Improving access to biologic medicines through biosimilars (9 min read) [1]

Access to Medicines [2]

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Biologic medicines, or biologics, have revolutionized therapies for hard-to-treat diseases, including certain types of arthritis and cancer[2]. And as patents for biologics expire, biosimilars can provide the same results more affordably[1]. This means that more patients have a better chance of getting treatment, which could significantly improve their lives.

One person who got her life back is Amye Leong. As a young woman living in California, the pain of rheumatoid arthritis kept Leong in a wheelchair for five years. Leong's long road to better health included multiple surgeries for 17 joint replacements; before biologic medicines became available, among the most common options for the treatment of severe arthritis were surgeries, joint replacements, or living with limited mobility. “These [treatments] were all related to the crippling effects of rheumatoid arthritis when no biologic medicines existed to put out the fire raging inside my joints,” she says.

"Biologics or biosimilars would have helped halt or slow the disease and prevent my going through years and years of pain, disability and suffering, which ultimately led to joint replacements and revisions of the older joint replacements."

Amye Leong, President & CEO, Healthy Motivation; Director of Strategic Relations, Bone and Joint Decade, the Global Alliance for Musculoskeletal Health; Chair, Arthritis Foundation Central California Leadership Board, U.S.A.
Yet help was on the way, in the form of biologics. These were life-changing medicines for Amye Leong, President and CEO of Healthy Motivation, a health education and advocacy consulting firm. Biologic medicine targeted the cause of inflammation, slowed joint damage and helped control the pain of arthritis, so she could get back on her feet. She was able to walk again. Increasingly, with biologics now on the market, other patients won’t have to suffer the ordeal Leong went through. This is what motivates her to speak out as a patient advocate for biologic medication.

Treatment with such life-changing medicines comes at a high price, however. Therapy can cost thousands of dollars per month. So biologics have revolutionized care, but only for patients who live in the right country, have the right health insurance, or who can finance the medication themselves. Leong worries that such life-changing drugs remain financially out of reach for many who have to pay costs out-of-pocket. The situation forces tough choices. “Do you want to pay rent, buy food and get your child through school, or do you want the drug that will hopefully make a difference in your disease and life? It should not have to be about that,” she told representatives of the U.S. Food and Drug Administration during a 2015 Advisory Committee hearing on the first biosimilar under review in the United States.

**Innovative Treatments**

Biological medicines are produced using living organisms.

**Small molecule drugs (Chemical)**

- Aspirin
  - 21 atoms

**Small biologic**

- Somatotropin
  - 3.091 atoms

**Large biologic**

- IGG Antibody
  - ~ 25,000 atoms

Biologics are not medicine like aspirin, which is made with chemicals. To get an idea of the relative size and complexity of molecules in chemical drugs versus biologics, compare a simple rowboat to a schooner and to a cruise liner.

Sources: [http://www.azbio.org/small-molecules-large-biologics-and-the-biosimilar-debate](http://www.azbio.org/small-molecules-large-biologics-and-the-biosimilar-debate)

Biologic medicines target diseases such as arthritis, anemia, multiple sclerosis and certain types of cancer. But it can take about ten years, and huge sums of money, to develop and
gain approval for a biologic\(^3\). Each one requires in-depth, state-of-the-art research, followed by long approval processes and very complex manufacturing processes using living microorganisms. This is why development costs much more than for “standard” industrial or chemical drugs.

The processes and the quality standards for producing state-of-the-art biosimilars – from the beginning of manufacturing through the finished product – are exactly the same as for biologics. Here, two productions specialists monitor the production process and discuss data.

This is where biosimilars come in. They can make treatment with biologics possible for more patients by increasing treatment options and lowering the cost of therapy for healthcare systems. Dr. Paul Cornes is an oncologist with the Comparative Outcomes Group in Bristol, England, a research group with an interest in better affordable healthcare outcomes. He has done the math on the financial side of biosimilar therapy. “Between 2013 and 2018, biologics worth $68 billion a year will lose patent protection.\(^4\) Even if we just got a 20 percent discount from biosimilars for these, this would give the world a $14 billion annual health fund, which could be used for things like patient care, nurse salaries or even free medication,” he told the audience at a 2016 biosimilars symposium\(^5\) of the European Association of Hospital Pharmacists. “We cannot do without biosimilars – it is as simple as that.”

We cannot do without biosimilars – it is as simple as that.

