Biosimilars Beyond Borders: Lessons from Europe — What Africa Can Learn

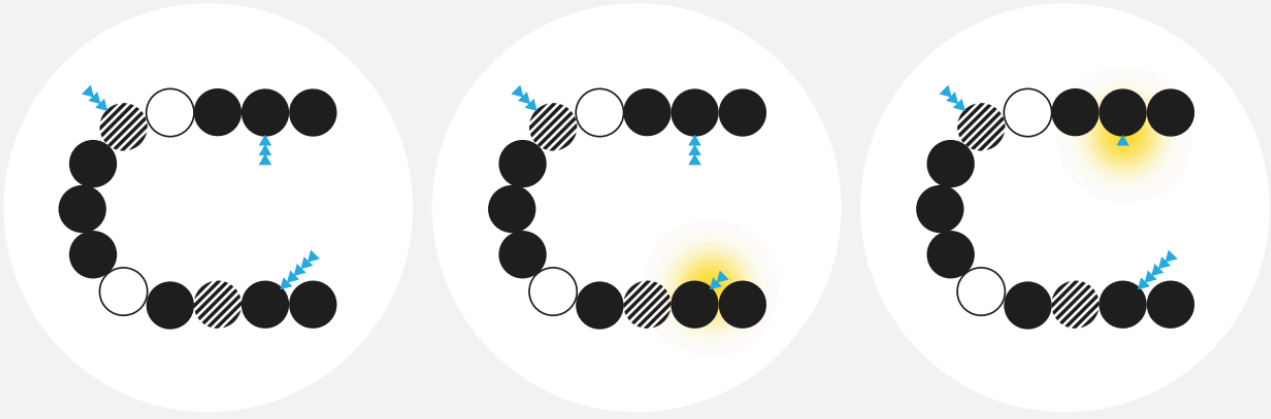
Two Continents, One Goal: Affordable Biologics for All

Europe's leadership in biosimilars has reshaped how the world thinks about access to biologic medicines. When the European Medicines Agency (EMA) approved *Omnitrope (somatropin)* in 2006, it marked the beginning of a new era: one where affordability, safety, and innovation could coexist.

A **biosimilar** is defined by the EMA as a biological medicine that is highly similar to another already approved biological medicine: the "reference medicine" or "reference medicinal product". Like all biologics, these medicines are produced from living systems such as human, animal, or microbial cells. Because of their biological origin and molecular complexity, small natural variations exist between manufacturing batches, making production of exact copies impossible. What defines a biosimilar, however, is not identicality but **equivalence** in safety, quality, and efficacy.

Figure 2. Example of variability between different batches of a biological medicine

Consecutive batches of the same biological medicine may show a small degree of variability (yellow shadow) within the accepted ranges, for example in glycosylation (sugar molecules attached to the protein, which are represented by small blue triangles). The amino acid sequence (represented by circles) and biological activity of the protein remain the same in all batches, even when these minor differences in sugar chains are present.



Biosimilars in Europe Information guide 13.11.2023

Europe's early and consistent regulatory clarity has turned the continent into the **global pioneer of biosimilar development**. The EMA and European Commission built a rigorous framework that has since become the international benchmark. They did not just create regulations; they built an **ecosystem of trust,** engaging scientific experts, physicians, nurses, pharmacists, and patient representatives in every stage of guideline development.

The results speak for themselves. Since 2006, the EMA has approved **144 biosimilars** across multiple therapeutic areas from oncology and rheumatology to endocrinology, while the U.S. FDA has approved **75** (GaBI Online, June 2025).

According to an IQVIA white paper titled *Impact of Biosimilar Competition in Europe* (2024), biosimilars represent only about 4% of EU pharmaceutical spending (~€10 billion in 2023), but their influence is far-reaching. By driving price competition and expanding patient access, they have generated **€56 billion in cumulative savings** as of mid-2024. These savings help European healthcare systems reinvest in new treatments, extend insurance coverage, and fund research.

For Africa, home to some of the world's fastest-growing populations and most dynamic healthcare markets, the implications are profound. The African Development Bank estimates that the continent's population will reach **2.4 billion by 2050**, and could double again within a century. Rising urbanization, improving healthcare systems, and growing disease burdens all point to an urgent need for affordable biologics.

Biosimilars offer Africa a unique opportunity: to **leapfrog barriers of access and cost** while fostering local scientific and manufacturing capacity. Yet, out of 54 African countries, only a handful such as South Africa, Nigeria, Ghana, and Egypt, have well-defined regulatory pathways for biosimilar approval. Most others still depend on EMA, FDA, or WHO models, have draft frameworks under development or one that is combined with other forms of medicinal products.

