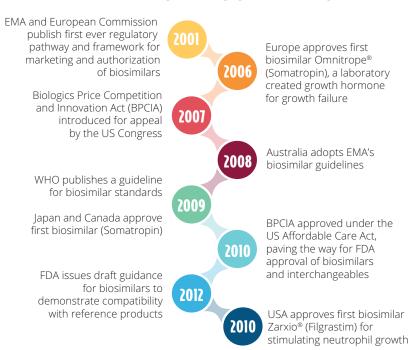
By the Numbers: Biosimilars

Section Editor: The ISPOR Student Network

DISTRIBUTION OF APPROVED BIOSIMILARS BY THERAPEUTIC AREA, FDA VS EMA

Therapeutic Area	FDA ¹	EMA ²	
Rheumatology	40%	27%	
Oncology	20%	22%	
Infectious diseases	10%	20%	
Hematology	10%	12%	
Endocrinology	0%	10%	
Gynecology	0%	5%	
Gastroenterology	20%	0%	
Cardiology	0%	2%	
Medical genetics	0%	2%	

TIMELINE FOR BIOSIMILARS^{1,2,3}



STAKEHOLDER PERSPECTIVES ON BIOSIMILARS



- 80% are ready to consider pharmacy-level substitution of biologics with biosimilars
- · 33% of patients are not confident about biosimilars even when prescribed and explained by the treating physician
- 17% feel biosimilars will become the norm in the next 3 years

PATIENTS'
PERSPECTIVE^{6,7}

- 90% patients believe that they had the right to make an informed choice about their treatment and did not support automatic substitution of a biosimilar for a reference product.
- · 75% were concerned about the extrapolation of indications for biosimilars



- · 88% believe that biosimilars will reduce specialty drug prices
- 80% consider biosimilars to be lower-cost branded options and not generics
- UK payers expect biosimilar market share to be 80% in next 5 years

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²http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_001832.jsp

https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580432.htm

³ https://www.slideshare.net/smallworldsocial/timeline-47574081

⁴ InCrowd Survey. Nearly Half of US Physicians Say They Will Prescribe More Biosimilars, Boston, MA. March 3, 2016. Available at: https://incrowdnow.com/press-release/nearly-half-of-us-physicians-say-they-will-prescribe-more-biosimilars-according-to-new-data-from-incrowd/

⁵ Cohen H, Beydoun D, Chien D, et al. Awareness, Knowledge, and Perceptions of Biosimilars Among Specialty Physicians. Adv Ther. 2016;33(12):2160-2172.

Peyrin-Biroulet L, Lönnfors S, Roblin X, Danese S, Avedano L. Patient Perspectives on Biosimilars: A Survey by the European Federation of Crohn's and Ulcerative Colitis Associations: J Crohn's Colitis. 2017;11(1):128-133. doi:10.1093/eccc-jcc/jjw138 2.

[?] Patient Views on Similar Biologic Medicines: "No Forced Change". Cision Canada. Toronto, Canada. July, 2017. Available at: https://www.newswire.ca/news-releases/patient-views-on-similar-biologic-medicines-no-forced-change-636923953.html

"How Do US Payers View Biosimilars From a Cost Perspective? The Center for Biosimilar Staff, December 2016. Available at: http://www.centerforbiosimilars.com/news/how-do-us-payers-view-biosimilars-from-a-cost-perspective