CPhI Pharma Insights reports: CPhI, the world’s leading pharmaceutical networking event, with over 100,000 attendees globally, is now using its collective resources to create Pharma Insight reports, analysing individual parts of the pharma industry as well as creating the well respected and eagerly anticipated Annual Report featuring a global panel of experts.

The vision is to harness the power of CPhI’s independent position within the industry so that it can produce unbiased analysis of the global pharmaceutical industry and help to see emerging trends and bring different perspectives together. The Annual Report utilises expert in-depth essays, looking at future contingencies, whilst the Pharma Insights series takes perspectives from CPhI exhibitors and the wider industry.

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Introduction

The MENA (Middle East and North Africa) region is a largely untapped, yet potentially hugely fruitful part of the world for the pharmaceutical industry, both as a sales region and for the establishment of manufacturing facilities. Some multinational corporations have already started to invest directly into the region – namely into Saudi Arabia, the most economically powerful country in MENA.\(^1\) However, it is by no means a simple task for international firms to enter this market. This is due to a variety of factors, such as vastly differing spending powers amongst its constituent nations, the lack of a centralised pharmaceutical regulator, and varying preferences for branded products vs generics. In order to achieve success in the region, entry into the MENA market must be thoroughly planned.

Market Share and Growth

Consisting of approximately 22 countries and with over 350m inhabitants, the MENA pharmaceutical market was worth $36bn in 2016, which represented 2% of the global market.\(^2\) However, this relatively low starting base is now seeing projected growth of 10%, vastly outstripping the current global growth rate of 4-6% – even surpassing the traditional ‘pharmemerging’ economies such as Brazil and China.\(^3\) This provides an enticing prospect for international firms – both generic and innovator focused – looking to penetrate a new market and expand their global footprint.

Demographics

The growth of the pharmaceutical market in the MENA region is driven by a number of demographic factors. These include rapidly changing population dynamics, where populations are expanding, but also ageing. For example, Africa is projected to become the 2nd most populous continent within the next 10 years, and the Middle East’s population growth rate has been around 2% for the past decade. Life expectancy of the average MENA inhabitant is now 73 years of age, close to that of many developed nations. Additionally, lifestyle changes have led to higher incidences of non-contagious chronic diseases and conditions – most notably cardiovascular disease, obesity and type-2 diabetes.\(^4\) This ageing, growing population with a shifting disease demographic is promising for foreign businesses looking to enter the market, as there are new challenges and demands to fulfil that domestic companies may not currently be able to meet. Speaking from the 2017 CPhI Middle East and North Africa roundtable, Abdelfattah Irshaid, Area Manager - Middle East, Laboratorios Ordesa, said “the Middle East and Africa are the future. With over 300m people, healthcare expenditure in the region at only 6% of GDP, and higher natality rates than in Europe, there is a great opportunity for many multinational companies.”

Pharmaceutical Usage and Government Policy

The current landscapes of the pharmaceutical markets in the MENA region varies greatly between different nations. A high spending power and a cultural preference for expensive foreign brands in Saudi Arabia has resulted in 85% of pharmaceuticals in the country being imported;\(^5\) whereas in Egypt, 90% of consumption is domestically produced with

\(^3\) Round Table Video
\(^4\) Round Table Video
a much greater market share for generics. Another country where production is low is Qatar, which, similarly to Saudi Arabia, is a wealthy oil state where high spending power results in a preference for imported branded products.

In some countries, it is likely that political unrest has contributed to the relatively muted foreign investment into the area. However, it is foreseeable that there will be a surge of new business in these countries once they reach a stable political situation, and the middle classes expand further, raising demand for pharmaceuticals, as is now happening in parts of sub-Saharan Africa such as Ghana or Nigeria.

Africa as a whole has grown its pharmaceutical industry well over the past decade, with it expected to reach a value of around $400bn by 2020. This is being driven significantly by urbanisation, with more economically developed cities meaning that more people have the means to access medicines. Government policy is also encouraging local manufacturing of drugs, as imports currently outweigh exports, with local manufacturing only covering basic medicines at the moment. However, the rise of non-communicable diseases, and rising healthcare costs are likely to attract foreign investment into the continent, as well as the further development of domestic manufacturing capabilities.

