Shaping the Biosimilar Opportunity
Middle East and Africa Perspective
Introduction

In the current decade, there is rapid and significant progress in healthcare management options and technologies, driven by the growing population, increased life expectancy, and increasing number of patients with chronic and life-threatening diseases. In theory, a shift from traditional medicines to personalized/targeted therapies using advanced technology has led to the development of biologics. In retrospect, biologics scientifically can be defined as medicinal products whose active substances are derived from a living organism, such as blood components, allergenics, recombinant therapeutic proteins, etc which are the main focus of this report, while gene therapy, somatic cells, tissues, and vaccines are beyond the scope of this report.

Since their inception, biologics are viewed as a prospect of differentiated care, generating more treatment options for stakeholders and bringing new source of healthcare value.

While biologics have been established over the past 10 years, the introduction of biosimilars has added an interesting shift in the targeted therapies market, particularly for cost-conscious healthcare systems such as emerging markets. Biosimilars are reverse-engineered approximations of marketed biologics, meaning that they are highly similar to their reference products, and can give similar results at a lower cost, hence creating an interesting proposition for healthcare systems.

Market practicalities strikingly differ from theoretical expectations, making it difficult to estimate the true potential of biosimilar products. This is more challenging in particular for emerging markets such as Middle East and Africa (MEA), where country local specificities, non-uniform regional guidelines and stakeholders’ awareness make it difficult for products to reaching their full potential.

The purpose of this report is to understand the biologics market dynamics in the MEA market and the impact of biosimilar introduction on these healthcare systems as well as the requirements for the MEA market to capture the full potential value.

The report is based on independent research and analysis undertaken by QuintilesIMS and draws on the analysis of trends from developed markets such as the US and Europe over the last decade and observations from these markets in terms of biologics maturity and biosimilar emergence.
Executive Summary

The US$250 billion global biologics market has exhibited a double-digit growth in the past 5 years and this is expected to continue. As a result, it is projected to account for up to 28% by value of the global pharmaceutical market by 2020 from 23% today. The ability of biologics to cure multiple life-threatening diseases has contributed to the significant growth. However, the high cost of biologics is a major restraint for their adoption, especially in cost-conscious healthcare systems such as emerging markets.

Most leading biologics will face a patent cliff in the next 5 years and pharmaceutical companies have realized this as a near-term opportunity for growth of biosimilars. This has ignited an interest and have pushed biosimilars to the forefront of R&D efforts. As a result, there are over 90 biosimilars in the development stage with about one-third of them in late-stage development and regulatory filing.

In the near future, biosimilars are expected to compete with originators across therapy areas, enabling stakeholders to benefit with more treatment options at an affordable price. Hence, it is assumed that biosimilars have an increasingly important role to play in the market.

This value proposition of ‘cost-to-value’ is a key decision enabler in markets such as MEA as most of these markets are out-of-pocket or payer driven. The MEA market is still in the nascent stages of biosimilar adoption and opportunities exist as the market is highly attractive. The market space is also competitive but there is a significant area for both foreign and local companies to thrive.

However, achieving success in the biosimilar space is a different ball game compared to traditional generics. Regulatory framework and guidelines have been challenging and stakeholders, including regulatory agencies, payers and prescribers, demand additional level of evidence to approve the use of biosimilars, and lately interchangeability often results in delayed approvals. These characteristics impact biosimilar adoption in the MEA region.

A regulatory framework coupled with efficient clinical trial investments can unlock the routes of entry for biosimilars in these markets. This will open up new avenues for market synergy, where patients and physicians will benefit from multiple disease management options and at the same time reduce the cost burden on payers and governments. The MEA market is visibly progressing in setting the regulatory framework, leading to the entry of more biosimilars in the market.

Given the decision power of each stakeholder across the biosimilar adoption value chain, pharmaceutical companies will need to engage with stakeholders early to communicate the value of biosimilars compared to biologics so that the perceived value of these products is not just limited to their price.
Shaping the Biosimilars Opportunity in MEA

2016-2020 will mark a momentous evolution in the global healthcare arena with the increasing use of biologics in several diseases and the rise of low-cost biosimilars

Since their entry into the market, biologics have expanded innovative care options for specialty diseases. Their clinical value has pushed them to the forefront of available treatment options since the last decade, and hence biologics have witnessed incremental growth and now contribute to 23% of the total pharmaceutical market. The clinical benefits of biologics have made them a treatment of choice in multiple indications and now six biologics feature among the top 10 drugs sold globally.

