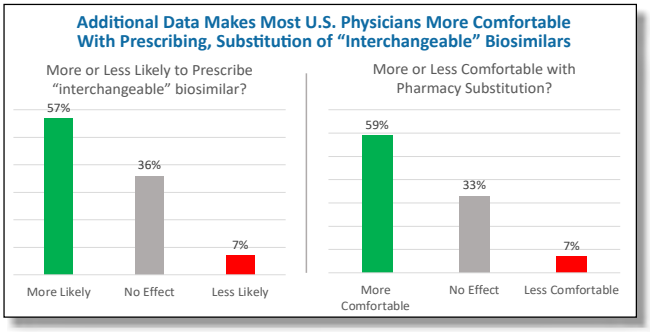
INTERCHANGEABLE BIOSIMILARS

EMERGING POLICY CHALLENGES

OVERVIEW OF CURRENT POLICY

While all FDA-approved biosimilars are safe and effective, interchangeable biosimilars have provided additional data to the FDA to demonstrate a patient can be switched between the interchangeable biosimilar and the originator and expect the same result with both products. Like physicians worldwide, most U.S. physicians (58%) strongly oppose substitution of biosimilars by someone other than the doctor for non-medical reasons (e.g. cost). But the extra data increases their confidence: **most physicians (57%) are more comfortable prescribing an interchangeable, and with an interchangeable being substituted in place of the prescribed originator product (59%)[1].**



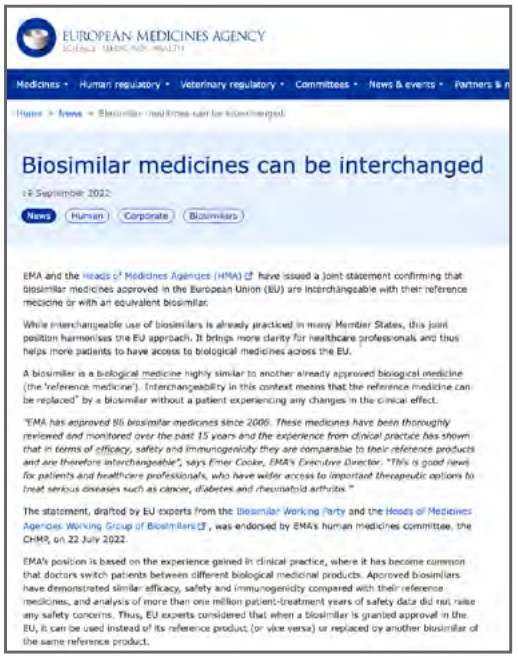
From 2013-2021, patient advocacy organizations including ASBM partnered with state medical societies, pharmacy organizations, and other stakeholders nationwide to successfully pass **legislation in all 50 states which limits automatic substitution at the pharmacy level only to interchangeable biosimilars.**

EMERGING POLICY CHALLENGES

Current policy regarding interchangeable biosimilars is being challenged at the international, federal, and state level. These challenges include attempts to blur the distinction between interchangeable and non-interchangeable biosimilars, to weaken the standard's data requirements, and to eliminate or circumvent existing barriers to the widespread automatic substitution of non-interchangeable biosimilars:

INTERNATIONAL

In September 2022, the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) released a joint statement [2] declaring all EMA-approved biosimilars to be "interchangeable." This statement sowed confusion in the U.S., creating the inaccurate impression that the U.S. lags far behind Europe with only a handful of interchangeable biosimilars. This statement was subsequently reiterated in a Q&A [3] and explainer video [4].


EUROPEAN MEDICINES AGENCY

Medicines • Human regulatory • Veterinary regulatory • Committees • News & events • Partners & n

Home > News > Biosimilar medicines can be interchanged

Biosimilar medicines can be interchanged

19 September 2022

News | Human | Corporate | Biosimilars

EMA and the Heads of Medicines Agencies (HMA) have issued a joint statement confirming that biosimilar medicines approved in the European Union (EU) are interchangeable with their reference medicine or with an equivalent biosimilar.

While interchangeable use of biosimilars is already practiced in many Member States, this joint position harmonises the EU approach. It brings more clarity for healthcare professionals and thus helps more patients to have access to biological medicines across the EU.

A biosimilar is a biological medicine highly similar to another already approved biological medicine (the 'reference medicine'). Interchangeability in this context means that the reference medicine can be replaced by a biosimilar without a patient experiencing any changes in the clinical effect.

"EMA has approved 86 biosimilar medicines since 2006. These medicines have been thoroughly reviewed and monitored over the past 15 years and the experience from clinical practice has shown that in terms of efficacy, safety and immunogenicity they are comparable to their reference products and are therefore interchangeable", says Emer Cooke, EMA's Executive Director. "This is good news for patients and healthcare professionals, who have wider access to important therapeutic options to treat serious diseases such as cancer, diabetes and rheumatoid arthritis."

