A generic drug is a copy that is the same as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use.

Generic drugs are less expensive because generic manufacturers don't have the investment costs of the developer of a new drug. New drugs are developed under patent protection. The patent protects the investment - including research, development, marketing, and promotion - by giving the company the sole right to sell the drug while it is in effect. As patents near expiration, manufacturers can apply to the FDA to sell generic versions. Because those manufacturers don't have the same development costs, they can sell their product at substantial discounts. Also, once generic drugs are approved, there is greater competition, which keeps the price down. Today, almost half of all prescriptions are filled with generic drugs.

Generic manufacturers do not incur the cost of drug discovery, and instead are able to reverse-engineer known drug compounds to allow them to manufacture bioequivalent versions. Generic manufacturers also do not bear the burden of proving the safety and efficacy of the drugs through clinical trials, since these trials have already been conducted by the brand name company. In most countries, generic manufacturers must only prove that their preparation is bioequivalent to the existing drug in order to gain regulatory approval. It has been estimated that the average cost to brand-name drug companies of discovering and testing a new innovative drug (with a new chemical entity) may be as much as $800 million.

The United States is the biggest generic drugs market in the world. In fact, nearly 80% of the prescriptions written in the US are for generic drugs.

Analyzing the Generic Drugs Sector of the US Pharmaceutical Industry 2017 - a comprehensive coverage of the generic drugs market in the United States. Beginning with a sectional description on generic drugs, the report covers topics such as the impact of the generics sector on major pharma companies, R&D strategies being implemented by major pharma companies in the generics sector, the long debate over generic drugs versus branded drugs, and much more – a cost analysis of branded drugs versus generic drugs being a highlight.

An overview of the global generics sector builds up the scene for the analysis of the US generics industry. The all-important Hatch-Waxman Framework, the DEFRA Regulation, and other recent regulatory measures are included in this analysis’s, along with the emerging issue of promoting generic drug competition in the US Market.

Being a major section of the report, Promoting Generic Drug Competition in the US Market covers topics such as issues with the FDA Approval Process, the role of the Orange Book, the positive and negative outcomes of the Hatch Waxman Act, the manipulation of this act, promoting methods for generic drug availability, amongst other points of discussion.

Strategies for survival employed by branded manufacturers, the role of generic drugs in lowering US drug re-importation, a case study on generic antidepressants, the approval of the generic version of GSK’s drug Coreg, the introduction of Bill S.438, and the substantial move by Blue Cross in major changes to its drug plans, are discussed and analyzed in this report.

We also include a Porter’s Five Forces analysis of the US Generic Drugs Industry.

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