White Paper

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Realizing Biosimilar Potential in the Middle East & Africa

The Middle East and Africa Perspective White paper

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Introduction

In the current decade, there has been a rapid and significant progress in healthcare management options and technologies. This progress has been driven by several factors, such as a growing population, increased life expectancy, improved diagnostic capabilities, an increasing number of patients with chronic and life-threatening diseases, rapid advancements in translation research and payer focus on reduction in healthcare costs while ensuring treatment effectiveness.

The improvements in molecular diagnostics for clinical purposes has led to a shift from traditional medicines to personalized/targeted therapies using advanced technology. This has further led to an uptake of biologics-based therapies in the current treatment paradigm. Biologics 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 focus of this report. Other products derived from biological sources, such as gene therapy, somatic cells, tissues, and vaccines, are beyond the scope of this report.

Since their inception, biologics have been viewed as a prospect for differentiated care, generating more treatment options for stakeholders and bringing a 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. Biosimilars are legally approved subsequent versions of innovator biologic products that have identical primary structures and comparable higher protein structures of their reference biologic. They must be similar in aspects, such as quality, pre-clinical and clinical outcomes. The principle of biosimilar development is based on reverse-engineering of marketed biologic molecule.

Regulatory bodies perform a rigorous clinical and analytical assessment of these products before granting marketing approval. Biosimilars are comparable to their reference products; they give similar results at a relatively lower cost (10-30% below reference product) and present an interesting value proposition for all the stakeholders of the healthcare systems.

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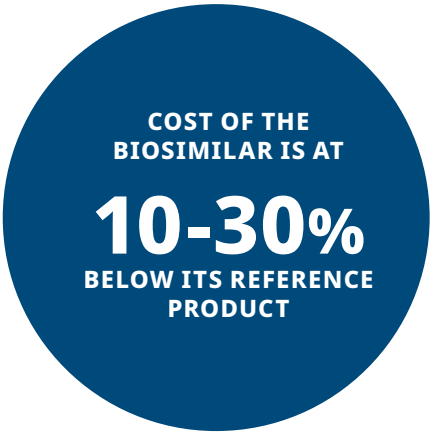


Market practicalities differ from theoretical expectations, making it difficult to estimate the true potential of biosimilar products. This is more challenging particularly for emerging markets such as the Middle East and Africa (MEA), where developing healthcare systems, country specificities, inconsistent regulations, clinical and treatment pathways and low awareness among stakeholders make it difficult for biosimilar products to realize their full potential.

The purpose of this report is to understand the biologics market dynamics in the MEA market and the impact of biosimilars introduction. This paper will build on a similar whitepaper published by IQVIA in 2017, along with a view on the evolution of the biosimilars landscape in general over the past three years.

The report is based on independent research and analysis undertaken by IQVIA and draws on the analysis of trends from developed markets such as the US and Europe. This whitepaper, however, is focusing specifically on countries in the MEA region over the last few years and drawing observations from these markets in terms of biologics maturity and biosimilars emergence.

MEA COUNTRIES FOCUSED IN THIS WHITEPAPER INCLUDE THE FOLLOWING:

Middle East: Egypt, Jordan, KSA, Kuwait, Lebanon, UAE

Africa: Algeria, South Africa, Tunisia, Morocco

Data Period: up to MAT Q4 2019

Executive summary

Globally, the EMA region has been the most proactive and an early adopter of biosimilars since 2006. About 58 biosimilars were approved in the EU until February 2020.

Both EU5 and the Nordics, including Finland, Sweden and Norway, have shown a very high penetration of biosimilars. The US, Canada, Japan and APAC are yet to adopt biosimilars to match EU levels as a result of the delay in introducing incentivizing policies to facilitate biosimilar uptake in those countries.

In 2019, the global biologics market was valued at nearly $360 billion in sales, with biosimilars accounting for approximately 3.5% share of this market in value, with a growth of approximately by 80% CAGR over the last 4 years (2015-2019).

Examples of different biosimilars driving the market in terms of value include Humira biosimilars: Amgevita and Imraldi; Remicade biosimilars: Inflectra and Remsima; Enbrel biosimilars: Benepali and Erelzi; and Lantus Biosimilars: Abasaglar and Basalog

Those products have gained market share from their original counterparts in recent years:

- Amgevita, Imraldi and Hyrimoz together now have approximately 6% market share of the adalimumab market
- Inflectra and Remsima together now have approximately 24% market share of the infliximab market
- Benepali and Erelzi together now have approximately 16% market share of the etanercept market
- Abasaglar and Basalog now have 9% market share of the insulin glargine market

Overall, a high penetration trend is still anticipated to continue for biosimilars with multiple blockbuster reference biologics facing loss of exclusivity soon, such as trastuzumab and bevacizumab in oncology. Trastuzumab biosimilar was recently launched in 2019 in France, Italy and Spain and additional biosimilars for reference drugs (such as ranibizumab, golimumab, aflibercept, etc.) are expected to be launched within this decade.

In 2019, the global biologics market was valued at nearly $360 billion in sales, with biosimilars accounting for approximately 3.5% share of this market in value, with a growth of approximately 80% over the last 4 years (2015-2019).

In contrast, the MEA market is still considered nascent in terms of biosimilar adoption and emerges as an attractive region with opportunities for biosimilars, considering recent evolution of biologic sales.

Achieving success in the biosimilar space requires a different approach compared to traditional generics. Regulatory framework, guidelines and pricing have been challenging because stakeholders (including regulatory agencies, payers and prescribers) demand additional level of evidence to approve the use of biosimilars and to provide evidence for interchangeability of biosimilars, often resulting in delayed approvals. These characteristics are likely to impact biosimilar adoption in the MEA region.

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 benefit of biosimilars relative to their reference biologics, so that the perceived value of these biosimilars is not limited to their price.

Biologics: An integral subset of the market

2020-2030 will mark a momentous evolution in the global healthcare arena with an increase in biologics adoption in several therapy areas and the rise of biosimilars

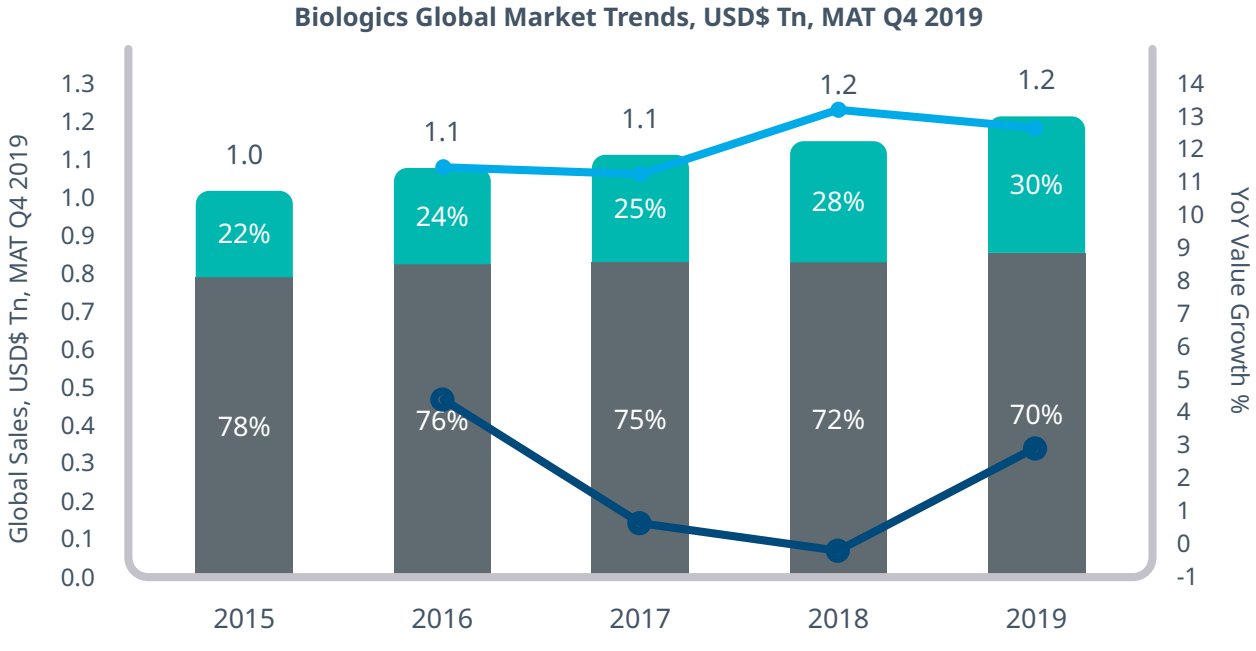
The Global Biologic Market

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. As a result, the market for biologics has expanded and now accounts for 30% of the total pharmaceutical market. The clinical benefits of biologics helped them become the treatment of choice in multiple therapy areas (such as oncology, rheumatology, neurology, etc.). Some biologics are approved in multiple indications in the same therapy area, while others are approved for indications in more than one therapy area, such as adalimumab and alemtuzumab.

Small molecules still lead the pharmaceutical market globally in value. However, their growth has stagnated since 2015 due to increased generic penetration and pricing pressure.

At the same time, biologics have registered an impressive growth rate of 12.1% CAGR between 2015 and 2019 (Figure 1), making them an indispensable component of the global pharmaceutical market.

