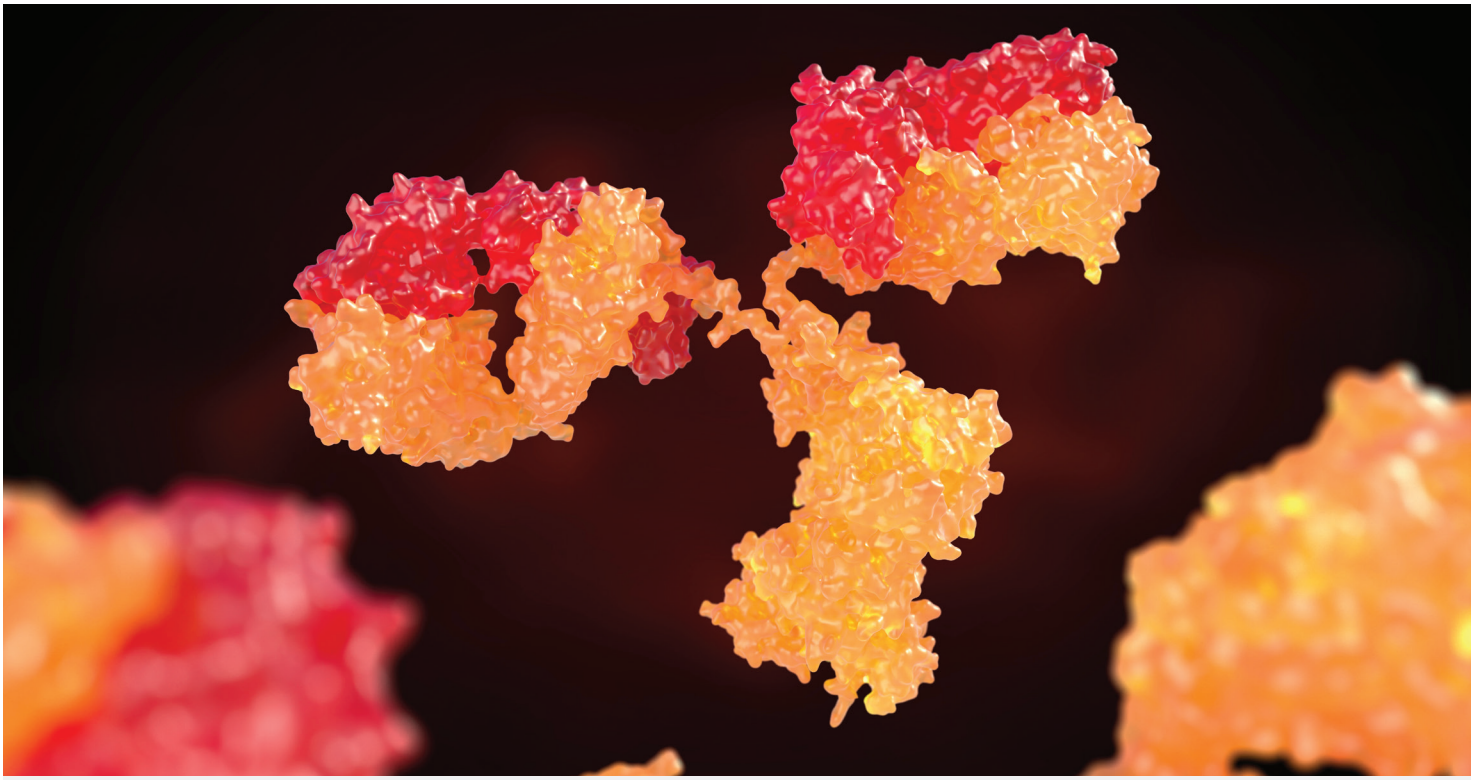

Unveiling the Potential of Biosimilars: Past Achievements and Future Prospects

Springer

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Introduction

Biosimilars are safe and effective treatment options for many illnesses, such as chronic skin and bowel diseases (like psoriasis, irritable bowel syndrome, Crohn's disease, and colitis), arthritis, kidney conditions, and cancer. These medicines are very close in structure and function to biologic medicines and increase access to lifesaving medications at potentially lower costs. They are highly similar to a biologic medication already approved by a regulatory body – the original biologic (also called the reference product).