Drawing inspiration from Europe's structured, transparent approach, Africa can establish **regionally harmonized standards** that reflect its own infrastructure, market realities, and public health needs. A continental framework, coordinated under the **African Medicines Agency (AMA)**, could unify fragmented systems and accelerate access to affordable biologics for millions.

Europe's Success Story: From Skepticism to Confidence

1. Building Trust Through Science and Education

When biosimilars were first introduced in Europe, they faced strong resistance. Physicians were uncertain about their efficacy and long-term safety. Patients, naturally guided by their doctors' opinions, were cautious too. This early hesitation was understandable: biosimilars were complex, unfamiliar, and often associated with misconceptions.

A clear example comes from gastroenterology. After the EMA approved CT-P13 (a biosimilar of infliximab) in 2013 for inflammatory bowel disease (IBD), many clinicians were hesitant to prescribe it because the supporting clinical trials were conducted in rheumatologic conditions. Understand here that the product was approved for rheumatologic conditions but as is done for biosimalars, there is what is called "Extrapolation" which means that the biosimilar's approval is extrapolated to all other indications for which the reference product was approved and without the need to conduct specific clinical trials on those conditions. However, as more studies confirmed comparable outcomes between CT-P13 and the originator biologic but this time on IBD patients,

skepticism quickly declined. Within two years, the proportion of physicians expressing uncertainty about the use of a biosimilar for their patients dropped from over 60% to around 20%.

Patient perceptions followed a similar path. Initial fear gave way to confidence once physicians started to adopt biosimilars and real-world data and post-marketing surveillance proved that they perform just as safely and effectively as their originators.

This evolution highlights a crucial point for Africa: **education builds trust faster than legislation**. Europe's success came not just from laws and guidelines, but from **open communication** and transparent information shared with healthcare professionals and patients alike.

The EMA maintains an extensive online hub dedicated to biosimilars, publishing reflection papers, FAQs, and practical guides for prescribers and patients. Their approach demonstrates that regulatory success depends on **scientific transparency and stakeholder education** as much as on policy.

2. Regulatory Leadership and Clarity

Europe's competitive advantage lies in the **rigor and predictability** of its regulatory process. The EMA's stepwise evaluation covering analytical, preclinical, and clinical comparability ensures that biosimilars meet the same standards as their reference medicines.

This scientific rigor, paired with transparent communication, reassures healthcare professionals that biosimilars have acceptable safety profiles and are effective. The European Commission's involvement further strengthens this trust by coordinating the publication of guidance documents, stakeholder workshops, and educational campaigns that align science with policy.

For Africa, this model offers a roadmap. Clear, harmonized regulations not only protect patients but also attract investment and accelerate approvals. A **regionally aligned biosimilar framework,** driven by the African Medicines Agency would prevent duplication, simplify manufacturer engagement, and reduce costs for regulators and companies.

3. Procurement and Pricing Reforms

Europe also learned that **policy incentives** matter as much as regulatory approval. National governments introduced procurement and reimbursement models that rewarded the use of biosimilars and stimulated competition.

In Denmark, for example, biosimilar uptake for some immunology treatments reached **85–97%** within a single year of launch. Germany, another leader, reports adoption rates between **27% and 89%**, depending on the molecule. These reforms didn't just reduce prices; they **expanded access**. Germany cut the average waiting time for rheumatoid arthritis patients to start biologic therapy from **7.4 years to just 0.3 years** after biosimilars entered the market.

This is a game-changing outcome that demonstrates how affordability directly translates to better patient outcomes. For Africa, similar policies grounded in transparency, competition, and incentives could reshape access to complex therapies like biologicals.

4. Collaboration Among Stakeholders

Europe's biosimilar success was built through **collaboration**, not isolation. The European Commission organizes annual workshops bringing together doctors, nurses, pharmacists, payers, regulators, patients, and industry representatives to discuss challenges and share data.

This open, multi-stakeholder approach helps maintain a balance between innovation, affordability, and patient safety. It also allows savings from biosimilar competition to be **reinvested into healthcare**, creating a virtuous cycle that benefits everyone.

Key Lessons for Africa:

- Harmonized regulation builds trust and accelerates access.
- Education is essential for confidence and adoption.
- Transparent pricing ensures long-term sustainability.
- Collaboration keeps the system adaptive and resilient.

Africa's Biosimilar Landscape: Momentum and Challenges

Africa is now entering a new phase of its biosimilar journey; one marked by both **promise and uneven progress**. Several countries are making bold moves toward regulatory clarity and local manufacturing.