In Sub-Saharan Africa, the largest pharmaceutical manufacturing market is found in South Africa, which is currently worth $2.8bn, with a highly developed private healthcare system that is comparable to other developed nations in Europe. However, historical class divides in South Africa have extended to its healthcare and pharmaceutical sector, with the public healthcare system, which caters for the majority of the population, being overstretched. This has resulted in a lot of people in South Africa being unable to gain easy access to basic medicines and treatments. However, in recent years South Africa has turned increasingly to generic drugs, providing a great opportunity for both domestic and foreign manufacturers, with the generics market forecast to grow by a robust 12% compound annual growth rate (CAGR) during 2017-2022.

Another promising pharmaceutical industry is in Nigeria, with its compound growth rate projected to be around 9%, hitting $3.6bn by 2026. Over this time period, Nigeria could contribute $1.9bn-$2.2bn worth to pharmaceutical sales growth – suggesting a rapidly advancing domestic base – with 55% of these being prescription drugs. Its population is also set to become the 3rd largest in the world by the year 2050, and with a young population at present, as it ages, its demand for pharmaceutical products will increase exponentially. However, there are some drag factors with

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6 https://www.pharma-iq.com/market-access/articles/middle-east-north-africa-pharmaceutical-market-in
8 http://newafricanmagazine.com/changing-landscape-health-africa-building-pharmaceutical-industry/
9 https://www.bmiresearch.com/articles/pharmaceuticals-healthcare-outlook-for-2016-sub-saharan-africa
the healthcare infrastructure in Nigeria, and around 5,000 people per year travel abroad for treatments. It would seem logical that due to the low spending power of the country - at just over $2,000 GDP per capita - the biggest growth area would be generics, either imported or through establishing manufacturing bases with the available workforce. Demand will likely come in part from communicable diseases such as malaria, HIV or tuberculosis – where there is already an endemic problem – as opposed to other diseases more typically associated with gentrifying or geriatric populations (e.g. heart disease and cancer).

However, due to the tropical climate of the country, outbreaks of polio, meningitis, cholera, pandemic influenza, yellow fever, measles, hepatitis and tetanus are also common. In the medium-term Nigeria is also forecast to experience lifestyle diseases associated with the adoption of western diet and sedentary lifestyle. This would suggest a longer-term paradigm shift in the disease burden profile towards non-communicable diseases (NCDs) – such as cardiovascular disease, cancer, diabetes and respiratory disease. These are currently at a relatively low rate but expected to accelerate from 2020 onwards.

Countries in North Africa that have managed to establish pharmaceutical manufacturing industries in recent years include Morocco, Tunisia and Algeria. In 2015, the industry in Morocco was able to cater for 65% of the demand in the country (compared to 49% in Tunisia and 30% in Algeria). Pharmaceuticals produced in Morocco were also exported to Europe, other parts of Africa, and the Middle East. These capabilities could lead to partnerships being made between foreign and North African firms that have strong manufacturing and distribution networks. For example, companies in North Africa could potentially become licensed manufacturers for various innovative or patented drugs for foreign firms and facilitate the penetration of the products into the market, as well as other African and Middle Eastern countries.

Governments are central to the pharmaceutical industry in the MENA region, with their Ministries of Health regulating the industry and product prices. In Lebanon, for example, the government recently cut prices of drugs by an average of 27%. However, they increased the prices of some low value drugs in order to improve their profit margins for pharmacists, to encourage them to stock more of the drugs and increase their availability to the public.\textsuperscript{10}

The Saudi government are actively trying to increase generic consumption through regulating imported branded drugs and promoting local generics production. This is an attempt to cut their healthcare spending and diversify their economy, presenting opportunity for local generics manufacturers and for foreign firms who are willing to move into the country. This has seen some notable recent investment from foreign firms into the country, including partnerships with domestic manufacturers, as well as the building of new facilities. For example, the French firm Sanofi opened a new production facility in King Abdullah Economic City in Saudi Arabia in December 2014, producing antibiotic drugs, diabetic treatments and cardiovascular drugs.\textsuperscript{11}

There was also a recent partnership established between Tabuk and Pfizer in Saudi Arabia, where Pfizer granted Tabuk the ability to carry out manufacturing under a commercial license, in exchange for Tabuk granting Pfizer the rights to 12 products in Saudi Arabia.\textsuperscript{12} Pfizer also recently opened a new manufacturing facility in Saudi Arabia, indicating the opportunity present for foreign firms, and their willingness to invest into the area.

