



Proposed Policy to House of Delegates

Biologic, Biosimilar, and Interchangeable Biologic Drug Products

Proposed Statements

The 2015-2016 APhA Policy Committee recommends that the American Pharmacists Association adopt the following statements:

1. APhA urges the development of programs and policies that facilitate patient access to and affordability of biologic products.
2. APhA urges the Food and Drug Administration (FDA) to expedite the development of standards and pathways to evaluate the interchangeability of biologic products.
3. APhA recognizes FDA's Purple Book as the authority on biologic product interchangeability within the United States and discourages development of nonconforming domestic interchangeability lists.
4. APhA opposes interchangeable biologic product substitution processes that require authorization, recordkeeping, or reporting beyond generic product substitution processes.
5. APhA encourages scientific justification for extrapolation of indications for biologic products to ensure patient safety and optimal therapeutic outcomes.