Dr. Paul Cornes, oncologist with the Comparative Outcomes Group, Bristol,
To understand the significance of biosimilars, it helps to look at the development of biologics. In the 1980s, researchers developed this new form of medicine that has much larger and more complex molecules than chemically synthesized, small-molecule drugs. To make biologics, scientists choose appropriate cells (such as bacteria, yeast, animal or human cells). These cells are then modified to become “factories” that endlessly produce a particular substance, usually a protein, which then effectively targets the causes of specific diseases in the body. Interestingly, because biologics are made by living cells, they come with a natural variability – so not all molecules are identical, nor do they have to be, to produce the desired therapeutic effect.

Biosimilars - Access for Patients

The biopharmaceuticals success story

Since biologics entered onto the healthcare stage over three decades ago, it has become possible to effectively treat formerly “incurable” diseases. Biosimilars can now provide access to treatment for more people.


Biosimilars are follow-on versions of biologics that have lost patent protection. Biosimilars are also made using living cells, so they have the same natural variability as any biologic, which is why they are not referred to as “generic biologics.” To be approved, a biosimilar must be proven in extremely strict laboratory and clinical trials to match the safety and efficacy, and to deliver the same therapeutic effect as the existing biologic. You might think of a biosimilar as a duplicate key. Even if it looks a bit different, it opens the lock (or has the same effect) as the master key.
Biosimilars – the results are the same

Biologic medicines (or “biologics”) are protein-based medicines made using living cells in a complex manufacturing process. These cells are modified to produce a protein that targets the specific cause of a disease and is tailor-made to interact with specific targets in the body. Because they are made by living organisms, biologics have natural variability and no two batches are identical.5

Biosimilars are follow-on medicines made by different pharmaceutical companies when a biologic loses patent protection. Biosimilars are also made using living cells, and have been shown to be as safe and effective as existing biologics. Think of a branded biologic medicine as a key, and a biosimilar as a duplicate made by a skilled locksmith. The second key may look slightly different to the original, but the results are the same: Both keys will fit the same lock, and open the door. The same is true of a biologic and a biosimilar, in spite of the natural variability, they will have the same therapeutic effect for a patient.5

Although massive investment is needed to develop and produce biosimilars, as well as to confirm their safety and efficacy, they can open the door to biologic medicines without increasing overall healthcare spending.6 For example, 2008 saw the launch of a biosimilar of granulocyte-colony stimulating factor (G-CSF), used to reduce the risk of infection in chemotherapy patients. Health authorities in the U.K. then reassessed G-CSF treatment and found it to be more cost-effective than alternatives. In the following six years, G-CSF uptake, including the biologics and biosimilars, increased by more than 100 percent.7

This scale of uptake shows that biosimilars can bring life-changing drugs to more patients. Because biosimilars offer the benefits of biologics at a lower cost to healthcare systems, more people can have state-of-the-art treatment. That’s why Amye Leong has become an advocate – because biosimilars can save other people from going through the ordeal that she did. She says, “That’s why improving access to care and treatments is vital to my work as a patient advocate, and experience as a grateful patient.”

Read more about Biosimilars [6]

Developing trust, sharing responsibility

Biosimilars: 2016 position paper of the European Society of Medical Oncology (ESMO)

In a 2016 position paper, the European Society of Medical Oncology (ESMO) has named biosimilars as “one of the ways forward to obtain sustainability,” because they provide cost savings, and more choice doctors and patients. The authors stress that physicians must base their decisions on patient needs when selecting biosimilars as a treatment method, particularly in oncology.
Information gathering, the authors emphasize, is at the heart of this decision: prescribers and pharmacists should collect data, “including findings from clinical studies,” to develop trust in this treatment process.

The paper notes the appeal of biosimilar products, as they promise to reduce the heavy financial burden of biopharmaceuticals on healthcare systems. However, the authors indicate that before switching medication, physicians should deeply understand both the reference biologics and the biosimilars. They must fully brief their patients before any change, and closely monitor patients afterwards. Neither physicians nor pharmacists may automatically substitute products. This is restricted, or even prohibited, in several E.U. member states.

Ensuring the safety and efficacy of biosimilars is essential. Along with the diligence of physicians and pharmacists, the “optimal safety and efficacy [of biosimilars] is, critically, the shared responsibility of both the manufacturers and the regulatory bodies,” conclude the authors.


1. IMS Institute, Delivering on the Promise of Biosimilar Medicines: The Role of Functioning Competitive Markets. 


3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4847363/


7. IMS Institute, Delivering on the Promise of Biosimilar Medicines: The Role of Functioning Competitive Markets. 