Figure 1: Global Market Trends (Biologics vs Non-biologics)

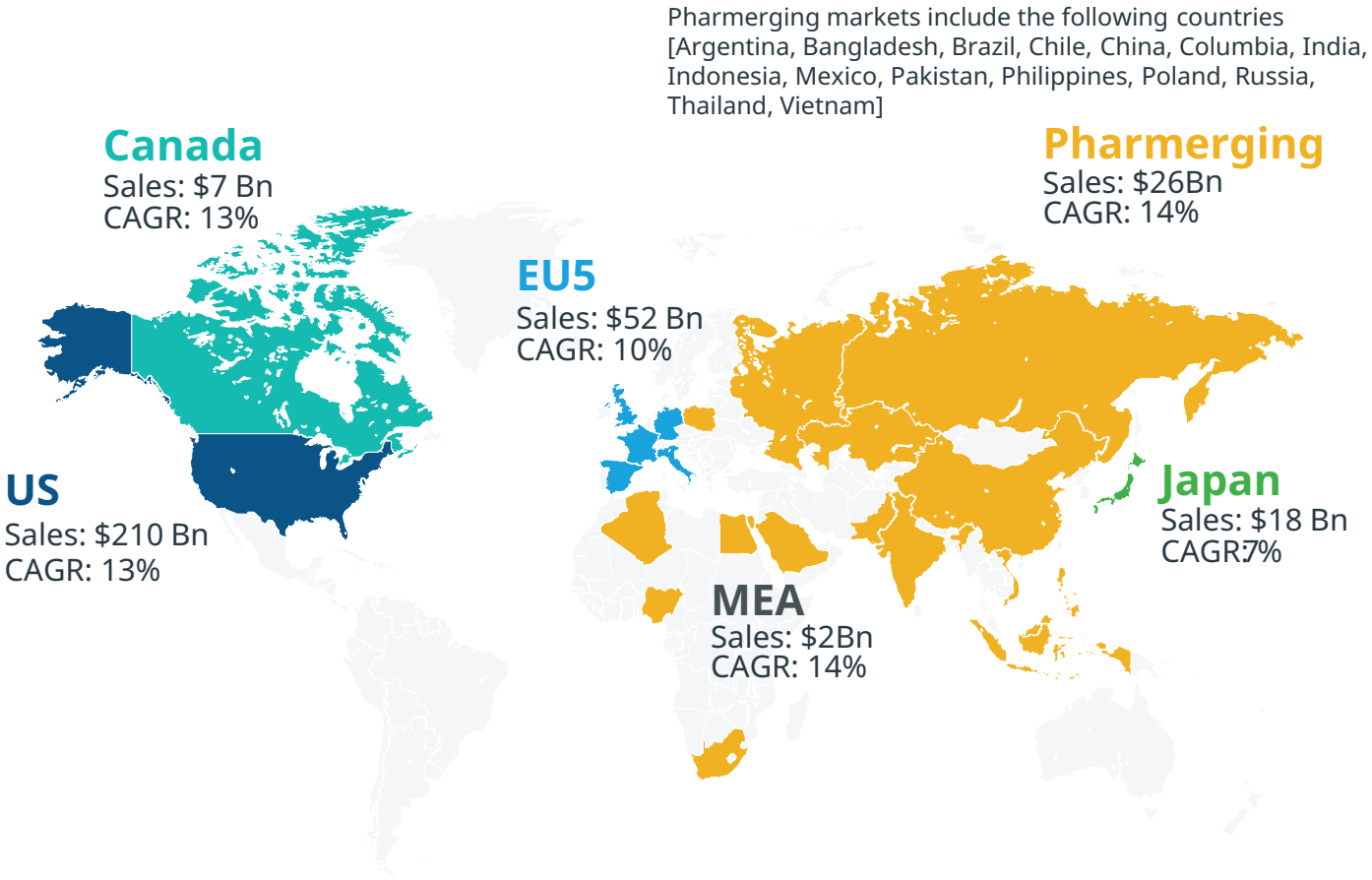


Segment	Value CAGR% ('15-'19)
Biologic Sales	12.1%
Non-biologics/SM sales	2%

There have been several biologics launches, including Keytruda (launched in Canada, USA and EU5 in 2015, across Emerging Markets starting 2016 and Japan in 2017) and Opdivo (launched in EU5, Japan and USA in 2015, Emerging markets and Canada in 2016).

Currently, the US, followed by the EU5, has the highest sales of overall biologics and biosimilars. The US dominates the market with $210 billion sales, growing at 13% in the past 5 years; the EU5 trails with $52 billion in sales, at 10% CAGR (15-19); and Japan's total sales add up to nearly $18 billion, at 7% CAGR (15-19). The Pharmerging markets have collectively grown at 14% CAGR (15-19) to reach $26 billion in the past 5 years. This growth has been influenced by numerous biologic launches, improved stakeholders' awareness and an increase in per capita pharmaceutical spending.

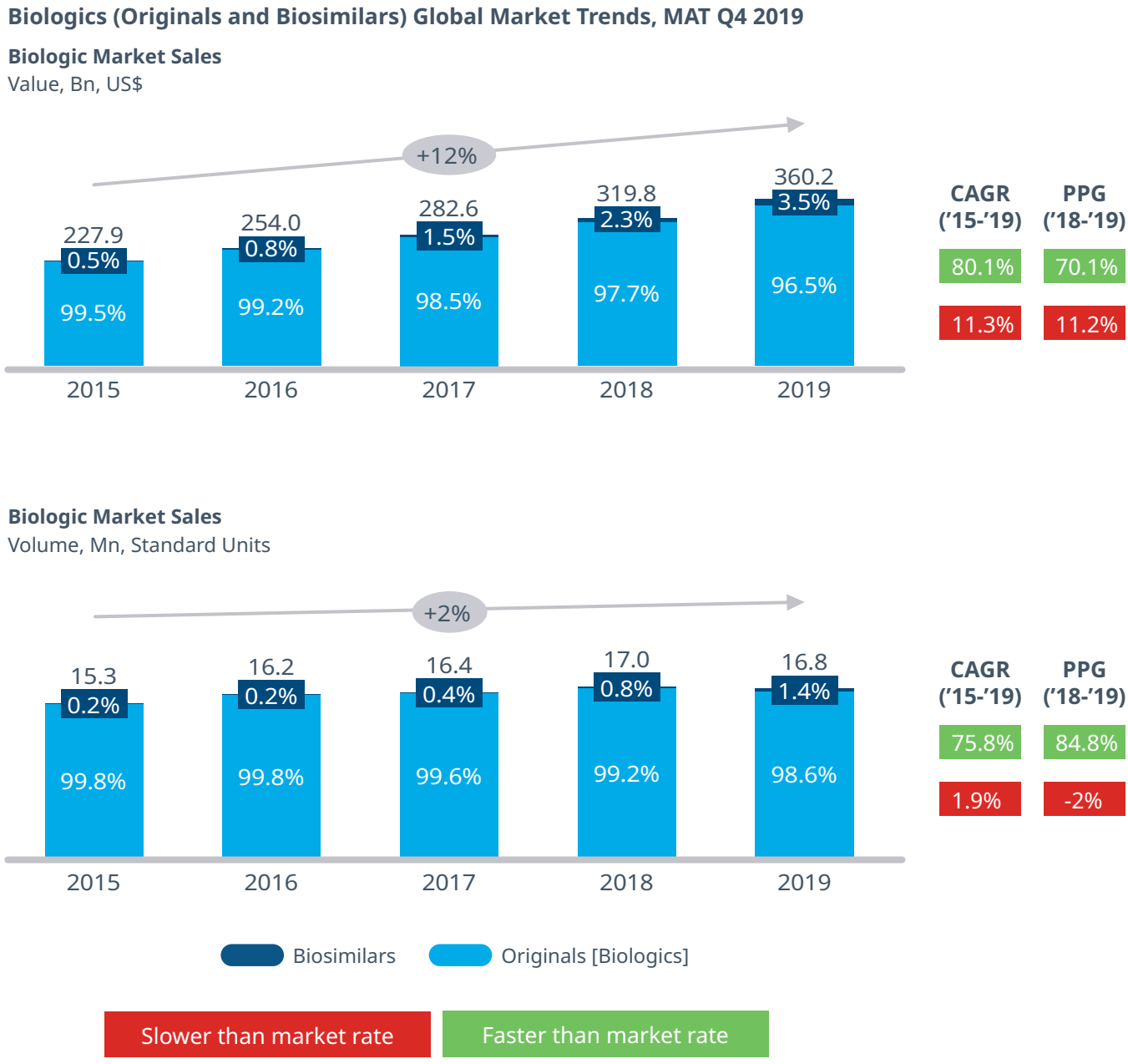
Figure 2: Global biologics sales in major regions (IQVIA MIDAS, MAT Q4 2019)



The overall global biologic market (inclusive of innovator biologics and biosimilar) is valued at $360 billion and 16.8 million Standard Units in 2019 (IQVIA MIDAS FY 2019 data). Innovator products comprise 96.5% of the value share and 98.6% of the volume share, yet biosimilars have grown at a staggering CAGR of 148.5% in value terms.

This was mainly driven by the introduction of biosimilars of Humira, Remicade, Lantus, Enbrel and Neupogen in most geographies.

Figure 3: Biologics market by Value and Volume (IQVIA MIDAS MAT Q4 2019)



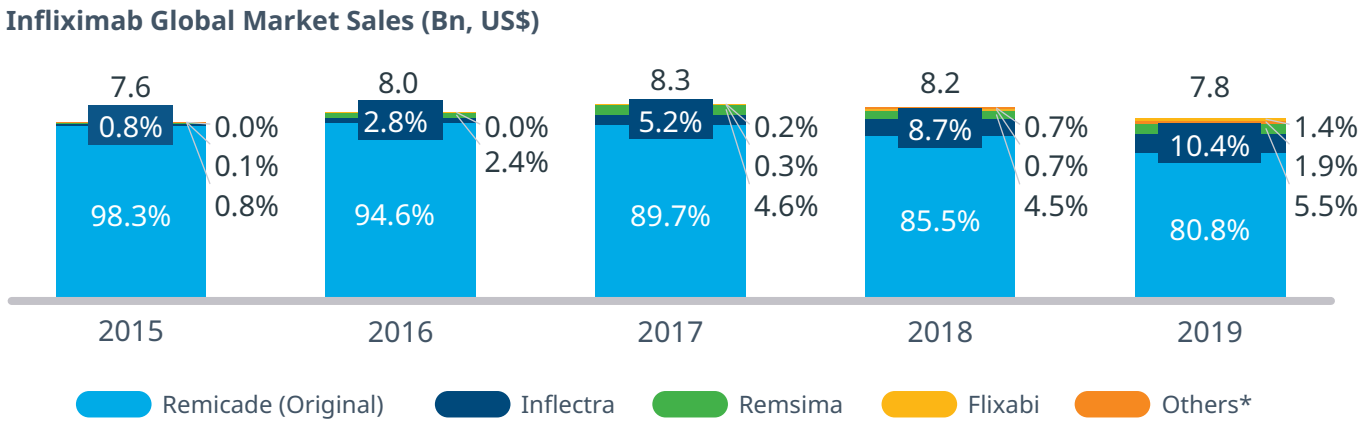
Multiple blockbuster biologics lost their one exclusivity before 2020 and already have approved biosimilars, some of which have been launched. These include rituximab, trastuzumab, adalimumab, and infliximab. Some of the other blockbusters and mainstay treatments are also set to lose their one exclusivity this decade, including molecules such as ustekinumab, denosumab, ipilimumab and certolizumab pegol.