The Global Biologics Market

In this report, the global biologics market includes low-molecular-weight biologics such as insulin, erythropoetin, GCSF, and filgrastim as well as high-molecular-weight immunoglobulins and monoclonal antibodies. This market is projected to exceed US$390 billion by 2020. Biologics by then will account for up to 28% by value of the global pharmaceutical market.

Although small molecules still lead the pharmaceutical market globally in value, their growth has stagnated from 2014 due to increased generic penetration and pricing pressure (Figure 1). At the same time, biologics have witnessed incremental growth, making them a key component of the global pharmaceutical market.

The steady growth of biologics has been driven by their safety and efficacy profile coupled with their ability to treat difficult, life threatening conditions such as cancer and auto-immune diseases (e.g., rheumatoid arthritis, psoriasis, etc).
Although biologics only form a small portion of the pharmaceutical market, their rapid growth is expected to transform the market shares in favor of biologics.

Currently, the US and EU5 represent more than 65% of global sales of biologics. US dominates the market with 50% market share growing at 12% in the past 5 years whilst EU5 and Japan have a lower growth of 6% and 8%, respectively. In contrast, the pharma-emerging markets have grown at 15% in the past 5 years influenced by numerous biologic launches, increased stakeholders awareness as well as an increase in per capita pharmaceutical spending (Figure 2).

In the recent times, the presence of biologics in new therapy areas is increasing, making them a vital part of the top 10 pharmaceutical products.

Over the last decade, more than 80 biologic molecules have been launched globally across a number of therapy areas. Traditional biologics were developed mainly for cancers and autoimmune diseases. Now, non-traditional biologics are being developed for the treatment of HIV, asthma and Alzheimer’s disease, which currently consist of highly genericized small molecules.

In 2016, five of the top 10 pharmaceutical products were biologics – Humira, Lantus, Enbrel, Remicade and MabThera.

As the case with all pharmaceutical products, biologics are also set to face the inevitable patent cliff. The period until 2020 is set to see the patent expiry of 10 major biologics, thus opening up US$79 billion worth of market for biosimilars.
Shaping the Biosimilars Opportunity in MEA

All these products will lose patent by 2020

**Global Top 10 Biologics sales by region and associated patent**

<table>
<thead>
<tr>
<th></th>
<th>US expiry date</th>
<th>EU expiry date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab (Humira)</td>
<td>2016</td>
<td>2018</td>
</tr>
<tr>
<td>Insulin Glargine (Lantus)</td>
<td>Expired</td>
<td>Expired</td>
</tr>
<tr>
<td>Etanercept (Enbrel)</td>
<td>2028 (extended)</td>
<td>Expired</td>
</tr>
<tr>
<td>Infliximab (Remicade)</td>
<td>2018</td>
<td>Expired</td>
</tr>
<tr>
<td>Rituximab (Mabthera)</td>
<td>2018</td>
<td>Expired</td>
</tr>
<tr>
<td>Bevacizumab (Avastin)</td>
<td>2020</td>
<td>2019</td>
</tr>
<tr>
<td>Trastuzumab (Herceptin)</td>
<td>2019</td>
<td>Expired</td>
</tr>
<tr>
<td>Insulin Aspart (Novorapid)</td>
<td>Expired</td>
<td>Expired</td>
</tr>
<tr>
<td>Glatiramer Acetate (Copaxone)</td>
<td>Expired</td>
<td>2017</td>
</tr>
<tr>
<td>Pegfilgrastim (Neulasta)</td>
<td>2015</td>
<td>2017</td>
</tr>
</tbody>
</table>

This will be of particular importance in emerging markets, especially in the MEA region. The reasons include pressure of cost-containment and a high inclination toward low-cost generics, which fuel opportunities for companies to launch biosimilars.
Biosimilar Development

The year 2016 marks a full decade since the approval of the first biosimilar in Europe. Sandoz’s human growth hormone Omnitrope (somatropin) received approval from the European Commission in April 2006, satisfying regulators that this biosimilar offered a safe and efficacious alternative to the original biologic. This paved the way for other biosimilars to enter the market across a range of therapy areas. Currently, the EU has approved 21 biosimilars referencing five innovator biological products – epoetin, somatropin, filgrastim, folliotropin, and infliximab – of which 19 are marketed.

