



## Biosimilars

**The Academy of Managed Care Pharmacy (AMCP) supports the expedited approval pathway to allow biosimilars to enter the market to ensure that consumers have access to safe and effective Food and Drug Administration (FDA) approved life-saving therapies for use in the treatment, prevention, and cure of inevitable and otherwise untreatable and incurable conditions.**

*AMCP specifically supports the following principles to encourage adoption of biosimilars in the United States:*

- Ensuring that the approval process balances bringing safe and effective therapies to market while maximizing patient access to affordable biologics.
- The requirement that applicants seeking approval of biosimilars be required to conduct clinical studies as part of the approval process if the FDA determines on a case-by-case basis that such studies are necessary.
- The requirement that applicants seeking approval of biosimilar products be required to conduct post-market studies as a pre-condition for approval if the FDA determines on a case-by-case basis that such studies are necessary.
- The authority granted to the FDA to determine whether an approved biosimilar is interchangeable with the brand name biologic. The determination of interchangeability by the FDA should not require any additional unnecessary requirements, such as prescriber notification, that reduce the potential for marketplace adoption of biosimilars.
- The requirement that the manufacturer of an approved biosimilar be allowed to use the same government approved international non-proprietary name (INN) as the innovator biologic without a hyphenated prefix or suffix. Prefixes and suffixes introduce confusion and unnecessary complexity by adding another piece of information that could result in inadvertent medication error selection by prescribers and pharmacists if they are not visible in database fields and may result in products not being listed alphabetically. Other proven methods currently exist for ensuring accurate product identification used for active surveillance, including national drug codes, HCPCS and J Codes, manufacturer name, and lot number. The existing tools should be more effectively utilized and others should not be unnecessarily added.
- Consistent with the *Biologics Price Competition and Innovation Act*, the market exclusivity time period should provide an incentive for the development of new biologics but allow a manufacturer to recoup its investment in the research and development of its product plus realize an appropriate profit; however, the specific time period should ensure a robust marketplace.

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*Academy of Managed Care Pharmacy (AMCP) is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to assist patients in achieving positive therapeutic outcomes. AMCP's nearly 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit. More news and information about AMCP can be obtained on its website, at [www.amcp.org](http://www.amcp.org).*