Case study: Global infliximab market

Let us consider infliximab biosimilars such as Inflectra, Remsima case for global launches. Since its first launch in 2015, there has been constant erosion of Remicade's share. In 2016, Remicade accounted for 95% of the overall market, yet, by 2019, its share had decreased to nearly 80% (Figure 4). The most successful biosimilar of Remicade is Inflectra, which accounted for nearly 10% of the infliximab market in 2019. Biosimilar launch prices are always below the innovator and decrease steadily after the launch. For example, by 2019, in Canada and the Nordics, the prices of Remsima and other biosimilars were approximately ~40% lower than that of the innovator product, Remicade. This price difference has been a key factor in the adoption of infliximab's biosimilars.

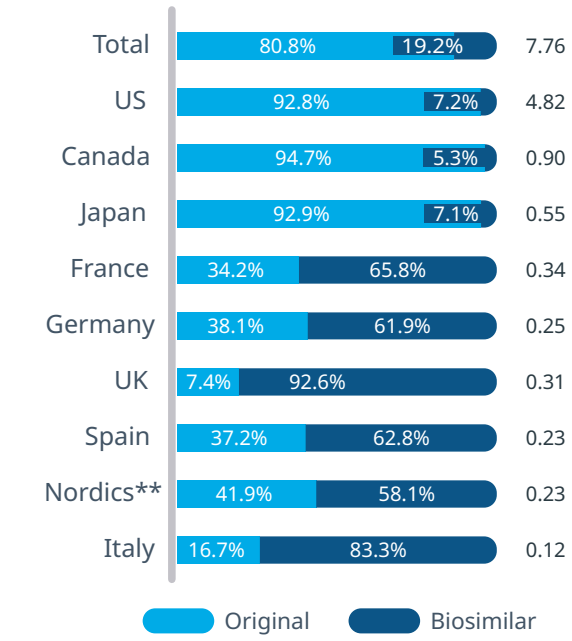
Although infliximab biosimilars were launched around the same time in developed markets, the EU5 and Nordics have shown greater receptivity towards incorporating these products into their health systems, while Japan, Canada and USA still lag in the trend. For example, in the UK, infliximab biosimilars represent more than 90% of the infliximab market while they represent ~62% in Germany & ~60% in Nordics (Figure 5). This is due to the fact that NHS in England has set a target of 80% penetration within the biosimilar's first year of introduction. In 2019, Germany introduced a new legislation to encourage greater pharmacy-level substitution for biological drugs. As a result, sales erosion is variable and could largely be ascribed to payer/government initiatives and pricing dynamics. Likewise, in Denmark, biosimilars approved by the EMA based on reference originator biologics are automatically considered to be interchangeable and there is a mandate to switch to the lowest cost medicine.

Figure 4: Infliximab global market share



* Others include local / regional biosimilars launched

Figure 5: Infliximab biosimilar penetration and price comparison between launch and in 2019



** Nordics include Sweden, Finland and Norway

PRICE OF BIOSIMILAR SIMILAR TO PRICE OF ORIGINAL

As mentioned earlier, biosimilars are usually launched at prices lower than their original counterparts. Taking a closer look at countries where infliximab biosimilars are launched, price differences between biosimilars and originals range from 3% less in France to 45% less in Nordic countries. (Figure 6)

In 2019, we can also see major price differences between biosimilars and originals ranging from 11% less in Italy to 48% less in Nordic countries.

Pricing dynamics in France and Spain, however, differ in this year, where we see no price difference between biosimilars and originals. In both countries, prices of originals have witnessed a drop to match biosimilar prices.

Figure 6: Infliximab original and biosimilar price comparison between launch and in 2019 (IQVIA MIDAS data)

Country	PRICE AT LAUNCH ($ PER STANDARD UNITS)			PRICE IN 2019 ($ PER STANDARD UNITS)		
	Original	Biosimilar	Biosimilar price % of discount versus original price	Original	Biosimilar	Biosimilar price % of discount versus original price
US	716	652	-9%	665	447	-33%
Canada	740	501	-32%	697	368	-47%
Japan	663	442	-33%	591	368	-38%
France	506	488	-3%	320	320	0%
Germany	723	643	-11%	275	197	-28%
UK	486	425	-13%	456	410	-10%
Spain	603	494	-18%	443	443	0%
Nordics	578	320	-45%	631	330	-48%
Italy	498	434	-13%	478	425	-11%

In some cases, we have considered prices at pack level to compare infliximab original prices and its respective biosimilars

Case study: Global insulin glargine market

Let us consider insulin glargine biosimilars such as Abasaglar and Basalog case for global launches. Abasaglar's share of the market has increased since its launch in 2016 from 1% to 18% share of market in 2019 (Figure 7). Basalog constitutes a negligible share of the market of less than 1% so far. Other biosimilars account for 2% share of market.

The insulin glargine biosimilars have seen a significant growth across the major focus countries over the past 3-4 years. Abasaglar is the leading biosimilar with 89% share of the global insulin glargine biosimilar market. The other important biosimilars present in different regions are Basalog (India), Simglee (EU & Australia), Glaritus (APAC), Glarzia (South Korea) Chang Xiu Lin (China) and Ringlar (Russia).

Regional level insulin glargine biosimilar market dynamics are as follows: (Figure 8)

1. US and Canada: Highest growth in biosimilars market since their launch in 2016. In Canada, sales almost doubled in 2019, showing the increase in the uptake of biosimilars
2. EU5: Germany and France contribute to 60% of the biosimilar market; France has seen 53% PPG; and the UK has seen 34% PPG, indicating the increase in demand for biosimilars in those countries
3. LATAM: Brazil contributes to 50% of the biosimilar market with a growth of 187% in the last two years
4. APAC: Among major biosimilar revenue-generating countries, Japan has witnessed the highest growth of 63% CAGR in the last 4 years

Figure 7: Insulin Glargine global market share

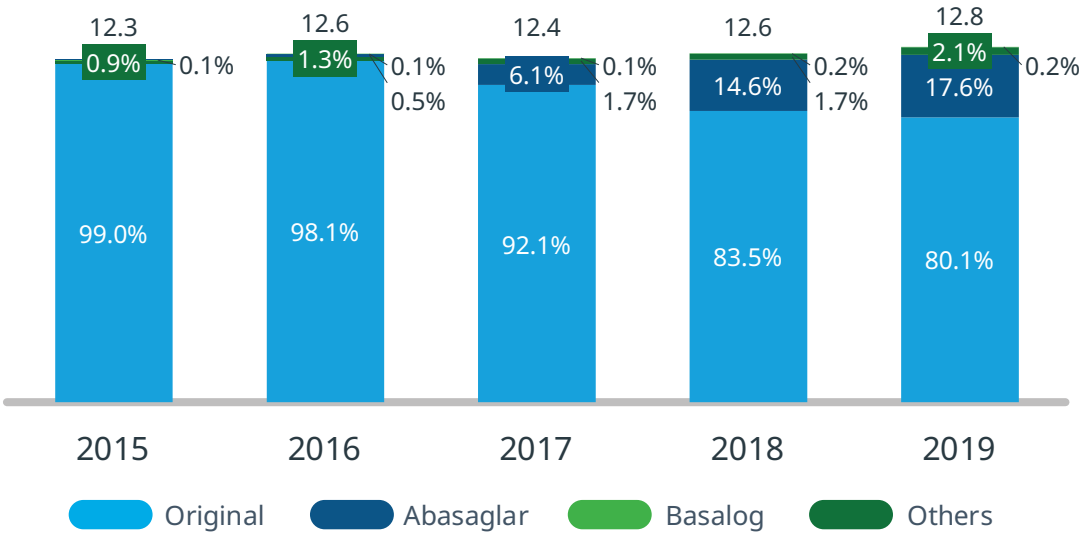
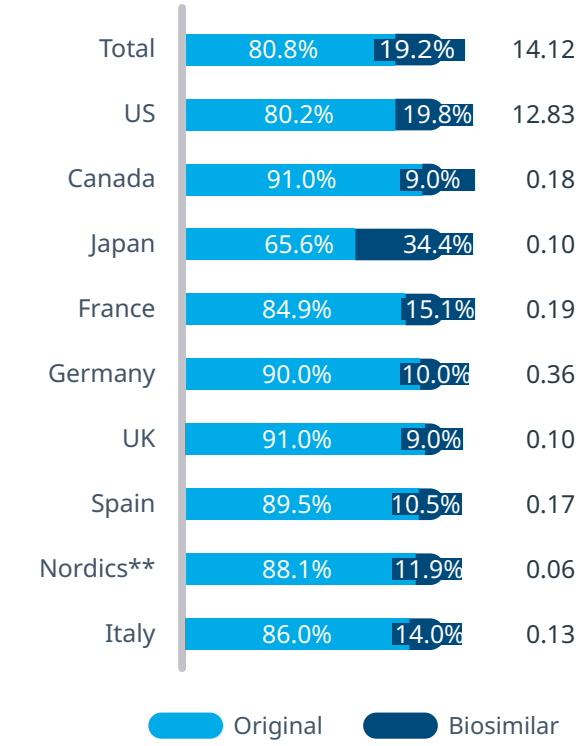


Figure 8: Insulin Glargine biosimilar penetration and price comparison between launch and in 2019