There have also been other movements to transition Saudi Arabia into more of a manufacturing market rather than an import-led pharmaceutical economy; the European excipient certification organisation EXCiPACT has now issued certificates in Saudi Arabia, indicating not only the development of the manufacturing industry in the country, but also its ability to meet high quality standards.\textsuperscript{13}

These new developments could represent new trends developing over coming years for foreign pharmaceutical firms. On one hand, these firms could provide foreign direct investment (FDI) into the MENA region in order to penetrate the market through locally manufacturing. Another trend could be the partnering with other domestic manufacturers or CMOs to license their products and bring them to the region that way.

\textsuperscript{10} https://www.zawya.com/mena/en/story/Lebanons_Health_Ministry_lowers_prices_on_some_drugs_by_up_to_70-SNG_110619559/
\textsuperscript{13} https://www.in-pharmatechnologist.com/Article/2016/03/01/EXCiPACT-s-excipient-certification-ambitions-extend-well-beyond-Europe
In Bahrain, government interventions, such as offering reimbursement for generic prescriptions, have already proved effective in increasing generic consumption. Jordan is currently the only country in the Middle East with a positive pharmaceutical manufacturing trade balance, as it has a well-established industry and many years of experience – exporting 80% of its pharmaceutical produce, with a generic penetration of over 50% in its market.14

Governments in the Middle East have also helped to facilitate ease of access for foreign companies offering innovative drugs, in order to entice firms to enter the market. Countries such as Saudi Arabia, Jordan, and Egypt are trusting authorities such as the European Medicines Agency and the U.S. Food and Drug Administration. These countries may fast track innovative drugs to be approved for local use in 30-60 days, if the drug has been previously approved by these trusted authorities, as opposed to a previous full year review.15 At the CPhI Round Table event on the pharmaceutical industry in the Middle East and Africa, Dr. Manel Chikh, Co-Founder and Chief Executive Officer, Zaphyr Pharmaceuticals said “the Middle East is a complex region at the moment [for foreign firms wanting to enter the market], due to the oil crisis and other factors; however, I think there is still good opportunity there, especially in certain therapeutic areas and innovation, where governments will help for quick entry”.

One of the crucial aspects of the MENA pharma market is the existence of the Gulf Cooperation Council (GCC). The GCC is a multinational partnership consisting of Bahrain, Oman, Saudi Arabia, Kuwait, the UAE and Qatar, who came together in 2014 to establish a drug price harmonisation strategy in order to standardise drug prices within the region.16

Saudi Arabia’s current price review strategy involves matching the lowest price for a certain drug from a list of 30 reference countries. This review occurs every 5 years after drug registration. However, under the new price harmonisation rules, if the current price for an approved pharmaceutical product is found to be lower in another GCC country than in Saudi Arabia, Saudi Arabia will reduce its price to the same level.17 This system will likely reduce drug prices significantly in all GCC-member markets. However, Qatar will likely see one of the largest effects as it currently operates upon a free pricing strategy. It typically has higher priced drugs than other GCC countries, and so Qatar will likely have to see significant price reductions. There will also be significant knock-on effects for non-GCC markets who use countries such as Saudi Arabia as a reference point for their own pricing strategies, such as Jordan and Morocco. This could cause a ripple effect of pharmaceutical price alterations across large areas of the Middle East and North Africa.

Although there was a growing awareness in many populations in the region for personal health and the benefits of over the counter pharmaceuticals, domestic regulations previously inhibited growth of some markets. The introduction of the GCC could see many of these regulatory barriers reduced, with an excellent example being the free trade agreement between the GCC and India that will likely result in further generic penetration into the Middle East market.18 It may be the case that final products are imported into the region from Indian generics manufacturers. However, due to a high average spending power and a cultural distrust of cheaper foreign made products, it is perhaps more likely that APIs will be imported, with local manufacturers providing the final product.

Another aspect to the Middle East pharmaceutical region that could be conducive for the growth of branded generics manufacturing is the increasing pressure on governments to cut healthcare budgets. This pressure could result in the implementation of compulsory healthcare insurance policies in order to reduce the burden on governments and pass costs onto private hands.19 This, in combination with a potential free trade agreement in India, could provide great opportunity for branded generics manufacturers. Due to insurance providers pushing for cheaper drugs to be used, plus a consumer preference for a recognisable brand, locally produced branded generics, perhaps using APIs from India, could thrive in coming years.

