



Biosimilars: A New Generation of Biologics

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Biologics have revolutionised the treatment of many severe conditions, delivering exceptional clinical results but also producing exceptionally high prices. As patents expire, copies and price competition are expected throughout the world. However, due to the intrinsic heterogeneity and molecular complexity of biologic medicinal products, their copies cannot simply be authorized under the “generic rule” valid for small chemical entities.

In response, a dedicated regulation was issued in the European Union. It is based on the concept of “biological medicinal products similar to a biological reference product”, or “biosimilars”. This book analyses the context of biotechnological production and addresses the European legal framework for biosimilar market approval. It highlights post-market authorisation issues, such as Risk Management Plans and substitution of products, and outlines some other issues, such as cost management and international nomenclature.

This book is primarily intended for hospital-based physicians and pharmacists. It will also be a valuable resource for all actors from all countries who want to better understand the emergence of these new medicinal products within the European context.

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