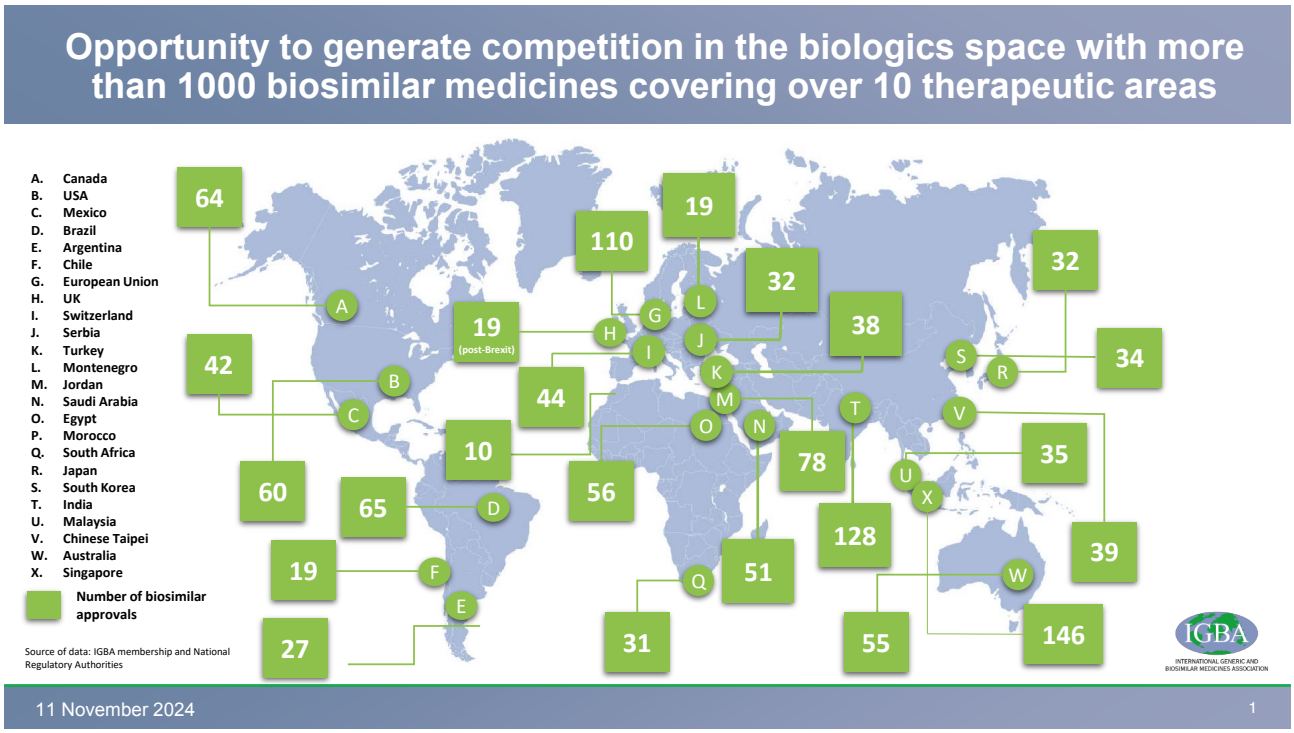
1. Regulatory Progress Across the Continent

- **Nigeria:** NAFDAC's 2021 biosimilar guidance requires manufacturers to demonstrate comparability in quality, safety, and efficacy. This alignment with international standards is a major step forward.
- **Kenya:** The Pharmacy and Poisons Board's guidelines cover recombinant biotherapeutics, including biosimilars, emphasizing scientific data and manufacturing quality. However that lack of an independent guideline for biosimilar can be seen as a shortcoming and a potential source of unclarity.
- **Rwanda:** On 20th October 2025, the Rwandan FDA approved *BioUcenta™* , a biosimilar of *Lucentis®* (ranibizumab) for eye diseases from Bio Usawa Inc. This landmark decision positions Rwanda and Bio Usawa Inc as regional leaders in biosimilar production and evaluation.
- **Egypt:** With **55 biosimilars** already available, Egypt is emerging as Africa's largest biosimilar market. The completion of the EIPICO 3 plant and new products such as *Adessia (Humira)* and *Zevanzia (Avastin)* demonstrate how clear regulation attracts investment.

- **Morocco:** The partnership between Biocad (Russia) and Sothema Labs has enabled local production of rituximab and bevacizumab biosimilars. However, the absence of a distinct approval pathway for true biosimilars versus "biocopies" underscores the need for stronger regulatory differentiation.

- **South Africa:** SAHPRA's framework mirrors EMA and WHO guidance, ensuring stringent evaluation. With **31 approved biosimilars** as of late 2024, South Africa is a continental pioneer.

Altogether, as of November 2024 (IGBA, 2024), Africa counts **97 biosimilars** across just three countries: **Egypt (56)**, **South Africa (31)** , and **Morocco (10)**. The rest of the continent still has significant room for growth, representing a huge opportunity for manufacturers and investors.