Egypt has a strong manufacturing industry; it is the largest producer and second largest consumer (after Saudi Arabia) of pharmaceuticals in the whole of the Middle East and North Africa. Prices of both OTC and prescription drugs are controlled by the government; in 2014, post-revolution when there were poor economic conditions: around

1200 drugs were actually sold for a lower price than their manufacturing costs. However, a 20% price increase on drugs costing less than EGP 30 was implemented in 2016 following pharmaceutical lobbying. In January 2017, the Ministry of Health issued a price rise of 3010 medicines by 30-50% following a widespread medicine shortage due to rising API cost, indicating that the government is open to loosening regulations upon the market, which may improve prospects for foreign firms, such as those importing APIs.\(^\text{19}\)

Another part of the Middle East region that has a strong established pharmaceutical market at the moment is Israel. The market has been projected to grow to $2.12bn by 2020, at a compound annual growth rate of 3.9%, according to a study by GlobalData.\(^\text{20}\) Although this level of growth is certainly lower than the average for the rest of the MENA region, this can be attributed to the fact that Israel already has a strong network of academic and research institutes, R&D facilities and advanced medical facilities. Advancing biotech will likely be a driver of the market in future. This contrasts to the other markets in the region, many of which are emerging and are only just starting to build up this infrastructure to support their pharmaceutical industries.

Israel’s generics market, which accounts for around 20% of the market sales, is underpinned by Teva, the world’s leading generics manufacturer, which owns several manufacturing and export facilities across Israel, North America and Europe. However, there has been talk in recent months about Teva transitioning away from generic drugs in the future, to focus more on branded drugs and the development of new speciality pharmaceuticals, in the wake of growing competition from manufacturers based out of countries with cheaper labours.\(^\text{21}\)

A prominent shareholder in Teva, Benny Landa, said in an interview with Times of Israel: “It is clear that generics will end up totally commoditized, and whoever can produce the products at the lowest price wins. There are Malaysian, Indonesian, Mexican and Indian companies, that all have relatively cheap labor, mass producing generic drugs more competitively than Teva, especially as Teva is an Israel-based company.”

This could present an opportunity for foreign businesses if Teva close or sells some of their generics operations in the country, as they made $9.85bn in generics revenue in 2016.\(^\text{22}\) This means a large portion of the generics market in Israel, as well as the countries that Teva export to, may be available for other businesses.

### Future Trends

Further growth of the pharmaceutical market in the MENA region is likely to manifest in the forms of more individuals getting private health insurance, the development of medical tourism, increases in domestic manufacturing, and better access to innovative drugs.

At the CPhI Round Table on the pharmaceutical industry in the Middle East and Africa, Claudia Palme, Partner at 55 East, had this to say regarding increased healthcare spending: “If countries have to spend more money on drugs and healthcare, it should be something that is at least in part localised, giving a benefit to our economy. This challenges the current industry approach which has looked at this part of the world as mostly a sales market, rather than fully integrating it into its value chain; where R&D and naïve populations with new phenotypes show great promise for clinical trials.”

The healthcare agendas of countries in this region are more heavily shaped by the government’s economic development agenda than those in Europe. For example, Saudi Arabia is trying to move away from being a purely oil-based economy,

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21 https://www.timesofisrael.com/teva-should-ditch-generics-focus-on-branded-drugs-activist-investor-says/
and so growing their healthcare sector is a good way of diversifying. However, this investment is also in part out of necessity – 25% of Saudis now have diabetes, as compared to just 10% of Americans. This may not only be due to increasing Westernised and sedentary lifestyles, but also to genetic predispositions, and so encouraging innovative drug discovery is highly in the country’s interest. This is a problem that is also facing Africa as well, as Western fast food grows in popularity\(^23\) and more people lead inactive lifestyles, it appears that there is great opportunity for innovative pharmaceuticals targeting metabolic and cardiovascular diseases.

Another area that is also increasing in incidence, and so may prove an area of investment for foreign business are the rising oncological concerns in the MENA region. This is linked to increasing life expectancy, as age is the largest risk factor in any given cancer. One way in which foreign firms could benefit countries facing an increased cancer incidence is through education and encouraging the population to take diagnostic tests to address diseases earlier on. However, due to a cultural reluctance in Africa towards taking precautionary or diagnostic tests; firms would have to prove the cost effectiveness of such programs to the government healthcare agencies, and it would likely require a bespoke approach to each individual country, in collaboration with their government, in order to formulate efficacious education campaigns.

