



PBMs Support the Proliferation and Use of Biosimilars

In 2023, the bestselling biologic drug in the world will—for the first time—face direct competition from biosimilars in the United States, presenting an opportunity to lower drug costs for thousands of patients.

PBMs value biosimilars and support efforts to increase the number of biosimilars coming to market because increased competition drives down costs. Having multiple products with equivalent patient benefits on the market gives us an opportunity to push manufacturers to compete on pricing and provide our clients with the lowest cost products. As production and licensing of biosimilar medications increases, the competitive marketplace for biologic medications is enhanced.

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Interchangeability: Focusing on Science

Last month, the European Medicines Agency (EMA) released a statement on the scientific rationale supporting interchangeability of biosimilar medicines in the European Union (EU). The statement included the following position on interchangeability:

Interchangeability refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect. [Heads of Medicines' Agencies] HMA and EMA consider that once a biosimilar is approved in the EU it is interchangeable, which means the biosimilar can be used instead of its reference product (or vice versa) or one biosimilar can be replaced with another biosimilar of the same reference product.¹

While the EMA has always considered interchangeability of approved biosimilars acceptable, this was the first time it released an official statement on the matter with the stated intention of reducing confusion and increasing uptake. The last 15 years of successful widespread use of biosimilars across the EU has resulted in evidence that, "switching between biological medicinal products manufactured and commercialized by different companies has become common in clinical practice, and interchangeability of EU-licensed biosimilars has been confirmed," further, "approved biosimilars have demonstrated comparable efficacy, safety and immunogenicity compared with their reference products."^{2 3 4 5 6}



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Considering the EU's 15 years of clinical experience with biosimilars, PCMA recommends removal of the interchangeability designation to reduce ambiguity and increase uptake, which will ultimately decrease health care costs. We encourage policymakers to support the scientific findings from the EU, which are consistent with the experience in the United States. Over the last 12 years, biosimilars in the US have established a similar track record of reliability. Recognizing the elimination of the interchangeability designation requires congressional action, we encourage the FDA to consider removing the requirement for additional clinical switching studies to meet interchangeability standards while we await a statutory fix. To further the aims of reducing confusion, eliminating unnecessary costs, and encouraging use, biosimilar product labels should include all indications approved under the biologic reference product's license.

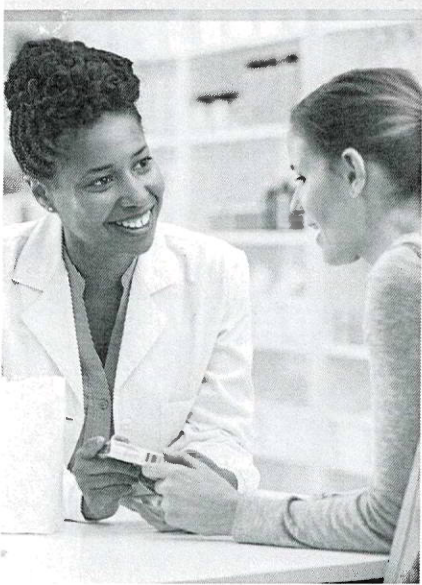
Patents: Further Enhancing the Competitive Marketplace

Three key changes could address most anticompetitive practices that suppress competition in the biosimilars market today.

- 1. Revise innovator biologic exclusivity to seven years.** Seven years (reduced from 12 years under current law) of market exclusivity would provide sufficient financial return for manufacturers while speeding biosimilars to market to promote affordability and access.
- 2. Prohibit "product hopping" and "patent thickets."** Product hopping occurs when a brand manufacturer makes marginal changes to a product and moves customers from one branded drug to a remarkably similar drug with a longer patent life to extend market exclusivity. Patent thickets are a group of overlapping patents used to again, prevent fair competition. Brand manufacturers often file patents after a product is on the market—sometimes, 70 to 90% of the patents filed on a product are filed after it has come to market⁷ Both anticompetitive practices should be prohibited.
- 3. End anticompetitive pay-for-delay agreements.** Patent settlements, or "pay-for-delay" agreements, allow brand drug and biologic patent holders to pay potential competitors to delay market entry or not produce a competing generic drug or biosimilar to keep their competitive advantage.

Plan Flexibilities: Quick Access to New Biosimilars

In 2023, we expect several new biosimilars to come to market; however, because formularies are set months in advance, patients are usually not able to benefit from the new more competitive marketplace and pay less for their drugs until the next set of drug pricing negotiations occur months—or even a year—later. To lower the cost of drugs quicker, as new biosimilars are released, PCMA recommends that the Centers for Medicare & Medicaid Services ensure plans have the flexibility to make midyear changes to formularies, replacing reference products with biosimilars not designated as interchangeable, without the need for additional permissions and notifications. To guarantee that all patients can benefit equally, plans in every state should have the flexibility to make midyear formulary changes when new biosimilars are released.



Additional Recommendations:

Aligning US scientific standards with those in the EU, curbing patent abuses, and enhancing plan flexibility will go a long way toward improving biosimilars production and uptake; however, more can be done to address known barriers. In every setting where biosimilars are discussed, it is noted that patients and providers do not always have the information they need to make informed decisions. Educational efforts by the FDA and other reliable sources should continue and more resources and public funding should be made available for patient and provider education. Additionally, more can be done to stop misinformation. Manufacturers of brand and biosimilar products who disparage biosimilars or imply they are somehow inferior to biologic reference products should be held accountable through increased oversight and enforcement of marketing violations.

Finally, some patients have faced challenges accessing their biosimilar medications at the pharmacy counter due to operational difficulty. The FDA's Orange Book provides product information for small molecule drugs including a list of approved generics and the FDA's Purple Book contains information about biological products, including biosimilar and interchangeable biological products. Today, pharmacies have substitution information for small molecule drugs at their fingertips through their electronic systems with integrated Orange Book data, but Purple Book data feeds are not as common. To improve patient access, pharmacy systems should be required to include both sets of data.

- 1 EMA. Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU. 2022, Sept 19. Available at https://www.ema.europa.eu/en/documents/public-statement/statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf.
- 2 Kurki P. et al. Interchangeability of Biosimilars: A European Perspective. *BioDrugs*. Apr 2017. 31(2):83-91
- 3 Barbier L. et al. Regulatory Information and Guidance on Biosimilars and Their Use Across Europe: A Call for Strengthened One Voice messaging. *Frontiers in Medicine*. 2022. Vol 9, 820755
- 4 Kurki P. et al. Safety, Immunogenicity and Interchangeability of Biosimilar Monoclonal Antibodies and Fusion Proteins: A Regulatory Perspective. *Drugs* 2021 Nov. 81(16):1881-1896
- 5 Ebbers H. et al. The safety of switching between therapeutic proteins. *Expert Opinion Biol Ther*. 2012; 12:1473-85
- 6 Biosimilars in the EU - Information guide for healthcare professionals (europa.eu)
- 7 Overpatented, Overpriced. I-MAK. 2022. Available at <https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf>.

ABOUT PCMA

PCMA is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans who have health insurance from a variety of sponsors including: commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, the Federal Employees Health Benefits Program (FEHBP), state government employee plans, Medicaid plans, and others.