The recent years have also witnessed a significant rise in the number of companies developing biosimilars. In addition to the traditional generic players, the big pharma innovators such as Lilly, Pfizer and Amgen and tech giants such as Samsung–Bioepis are also competing. The emerging and domestic players are among the other competitors.

Based on QuintilesIMS understanding of the biosimilars market and considering the market factors, the companies developing and commercializing biosimilars have been divided into three distinct groups:

- **Established companies with international reach**: Companies having a global presence and a strong R&D vertical have spearheaded the development of biosimilars. These include companies specializing in generics such as Sandoz, Pfizer, Amgen, Lilly, Celltrion, etc.

- **Emerging market players**: Several companies in emerging markets are entering the biosimilars market. These companies have the advantage of production and manufacturing at a lower cost. These include Cipla, Intas, Dr. Reddy’s, 3SBio, LG, Emcure, Dong–A Pharm, Harvest Moon Pharmaceuticals, Tuteur, and Kalbe.

- **Domestic players**: A number of companies developing biosimilars are making their presence felt in the MEA. These include Fosun Pharma, SG Bio, Julphar, pharmADN, Beijing Kawin Bio–Tech, GenSci, Cinnagen, Sotex, Dem Ilac, Bionovis, Pharco and Probiomed.
The factors for the rise in interest for biosimilar development is not limited to the patent expiry of highly priced biologics, but is also driven by high payer concerns with regards to skyrocketing healthcare expenses. Biosimilar competition is expected to deliver total savings of up to US$110 billion to healthcare systems across Europe and the US through 2020. Governments are thus responsive supporting manufacturers to replace for branded biologics with lower-cost biosimilars to help reduce government healthcare costs.

Due to these drivers, MNCs and local players have gained traction and are therefore increasing their focus on biosimilar development and commercialization. Currently, there are > 200 biosimilars in development globally, with about 50% of them already in late-stage development, and majority of them targeting oncology and autoimmune indications.

**Figure 3: Global Biosimilar pipeline by molecule – 2016**

Based on the above data, it is clear that pharma companies are looking at the biosimilars sector as a lucrative opportunity in the near future.
The Biosimilars Macro Environment

Biosimilars offer an advantage for both pharma companies and healthcare systems by creating a balanced alternative, where pharma companies benefit with new product sales and healthcare systems benefit with efficacious and cost-effective treatment.

Although biosimilar acceptance and uptake is growing in the recent years, the realization of its true potential has been delayed. As an evidence, forecasts for 2007 indicated a strong acceptance of biosimilars (low-molecular-weight biologics) with a global market outreach of US$16 billion by 2011. In actuality, the market opportunity lapsed, with only US$0.6 billion in realized sales in 2011 (Figures 5 and 6).

Biosimilars have not demonstrated the expected success because of several delays in the regulatory, clinical, and patient environment.

The delay can be attributed to the awareness of biosimilars and regulatory events pertaining to it:

Firstly, the US biosimilar guidance pathway began in 2010 with the enactment of the Biosimilars Patent Cooperation and Innovation Act (BPCIA) and therefore has only one approved biosimilar, Sandoz’s filgrastim-sndz called Zarxio in 2015. Around 2005, the EU was the first to develop a legal and regulatory framework for the approval of biosimilars in terms of clinical trial requirements, pricing, and reimbursement policies, but unfortunately it was not harmonized among the different countries causing staggered approvals.

Sub-optimal level of awareness about the safety and efficacy of biosimilars among payers and policy makers, coupled with non-directional regulatory framework, restricted access to biosimilars in some countries and delayed it in others.
Furthermore, complex manufacturing and cost of a biosimilar is not significantly different from the corresponding reference originator biologic. Hence, pricing negotiations with payers pose an additional challenge resulting in additional delays in access.

On the other hand, in countries where biosimilars are approved, physicians have been very wary of clinical outcomes of switching existing patients, already being treated by biologics, to its respective biosimilar. The clinical consensus as of now is for biosimilars to be prescribed to treatment-naïve patients only while trials on switching are underway (e.g. in Norway).