Both a biosimilar and its original biologic:

- Are made from the same types of sources (e.g. living sources)
- Provide the same benefits when treating diseases or medical conditions
- Are provided at the same strength and dosage
- Are not expected to cause new or worsening side effects

Biosimilars versus generics

Biosimilars and Generics are alternate versions of medications that are already approved by a regulatory body, but these two types of medicines show some significant differences:

Biosimilars		Generics
Generally made from living organisms		Generally made from chemicals
Require a specialized process	V	Have a simpler process to copy
Very similar but not identical to original biologic	E	Copy of brand-name drugs
Faster development process using public information from original biologic approval	R S U S	Faster development process using public information from brand-name drug approval
Usually less expensive than original biologic		Usually less expensive than brand-name drugs

Advantages of biosimilars

- Biosimilars provide a lower-cost option to replace original-brand products
- Improve access to patients when compared to the reference biologics
- Provide more treatment options for patients with serious and life-threatening diseases
- Similarly effective as the reference biological medicines

Global distribution of biosimilars approvals (5 years)

In recent years, biosimilars have gained significant attention and importance in healthcare, particularly in the United States and Europe. These biological products, which are highly similar to reference biologic medicines, offer increased access to cost-effective treatments and can potentially lower healthcare expenditures.

In 2019, the United States witnessed a remarkable number of biosimilars being approved, which resulted in the Food and Drug Administration (FDA) granting marketing authorization to a record-breaking number of these products (10). These FDA approvals covered various therapeutic areas, including oncology, immunology, and endocrinology. The greater availability of biosimilars in the United States is expected to enhance competition, potentially leading to reduced healthcare costs and increased patient access to critical biological treatments.

The European Medicines Agency (EMA) has been involved in the approval of biosimilars in Europe since 2006. Europe has been at the forefront of biosimilar adoption, with the highest number of biosimilar approvals observed in previous years. As of 2021, the European Union has continued to see a significant number of biosimilar approvals (9), with numerous products gaining authorization for use.

Biosimilars approved in 5 years

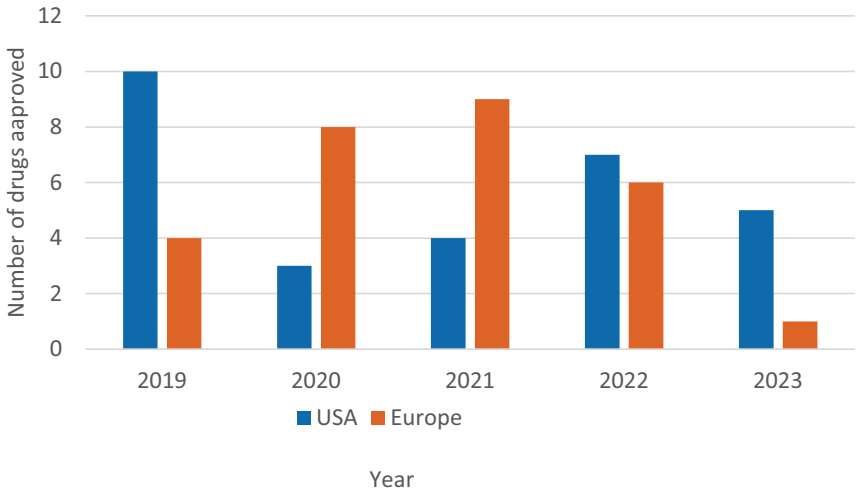

Fig. 1: Yearly trend of biosimilars approved from 2019-2023 in US and EU

In the last five years the US FDA and EMA have approved 28 and 30 biosimilars respectively (Table 1 and Table 2). The highest number of biosimilars have been approved for cancer (19), followed by immunological disorders (17).

Table 1: Approved biosimilars in USA (5 Years)

Name	Company Name	FDA Approval date
Actemra (tocilizumab) biosimilars		
Tofidence (tocilizumab-bavi)	Biogen Inc.	29-Sep-23
Avastin (bevacizumab) biosimilars		
Avzivi (bevacizumab-tnjn)	Bio-Thera Solutions, Ltd.	6-Dec-23
Vegzelma (bevacizumab-adcd)	Celltrion, Inc.	27-Sep-22