The statement, drafted by EU experts from the Biosimilar Working Party and the Heads of Medicines Agencies Working Group of Biosimilars, was endorsed by EMA's human medicines committee, the CHMP, on 22 July 2022.

EMA's position is based on the experience gained in clinical practice, where it has become common that doctors switch patients between different biological medicinal products. Approved biosimilars have demonstrated similar efficacy, safety and immunogenicity compared with their reference medicines, and analysis of more than one million patient-treatment years of safety data did not raise any safety concerns. Thus, EU experts considered that when a biosimilar is granted approval in the EU, it can be used instead of its reference product (or vice versa) or replaced by another biosimilar of the same reference product.

In reality, the EMA/HMA statement explicitly states that "interchangeable" means only that "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." In other words, European prescribers, just like their U.S. counterparts, can substitute a biosimilar for the reference product or a biosimilar to that product. The EMA/HMA also explicitly state that their statement does not refer to pharmacy level-substitution: "the practice of dispensing one medicine instead of another medicine without consulting the prescriber, such as automatic substitution at the pharmacy level, are not within the remit of EMA and are managed by individual member states."

Notably, automatic substitution of biosimilars is rare in Europe, and indeed banned in many countries. In nearly every Western European country, physicians are largely free to choose among many reimbursed products, including the originator and several biosimilars.

FEDERAL REGULATION

In November 2023, CMS published a Proposed Rule for 2025 [5] which would permit Medicare Part D plan sponsors to switch patients to - that is, to automatically substitute- non interchangeable biosimilars.

This policy represents a stark departure from the substitution practices of most advanced countries of the world (for example, Western Europe), the perspectives of the U.S. medical community and patient advocacy organizations, a decade of state-level policymaking nationwide, and CMS' own assurance [6] less than a year earlier, that this would not be permitted.

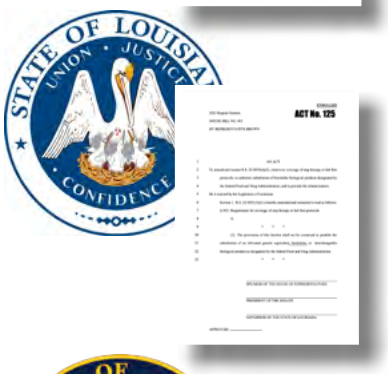
FEDERAL LEGISLATION

S.6/S.2305, introduced in 2022 and updated in 2023, "The Biosimilar Red Tape Elimination Act"is sponsored by Senator Mike Lee (R-UT) [7]. It combines two proposals from earlier Senate bills that would weaken the interchangeability standard in different ways: One of these would deem all FDA-approved biosimilars interchangeable (i.e., automatically substitutable at the pharmacy level nationwide under existing state law) and the other would heavily restrict the FDA's use of switching studies when making a determination that a biosimilar is interchangeable, limiting the FDA's flexibility and weakening data requirements.

STATE LEGISLATION

Louisiana HB 403 (2023) [8] added language permitting any (i.e., a non-interchangeable) biosimilar to be substituted at the pharmacy level without prior physician approval, where previously only an "interchangeable biosimilar" could be substituted in this manner.

This bill highlights the vulnerability of the state substitution legislation passed nationwide from 2013-2021.



PRESCRIPTION DRUG ADVISORY BOARDS (PDABs)

In December 2023, the Oregon PDAB issued its recommendations [9] to the Oregon Legislature, which included a recommendation to enact proposals from America's Health Insurance Plans (AHIP) to change Oregon law to permit the automatic substitution of non-interchangeable biosimilars and to eliminate the requirement for the patient to be notified in the event of a biosimilar substitution. Critically, in Oregon as in other states the support of patient and physician groups for legislation permitting any pharmacy-level biosimilar substitution at all was contingent on assurances from lawmakers that it would be limited to interchangeable biosimilars and that patients would be notified.

PDABs (or equivalent state drug pricing boards) now exist in Colorado, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Ohio, Oregon, and Washington. In addition, PDABs are also in development or being considered in Illinois, Michigan, Nebraska, Vermont, and Virginia.

These boards are known to collaborate and coordinate on tactics and policy, indicating a strong likelihood that other PDABs will soon follow Oregon's lead.

1 https://tinyurl.com/USPhys2021
2 https://www.ema.europa.eu/en/documents/public-statement/statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf
3 https://www.ema.europa.eu/en/documents/other/qa-statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf
4 https://youtu.be/VkVDzo2EB1o
5 https://www.cms.gov/newsroom/fact-sheets/contract-year-2025-policy-and-technical-changes-medicare-advantage-plan-program-medicare?trk=feed_main-feed-card_reshare_feed-article-content
6 https://www.federalregister.gov/documents/2022/12/27/2022-26956/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program
7 https://www.govtrack.us/congress/bills/118/s2305/text
8 https://legiscan.com/LA/bill/HB403/2023
9 https://dfr.oregon.gov/pdab/Documents/reports/2023-PolicyRecommendations.pdf