

BIOSIMILARS

— A Podcast Series —



The New Era of Management in
Gastroenterology and Rheumatology

The Difference Between Biosimilars & Generic Drugs

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Learning Objective	Podcast Discussion Summary
Compare and Contrast Molecular Size and Structure	<p>Generic medications are much less complex, smaller molecules. They are often referred to as small molecule generics. The great majority of generics have a molecular weight of less than 500 Daltons. That's in contrast to biosimilars, which tend to be very large and are often a mixture of related molecules. To put things into perspective, adalimumab has a molecule weight of about 150 kilodaltons. That's 150,000 Daltons for a biosimilar versus less than 500 for most generics. So there's a noticeable difference. In regard to molecular structure, generics are simple, well defined, and independent of the manufacturing process, which is very different from biosimilars, which are complex, heterogeneous, and defined by the exact manufacturing process.</p>
Compare and Contrast Complexity of Development	<p>Developing small molecule generics involves a simpler process. The generic manufacturer needs to demonstrate bioequivalence to the reference drug, typically through in vitro dissolution testing and in vivo pharmacokinetic studies. Extensive clinical trials are not typically required unless there are specific concerns related to the drug's safety or efficacy such as those previously discussed in this podcast (see Ep. #3).</p>
Compare and Contrast Cost of Development	<p>Generics tend to take about 2 years to develop and cost 2-4 million dollars. Now, that's probably a lot of money to most people, but it's tiny compared to the up to 9 years and 100-250 million dollars it can cost to develop a biosimilar. This is much smaller than the over 10 years and approximately 2.6 billion dollars it can cost to develop a new biologic agent.</p>