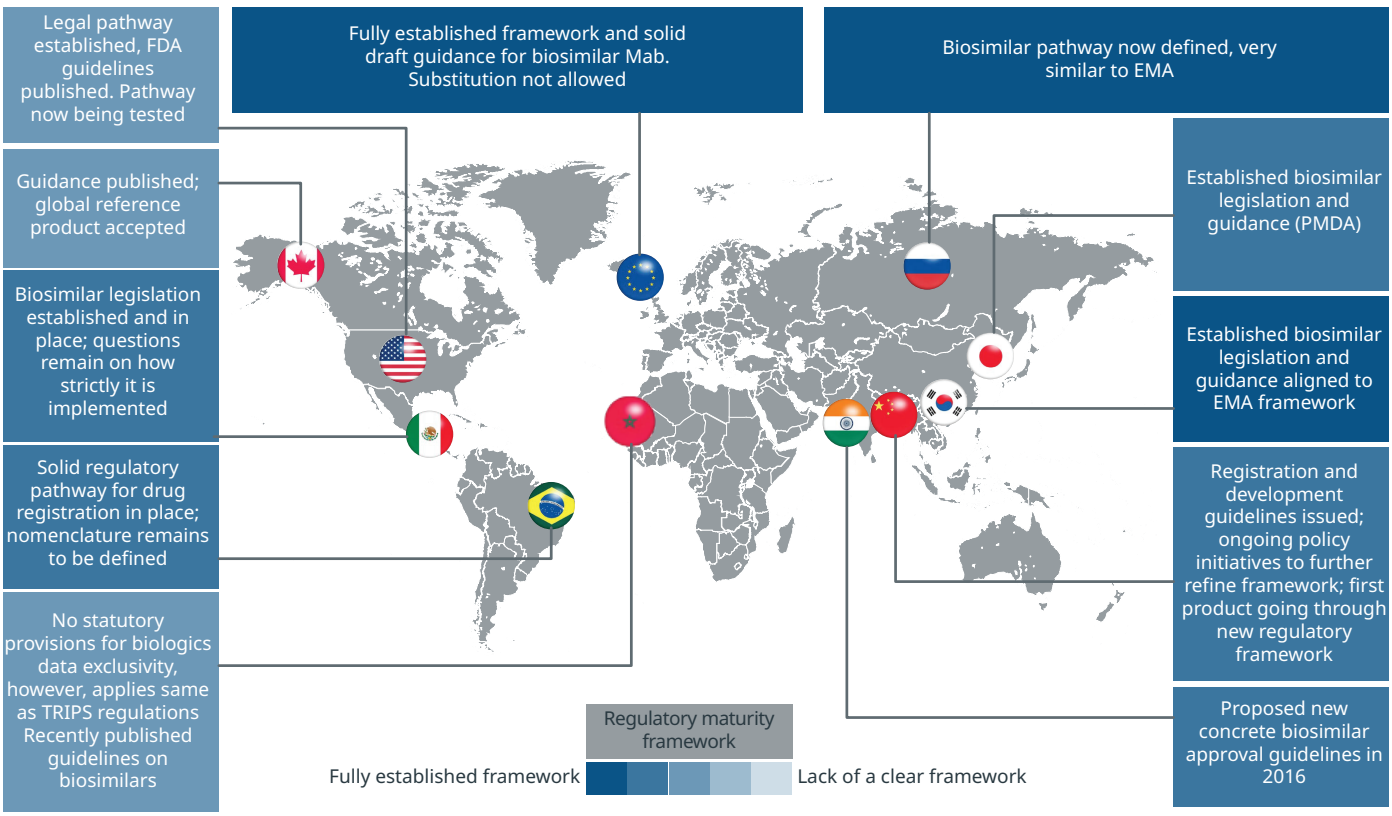
"Biologics represent an increasingly common treatment option and make up 40 percent of American drug spending, competition from biosimilars is desperately needed"

- Alex Azar (HHS Secretary, USA praised FDA's Biosimilars Action Plan in 2018)

Developing countries, such as India, Russia, Mexico, have also put in place regulatory guidelines to address the concerns related to biosimilars. The debate is shifting towards increasing regulatory feasibility for successful launches within the countries. (Figure 9)

Given the regulatory differences across borders and internal delays in implementation, there is a need for a regulatory convergence and harmonization at an international/regional scale to facilitate 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, and (3) where physicians are at the heart of decision-making, since they influence biosimilars' uptake and usage.

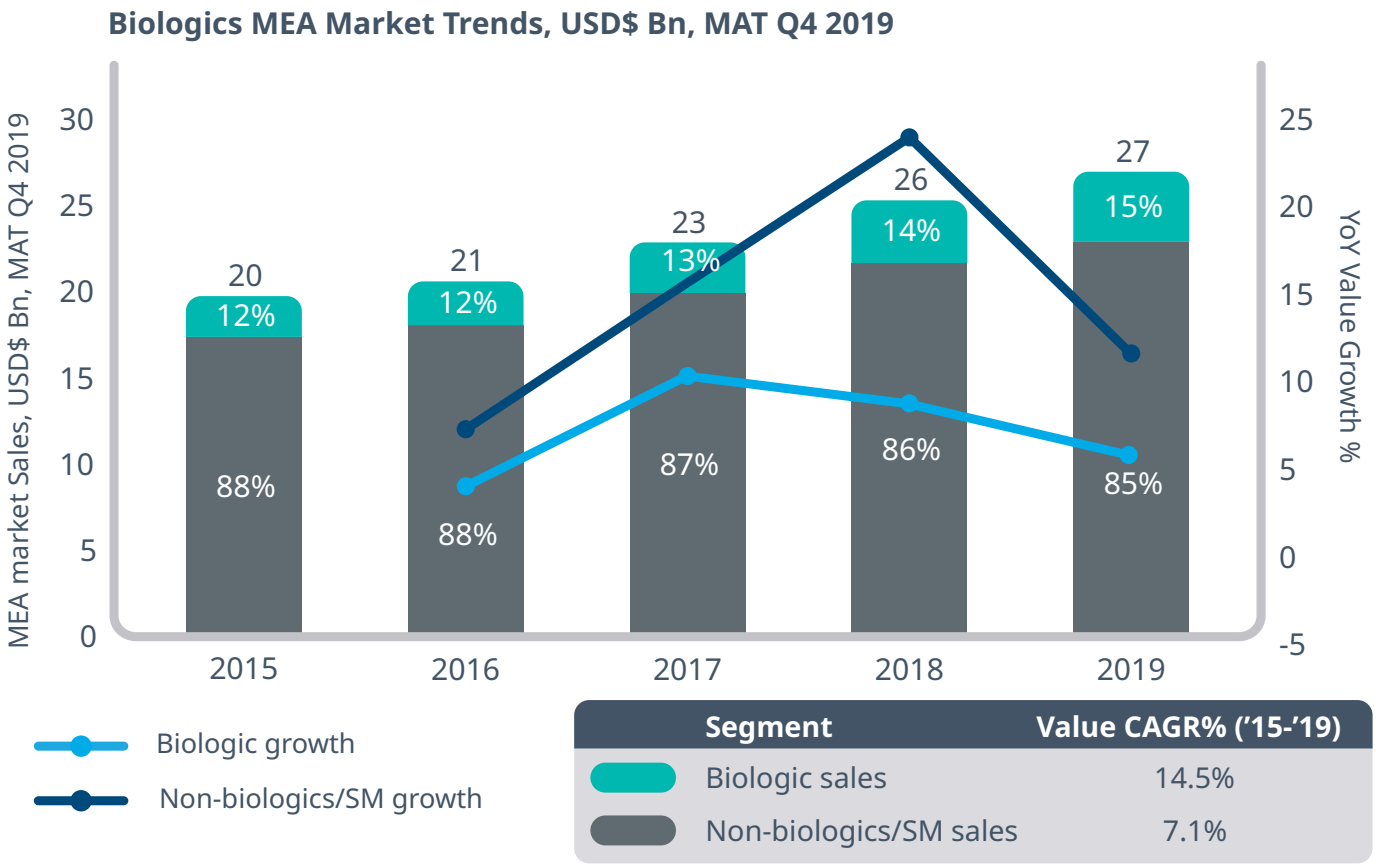
Figure 9: Regulatory maturity framework of select countries



Biologic and biosimilar landscape in the MEA

The MEA market shows similar trends to those found in the global market, with biologics' value share on the rise over the last few years, growing 14.5% annually from 2015 to 2019 to reach ~$4.1 billion (Figure 10). In 2019, Biologics accounted for nearly 15% of the total MEA pharmaceutical market (vs. 30% biologic share in the global market).

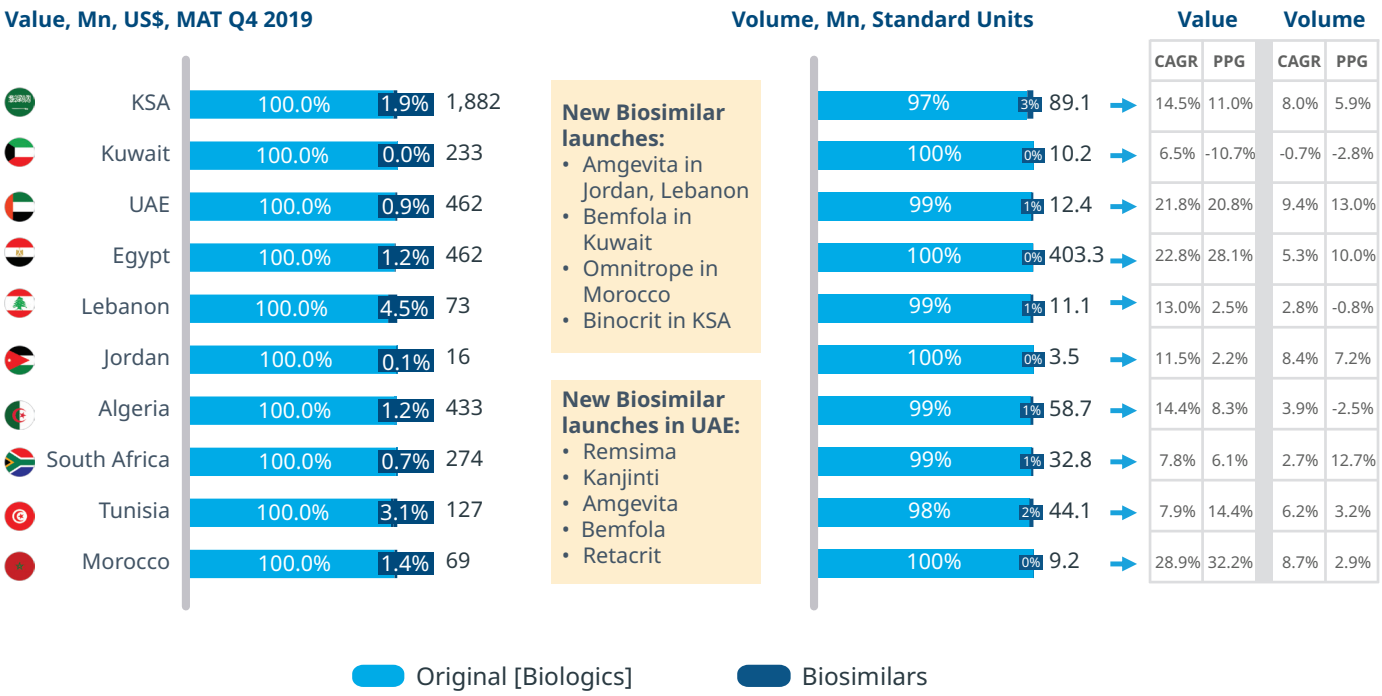
Figure 10: Total biologic market in MEA



Segment	Value CAGR% ('15-'19)
Biologic sales	14.5%
Non-biologics/SM sales	7.1%

Within the region, the KSA is the market leader accounting for more than $1.8 Bn sales followed by the UAE, Egypt and Algeria at nearly $450 Mn each (Figure 11). The UAE's and Egypt's biologic markets grew 20% annually, while Algeria grew at ~15%.

