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Next Decade Generic String Of Pearls Opportunities: Sustainability Assessment With Respect To Therapeutic Positioning

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Abstracts

The rapid growth of the generic industry has come with a number of challenges, such as heavy competition, including from authorized generics and government-mandated price cuts. All contribute to diminishing prices and ever decreasing margins. In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns. Diversification of product portfolios, vertical integration across the manufacturing process, and expanding their geographic presence, especially into emerging markets are some of the key strategies which can be implemented by the generic companies to overcome the existing challenges.

One of the most initial and important step for the development of a prospective generic drug product comprises of product (Active Pharmaceutical Ingredient-API) selection and identification. API is the primary constituent of a pharmaceutical drug product that governs the final cost of the drug product as well as the commercial profit earned by the company. Early access to high-quality active pharmaceutical ingredients (API) that are not infringing patents is critical to success in regulated finished-dose markets as a significant part of generics' profits is made during the early days of their availability.

Factors which have to be taken into consideration during the generic product evaluation process include:

The total geographical and target disease market size.

Therapeutic areas of the product-whether the drug in question is approved for a

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niche condition or is trying to make a space for itself in the already crowded therapy class.

Competitor intelligence.

Current market sales of the innovator product.

Patent/exclusivity time frame.

Complexity in the development and time frames.

Availability of API, equipment and expertise.

Budget required and return on investment.

Keeping in mind the above mentioned elements we have scrutinized and selected 10 drug molecules. This information in the report can aid a prospective generic developer to review and evaluate products which can be incorporated in the company's developmental pipeline.

The therapy classes covered in this report are:

Oncology

Cardiovascular

Respiratory

Gastroenterology

Psychiatry

Infectious disease

The following points were considered while selecting the products:

Blockbuster drugs with a likelihood of lucrative future sales.

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Drugs with novel therapeutic approach for rare disease.

Specialized products in niche therapeutic markets with no existing competitors.

Products with robust ongoing clinical trials which will lead to future label expansions and ultimately act as sales booster.

First in class drug products with novel targeting mechanism.

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