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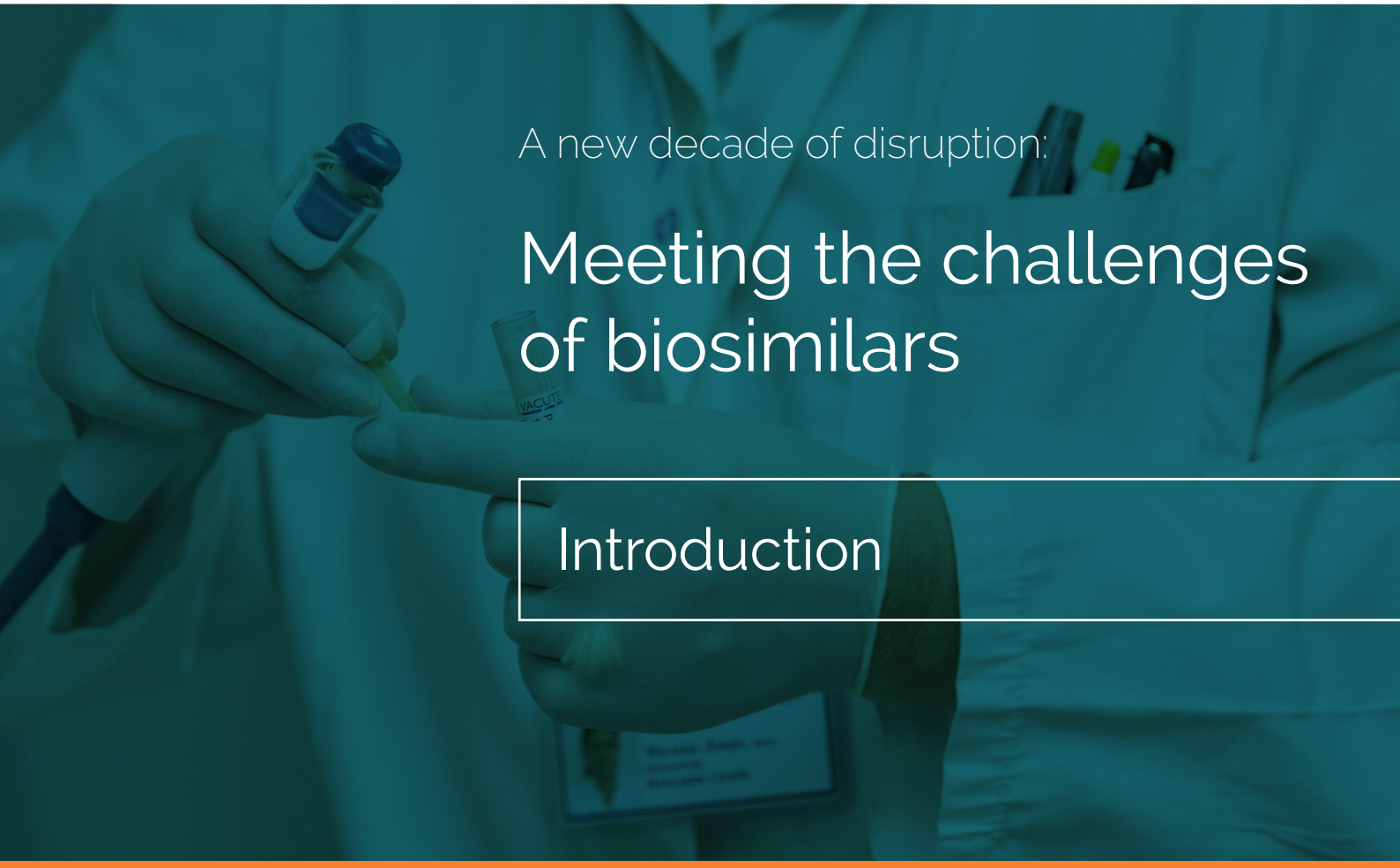


A new decade of disruption:

Meeting the challenges of biosimilars

Introduction

Biosimilars: Are you ready for the next 10 years?

Biosimilars are on the rise and gathering momentum, rich with potential for health systems and patients but fraught with challenges for industry players. As an impending wave of new entrants increases the pressure, how can biologics manufacturers best prepare for the future?

Introducing a trilogy of biosimilar briefs, we consider the importance of addressing three key questions in developing successful strategies.

