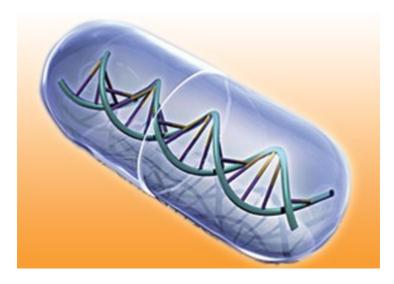


Global biosimilar market to touch \$2-3 billion by 2015, says Fitch report

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According to a new Fitch Ratings report, the global pharmaceutical biosimilar market is set for significant growth over the coming years. However, regulatory uncertainties will likely temper growth over the medium term.

The global biosimilars market is estimated to be \$2-3 billion by 2015, concentrated mainly in Europe. Fitch expects the biosimilar market will grow significantly over time, given expanding efforts to develop reference biological therapeutics. Fitch also believes that sponsors will need to invest significant resources, given that the complex nature of biological therapeutics demands more analysis than that of the traditional small-molecule generic market.

The FDA issued draft guidance in February 2012 on how the industry can gain regulatory approval to market biosimilar drugs, although the agency has not yet finalized its guidance. Fitch believes that it could reflect stakeholder feedback, which largely appears to be focused on gaining more clarity or specificity regarding the approval process.

Fitch also expects that price discounts and market share gains of biosimilars will be less than those in the traditional generic market, since most approved biosimilars will probably not be interchangeable with the original reference therapeutic early on. Nevertheless, there will be financial opportunities for biosimilar sponsors, pharmacy benefit managers and drug distributors. Conversely, innovators will face some headwinds.