

INTERCHANGEABLE BIOSIMILARS

COMPARING EUROPE & THE U.S.

There is a **common misconception** that “all biosimilars are interchangeable in Europe”, and that the U.S. lags far behind with only 7 of its 44 biosimilars (roughly 16%) interchangeable.

This misunderstanding stems from the fact that the word “interchangeable” has different meanings in the U.S. and Europe:

IN EUROPE: “INTERCHANGEABLE” MEANS “SUBSTITUTABLE BY THE PHYSICIAN”

The European Medicines Agency (EMA) has **stated**¹ all biosimilars it approves are “interchangeable” in that they “may be **prescribed interchangeably**”. It reiterated that **this does not refer to pharmacy substitution**: “Member States will continue to decide...whether automatic substitution is allowed at the pharmacy level.”

Most European physicians (73%) **strongly oppose substitution of biosimilars by someone other than the doctor** for non-medical reasons (e.g. cost)²

Accordingly, this controversial practice is **extremely rare in Western Europe and banned in many countries**.


Some resource-constrained Eastern European countries do permit the practice, however.

IN THE US: “INTERCHANGEABLE” MEANS “SUBSTITUTABLE BY A PHARMACIST”

In the U.S. “interchangeable” refers to a biosimilar **which under state law may be substituted without prescriber authorization at the pharmacy level** because its manufacturer has provided **additional data** to the FDA which demonstrate a patient can be **switched between the interchangeable biosimilar and the originator and expect the same result** with both products.

Like their European counterparts, most U.S. physicians (58%) **strongly oppose substitution of biosimilars by someone other than the doctor** for non-medical reasons (e.g. cost).³

Extra data increases physician confidence: **most physicians (57%) are more comfortable prescribing an interchangeable, and with an interchangeable being substituted in place of the prescribed originator product (59%)**³



In other words, all U.S. biosimilars are interchangeable under the European definition, in that they may be prescribed interchangeably by the physician.

Additionally, seven biosimilars can be substituted automatically at the pharmacy because extra data provided to the FDA demonstrated substitution didn't diminish safety or efficacy.