1. What price has success?

2. Who's influencing who?

3. What's driving physician behavior?

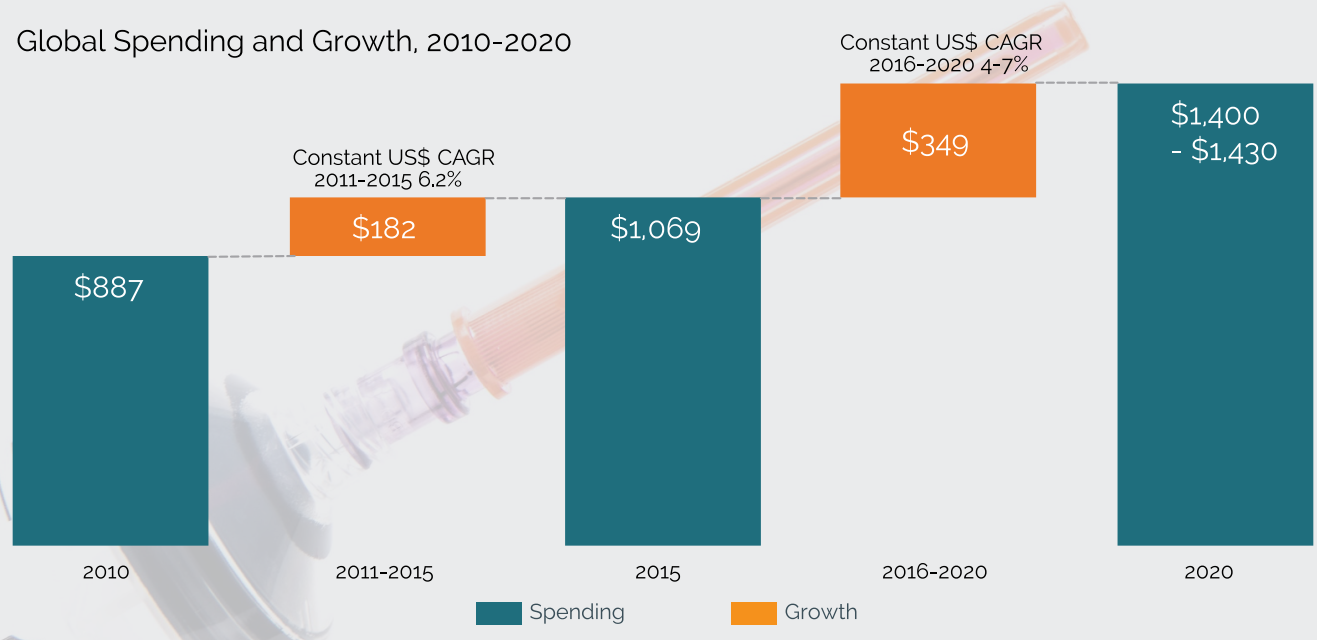
Biosimilars: A new decade of disruption

Of all recent developments to roil global pharma, few have courted quite such controversy and commotion as biosimilars. Almost but not quite identical to their reference biologic, worlds apart from generics in their structure, complexity and manufacture, and sufficiently unique to demand their own regulatory pathway, they have tested stakeholders across the healthcare spectrum for more than a decade.

Today, the once elite biotech sector commanding blockbuster prices is a crowded and competitive marketplace, upturned by a swell of biosimilars. Since the landmark approval of the growth hormone Omnitrope (somatropin) in Europe in 2006, more than 35 biosimilars of leading biologics have been launched in the region, challenging the original brands at lower cost in various chronic inflammatory diseases, kidney failure, supportive cancer care and diabetes. And with the breakthrough entry of biosimilar monoclonal antibodies (MAbs) (infliximab, etanercept, rituximab and adalimumab) marking a new level of complexity overcome, the market is gathering pace in its continued evolution, heralding a much tougher environment for biologics originators.

As the dust settles on the first ten years of disruption, the spotlight is now on the future as more MAbs encounter biosimilar competition. Avastin (bevacizumab) and Lucentis (ranibizumab) are among several top-selling biologics facing patent expiration in key countries through 2019, heralding an anticipated influx of biosimilar versions. Forecasts project that sales of biosimilars will exceed $25bn globally by 2020[1,2], with potential to realize cost savings of between $56–$110bn in Europe and the USA alone. As they prepare to compete for market share with originator products currently achieving annual sales of $50bn[3], a new storm is surely in the making.

Global Spending and Growth, 2010-2020



Source: Global Medicines Use in 2020. Report by IMS Institute for Healthcare Informatics, Nov 2015.
Note: Growth in 2011-2015 was reduced by $100Bn and in 2016-2020 increased by $26Bn due to exchange rate effects.

Key questions

For biologics manufacturers under pressure in this turbulent landscape, lessons learned so far can help to guide their strategic direction. Based on our experience, we believe there are three key questions that are critical to answer:

1. What price has success?

This is a market being driven mainly by cost. Biologics are among the most expensive medicines available with prices averaging 22 times those of small molecule brands[4]. They are projected to account for $390bn – representing around 28% – of global spending on pharmaceuticals by 2020[5]. All healthcare systems are seeking ways to lower costs and biosimilars offer one way forward in an expanding number of conditions served by high-priced biologics. With incentives in place to stimulate usage, biologics manufacturers must find new, creative ways to stay competitive.

2. Who's influencing who?

The lower price of biosimilars may be attractive to payers but to what extent does this correlate with usage in the market? Evidence to date suggests a complex landscape with multiple factors and stakeholders playing a role in uptake. Understanding the nature and scope of these influencers across different therapy areas and countries, how they prevent or encourage a switch to biosimilars, and whether this may change in the future, will be fundamental to accurately measuring the impact of biosimilar competition and developing effective strategies.

3. What's driving physician behavior?

As the ultimate decision makers in treatment choice together with their patients, physician attitudes towards biosimilars are critical. This is especially true given their growing involvement in the administrative and financial aspects of healthcare, including hospital governance[6]. With many directly accountable for their expenditure and under pressure to meet budgetary targets, an understanding of their mindset will be essential to generating the right evidence, messages and outreach programs to slow down the use of biosimilars. Gathering knowledge of what drives prescribing behavior, the multiplicity of factors that influence their decision, and the latitude they have in their choice of a biologic vs. biosimilar will be a key part of this process.

Trilogy of biosimilar briefs

Based on extensive healthcare research experience and desk research on the latest biosimilar developments, SKIM's biologics experts have written a series of in depth articles on the challenges of biosimilars for biologics manufacturers. After having provided you with an introduction on this topic in this document, we will address each of the key questions in 3 separate briefs.

Sources

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About SKIM

SKIM is a global insights agency helping leading companies thrive by understanding decision-making. To stay ahead today, it's critical to know how decisions are made and how the changing environment influences decisions for consumers, healthcare and B2B professionals. We combine decision-behavior know-how with analytical rigor, a thorough understanding of marketing challenges, and innovative research techniques. The result? Practical recommendations you can use to propel your business forward, online and offline.

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