**The underlying elements of achieving the full potential from biosimilars are neither well understood at a policy level nor implemented effectively at a practical level (Figure 7).**

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**Figure 7:** Global Biosimilar Regulatory Landscape

- **Fully established framework and solid draft guidance for biosimilar Mab Substitution not allowed**
- **Pathway under development. Access through national and regional tenders**
- **Established biosimilar legislation and guidance aligned to EMA framework.**
- **Established biosimilar legislation and guidance (PMDA).**
- **Behind in terms of regulation, particularly on clinical requirements and length of regulatory process.**
- **Proposed new concrete biosimilar approval guidelines in 2016.**
- **No statutory provisions for biologics data exclusivity, however, applies same as TRIPS regulations. Recently published guidelines on biosimilars.**
- **Guidance finally in 2010. Dual pathway with abbreviated non-clinical and clinical data.**
- **Guidance published. Global reference product accepted.**
- **Legal pathway established, FDA guidelines published. Pathway now being tested.**

**Source:** QuintilesIMS
Given the regulatory differences across borders and internal delays in implementation, there was a dire need of a regulatory alignment to encourage biosimilar uptake. The markets that are best placed to capitalize the benefits are those (1) where biosimilar guidelines are established, (2) where manufacturers are motivated to participate over a longer period of time, (3) those countries where physicians are at the heart of decision-making, since they influence a higher uptake of biosimilars.

Similar to developed markets, emerging countries in the MEA hold high potential for biologics and biosimilars considering similar demographics such as increase in the aging population and incidence of chronic diseases. In addition, the growing middle class population and their ability to pay for newer therapies has increased. Other factors spurring opportunity in the region is the support from the government and its regulations making a conducive business environment for manufacturers as well.

The introduction of biosimilars in the MEA countries should not only facilitate access to effective biologics, but also must have the potential to create substantial savings for national health sectors within the MEA region.

The MEA countries have demonstrated openness and acceptance to the latest technologies and biologics.

The biologics market in the MEA has seen a steady growth in the recent years and the biologic opportunity was estimated at US$2.75 Billion in 2016. However, in line with global markets, biologics in the MEA are also nearing the patent cliff as patents for several biologics have expired or are about to expire by 2020.

**Selected biologic products**

<table>
<thead>
<tr>
<th>Biologic Product</th>
<th>CAGR 12'-16'</th>
<th>EU expiry date</th>
<th>US expiry date</th>
<th>MENA expiry date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin Glargine (Lantus)</td>
<td>17%</td>
<td>Expired</td>
<td>Expired</td>
<td></td>
</tr>
<tr>
<td>Adalimumab (Humira)</td>
<td>20%</td>
<td>Expired</td>
<td>Expired</td>
<td>2021</td>
</tr>
<tr>
<td>Insulin Aspart (Novomix)</td>
<td>21%</td>
<td>Expired</td>
<td>Expired</td>
<td>Expired</td>
</tr>
<tr>
<td>Trastuzumab (Herceptin)</td>
<td>14%</td>
<td>Expired</td>
<td>Expired</td>
<td>2019</td>
</tr>
<tr>
<td>Interferon Beta-1a (Rebif, Avonex)</td>
<td>14%</td>
<td>Expired</td>
<td>2028 (extended)</td>
<td>Expired</td>
</tr>
<tr>
<td>Rituximab (Mabthera)</td>
<td>4%</td>
<td>Expired</td>
<td>Expired</td>
<td>2018</td>
</tr>
<tr>
<td>Etanercept (Enbrel)</td>
<td>0.3%</td>
<td>Expired</td>
<td>Expired</td>
<td>2028 (extended)</td>
</tr>
<tr>
<td>Ranibizumab (Lucentis)</td>
<td>26%</td>
<td>2020</td>
<td>2020</td>
<td>2020</td>
</tr>
<tr>
<td>Infliximab (Remicade)</td>
<td>1%</td>
<td>Expired</td>
<td>2018</td>
<td></td>
</tr>
<tr>
<td>Bevacizumab (Avastin)</td>
<td>2%</td>
<td>2019</td>
<td>2020</td>
<td></td>
</tr>
<tr>
<td>Pegfilgrastim (Neulastim, Neulasta)</td>
<td>19%</td>
<td>2017</td>
<td>Expired</td>
<td>Expired</td>
</tr>
<tr>
<td>Glatiramer Acetate (Copaxone, Gitaxon)</td>
<td>26%</td>
<td>2017</td>
<td>Expired</td>
<td>Expired</td>
</tr>
</tbody>
</table>

**Biologics market (MEA)** was US$960 Mn in 2016 (CAGR 9.6%).

However, including all biologic products like vaccines etc – opportunity size is US$2.75 Bn.