Figure 11: Biologics market sales in MEA



The region's biosimilar market is still in the nascent stage. making up a small share (2%) of the total biologics sales. The KSA is the largest biosimilar market that accounts for nearly $35 million.Egypt and the UAE follow at ~$6 million and ~$4 million respectively.

Products dominating the market in most of the regions include Amgevita, Nivestim, Abasaglar and Remsima, among others (Figure 12).

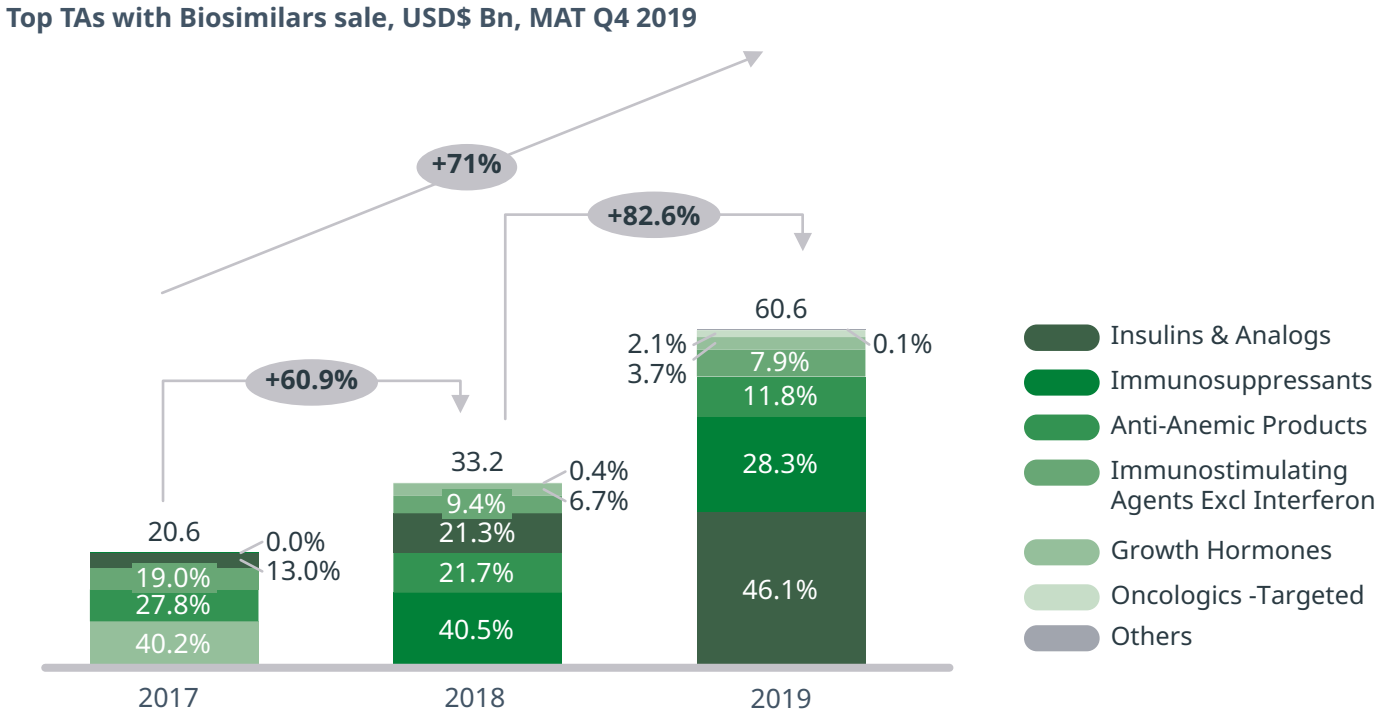
Compared to our 2017 report, we observe that the commercial environment of the MEA region is becoming more conducive for a strong uptake of Biosimilars, considering increased government focus on expanding patient access to medicines, budget constraints and availability of a regulatory framework.

Figure 12: Biosimilar launches in MEA

NEW BIOSIMILAR LAUNCHES IN THE REGION								
Jordan	**Lebanon**	**Kuwait**	**Morocco**	**Algeria**	**KSA**	**UAE**	**South Africa**	**Morocco**
Amgevita	Amgevita, Hyrimoz, Rixathon	Bemfola	Omnitrope	Abasaglar Canmab	Abasaglar, Binocrit, Remsima	Remsima, Kanjinti, Amgevita, Bemfola, Retacrit, Rixathon, Hyrimoz	Filgrastim, Ogivri	Nivestim, Remsima, Omnitrope

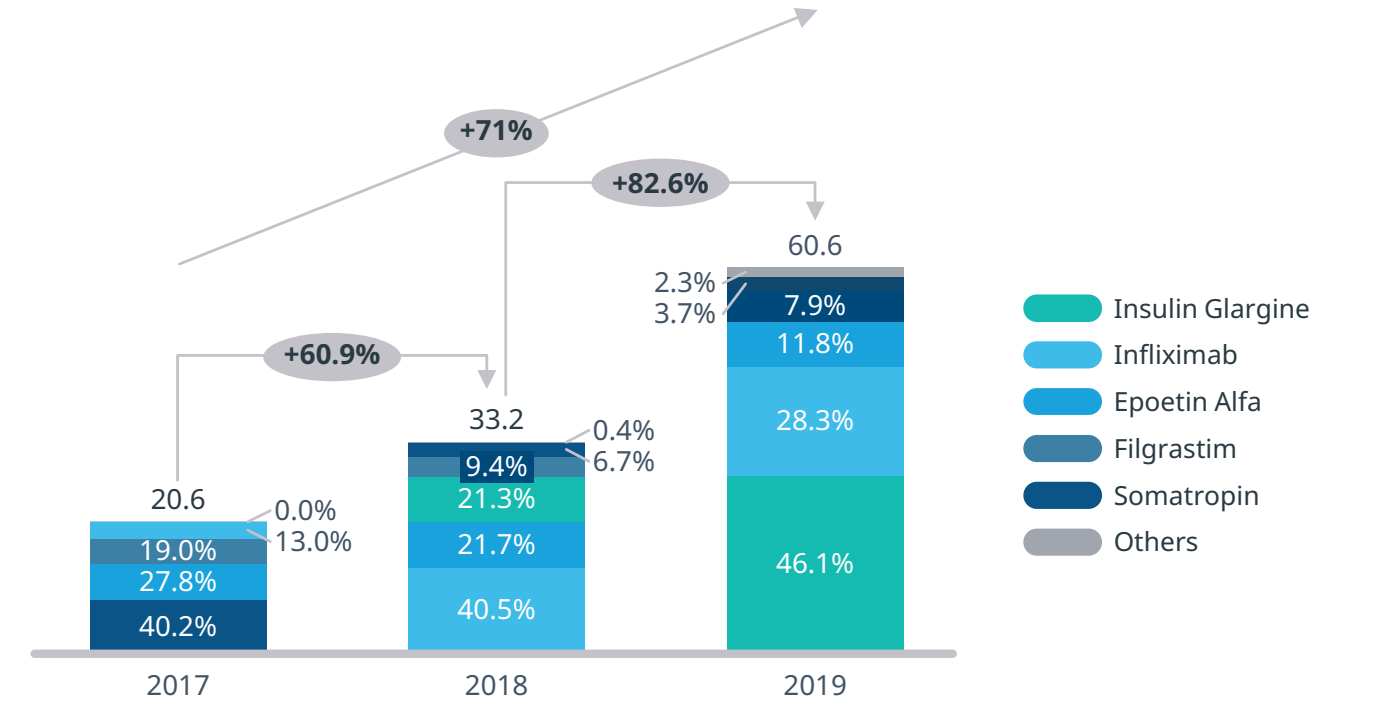
The top 3 therapeutic classes include Insulin, Immunosuppressants and Antianemia products (Epoetin Alfa) which contribute to nearly 86% of the biosimilar market. (Figure 13).