Source: IGBA

2. Building Local Manufacturing Capacity

Local production is essential for sustainability. African pharmaceutical companies are increasingly exploring partnerships with global manufacturers to transfer technology, knowledge, and skills.

The African Development Bank's recent €15 million loan to **Minapharm Pharmaceuticals** in Egypt exemplifies how financing can catalyze biosimilar manufacturing capacity for oncology and autoimmune diseases. Similar initiatives in Egypt, Morocco, Rwanda and South Africa are emerging, pointing toward a future where Africa can supply its own biosimilars instead of relying entirely on imports.

However, local production must go hand in hand with **quality assurance, skilled workforce development, regulatory oversight and pharmacovigilance post launch**. As noted by researchers Stuart Ssebibubbu, Denis Kibira, and Adriano Lubanga (2025), strengthening local pharmaceutical production is fundamental to achieving health equity and self-reliance.

3. Continental Coordination Through the African Medicines Agency

The **African Medicines Regulatory Harmonization (AMRH)** initiative, launched in 2009, laid the foundation for today's African Medicines Agency (AMA). Established in 2019, the AMA aims to harmonize drug regulation across member states and facilitate joint assessments of complex products, including biosimilars.

Biosimilars have already been prioritized for centralized evaluation under AMA, a move that could drastically reduce approval timelines and ensure consistent quality standards. This step represents a turning point for Africa's pharmaceutical sovereignty; transitioning from fragmented national systems to an integrated continental regulator.

4. Bridging Knowledge and Awareness Gaps

Despite regulatory progress, awareness of biosimilars among the African healthcare professionals remains limited. A systematic review by Alqawasmeh et al. (2024) found that many physicians and pharmacists in the MENA region lacked confidence in prescribing or switching patients to biosimilars due to misconceptions about variability and interchangeability.

In Africa, these barriers are even more pronounced with biosimilars unheard of by many healthcare professionals and patients. Addressing them requires **structured training** and integration of biosimilar science into medical, pharmacy, and regulatory curricula. Continuous professional education, transparent post-marketing data, and partnerships with manufacturers, patient's associations, universities, NGOs and experienced agencies such as the EMA or FDA could accelerate learning and build trust.

A Roadmap for Africa: From Regulation to Innovation

Europe's experience offers a clear roadmap for Africa's biosimilar future; a path built on **harmonization, education, and collaboration**.

1. **Harmonize and Strengthen Regulation**
   A unified biosimilar framework under the African Medicines Agency would ensure consistent evaluation standards and faster approvals. This would also make Africa a more attractive destination for clinical trials, manufacturing investment, and marketing authorization applications.

2. **Invest in Education and Communication**
   Regulators, professional associations, and manufacturers should prioritize awareness campaigns that explain biosimilar science, safety, and benefits to policy makers, healthcare workers and patients. Trust is built through understanding.

3. **Encourage Local Manufacturing and Partnerships**
   Strategic partnerships between African firms and global biopharma companies as well as South-South cooperation can accelerate technology transfer, reduce dependency on imports,

and stimulate job creation.

4. **Promote Transparent and Competitive Pricing**
   Pricing reforms should encourage fair competition while protecting sustainability. Transparent procurement and reimbursement systems can make biosimilars widely accessible without undermining innovation.

5. **Leverage Political Will for Pharmaceutical Sovereignty**
   The growing momentum around the African Medicines Agency and initiatives like the African Continental Free Trade Area (AfCFTA) should be harnessed to create a strong, integrated biopharmaceutical market.

Conclusion: A Shared Vision for the Future

Europe's biosimilar success story shows what is possible when science, regulation, and trust align. Africa now stands at a similar crossroads with the potential to transform access to biologic medicines for its people while fostering innovation at home.

By combining **clear regulation, local expertise, and stakeholder collaboration**, Africa can move from being a passive importer to a **continental hub for biosimilar innovation, research & development, and manufacturing**.

The goal is not just access, it is **self-reliance**, **affordability**, and **equity** in healthcare. The lessons are already written in Europe's experience; Africa's opportunity is to adapt them to its own reality and lead the next chapter in the global biosimilar journey.

If you enjoyed this edition of **Biosimilars Beyond Borders**, I invite you to **subscribe** to stay updated on future insights into biosimilar development, regulation, and access across emerging markets.

Your **comments, thoughts, and shares** help spark the conversations that move our industry forward. Let's keep learning, collaborating, and shaping the future of biosimilars together.

#Biosimilars #PharmaAfrica #HealthInnovation #Regulation #Biotech #EmergingMarkets #BioSenPharma #BiosimilarsBeyondBorders #Act4Biosimilars #IGBA #AUDANEPAD #AMA