Accelerating Biosimilars

To ensure patients continue to experience the benefit of biosimilars, a solution to accelerate access will be vital in helping healthcare systems address some of their most critical challenges

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"This is not the time for small changes and temporary solutions. This is the moment for bold leadership and action, and for following through on commitments. Future generations are depending on us." – Dr Tedros Adhanom Ghebreyesus, WHO Director-General (1).

It's Time For Change

Access to healthcare is a significant global challenge – not one restricted to developing or economically poorer countries. In Europe, while most of the population is covered by a public health system, funding into this system varies (from 3% of GDP in Cyprus up to 9.4% GDP in Germany) and significant proportions of the population – ranging from the self-employed to those who are undocumented – are not automatically covered (2). In addition to funding and access issues, healthcare budgets are stretched, and with the ongoing COVID-19 pandemic, many countries are experiencing shortages of healthcare professionals, medicines, and medical equipment, limiting access to primary care and putting patient care at risk (2-3).

Even before the COVID-19 pandemic, patients struggled to receive state-of-the-art treatments, largely due to rising costs of treatment, a health workforce under pressure, and long waiting times (4). Those with chronic diseases are particularly susceptible to pricing issues, with treatment for some illnesses remaining prohibitively expensive. That, alongside indirect costs, such as lost wages, lost productivity, the need for an additional home, or childcare, all add up to a bigger problem.

It is clear something needs to change. And fast.

As the world moves from action and reaction to recovery mode, we have a unique opportunity to review, rethink, and rebuild the way we treat our patients – focusing on reducing inequalities and building sustainable healthcare systems for the benefit of all.

Biosimilars: Part of the Solution?

For decades, it's been widely known that one of the fundamental roles of the generic and biosimilar medicine industry is to provide affordable and high-quality medicines which are safe, effective, and widely available. A cursory glance reveals the many benefits of the biosimilars business. For example, developing a biosimilar takes around 8 to 10 years at a cost of between $130 and $260 million (5). This is in stark contrast with the nearly 15 years and $2.6 billion it takes to develop a new drug (6-7). When it comes to biosimilars, speed doesn't equal reduced quality. Not only are biosimilars subject to the same standards of manufacturing quality control as biologics, but each biosimilar is put through rigorous state-of-the-art preclinical analytical testing. This assures that the quality, efficacy, and response of the biosimilar is a close a match as possible to the originator (or reference) medicine.

This reduced cost (in time and money) means biosimilar companies can afford to be agile and adaptable. It also means they can pass on cost savings to their customers. Research suggests patients and the healthcare system in the US saved approximately $313 billion in 2019 thanks to the use of generics with an additional $2.2 billion saved through use of biosimilars medicines (8). Over the last decade, savings in the US alone add up to $2.2 trillion and $4.5 billion thanks to generic and biosimilar medicines respectively.

With these savings and competition comes benefit. Healthcare providers can offer a wider range of treatment options for patients at a lower cost to the health system – helping to alleviate budget constraints. More affordable options mean potential reallocation of resources to other areas of patient care, allowing a range of therapeutic options – from patient networks to nutritional support. This isn't just blue-sky thinking, in the European Economic Area, biosimilar competition has already reduced average list prices and increased patient access to biologics (9). In research from the EMA, the six established therapy areas with biosimilar competition showed a consistent picture of reduced list prices – the price of epoetin alfa has declined by 27% and human growth hormone (HGH) prices have dropped by 15%. The same research shows this increased competition has led to increased volume of both the reference product and biosimilars, increasing access. Granulocyte-colony stimulating factor has benefitted from a market increase of 58%, the HGH market has grown by 45% (9).

Over the last five years, the biosimilars market has grown significantly, and forecasts look positive: most recent estimates suggest the European biosimilars market is expected to grow to $8.21 billion by 2025 (10).

However, this progress, while impressive, isn't enough. We need to double down on our efforts to see the full benefit of biosimilars for patients and society.

