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similar to originator biologic products,  
biosimilars represent an opportunity

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to increase access and reduce costs for patients and healthcare systems. Biosimilars of monoclonal need to demonstrate similar but not identical quality of nonclinical and clinical attributes.

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2016;34(4):698-705. Epub 2016 Jul

4. Authors João Gonçalves 1 , Filipe

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Addressing a significant need by  
describing the science and process

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Spanish researchers investigated the



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current status of biosimilar  
monoclonal antibodies (mAbs) in the  
European Union (EU) by reviewing the  
regulatory pathway, the rationale for  
extrapolation and switching and the  
current status and future perspectives  
of the biosimilars approved in the EU.

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Monoclonal antibody biosimilars and  
cancer in the EU ...

Monoclonal antibodies have become  
mainstays of treatment for many  
diseases. After more than a decade on  
the Canadian market, a number of  
authorized monoclonal antibody  
products are facing patent expiry.

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Given their success, most notably in the areas of oncology and autoimmune disease, pharmaceutical and biotechnology companies are eager to produce their own biosimilar versions and have begun manufacturing and testing for a variety of monoclonal antibody

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Biosimilar monoclonal antibodies (mAbs) are complex, large proteins of the biosimilar family used by the immune system to identify and neutralize foreign bodies, such as bacteria, viruses, and others.

Biosimilar Monoclonal Antibody

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Market Size, Global Trends,

The approval pathway for biosimilars of monoclonal antibodies in the European Union is aimed at ruling out the presence of significant differences with the original biological in quality attributes, efficacy, immunogenicity and safety. It also provides the

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rationale for extrapolating the evidence obtained with a biosimilar in at least one indication to the rest of the approved indications of its original biological, thus simplifying the development programme of biosimilars.



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Biosimilar monoclonal antibodies  
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substances such as...

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monoclonal antibody biosimilars, the  
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number of key recombinant biologics,

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A Practical Guide To  
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Development  
including the first approved  
monoclonal antibodies (mAbs) [1–3],  
is expected to provide cost savings to  
healthcare systems and offers the  
potential to expand patient access to  
important medicines [4, 5]. Outside of  
the EU or the USA, experience of the  
regulatory pathway leading to

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approval of mAb or fusion protein biosimilars by major health authorities remains limited.

Monoclonal Antibody and Fusion Protein Biosimilars Across ...

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Antibodies Christian K Schneider, MD  
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Antibodies, a main component of the immune response, have been recognized, more than a century ago, for their proven therapeutic value.

The hybridoma fusion technology, proposed in the early 1970s, for the first time gave easy access to the production and engineering of murine

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