*Source: IMS MIDAS Dec 2016. Countries include Algeria, Egypt, Saudi Arabia, South Africa, UAE, Tunisia, Morocco, Lebanon, Jordan, Kuwait, Fr. West Africa etc. The data is captured for key biological products in MEA market*.

*Not considered existing biosimilars such as Epoetin Alfa expired in EU, but still patent protected in the US*
This is opening new doors and avenues for biosimilar market players. From the opportunity standpoint of biosimilars in the MEA countries, Algeria, South Africa, and Saudi Arabia (KSA) are the largest markets, of which South Africa and KSA are the most attractive owing to the availability of regulatory guidelines and biosimilar experience.

**Top Companies in the MEA Developing Biosimilars**

**Pharma companies will show keen interest in developing biosimilars in pharma-emerging markets, which have both purchasing power and growth opportunities for biosimilars.**

Pharma companies understand the ripe opportunity of biosimilars and are eyeing their place in the market. In the MEA, local companies fare better than MNCs for tapping the potential as foreign MNCs are unfamiliar with the MEA country’s regulatory nuances. This puts the local companies at an advantage as they can collaborate with large foreign companies to receive technical knowhow and funds for developing and commercializing biosimilars.

Currently, MNCs and multiple local companies are synergistically developing biosimilars in the MEA and analysts predict a surge in such collaborations across the regions. The examples (non-exhaustive) of such collaborative efforts include:

- **UAE’s Julphar** is the first company in the Middle East which is involved in biosimilar clinical research. Julphar concluded a Phase I trial of its biosimilar Human Insulin that demonstrated non-inferiority compared to the EU-licensed reference product Eli Lilly’s Huminsulin. Julphar has a clinical trial filing accepted under the European Medicines Agency (EMA) biosimilar guidelines.

- **Egypt’s SEDICO** has been producing biosimilars for more than 6 years. The biotechnology products include insulin, erythropoietin, streptokinase, angiokinase, follicle-stimulating hormone, aprotinin, filgrastim, and somatropin.

- **Jordan’s Hikma** is developing nine biosimilars products under an agreement with Celltrion.

- **Egypt’s Pharco** have signed a public private partnership with minister of health to build the first oncology medicine; this deal sees the private company partnering with the state-owned Holding Company for Biological Products and Vaccines (VASCERA).

- **Algeria’s El Kendi**, an affiliate of the Jordanian MS Pharma, has recently launched its biosimilar plant, focusing mainly on biosimilar as part of their growth strategy.

- **Algeria’s Frater- Razes** has announced in 2015 an investment to support the production of local biosimilars.

- **Biocard (Russia)** is planning to build a local biosimilar plant in Morocco.
**Current Market Trends of Biosimilars in the MEA**

For these players to enter the MEA market, it is important for them to first understand the current biosimilar trends. Pricing and market access levers are key to KSA being the biggest market for biologics in the MEA and was the first to implement a distinct regulatory route for biosimilars in 2010 following the guidelines issued by the EMA and the International Council on Harmonization (ICH). This led to the registration in KSA of the biosimilars filgrastim (Hospira), epoetin alfa (Sandoz) in 2015 and Remsima (Celltrion) in 2016, which is now expected to open the door for the entry of other biosimilars.

Other countries in the region are also preparing themselves commercially and technically to create space for biosimilar adoption. For instance, Jordan’s first biosimilar was approved in 2009 following the EU guidelines and now has its own regulatory guidelines approved. Algeria, despite nascent regulatory framework, is seeing more and more biosimilar reaching the market (i.e., Hikma is in the final phases of registration of trastuzumab)

Table 1 provides a snapshot of the availability of guidelines and the presence of biosimilars in the countries in the MEA region.

