MiGenTra
Healthcare Transforming Medicines

How biosimilars are transforming healthcare...

How Biosimilars Are Transforming Healthcare

A MiGenTra White Paper

December, 2022

There are more than 10,000 known diseases in the world, of which several are life threatening or chronic. Common examples include immune-mediated disorders (e. g. rheumatoid arthritis, ulcerative colitis, Crohn's disease, or psoriasis), cancer, or cardiovascular diseases.

For many years, these diseases were treated through lifelong prescription of small-molecule drugs. However, these treatments often were not specific enough causing adverse events through off-target effects.

Biological drugs ("biologics") were able to address this as they are designed to interact with the immune system in specific ways; they bind with high affinity to their targets. Biologics such as vaccines have been marketed since the 19th century; however, the first biologic generated from bacteria, recombinant human insulin, was approved by the U.S. Food and Drug Administration (FDA) only 40 years ago[1]. In 2019, the market for biologics was valued at $360 billion or 30% of the worldwide pharmaceutical market[2].

Complex in their molecular makeup, biologics are several folds larger than small-molecule drugs such as aspirin.

Driven by their development costs and highly complex manufacturing process using **genetically engineered living organisms** (e. g. microorganisms or animal cells), biologics are expensive medications. Consequently, most healthcare systems and patients in low to middle income countries (LMICs) cannot afford them, limiting their access to these effective treatment options.

A barrier that biosimilars are addressing.

What Are Biosimilars?

Upon expiry of all regulatory exclusivity and intellectual property of a given biologic, manufacturers can seek approval to market a highly similar version of it known as a biosimilar.

Like biologics, biosimilars are made from genetically engineered living organisms. And like biologics, their manufacturing is complex and involve multiple steps which each can introduce inherent minor variability. The creation of exact copies to their reference biologics is thus impossible — **similar but not identical**.

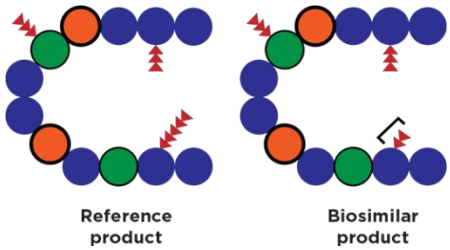


Figure 2: Similar but not identical. Minor variations between reference and biosimilar products may occur in process or structure (Bracket). (Adapted from the FDA.)

To prove that these minor variabilities in biosimilars have no **clinically significant differences in safety and efficacy** versus reference biologics, their development undergoes rigorous multi-steps process as described in guidelines issued by the

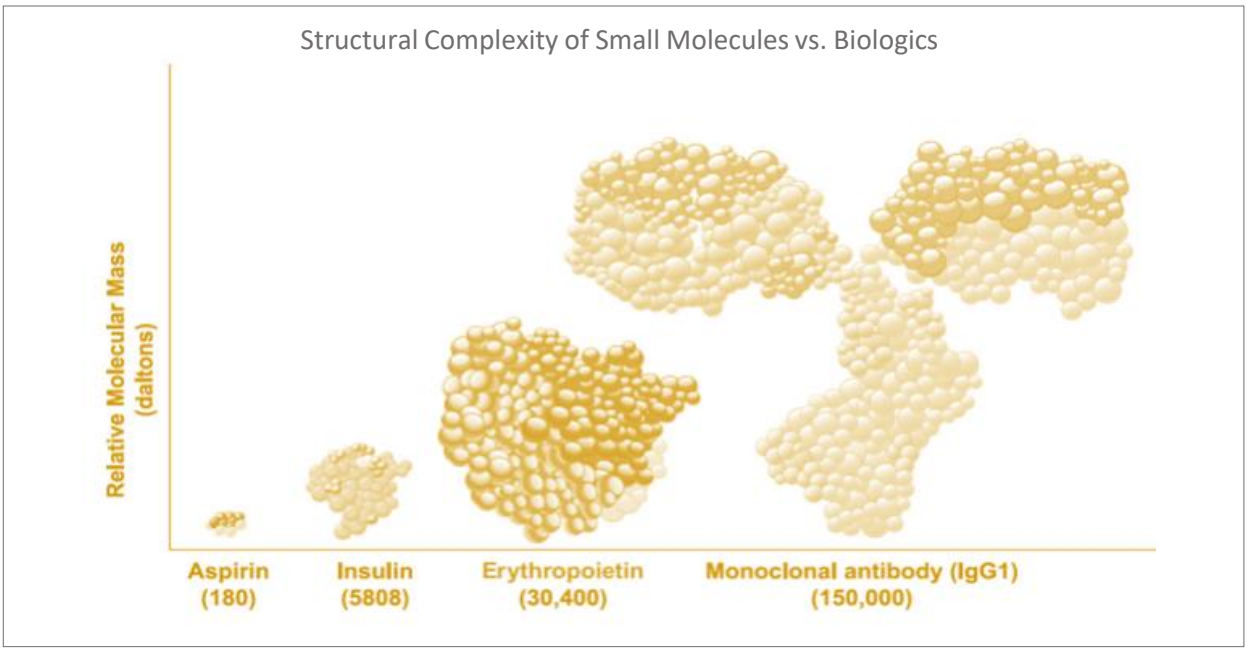


Figure 1: Monoclonal antibodies are structurally more complex than small-molecule agents and lower molecular weight biologics. (Adapted from Mellstedt H. (2013) Clinical considerations for biosimilar antibodies)

FDA, the European Medicines Agency (EMA) or the World Health Organization (WHO). And by referencing data of approved biologics, biosimilar development can avoid unnecessary duplication of clinical trials, saving time and resources.

