

# Biosimilars

## Considerations for oncology nurses

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**BACKGROUND:** Biosimilars are developed to be highly similar to and treat the same conditions as licensed biologics. As they are approved and their use becomes more widespread, oncology nurses should be aware of their development and unique considerations.

**OBJECTIVES:** This article reviews properties of biosimilars; their regulation and approval process; the ways in which their quality, safety, and efficacy are evaluated; their postmarketing safety monitoring; and their significance to oncology nurses and oncology nursing.

**METHODS:** A search of PubMed and regulatory agency websites was conducted for references related to the development and use of biosimilars in oncology.

**FINDINGS:** Because biologics are large, structurally complex molecules, biosimilars cannot be considered generic equivalents to licensed biologic products. Consequently, regulatory approval for biosimilars is different from approval for small-molecule generics. Oncology nurses are in a unique position to educate themselves, other clinicians, and patients and their families about biosimilars to ensure accurate understanding, as well as optimal and safe use, of biosimilars.

### KEYWORDS

biologics; biosimilars; oncology; postmarketing safety; clinical practice

### DIGITAL OBJECT IDENTIFIER

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**THE INTRODUCTION OF BIOLOGIC THERAPIES** has revolutionized the treatment of patients with cancer and autoimmune inflammatory disorders. Biologics are drugs that are derived from a living organism or its products and are typically made by genetically engineering living systems, such as bacterial, yeast, animal, or plant cells. Biologic drugs are an essential part of cancer treatment, providing targeted therapy and supportive care. The biologics bevacizumab (Avastin®), epoetin alpha (Epogen®), infliximab (Remicade®), pegfilgrastim (Neulasta®), rituximab (Rituxan®), and trastuzumab (Herceptin®) are among the top 15 medications used in hospitals and clinics (Hoffman et al., 2013). Many patients cared for by oncology nurses will receive a biologic therapy at some point during their treatment.

Patents for several biologics have expired or will soon expire, fueling interest in and removing barriers to the development of highly similar versions of licensed biologics (also known as “reference” or “originator” products). Table 1 provides U.S. patent expiration dates for selected biologics. In contrast to small-molecule drugs, which are typically created through chemical synthesis, biologics are large, structurally complex proteins developed using living systems and often requiring development of cell lines specifically engineered to produce highly targeted molecules. Because biologics have inherent complexity and heterogeneity, making an identical copy of a biologic without the originator’s cell line and specific manufacturing conditions is not possible. Accordingly, “biosimilar” refers to a biologic product developed to be highly similar to and used to treat the same conditions as a licensed biologic. By providing additional treatment choices (Rompas et al., 2015), biosimilars may increase access to and expand use of biologic therapies, which may lead to better overall health outcomes and patient care. In addition, the introduction of biosimilars has the potential to deliver savings and increase efficiencies for healthcare systems, thereby freeing resources for other facets of health care.

Legislation enacted across the world allows for the approval and licensing of biosimilars (European Medicines Agency [EMA], 2014; Health Canada, 2016a; U.S. Food and Drug Administration [FDA], 2015b). As biosimilars are approved and their use becomes more widespread, oncology nurses should understand the unique development of and considerations for biosimilars. This article reviews key properties of biosimilars and how they differ from generic drugs; summarizes the regulation and approval of biosimilars; describes evaluation of biosimilar quality, safety, and efficacy; outlines postmarketing safety monitoring; and highlights the role that oncology nurses, who are often the first and most frequent point of contact for patients undergoing cancer treatment, play in the education of patients and their families about biosimilars.