Table 1: Country-wise categorization of access and presence of biosimilars

<table>
<thead>
<tr>
<th>Country</th>
<th>Availability of guidelines</th>
<th>Time to market (months)</th>
<th>Biosimilar experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saudi Arabia</td>
<td>Yes</td>
<td>18</td>
<td>Yes</td>
</tr>
<tr>
<td>Egypt</td>
<td>Yes</td>
<td>8-10</td>
<td>Yes</td>
</tr>
<tr>
<td>South Africa</td>
<td>Yes</td>
<td>18-24</td>
<td>Yes</td>
</tr>
<tr>
<td>Jordan</td>
<td>Yes</td>
<td>6-12</td>
<td>Yes</td>
</tr>
<tr>
<td>UAE</td>
<td>Yes (not published)</td>
<td>12-18</td>
<td>Yes</td>
</tr>
<tr>
<td>Morocco</td>
<td>Yes</td>
<td>24</td>
<td>Yes</td>
</tr>
<tr>
<td>Algeria</td>
<td>No (in draft)</td>
<td>24</td>
<td>Yes</td>
</tr>
<tr>
<td>Lebanon</td>
<td>No (in draft)</td>
<td>6-12</td>
<td>Yes</td>
</tr>
<tr>
<td>Tunisia</td>
<td>No</td>
<td>24-36</td>
<td>Yes</td>
</tr>
<tr>
<td>Kuwait</td>
<td>No</td>
<td>6-24</td>
<td>No</td>
</tr>
</tbody>
</table>
Biosimilars have already started making inroads to most important MEA markets. For instance, biosimilars contribute to more than 40% of the total biologics market in loosely regulated Lebanon and French West Africa. Further, in Egypt, biosimilars have already penetrated into key biologics space and currently contribute to ~14% of the biologics market. While UAE with its active local companies is also picking up the pace, with biosimilars penetration reached up to 5% of biologics market in 2016.

**Contribution of biosimilars to the selected biologic molecule sales in MENA – 2016**

*includes only biologic products where biosimilar competition has occurred i.e., filgrastim, erythropoeitin, somatropin & Infliximab*

- **Sandoz and Pfizer currently available**
  - Regulatory framework based on FDA/EMA approval making it difficult for local players

- **Driven by Julphar EPO and Lilly’s Abasaglar**
  - Regulatory framework similar to KSA

<table>
<thead>
<tr>
<th></th>
<th>MENA</th>
<th>KSA</th>
<th>UAE</th>
<th>Egypt</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Biosimilar</strong></td>
<td>5.03%</td>
<td>0.05%</td>
<td>5.41%</td>
<td>13.56%</td>
</tr>
<tr>
<td><strong>Biologic</strong></td>
<td>94.97%</td>
<td>99.95%</td>
<td>94.59%</td>
<td>86.44%</td>
</tr>
</tbody>
</table>

Source: QI MIDAS/Local Data 2016, Kuwait & Jordan – No biosimilar currently available, Algeria no data available

Clearly, publicly funded healthcare archetype countries such as the MEA are always wary of their spending capacity compared to that of developed markets. Thus, pricing is always a key proposition to make or break a brand in these markets.

In the MEA, the majority of markets and their healthcare systems are price conscious. For instance, most of the markets in the MEA have scheduled phased price cuts on essential drugs as a cost-containment measure and to improve affordability. Furthermore, the economic turmoil related to oil price adds more pressure on healthcare systems such as those in KSA and the UAE to contain costs.
Hence, biosimilars, as an alternative to expensive biologics, should find themselves better placed for adoption after the biologic’s patent expires.

Depending on the channel of negotiation, biosimilars can cost 30–50% lesser compared to the originator biologic, in fact, in some markets such as Lebanon and Egypt, the difference may go up to 70–80% especially for Erythropoetin and filgrastim biosimilar; Infliximab biosimilar cost around 30–40% less than originator. This price difference can definitely work as an inflection point for biosimilars, as KOLs opine that price difference of >40% from biologics, can influence their decision to use biosimilars.

Hence, along with guidelines development, pricing will stay as a key driver to biosimilar growth in the MEA.

**Price is a major driver for biosimilar adoption as the biosimilars cost ~50% less than the original biologics in the MEA. This is in sharp contrast to markets such as the EU which see ~25%–30% discount in biosimilar prices. The price difference between original biologics and biosimilars range from 30% to 85% in Egypt, Lebanon, and South Africa, with the highest difference seen in Lebanon (Figure 8).**

*Figure 8: Price difference between biologics and biosimilars in US$/SU*
Country Archetypes

Several companies from across the globe are looking at countries in the MEA for lucrative opportunities in biosimilars.

