Approval Process
An overview of biosimilars in the oncology setting

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**BACKGROUND:** Following approval of the Biologics Price Competition and Innovation Act of 2009, biosimilars are gradually entering the market in the United States. With the introduction of more biosimilars into the marketplace, all healthcare providers should be familiar with the approval and evaluation process, the naming convention applied to these agents, and the importance of accurate pharmacovigilance.

**OBJECTIVES:** This article aims to describe the approval process of biosimilars, including extrapolation, and to help healthcare providers understand when a biosimilar may be interchanged for the reference biologic and the naming convention used for biosimilars. In addition, this article explores how these topics affect confidence in dispensing and pharmacovigilance.

**METHODS:** A literature review was conducted, and search terms and variation included biosimilar agents AND FDA approval, legislation, interchangeability, naming conventions, confidence in dispensing, and pharmacovigilance.

**FINDINGS:** Healthcare providers involved in the dispensing and administration of biosimilar and interchangeable biologics need to be continually educated to ensure confidence, familiarity, and accuracy with the processes surrounding biosimilars.

**KEYWORDS**
biosimilar; legislation; interchangeability; pharmacovigilance

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