The Need for Regulation That's Fit for Purpose

The first biosimilar was approved in Europe in 2006 (11). Since then, the EMA has recommended the approval of a further 77 biosimilars for use in the EU (12). Although Europe is well ahead of the US (with the FDA only approving 30), there are still fundamental challenges with the EU's current legislative structures.

Regulatory authorities play a crucial role in opening up the biologic and biosimilar markets. However, technology often progresses much faster than the systems that implement it. Current legislation for the approval of new drugs, in Europe and around the world, is often more tailored to small-molecule drugs. While novel drugs rightly require extensive safety and efficacy testing, biosimilars are, by their nature, highly similar to their originator. Clinical testing requirements, therefore, could be greatly reduced (or even removed altogether). The Medicines and Healthcare Products Regulatory Agency has already taken this step – removing the requirement for biosimilar drugs to undergo confirmatory clinical trials in humans before being approved for use (13).

Legislation hasn't adjusted or advanced in line with new science and discoveries.

Concrete processes for the efficient approval of biosimilars – those with an eye on the future and the next generation of biologics and biosimilars – is fundamental for biosimilars to reach patients quickly, without compromise on quality, safety, or efficacy.

As well as biosimilar uptake being hampered by regulatory challenges, European countries may not be realising the full potential of biosimilars and their cost savings due to unbalanced payer pricing and procurement policies (14). More work is needed to put in place a fair, competitive, and sustainable market for biosimilars – one which applies incentives on both the supply and demand sides, while in line with clinical best practice and with the patient front of mind.

Having the right regulations and incentives in place is the first step but there's a second, arguably more important, element to tackle to widen patient access to biosimilars – raising awareness of biosimilars.