The regulatory guidelines and biosimilar experience in terms of price negotiations and acceptance in some MEA countries is driving the uptake of biosimilars making them more attractive than other countries. A comparison of a country’s biosimilar readiness and the biosimilar opportunity will help identify the top MEA countries where biosimilar companies can prioritize their entry.

QuintilesIMS conducted an analysis which compared the biosimilar readiness of a country with the biosimilar opportunity (Figure 9). Based on the analysis, three tiers of opportunities in the MEA were identified.

Figure 9

Prioritisation framework - for guidance only

Tier 3 countries
Tier 1 countries
Tier 2 countries

Low
Moderate
High

Biosimilar opportunity

Source: QuintilesIMS Analysis
**Shaping the Biosimilars Opportunity in MEA**

**Tier 1 countries: Countries with sizeable or potential biosimilar opportunities**  
**Algeria, KSA, South Africa, Egypt, and Morocco**

These countries have developed their own regulatory guidelines and are ready to approve biosimilars. The presence of biosimilars and the infrastructure to develop them allows companies to develop and launch biosimilars in these countries.

Although the underlying regulatory dynamics are positive, companies wanting to enter these markets may face a few challenges in conducting clinical trials, getting regulatory approvals, and promoting and marketing them. However, these countries act as a good starting point for short-term prospects.

**Tier 2 countries: Countries with moderate potential**  
**Tunisia, Jordan, and the UAE**

These countries do not have a regulatory guidance system for biosimilars in place and initiatives are required to shape and accelerate regulatory support. The companies will have to look at these countries as growing opportunities and prepare to face regulatory delays in approvals and launches. In addition, companies may face delays in biosimilar acceptance and sales.

**Tier 3 countries: Countries with lower potential**  
**Kuwait and Lebanon**

These markets have lower opportunities and also do not have regulations for biosimilars in place and companies can expect minimal support from regulatory agencies. Companies which are looking at long-term gains and creation of markets in these countries may enter with limited expectations of immediate gains.

**Based on the biosimilar potential, tier 1 countries could be the focus countries for companies planning to enter the biosimilar market in the immediate future.**
**Business Models to Enter the MEA Biosimilars Market**

Market entry and a sound commercial business model are other important characteristics that will impact individual market adoption and share of biosimilars. Hence, companies need a defined and robust business model to tap the biosimilar potential in the MEA.

Prerequisites for success of biosimilars in the priority markets of the MEA depends on the speed at which companies can enter the space. There are several vital strategies that the companies will need to implement to achieve success in biosimilar sales (Figure 10).

Figure 10

To demonstrate a strong presence in the MEA biosimilars market, companies will have to enter the market quickly with an active involvement throughout the value chain and a holistic approach from a multi-stakeholder engagement.

**Clinical development/ Real data generation:** The agreements with local companies may incur costs for clinical trials and molecule development and royalties. Conducting clinical trials in the MEA countries may be less expensive than in the developed countries and could help generate real world data which could be instrumental in generating awareness and uptake.

*Example: Sandoz (Zarxio) has done a hospital based trial in KSA which has allowed them to generate real world data as well as accelerate their time to market*
Business Models to Enter the MEA Biosimilars Market

**Manufacturing:** Manufacturing can either be conducted locally or raw materials may be imported from other countries.

Localization of manufacturing might be an area to explore. The agreement can either be for the manufacturing of biosimilars or for the construction of a manufacturing facility. This model will enable companies to leverage the advantages of low-cost manufacturing in local areas.

*Example:* Local manufacturing (secondary packaging) of some biologics is already happening with examples such as Herceptin and Mabthera from Roche manufactured by Spimaco in KSA or Al Misr in Egypt. Another example is Hikma’s recent acquisition of EIMC United Pharmaceuticals in Egypt.

This could be an area to explore, especially in GCC and Algeria where stronger push to localization is happening.

