

# US Generic Drug Market Opportunity Outlook 2020

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## Abstracts

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Advent of generic medicine in US market is few decades old and its roots could be traced back to the Drug Price Competition and Patent Term Restoration Act of 1984. It is also known as Hatch-Waxman Act which paved the path for generic drugs in US. No proper guidelines were available in US before introduction of this law. Generic drug makers have to go through ordeal before this law was applied. Its implications are wide and numerous that has helped in shaping present US generics drug market. It has helped in both government's spending on healthcare system and relieving burden on patient's financial expenditure. It has also helped in development of global generic pharmaceuticals industry. Several developing nations have been able to take part of these regulations in past years due to which US generic drugs market has increased several folds.

US regulators are continuously improving the existing infrastructure for approval of generic drugs. Development of regulations is quite important for achieving higher cost savings without compromising with patients' health. Orange book has been made which consists of list of RLD and generic drugs. Physicians can use it as reference to prescribe less costly alternative containing same API. Role of health insurance companies is also being investigated in prescription of generic drugs because they will go for cheaper alternative with same pharmacological efficacy. Orange book is expected to help in this scenario by being used as a comparator. Generic drug developers are expected to take advantage of this scenario by promoting their products as patient friendly solutions. FDA is continuously involved in the updating of orange book so that physicians may recommend newly available generic drugs to the patients.

Generic drugs are being actively accepted by various stake holders of US pharmaceutical industry due to higher cost arbitrage without compromising in quality.

They do not have to go through legal issues due to which number of generic firms is increasing. Manufacturing process is already standardized due to which lesser input in terms of technological development is required. Physicians also have familiarity with these drugs making them easy to try generic versions of branded drugs. It helps both patients and government in long-term to achieve higher cost arbitrage. Several regulations have been made in past years which makes it easy for generic firms to enter in competition. With time, improvement has been made in existing infrastructure making it possible to achieve higher growth in US market.

Generic drugs have emerged as an important part of US pharmaceutical industry due to which it has become imperative to develop this industry. However, some critics have raised concerns over increasing commercialization of generic medicines. Developers of new drugs are investing a lot in research and development segment and presence of generic will compete with their product in same category leading to loss of market shares. This scenario will lead to aversion among pharmaceutical developers leading to lesser innovation and introduction of costly drugs. Balance between rights of developers and profits has to achieve by regulators in coming years. FDA is patient centric organization and it would not expose patients to undue risk for cost saving purposes. Their regulations have been changed with time in order to make them more amenable for both patients and drug developers.

“US Generic Drug Market Opportunity Outlook 2020” Report Highlight:

Introduction to US Generic Drugs Market

Hatch-Waxman Act & Its Implication

FDA Review on Generic Drugs

Supportive Features of US Generic Drug Laws

Effect of Generic Drug Import on US Economy

Methods to Achieve Higher Cost Arbitrage by Generic Drugs

Role of Online Pharmacies in Expansion of US Generic Drugs Market

US Generic Drugs Market Future Prospects

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### COMPANIES

Accord Healthcare

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Amneal Pharmaceuticals,

ANI Pharmaceuticals,

Apotex,

Aurobindo Pharma,

Baxter Healthcare Corporation,

Dr. Reddy's Laboratories,

Fresenius Kabi,

G & W Laboratories,

Glenmark Generics,

Impax Laboratories,

Lupin Pharmaceuticals,

Mallinckrodt Pharmaceuticals,

Momenta Pharmaceuticals,

Mylan,

Par Pharmaceutical,

Perrigo Company,

Sagent Pharmaceuticals,

Sandoz,

Sun Pharmaceutical Industries,  
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Therapeutic Proteins International,  
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Wockhardt,  
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