Another market related to pharmaceuticals that is likely to grow considerably over the coming years is the medical device market. The Middle Eastern medical device market is expected to be worth $31.6bn by the year 2025, as more of the population reach geriatric age, and increasing diabetes and obesity occurrence increases the demand for technology to aid with these conditions. There is a rising competitive pressure in this area, due to a high ratio of demand to supply, suggesting there is opportunity for firms to quickly move into this market to meet the demand.\(^24\)

However, some difficulty may be experienced by foreign pharmaceutical firms attempting to invest in the MENA region due to the various rules, standards, and regulations regarding market access and pricing. Although referred to as one area, MENA does consist of many different countries, with different cultures, regulations and spending power that have been cause for hesitation amongst foreign firms in entering the market. For example, in Africa, personal meetings are more common than in the West and are important for establishing business relationships and building trust. At the CPhI roundtable for the Middle East and North Africa, Claudia Palme, Partner at 55 East said ‘Although in the West you go by the company someone works for, or their education, as a mark of their credibility and trustworthiness, this didn’t exist in the MENA region for a long time. So you must establish credibility through relationships. This can be meeting with them over tea for 4 hours, but only speaking about business for 20 minutes! I advise that businesses invest their time into building these relationships, it’s both worth it and very enjoyable’.

There are also some difficulties faced when foreign companies attempt to introduce generics to the market in the MENA region. Stringent registration processes of a generic product and even its packaging, means a lot of effort is required to introduce a generic into a country. A lack of a centralised regulator means that these protocols will also differ from country to country, resulting in a reluctance for some foreign businesses to attempt to enter the generics market. However, the growing demand for generics in the region due to potential private insurance schemes and an increasing general awareness of pharmaceuticals may still be enticing enough for companies. At the CPhI roundtable for the Middle East and North Africa, Dr. Manel Chikh, Co-Founder and Chief Executive Officer, Zaphyr Pharmaceuticals said ‘although the market penetration of generics is increasing where it used to be very low, for foreign companies who are not already established in the region, the amount of paperwork that can be required to register generics, as well as sample requirements, means that some are reluctant [to enter the market]’.

\(^{23}\) [https://www.nytimes.com/2017/10/02/health/ghana-kfc-obesity.html]
Generic manufacturers in the region generally have good growth prospects due to the ageing, growing population, and many countries in MENA looking to cut their healthcare costs. There are billions of dollars’ worth of drugs that lose their patents every year, and as first generic prices in the region range between 20-50% of the originator, this represents hundreds of millions of dollars. However, this growth may be limited by the fact that at the moment they generally stick to their own domestic markets. This limits their marketing potential and presents opportunity for international generics manufacturers to gain market share in these countries. It may be beneficial for local generic manufacturers to undergo acquisitions and mergers to protect their market shares, as well as diversifying their product mix and enter some international markets. International pressure to instil fair-trade practices in countries that tend to favour local pharmaceutical production may also lead to better prospects for international firms looking to move in.

Conclusion

The diverse economic, political, cultural, and public health profiles in the MENA region are mirrored by a highly varied market environment for the pharmaceutical industry. In general, prospects look good for both foreign and domestic firms, with growing populations and longer life expectancies producing a much greater demand for pharmaceuticals in the Middle East and North Africa, with huge growth in the market projected over the coming years. Local generic manufacturers, and potentially foreign generic firms from countries such as India, who could set up manufacturing bases in the region and export from there, are likely to have good prospects. However, this may not be the case for all international firms looking to enter the region; there is a current preference amongst several MENA countries to reduce imports of foreign branded drugs, and increase both domestic production and consumption of generics. However, foreign firms producing branded products have also recently begun to enter the region with direct investment in manufacturing facilities, such as Sanofi in Saudi Arabia, and this may be one of the optimal ways to enter this potentially highly lucrative market.
About CPhI

CPhI drives growth and innovation at every step of the global pharmaceutical supply chain from drug discovery to finished dosage. Through exhibitions, conferences and online communities, CPhI brings together more than 100,000 pharmaceutical professionals each year to network, identify business opportunities and expand the global market. CPhI hosts events in Europe, China, India, Japan, Southeast Asia, Russia, Istanbul, Korea and South America co-located with ICSE for contract services, P-MEC for machinery, equipment & technology, InnoPack for pharmaceutical packaging and BioPh for biopharma. CPhI provides an online buyer & supplier directory at CPhI-Online.com.

For more information visit: www.cphi.com

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