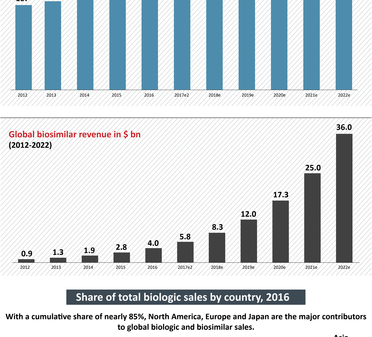
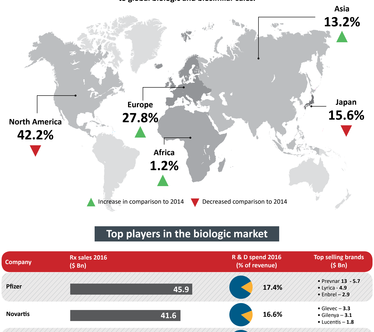
Biosimilar Market Landscape Analysis

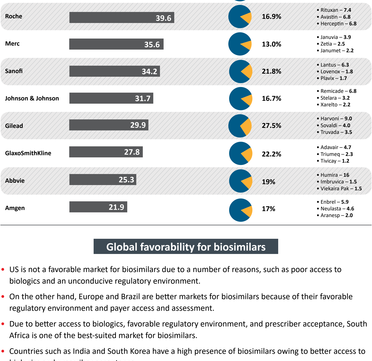
By 2022, the global biosimilar market is expected to reach USD 36 billion, while the biologic market is expected to reach USD 261 billion.





Share of total biologic sales by country, 2016

With a cumulative share of nearly 85%, North America, Europe and Japan are the major contributors to global biologic and biosimilar sales.



Top players in the biologic market

Company	Rx sales 2016 ($ Bn)	R & D spend 2016 (% of revenue)	Top selling brands ($ Bn)
Pfizer	45.9	17.4%	• Prevnar 13 - 5.7 • Lyrica - 4.9 • Enbrel - 2.9
Novartis	41.6	16.6%	• Gleevec – 3.3 • Gilenya – 1.1 • Lucentis – 1.8
Roche	39.6	16.9%	• Rituxan – 7.4 • Avastin – 6.8 • Herceptin – 6.8
Merc	35.6	13.0%	• Januvia – 3.9 • Zetia – 2.5 • Janumet – 2.2
Sanofi	34.2	21.8%	• Lantus – 6.3 • Lovenox – 1.8 • Plavix – 1.7
Johnson & Johnson	31.7	16.7%	• Remicade – 6.8 • Stelara – 3.2 • Xarelto – 2.2
Gilead	29.9	27.5%	• Harvoni – 9.0 • Sovaldi – 4.0 • Truvada – 3.5
GlaxoSmithKline	27.8	22.2%	• Advair – 4.7 • Tivumeq – 2.3 • Tivicay – 1.2
Abbvie	25.3	19%	• Humira – 16 • Imbruvica – 1.5 • Viekaira Pak – 1.5
Amgen	21.9	17%	• Enbrel – 5.9 • Neulasta – 4.6 • Aranesp – 2.0

Global favorability for biosimilars

- US is not a favorable market for biosimilars due to a number of reasons, such as poor access to biologics and an unconducive regulatory environment.
- On the other hand, Europe and Brazil are better markets for biosimilars because of their favorable regulatory environment and payer access and assessment.
- Due to better access to biologics, favorable regulatory environment, and prescriber acceptance, South Africa is one of the best-suited market for biosimilars.
- Countries such as India and South Korea have a high presence of biosimilars owing to better access to biologics and prescriber acceptance.

Regions		Access to biologics	Regulatory environment	Payer access & assessment	Prescriber acceptance	Patient acceptance	Biosimilars presence
Developed countries	US	🔴	⚪	🔴	🔴	🔴	🔴
	EUS	🔴	🟢	🟢	⚪	⚪	🟢
	Japan	🔴	🟢	⚪	🔴	🔴	🟢
BRICS	Brazil	🟢	🟢	🟢	⚪	⚪	🔴
	Russia	⚪	🟢	🔴	🔴	⚪	🔴
	India	🟢	🟢	🟢	⚪	⚪	🟢
	China	🟢	🟢	🟢	⚪	🔴	🔴
	South Africa	🟢	🟢	🟢	🟢	⚪	🔴
MIST	Mexico	⚪	🟢	🟢	⚪	⚪	🔴
	Indonesia	🟢	🔴	⚪	⚪	🔴	🔴
	South Korea	🟢	🟢	🟢	⚪	⚪	🟢
	Turkey	⚪	🟢	🔴	⚪	⚪	🔴

🟢 Highly favourable for biosimilars ⚪ Moderate / Neutral for biosimilars 🔴 Unfavorable for biosimilars

Timeline and budget - biologics vs biosimilars

Biologics are more expensive and take longer to reach the market compared to biosimilars.

	Generic	Biologics	Biosimilars
Development cost (US$)	3-4 Million	700-800 Million	200-300 Million
Time to market	3-4 Years	8-9 Years	6-7 Years
Clinical studies	Bioequivalence studies in healthy Volunteers	Phase I-III efficacy and safety studies	Comparative pharmacokinetic and Phase III studies
Patients enrolment (approximate)	50	1000	500
Post approval activities	Pharmacovigilance	Phase IV, Risk management Plan including Pharmaco vigilance	Phase IV, Risk management Plan including Pharmacovigilance

Number of autoimmune biosimilars in the pipeline (US and EU)

The US Food and Drug Administration has approved the second biosimilar (first monoclonal antibody) in the US, known as Inflectra (infliximab), which is similar to Janssen's Remicade (infliximab). The infliximab by Pfizer and Celltrion is approved as biosimilar and not as an interchangeable product. The same biosimilar was approved in the EU in 2013. Netscribes estimates that around 16 to 20 biosimilars will be approved and launched between 2018 to 2021 in both US and EU.

*ABP 501 is in clinical research for rheumatoid arthritis in US and for rheumatoid arthritis and psoriasis in Europe; # Under clinical development in Europe; Abbreviations: PS - Psoriasis; RA - Rheumatoid Arthritis; CD - Crohn's Disease; BI - Boehringer Ingelheim; FKB - Fujifilm Kyowa Kirin Biologics; EB - Epirus Biopharmaceuticals; ONS - Oncobiologics; SB -Samsung Biepis; BLA - Biologic license application , June 2016.

Rituximab Biosimilars Timeline

About Netscribes

Founded in 2000, Netscribes is a global market intelligence and content management firm with services across the research and information value chain. Venture-funded by US and Singapore private equity firms, Netscribes provides tactical and actionable insights to its clients and enables effective decision-making and strategic implementation.

For healthcare firms, Netscribes provides market intelligence solutions to address various needs such as concept testing of medical devices, patent research and analysis, investment decision analysis, innovation research, channel management and consumer analysis.

For detailed research on biosimilars, contact info@netscribes.com.

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