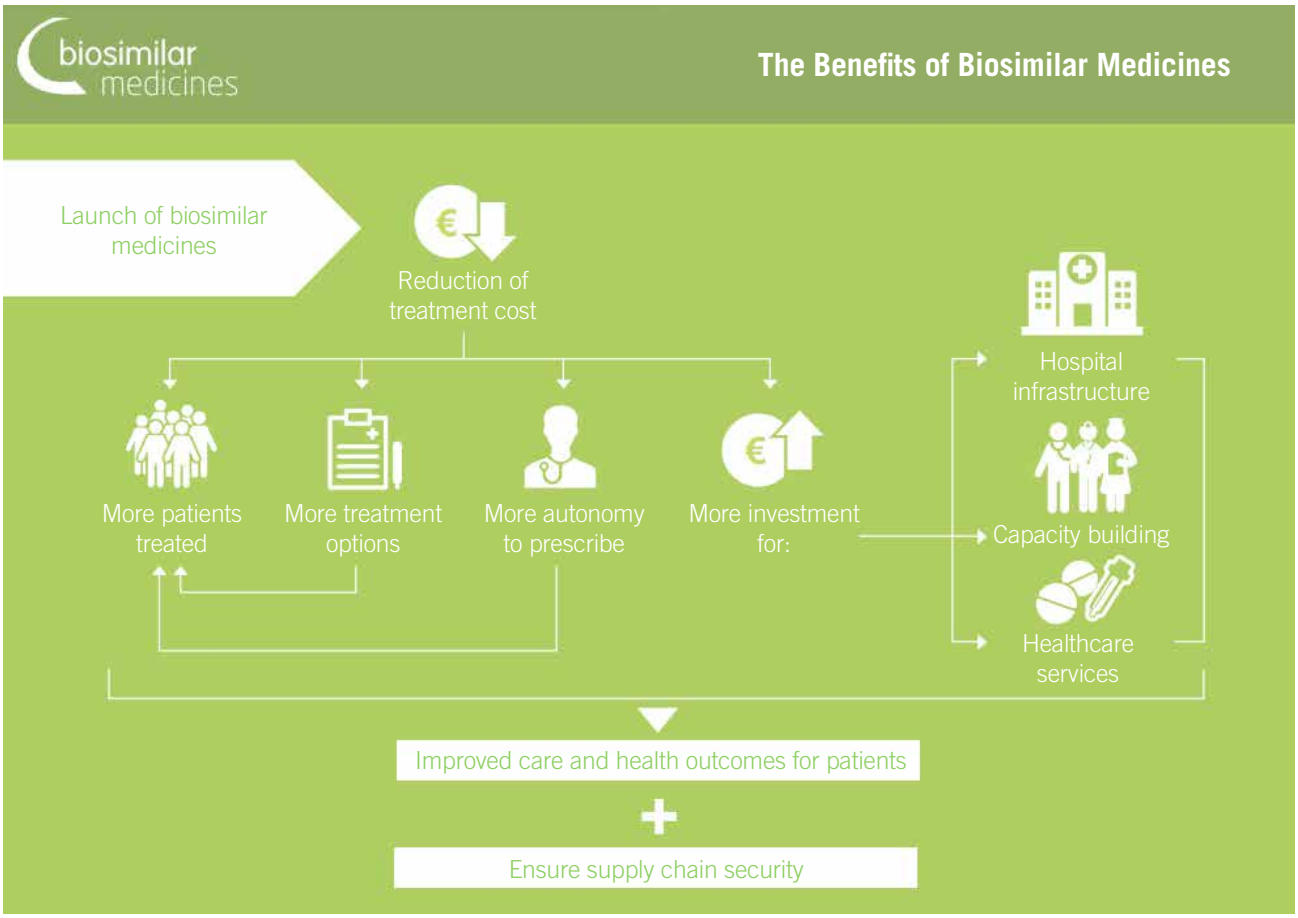

Figure 1: The benefits of biosimilar medicines (Source: Medicines for Europe [15])

Bolstering the Biosimilar Reputation

In order to see the benefits of biosimilars to healthcare budgets, access, and patient care, biosimilars need to be more widely adopted and used. To increase patient access to biosimilars, we rely on educating healthcare professionals about the benefits of adopting them as a treatment option. Even among seasoned professionals, there is a degree of confusion over biosimilars and the role they can play in sustainable healthcare.

Research suggests that patient understanding of biosimilars is crucial for treatment success and avoiding nocebo effects (16). Because most patients who take biologics have trust in their doctors to make the right decisions for them, it's clear that healthcare providers are the key to boosting the reputation of biosimilars as a viable, affordable alternative to biologics (17).

Taking Collective Responsibility

Nothing drives progress like necessity. Just as the COVID-19 pandemic has opened up opportunities never previously considered (such as whole organisations working from home), it has also given us the time to reassess how biologic medicines are regarded within the pharma industry and with regulators.

Ensuring that patients experience the continued benefit of biosimilars and the resulting increase in access and health system sustainability is dependent on the decisions made today.

If, as an industry, we are serious about our core commitments to patients, we must be adaptable. We need to work with policymakers and regulators, facilitating information sharing, offering flexibility, and providing them with accurate and clear information to help move public health, and its regulation, forward.

It is clear that a new approach is needed from all key healthcare stakeholders – payers, prescribers, healthcare professionals, and manufacturers – to support these goals. We should all seek to provide patients with improved access to care while maintaining the necessary standards of safe and efficacious medicines. Such a goal may only be met through tight collaboration between regulatory authorities, therapeutic manufacturers, healthcare professionals, and, of course, patients.

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Georg Feger has 25 years' of experience in the pharma and biotech industry in senior leadership positions. Currently serving as Executive Vice President, Business Unit, Biosimilars at **Fresenius Kabi SwissBioSim**, Georg's experience includes previous senior positions in R&D, manufacturing and supply of biosimilars, NBE technologies, new products discovery, chemistry, manufacturing, and control development for Fresenius Kabi, Merck, Serono, and GSK.

Throughout his career Georg has led the discovery and development of NCEs, NBEs, and biosimilars in oncology, neurology, and autoimmune diseases resulting in two marketed products and several programmes in late stage development and submission. He successfully led international organisations in biotech and pharma including a research site for Merck/Serono with more than 300 scientists.