First introduced in early 2000, biosimilars reached global sales of $17.9bn in 2020[3]. They are expected to continue growing at a CAGR of 15% until 2030 reaching an estimated $75bn by the end of the decade[3].

How Biosimilars Are Benefiting Healthcare

As direct consequence to their **faster** and **cheaper development**, biosimilars are made available upon launch at more **affordable prices** than reference biologics (10-30% discount[1]). Their launch is introducing much needed **competition** as reference biologics are in turn incentivized to lower their prices to maintain their market position.

All **key stakeholders in the healthcare ecosystems can benefit** from the introduction of biosimilars:

- **Healthcare systems** by generating significant savings[4]: $7.9 billion in 2020, up from $2.5 billion saved in 2019;
- **Patients** by driving up access and providing new treatment options: biosimilars for oncology indications show rapid uptake, above 70% in volume[3];
- **Innovators** by creating budgetary room for the financing of innovation by payers and healthcare systems across the globe.

Serving Patients Across Africa and the Middle East

MiGenTra was incorporated in 2021 by ProBioGen and Minapharm Pharmaceuticals with the mission to commercialize quality and affordable biologics for patients across Africa and the Middle East as these regions carry a disproportionate share of the global disease burden in part due to a lack of access to high-cost biologic treatments.[5]

Biosimilars are central to what we do at MiGenTra. By leveraging expertise available at ProBioGen (highly productive cell lines and processes in Berlin) and Minapharm Pharmaceuticals (efficient and cost-effective biomanufacturing in Cairo), we are uniquely equipped to develop and manufacture these therapies at low cost, and passing on the benefits directly to patients. By way of example, the launch in Egypt in 2006 of Reiferon Retard® (biosimilar to pegylated interferon) for the treatment of Hepatitis C led to significant price reduction (6-fold vs originator) and market expansion (115-fold increase in number of treated patients).[6]

MiGenTra's established network of partners and distributors in Africa and the Middle East will ensure efficient delivery of these needed medicines to patients across the continent.

References

[1] Chan, Juliana CN, and Anthony TC Chan (2017). Biologics and Biosimilars: What, Why And How?

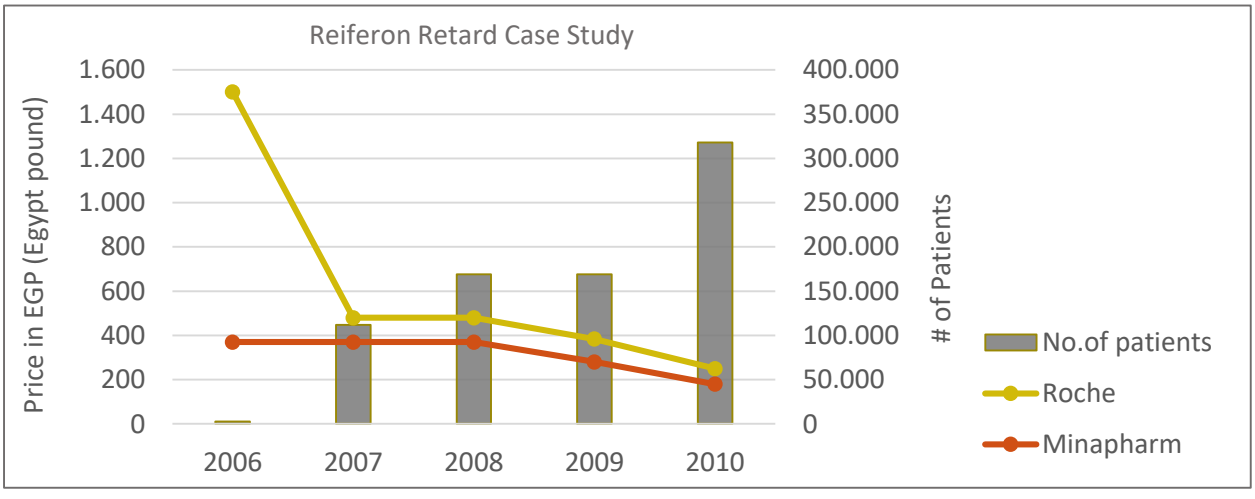
[2] IQVIA. (2020). Realizing Biosimilar Potential in the Middle East & Africa - The Middle East and Africa Perspective White paper.

[3] IQVIA. (2022). Biosimilars to continue rapid growth over the next decade.

[4] AAM Association for Accessible Medicines. (2021). The U.S. Generic & Biosimilar Medicines Savings Report.

[5] Institute for Health Metrics and Evaluation. (2013). The Global burden of disease: GeneraTinG evidence, Guiding Policy - Middle East and North Africa Regional Edition.

[6] Médecins Sans Frontières Access Campaign. (2013). The Diagnosis and Treatment of Hepatitis C - A Technical Landscape.



Healthcare is a Human Right

Mission

Providing quality and affordable biological medicines to more patients across Africa & the Middle-East

Vision

Transforming healthcare in Africa & the Middle East

Be Part of the Transformation of Healthcare Across Africa and the Middle East

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