

## Biosimilars

### The topic

Follow-on biologics, or “biosimilars,” are biologic products manufactured using different cell lines and manufacturing processes with the goal of closely mirroring the composition and treatment profile of the original product produced by another company. Due to the innate complexity of biologics, the production of biosimilar products will invariably lead to some differences between the biosimilar and the original product. Unlike generic copies of traditional small molecule drugs, biosimilar biologic products are therapies that are similar to, but not the same as, innovator therapies.

According to the US Food and Drug Administration, biosimilars have no clinically meaningful differences in safety, purity, or potency, compared to the reference product. However, minor differences in clinically inactive components in biosimilars, or in biosimilar injection devices, may lead to different patient experiences. Patient, physician, pharmacist, and payer confidence in biosimilars requires scientifically appropriate regulatory standards, trusted manufacturing and supply, and transparent interchangeability/substitution policies. We want patients and providers to be informed so that any differences in response can be documented.

### UCB’s Values

Our purpose is to create value for patients now and into the future. We continuously innovate to bring differentiated solutions with unique outcomes that help patients achieve their life goals and create for them the best individual experience. This also means ensuring access for all who need these solutions, in a way which is viable for UCB, for patients, for communities, and for society.

UCB is dedicated to the continued evolution of a public policy environment that recognizes and rewards innovation, encourages value-based care, and promotes affordable access to medicines for patients. We believe that generic and biosimilar medicines are important for sustainable health systems.

### UCB’s Approach

As intellectual property is a key facilitator of medical progress, we support policies that enable sustainable protection of IP to reward and strengthen innovation that provides value to patients. Generic and biosimilar medicines play an important role in the sustainability of health systems and the promotion of a healthy innovation lifecycle. With this in mind, we use our patent rights in a manner that encourages effective and fair marketplace competition that ultimately benefits patients, and support policies which seek to prevent unfair barriers to competition.

## Supporting Sustainable Healthcare Systems

Sustainable healthcare systems, critical for consistently providing quality patient care, must allow for informed decision making between patients and their health care providers and space for continued innovation in drug research and development. We support continuity of care, allowing continued access (or parity access) to branded molecules for patients who need them. We also support flexible policies that encourage sustainability or security of supply.

Patients must be able to access the best treatment for their condition. Prescribing physicians and their patients are in the best position to evaluate a patient's therapeutic options, and thus it is important for the treating physician and the patient to be able to designate exactly which product they believe should be dispensed to the patient.

## Driving Innovation and Creating a Brighter Future for Patients

As a global biopharma company leading the way in immunology and neurology, UCB supports programs for patients and their families, state of the art disease education, scholarship programs, and **UCBCares**, a dedicated service providing support to patients and healthcare professionals throughout the treatment journey. Meaningful savings and long-term stability can accrue from the increased competition with biosimilars and promote sustainability of the healthcare system. UCB supports the development and marketing of biosimilars in a science-based approach, including head-to-head studies of originator vs biosimilar therapies and promotion based on scientifically accurate education.