

Pharma Sci-Commercializing Biosimilars: Challenges, New Strategies and Finding Path to Success- Prashant A Pandya-Reliance Lifesciences

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Introduction

Market for the biosimilar is growing in faster pace and development is currently at peak. Here is an ever-increasing pressure to reduce healthcare costs as treatment with biologic cost around \$1,00,000-4,00,000 a year to patient. Here are unique development and commercialization challenges in biosimilar hence requiring detailed clinical development plan including better defined regulatory pathways and information about market access

Biosimilar market

The global biosimilars market is expected to reach USD 14 Billion by 2022 from USD 3.5 Billion in 2016, at a CAGR of 26% during the forecast period.

Below factors influence market potential of biosimilar:

- Physician preference-Since biosimilar are not like simple generics hence it's difficult to prove that drug is similar enough like originator.
- Patient acceptance.
- Reimbursement from Insurance agency.
- Development cost.
- Cost difference with originator.
- Indication (chronic v acute).
- Sales experience and global tie-ups.

It is not easy to convenience multiple stakeholders to switch from originator to biosimilar unless having unique marketing strategy and significant cost difference.

Commercialization Challenges

Traditional products are created through chemical process due to simple and well-defined structure & having small molecules (Molecular weight ~150

Daltons) hence it is easy to produce identical API unlike biosimilar having large molecule (Molecular weight ~150,000 Daltons having complex structure and structural variation) needs larger clinical trials. Biologics generally derived from the living sources like bacteria, yeast and are typically proteins and antibodies. Below are the key commercialization challenges

Funding for product development and commercial manufacturing It is difficult to obtain adequate funding from Venture Capitalist (VC), Angel investor or Govt. for the product development and commercialization due to competitive market space. Identification of proper funding option is important for the successful commercialization. Scaling manufacturing to meet commercial requirements Unlike the manufacturing processes of small-molecule drugs that can be chemically synthesized and easily replicated, a biologic is produced from living organisms and has more complexity and heterogeneity (duplicate text was observed in above two lines, please modify) hence it is difficult to scaling manufacturing. Identification of cost effective raw material and finding effective manufacturing partner (considering geographical proximity) is key for the commercialization success. Meeting regulatory obligations/compliance of Biosimilar Products Regulations are still evolving hence meeting regulatory obligations and compliance is difficult in biosimilar development unless company adopt integrated strategic plan at the start of program having opinion from experts and stepwise input on regulatory and market to meet obligations.

Strategies and Path to Success

Commercialization of biosimilar encounters series of unexpected challenges as well as opportunities. It requires app. \$40-70 million investment and typically priced at around 30% discount in comparison to innovator. Evolving regulatory framework in relation to patient, payer and physician demand careful

strategic consideration while implementing commercialization strategies.

Biosimilar sponsors will need to do following:

- Take position on fundamental regulatory issues and develop global strategy. • Optimizing global, regional and cross-functional collaboration.
- Conduct in-depth pricing analysis and formulate regional strategy. • Develop patient education series/campaign. Patients must be educated so that they're willing to switch to a newer product that may not offer the same level of patient support.
- Choose markets with limited or no access to innovator biologic.
- Select country/ region where regulatory agencies are willing to work with companies to bring biosimilar market to reduce healthcare cost.
- Prioritize market entry based on changes in regulatory approvability commercial viability.

Conclusion

The biosimilar market will continue to evolve rapidly and with uncertainty. Successfully developing and marketing a biosimilar presents a unique and contradictory challenge. In biosimilar, commercialization strategies go beyond target audience team to include prelaunch, customer profiling, data management, program management, scaling manufacturing, data analytics, quality control and more. Outsourcing the commercialization

Biography

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operation can be advantageous in a wide range of biosimilar portfolio.

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