Figure 13: Top therapy areas for Biosimilars sale in MEA



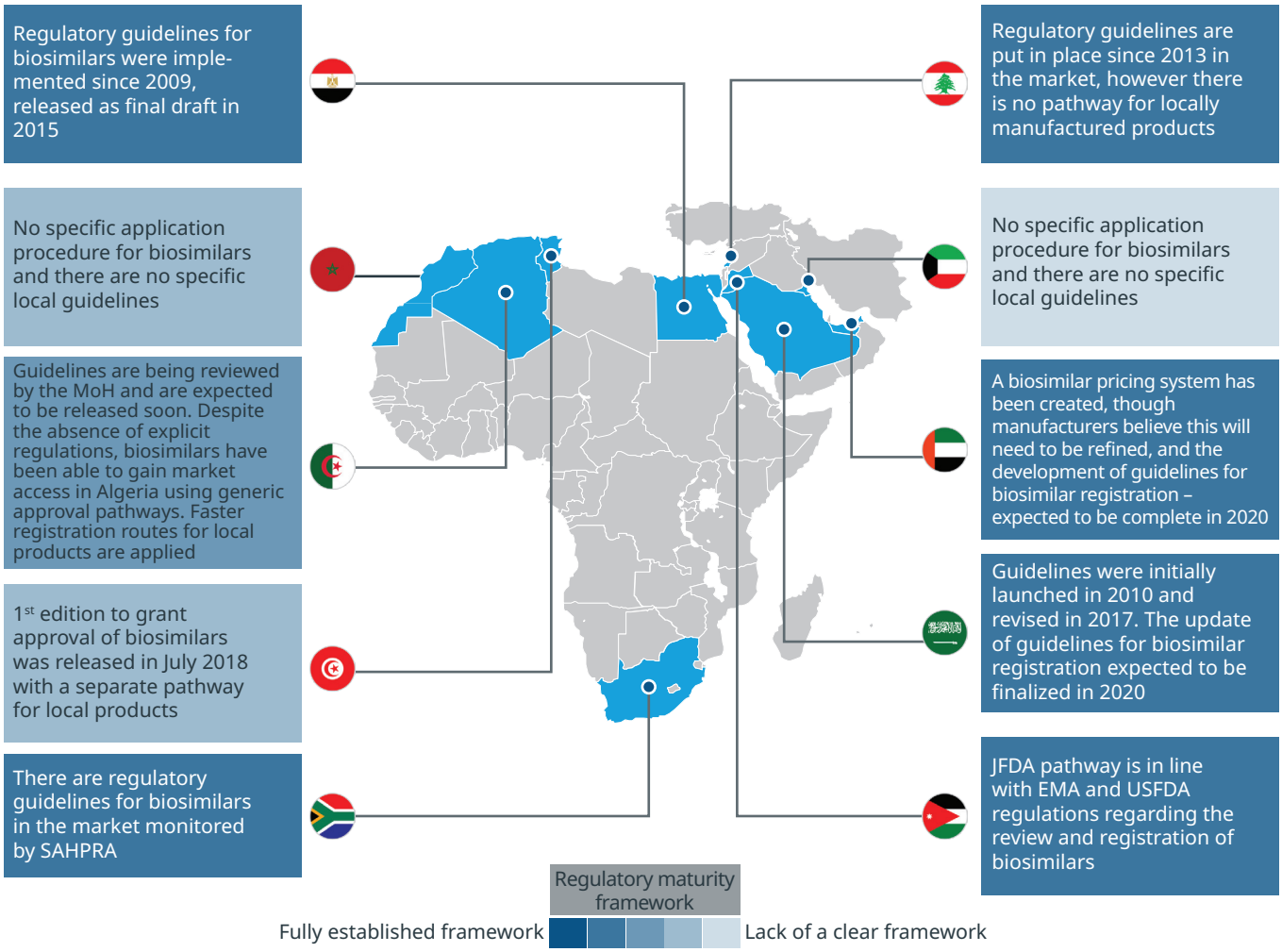
As of 2019, the top selling biosimilar molecules in the region were insulin glargine and infliximab, comprising nearly 75% of the market (Figure 14).

Figure 14: Top selling biosimilar products in MEA



Regulatory environment for biosimilars in MEA

Figure 15: Regulatory Maturity Framework of MEA countries



As far as regulations are concerned, most of the MEA countries have a well-defined regulatory apparatus in place for biosimilars.

Apart from co-commercialization and co-development nuances, the other market trends that exist in the MEA markets include ambiguity on pricing regulations and varying international references for local regulators (Figure 15). In general, MEA markets tend to follow both US FDA and EMA in setting regulations and guidelines (Figure 16).

Figure 16: MEA countries and their international reference bodies

NEW BIOSIMILAR LAUNCHES IN THE REGION								
KSA	UAE	Egypt	Lebanon	Jordan	Algeria	S Africa	Tunisia	Morocco
EMA FDA	EMA WHO	EMA WHO FDA	EMA FDA	EMA	EMA FDA	EMA FDA	EMA	WHO

WHO: World Health Organization | **FDA**: Food and Drug Administration | **EMA**: European Medicines Agency

In the majority of Middle Eastern and African countries, there are no specific pricing guidelines for biosimilars, they usually follow the generics pricing rule versus the originators.

Table 1: Biosimilar pricing regulations of MEA markets

				
In general, the pricing difference between biosimilars and originators ranges from 10% in KSA and Morocco up to 20% in Jordan, 30% in Algeria and a maximum of 40% observed in Egypt	In UAE, the MOHAP recently published pricing guidelines for biosimilars following different options including having 70% of the CIF price of the originator before any reductions or having the ex-factory price in the country of origin amongst other options	In Egypt, CAPA prices the first 5 biosimilars at 35% below the originator and subsequent biosimilars are priced at 40% below the originator	In South Africa, the price that a manufacturer can charge for a drug is based on a Single Exit Price (SEP) which is agreed between the applicant and the Pricing Committee of the Department of Health and published afterwards	In Lebanon, Kuwait and Tunisia, there are no specific guidelines for biosimilar pricing in products will follow pricing for generic products

Top companies in the MEA developing biosimilars

Pharma companies understand the ripe opportunity of biosimilars and are eyeing their place in the market.

There has been increased investment by local and regional companies in the biosimilar space considering the untapped opportunity. Examples include Spimaco in the KSA in partnership with Roche, Julphar in the UAE in partnership with Biocad, Sedico and Pharco in Egypt, Arwan and Benta in Lebanon, El Kendi in partnership with mAbxience in Algeria, Hikma in Algeria, Medis in Tunisia and Sothema in Morocco in partnership with Biocad. Hikma, in partnership with Celltrion, is to launch infliximab biosimilar in the main MEA markets.

Table 2: Biosimilars Activities Examples in MEA

AstraZeneca **Spimaco Addwaeih** **Roche**	• Roche signed an agreement with Spimaco; which will allow the latter to participate in the local manufacturing of biologics • AstraZeneca to work closely with SPIMACO starting Mid 2018 to deliver local manufacturing of AstraZeneca pharmaceutical products, leveraging added value through SPIMACO's manufacturing expertise to patients in the Kingdom • Alvogen submits a marketing authorization application for Teriparatide (PF708) to the Kingdom of Saudi Arabia Food and Drug Authority
Julphar	• Julphar is dominating the market of biosimilars with the stable growth that has been witnessed in recent years • Julphar partnered with Biocad and Health Authorities to register three leading specialized products to the UAE, which are indicated for breast cancer; B-cell non-Hodgkin's lymphoma, chronic lymphocytic leukemia, colon cancer, lung cancer and glioblastoma
Sedico **Pharco**	• SEDICO, one of the leading companies in Egypt, has been producing biosimilars at a lower cost for more than 6 years. Their biotechnology products include insulin, erythropoietin, streptokinase, angiokinase, follicle-stimulating hormone, aprotinin, Filgrastim, and Somatropin • Pharco has signed a deal with the government to build the first tumor factory - drugs will be produced in partnership with state-owned Holding Company for Biological Products and Vaccines (Vacsera) • The Saudi Authority for Industrial Cities and Technology Zones (MODON) has signed an industrial land lease with Egypt's Pharco Pharmaceuticals, covering more than 62 thousand square meters in the city of Madinah • The agreement was made to build a pharmaceutical complex including research and development centers, with a total investment reaching SR 570 million
BPI **Arwan**	• Benta is the first biotech facility in Lebanon for the production of biosimilars. It launched Epotex and Neograstim in the Lebanese market before 2014 • Arwan, a Lebanese company catering for the MEA region launched its Biosimilar Alpeen in 2018 to the retail market

Abdi Ibrahim Elkendi	• A technology transfer agreement between El Kendi and Spanish company mAbxience for the production of several biosimilars at El Kendi's new plant in Sidi Abdellah is in progress • Abdi Ibrahim Remede Pharma (AIRP) as Biocon's commercialization partner in Algeria launched the first biosimilar of trastuzumab named CANMAb in 2016; AIRP also launched the first biosimilar of insulin glargine named Basalog One in 2017
Medis International	• MédiS is the First Tunisian pharmaceutical company to produce and market its biosimilar EPO commercially appointed as EPOMAX
Sothema	• Local player Sothema announced that it will begin manufacturing Russian biotechnology Biocad's biosimilar versions of rituximab and bevacizumab in its facility in Casablanca. The manufacturing of the biosimilars was approved in the first half of October 2017. The facility was inaugurated in January 2019 and the drugs manufactured will be priced at 30% cheaper than those currently commercialized. Besides Morocco, these biosimilars are planned to be marketed in Senegal, Gabon, and Côte d'Ivoir • A center for medical imaging and oncology opened in Oujda, northeast Morocco, announced Oncology & Diagnosis of Morocco (ODM), Morocco's leading healthcare platform offering oncology and diagnostics services, earlier this year in March
Saja Pharmaceuticals	• SAJA signed licensing and manufacturing cooperation with Sanofi in 2016 to launch the anti-diabetic drug Vivaro, as a second brand of Sanofi blockbuster Lantus
Cipla	• Cipla is planning to move its growing South Africa production capacity into a bigger facility in the Dube Tradeport special economic zone it had originally earmarked for manufacturing hi-tech biosimilar drugs
Hikma **Celltrion Healthcare**	• Hikma now has an exclusive agreement with Celltrion for the market authorization of three biosimilar products including rituximab, infliximab and trastuzumab - in all its MENA markets.