**Regulatory and market access:** The MEA market has an underdeveloped regulatory system which may take up to 12–18 months for regulatory approval and authorization of generics. This is expected to be further delayed for biosimilars, where development complexity is even higher. Moreover, certain market access decisions are fragmented from national to regional and local levels (e.g. KSA), further delaying drug access and reimbursement. Hence, companies need to align with healthcare systems earlier than the standard drug development value chain in order to accelerate their time to market. In addition, local partnerships with local manufacturers can provide MNCs a definitive edge in terms of time to market.

Sometimes, agreements with local/regional players might also help to ease the entry into the biosimilars market.

*Example:* Hikma and Celltrion signed a partnership in which Hikma will have the exclusive rights to market and distribute nine Celltrion biosimilars throughout the MEA region.

**Sales and marketing:** Given the complexity of biosimilars and their use in specialty indications, it is imperative to bring the technical aspects into marketing tools to gain trust among healthcare stakeholders. Companies need to blend their commercial and technical capabilities to design effective marketing and sales strategy for biosimilars.
A multi-stakeholder engagement is required to ensure alignment and garner a strong competitive advantage (Figure 12).

**Figure 12: Key stakeholders for the launch of biosimilars in a new market**

| Payer / Government | • Establish clear pathways for regulatory process  
|                    | • Ensure safety and clinical efficacy  
|                    | • Provide attractive incentives for local and multi-national players |
| Physician          | • Need to build learning curve on biosimilars  
|                    | • Provide incentives such as higher reimbursement for appropriate biosimilar use, could drive adoption |
| Aspiring player    | • Competitive intelligence/benchmark on biologics and biosimilars for high upfront investments in emerging markets  
|                    | • Must take into consideration capabilities & experience of emerging market players  
|                    | • Tailor customized go-to market strategies for different markets  
|                    | • Have to find the right balance between pricing to drive uptake and pricing profitability  
|                    | • Effective sales communication to the scientific community  
|                    | • Effective market activities for commercialization of biosimilars |
| Originator         | • With increasing number of biologics going off-patent, more companies are expected to enter biosimilar space  
|                    | • Originators prepare themselves for the upcoming competition, via strengthening capabilities and engagement with key stakeholders |

In countries where the health expenditure is borne by the state, individual or insurance companies, having a strong relationship with the payers is imperative for quick uptake of biosimilars. Pharma companies may need to competitively price their products and give adequate discounts on par with expectations of payers to launch biosimilars quickly.

Since the MEA market is still ingenuous to biosimilars, providing educational support to physicians is a must-do for pharma companies. Promotional activities such as incentives and learning programs can drive the adoption of biosimilars.

All aspiring biosimilar companies will have to follow innovative and customized marketing strategies to enter into the specific MEA markets. Inventive communication strategies for patients and scientific communities and market activities for commercialization of biosimilars are necessary.

With the growing interest in biosimilars, originator companies are also trying to make a mark in the field of biosimilars. With their experience, capabilities, and vast presence in the markets, these companies have a strong advantage while entering the biosimilar space.

Companies entering the growing field of biosimilars in the MEA markets will need to keep in mind the competitors, regulatory pathways and processes, as well as market sentiments to achieve success in biosimilar launch.
Conclusions

The current biosimilar environment is promising and the market continues to expand. Opportunities for biosimilar growth is expected to increase in the near future with patent expiry of high-cost biologics. Furthermore, as the cost of originator biologics puts a strain on the payers and governments, regulatory bodies are now open to accept biosimilars as cost-effective substitutes for biologics. High entry barriers and associated financial risks will make the biosimilar competitive landscape less crowded as compared to the generic market. This is an added advantage for companies looking to cater to a niche market segment.

However, there are several obstacles to the growth of biosimilars. The biosimilar market is still in the nascent stages in several MEA countries. Emerging markets lack a well-defined regulatory framework to allow quick biosimilar approvals. This creates confusion among domestic and foreign biosimilar developers. In addition, foreign companies find it very challenging to directly launch biosimilars in these markets. Finally, KOLs are hesitant to try biosimilars due to concerns over safety and efficacy and might tend to limit it to new patients only.

**Regulatory guidelines and cost-containment measures are key to fuel the growth of biosimilars and there will be further growth if biosimilar usage is commoditized.**
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A special thanks to our colleagues for their support in this article:

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**Editorial:** Hemalata Krishnan, Parima Desai and Suraj Prasad

**Design:** Vijay Shankar, Krishnakumar Thenkrushi, Raghavendra Prasad K.S, Balaji P
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