the Arab region
- The Egyptian pharmaceutical market is **facing a major drug shortage***. Vital drug supplies, like those for cancer treatment and diabetes, are dwindling. Pharmaceutical companies face the dual obstacle of **a drop in foreign currency reserves making imports harder**, as well as **government fixed prices being too low**
- In 2012, 57% of the total Egyptian population (48 million people) was covered by various health coverage schemes (public and private)
- As a result there is a **quick market value growth of the pharma industry,** expected to reach $5.3bn by 2020; driven by rising incidence of a number of **chronic diseases**
- A growing and unmet need (in 2010, **domestic manufacturers accounted for 35% of the pharma market** in Egypt, producing mainly **generic drugs**)
- **Egyptian Drug Authority (EDA);** a key regulatory authority for pharmaceutical products and medical devices. Works under the **Ministry of Health and Population (MoHP)**, and the **Central Administration of Pharmaceutical Affairs (CAPA)**, responsible for issuing licenses for the manufacture, sale, import and export of drugs or medical devices, following evaluation and investigation, and the **National Organization for Research and Control of Biologicals (NORCB)**, responsible for regulating clinical trial approval

** Egypt is facing a drug shortage, unlike other MEA countries, primarily because of the macroeconomic situation of the country. Since 2011, Egypt has faced severe dollar shortage, a major drop in the country's foreign exchange reserves of its central bank, successive devaluation, political instability and growing poverty, against a backdrop of very high consumer prices (over 30% on an annual basis).*

Iran is characterised by:

- The Iranian pharmaceutical market is a **hub for local manufacturers**, **API producers and distributors**. Besides a large market, it has strategic location in the Middle East and political relationships with Iraq, Afghanistan, Syria, Lebanon, and Yemen as well as CIS countries
- The country's Pharma market experienced a 30% growth over 2009-2014, and was worth $2.4bn by 2014 (market volume of 39.4 billion units). It's predicted to reach $3.3bn by 2019
- **High medicine consumption rates**, with Iran ranked as the **2nd largest consumer** per capita in Asia, and the **20th in the world**
- **Iran exports** amounted to $159 million in 2014; key 2014 export countries were Afghanistan (33%), Russia (18%), Germany (16%), Syria (11%) and Iraq (8%)
- **Iran imports** amounted to $1.5 million in 2014; key 2014 import countries were Germany (19%), Switzerland (14%), UAE (13%), and France (9%)