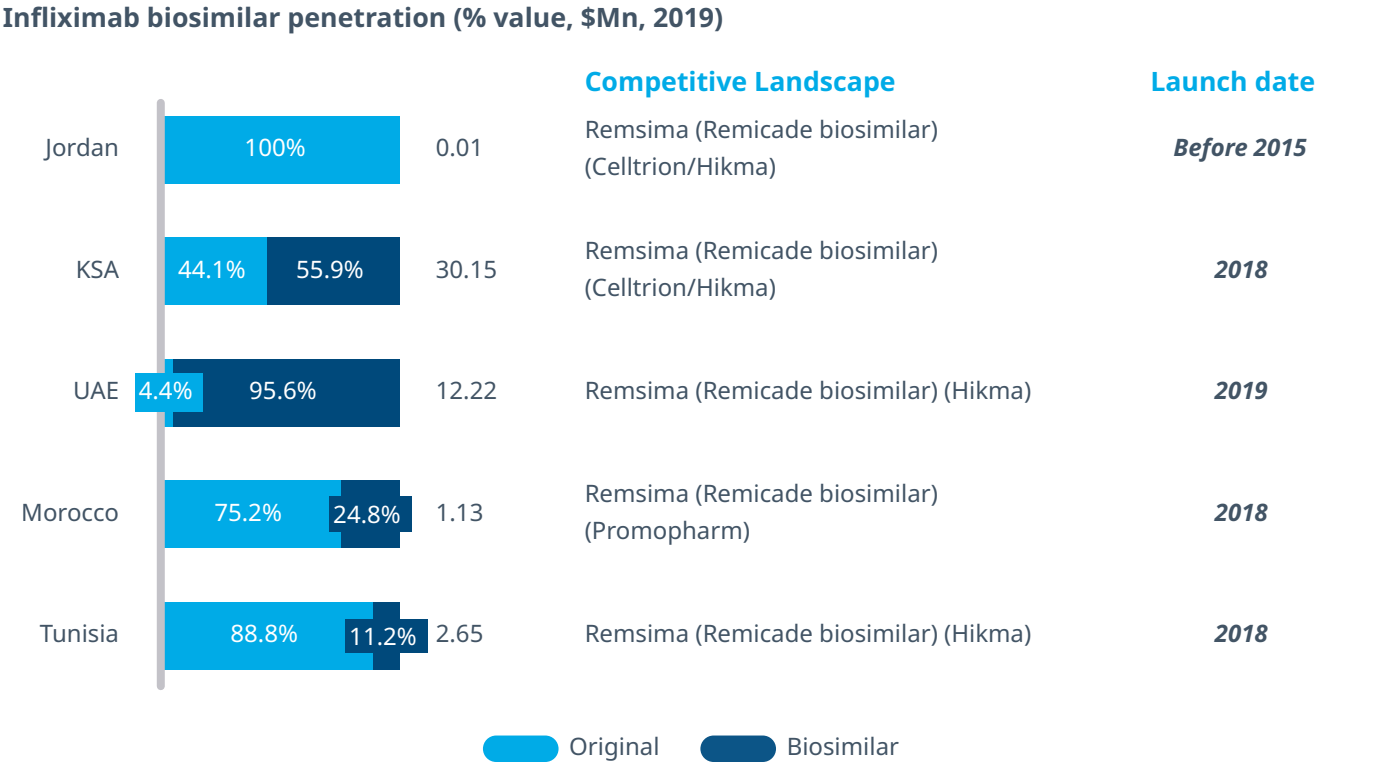
Current market trends of biosimilars in the MEA

Most MEA markets run price-conscious health systems, with drug prices and clinical outcomes having an impact on reimbursement decisions. For instance, most of the markets in the MEA have scheduled phased price cuts on drugs. Furthermore, the economic turmoil related to oil prices added more pressure on healthcare systems, such as those in the KSA, the UAE and Algeria, to contain costs.

Overall, MEA countries are always wary of their spending capacity compared to that of developed markets.

BIOSIMILAR PENETRATION: CASE STUDY OF INFLIXIMAB & INSULIN GLARGINE

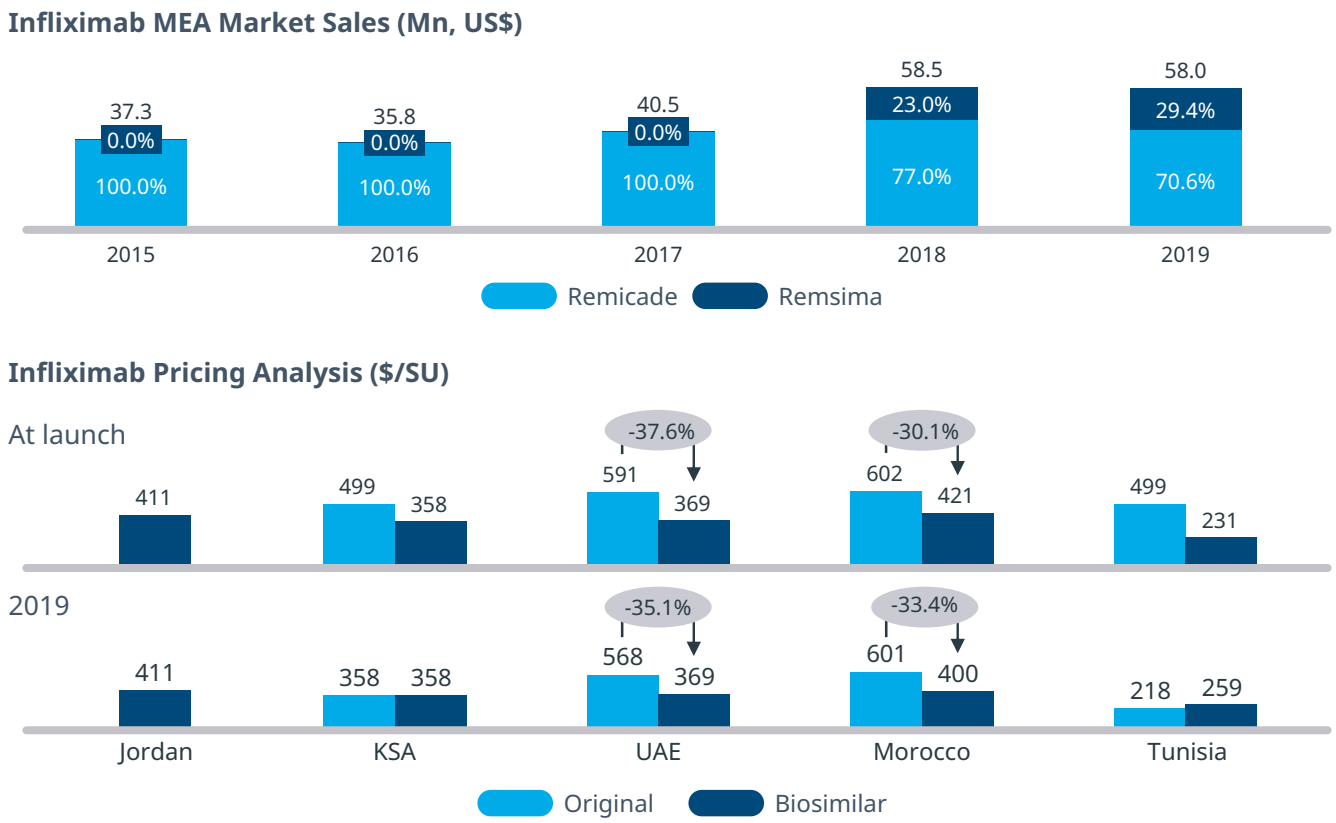
Figure 17: Market penetration of infliximab in select MEA countries



- Originator product dominates the Moroccan and Tunisian markets with 75% and ~89% contribution to the total biologics sales
- Infliximab biosimilar has been also launched to the hospital market in Algeria in the end of 2019

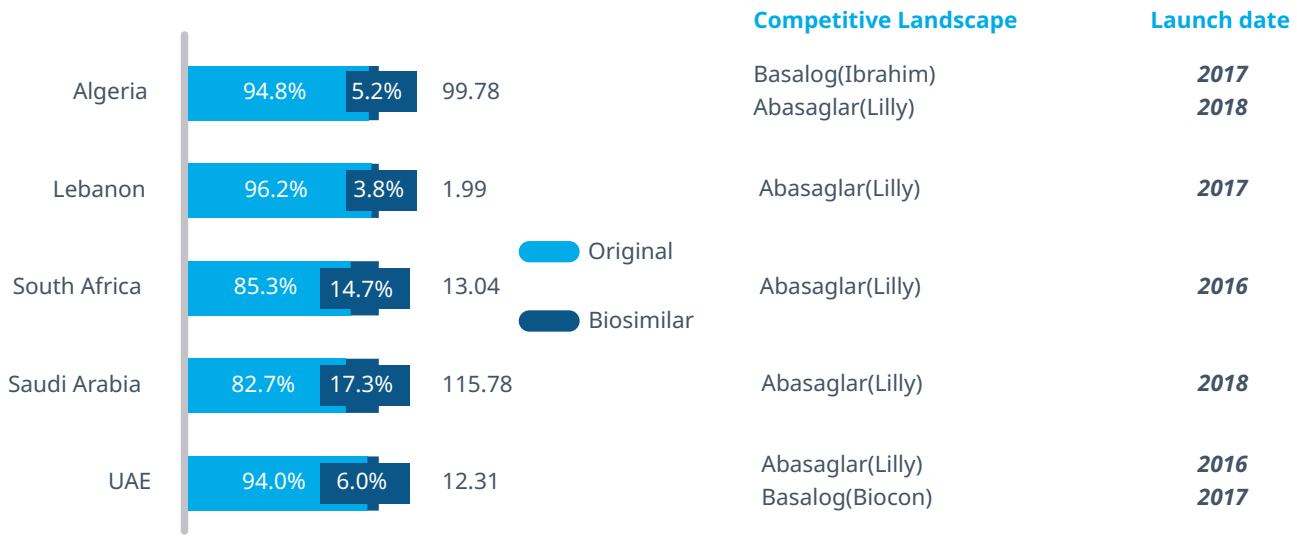
Remsima sales in the MEA market has seen a significant growth since launch in 2018.

Figure 18: Infliximab market share and pricing analysis in select MEA countries



In terms of price, UAE and Morocco have witnessed the highest decrease in prices between originals and biosimilars of 35% and 33% respectively in 2019 (Figure 18)

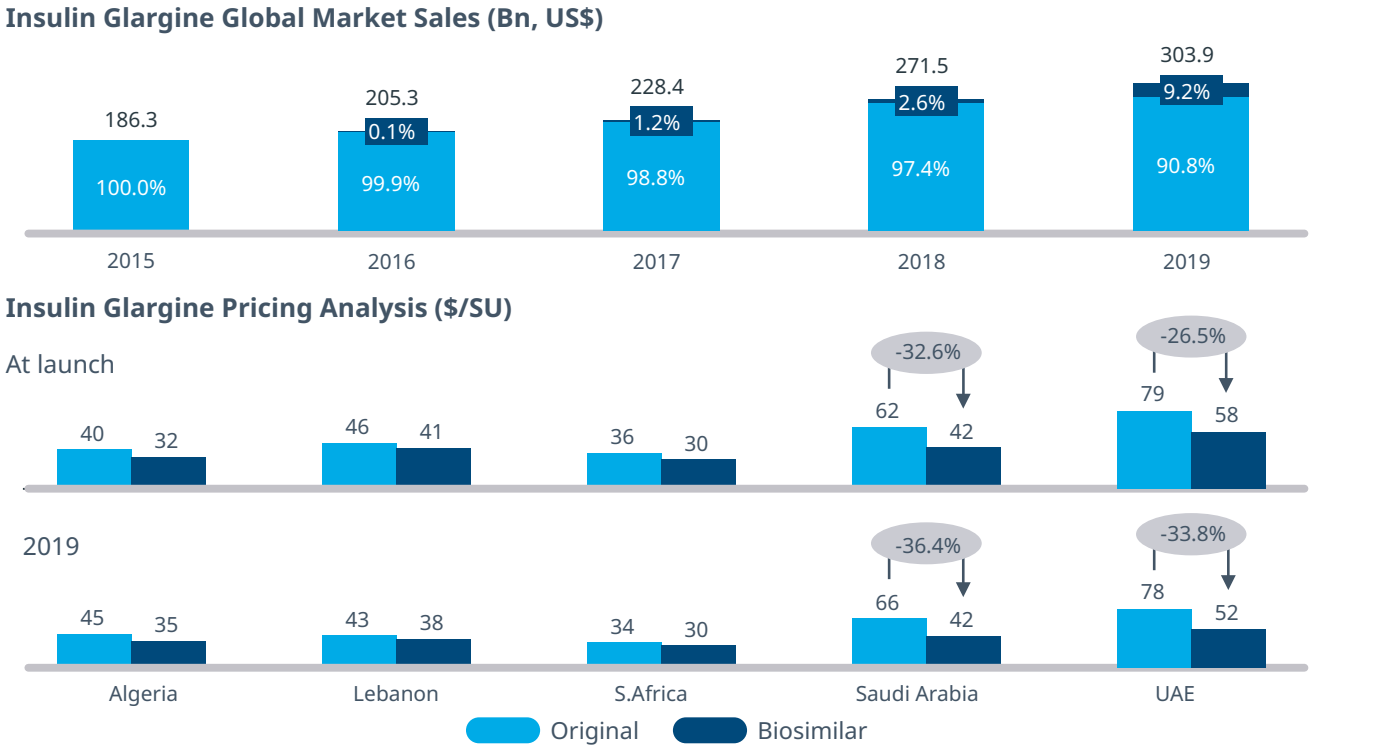
Figure 19: Market penetration of Insulin Glargine in select MEA countries



Highest contribution of biosimilars is observed in Saudi Arabia and South Africa with 17.3% and 14.7% respectively recorded for Abasaglar by Lilly, launched in 2016 and 2018 in those markets (Figure 19)

- Vivaro in collaboration with Sanofi was launched by SAJA in Saudi Arabia in 2016; noting that its sales have increased by 64% to reach 2.5 Mn $ in 2019
- Lantus biosimilar, Basalog by Ibrahim in Algeria and by Biocon in the UAE, was launched in 2017
- Lantus continues to dominate the Lebanese market. They account for 96% of the market sales in value in 2019. Biosimilar Abasaglar by Lilly was launched to the market in 2017
- Insulin glargine biosimilar sales in the MEA market have seen a significant growth since their launch in 2016 (Figure 20)
- In terms of price, Saudi Arabia and the UAE witnessed the highest decrease in prices between originals and biosimilars of 36% and 34% respectively in 2019 (Figure 20)

Figure 20: Insulin glargine market share and pricing analysis in select MEA countries



Conclusions and takeaways

Table 3: Conclusions and Takeaways

CONCLUSIONS	TAKEAWAYS
The share of global biologicals market is on the rise	This growth is driven by both innovators and biosimilar products. Growth is consistent across most regions, with the US and the EU5 representing most of the global sales at >80% share of the market. The biosimilars market reached 3.5% of the overall value share in 2019 as a result of newer generation biosimilars launches (including Mabs, Insulin glargine, etc.).
Western Europe has been the most proactive region and an early adopter of biosimilars since 2006	The current high penetration trend is anticipated to continue for biosimilars with additional blockbusters facing loss of exclusivity soon. Although regulatory and clinical trial frameworks vary, the FDA and EMA biosimilar approvals are growing, with more biosimilars launches expected globally.
The MEA region lags behind Europe and the US in terms of biosimilar approval rates	Although, lower than developed markets, the rate of biologic adoption in the MEA has grown consistently since 2015, now constituting 16% of the MEA pharma market. This could be attributed to the progress in terms of regulations and product availability. The KSA has the largest biological market followed by the UAE, Egypt and Algeria.
Regulatory maturity is still variable across the MEA markets with no recent launch of regulatory guidelines for biosimilars	It is relevant to note here that regulatory systems are still in transition and guidelines are under development in most MEA countries. In Algeria for example, guidelines are expected to be released in 2020. KSA is working on an update on its biosimilars guidelines, which were initially published in 2010. However, the lack of guidelines hasn't hindered the growth of the biosimilar market.
The level of biosimilar experience varies across the markets in the MEA region	**Countries with prominent biosimilars experience:** these comprise markets with clear biosimilars guidelines, including a path for locally manufactured products, such as Tunisia and Egypt, in addition to countries with guidelines but without a path for locally manufactured products such as Lebanon, the KSA, the UAE and South Africa. **Countries with moderate biosimilars experience:** these include countries without clear guidelines but with biosimilars on the market such as Algeria and Morocco. **Countries with negligible biosimilar experience:** these include Kuwait where there are currently no guidelines for biosimilars and few biosimilars on the market.

Constraints and growth drivers

CONSTRAINTS

- Just as they exist in every pharmaceutical environment, constraints also exist in biosimilar markets, but they can be challenged. Uncertainty in certain markets, from a political and economic point of view, might hinder initial launch plans.
- Political risk index is at its highest in countries such as Lebanon, Algeria and Egypt .
- Navigating a complex patent environment, specifically in some countries in North Africa such as Tunisia and Morocco, where IP protection index is low.
- Regulations in some markets are either inexistent for biosimilars or are still slow and evolving, which makes it slower for biosimilars to access the market.

GROWTH DRIVERS

- In order to address the multiple constraints in the market, tailored strategies by pharmaceutical companies are necessary to navigate the markets successfully.
- Build local partnerships to ensure expansion of local footprints with an existing player that would have a clear understanding of the market to commercialize biosimilars.
- Improve the patient care pathway by offering patient support and patient assistance programs in alliance with insurance companies and payers where both economical and psychological support is offered for the patients.
- Offer educational sessions and workshops for regulators and KOLs to raise awareness on the efficacy, safety and cost effectiveness of biosimilars.
- Undertake a dual branding strategy, even in the same markets, by launching biosimilars targeting different target audiences and with different pricing.
- Prioritize markets with a maturing regulatory environment and policy incentives that create a supportive environment for biosimilars.

List of abbreviations

Abbreviation	Expansion
ANPP	National Pharmaceutical Agency (Algeria)
BPCIA	Biologics Price Competition and Innovation Act of 2009
CAGR	Compounded Annual Growth Rate
CAPA	Central Administration of Pharmaceutical Affairs (Egypt)
CTSP	Technical Committee for pharmaceutical specialties (Tunisia)
DMP	Directorate of Medicines and Pharmacy (Morocco)
DPM	Pharmacy and Drug Authority (Tunisia)
DRTC	Drug Registration Technical Committee (Lebanon)
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration
HTA	Health Technology Assessment
ICH	The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
JFDA	Jordan Food & Drug Administration
KSA	Kingdom of Saudi Arabia
LNCM	National laboratory for Medicines control (Tunisia)
MA	Market Authorization
MAT	Moving Annual Turnover
MEA	Middle East & Africa
MoH	Ministry of Health
MOHAP	Ministry of Health and Prevention (UAE)
MOPH	Ministry of Public Health (Lebanon)
SAHPRA	South African Health Products Regulatory Authority (South Africa)
SFDA	Saudi Food & Drug Administration (Saudi Arabia)
UAE	United Arab Emirates
UNOP	National Union of Pharmacy Operators (Algeria)
WHO	World Health Organization

List of sources

Sources	Link Source
Biosimilar development	https://www.biosimilardevelopment.com/
Center for biosimilars	www.centerforbiosimilars.com
EMA	https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview
Fierce pharma	www.firecepharma.com
Gabionline	http://www.gabionline.net/Generics/News/EMA-recommends-four-new-generics http://www.gabionline.net/Generics/General/Russian-drug-shortages-at-crisis-point http://www.gabionline.net/Generics/News/EMA-recommends-four-new-generics http://www.gabionline.net/Biosimilars/News/Bio-Thera-launches-first-adalimumab-copy-biological-in-China
IQVIA	https://www.iqvia.com/search#q=biosimilars https://www.iqvia.com/blogs/2019/02/early-dawn-of-humira-biosimilars https://www.iqvia.com/blogs/2019/03/one-hundred-days-of-humira-biosimilars https://www.iqvia.com/blogs/2018/08/what-you-need-to-know-about-getting-biosimilars-to-market https://www.iqvia.com/blogs/2020/01/why-is-forecasting-biosimilar-impact-so-difficult https://www.iqvia.com/blogs/2018/12/new-horizons-oncology-biosimilars https://www.iqvia.com/blogs/2019/07/multiple-sclerosis-market-slowed-by-generics-and-biosimilars-despite-promising-new-therapies https://www.iqvia.com/blogs/2018/10/biopharmaceutical-landscape-in-australia
IQVIA MIDAS Datasets	MIDAS Global Data sets MAT 2015-2019
Korea bio med	www.koreabiomed.com
Morocco Word News	www.moroccoworldnews.com
NCBI	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5440034/
PM live	http://www.pmlive.com/pharma_intelligence/Will_biosimilars_ever_catch_on_in_the_US_1322729
The rheumatologist	Therheumatologist.org

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Nathalie leads the consulting and analytic team in the Middle East and Africa, supporting local, regional and international clients within the pharmaceutical and healthcare sector including public and private players. Over 12 years of strategy consulting experience, specializing in pharmaceuticals. Successfully managed a wide range of consulting engagements, including: commercial due diligence, geographic and therapy area expansion strategies, assessments for new therapies, portfolio prioritization, identification and evaluation of licensing opportunities and commercial design. Nathalie holds a doctorate degree in pharmacy from Saint-Joseph University and a degree in business administration from HEC, France.

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