The Future of Generic Drugs and Strategies for Commercial Success

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**GBI Research Report Guidance**

- Chapter two provides an introduction to generic drugs, including a definition of the various types of generic drugs available and how they differ from one another. It also provides an overview of the generics market and outlines the results of GBI Research’s proprietary industry survey, which examined – among other trends – the therapy areas that will witness the highest levels of genericization in the next five years.

- Chapter three provides an analytical review of the main drivers and restraints in the generics market by analyzing industry survey results and a range of secondary and internal research. Additionally, results of the emerging markets which will witness the highest level of genericization in the next five years are also included.

- Chapter four considers some of the key small molecule drugs whose patents expire in the near future. Most of these drugs have generated annual revenue worth more than $XX billion. This chapter analyzes prospects after the patent expiry of these drugs, including potential generic competition and expected launch, as well as the overall impact on revenue at a global level until 2021.

- Chapter five provides an overview of strategies leveraged by generic companies to promote the usage of generic drugs, which include taking advantage of the regulatory policies regarding generic drugs, such as authorized generics (AG) and paragraph IV filing.

- Chapter six discusses the various policies and strategies used by governments to increase generic drug usage. Insights from the industry analysis of the survey are included.

- Chapter seven assesses how mergers and acquisitions (M&A) help diversify the portfolio and R&D technologies of a company and improve the value chain of generic drugs. The aim with which companies perform M&As is also discussed via the analysis of the industry survey results. The generics industry has witnessed many M&As in the recent past and their impact on the market is debated. The chapter concludes with results from another industry survey discussing the impact of M&As in the market.

- Chapter eight lists the top global companies in the generics market. The sections provide analysis on top generic manufacturers, their recent activities, developments, generic product portfolios and performance within the generic drugs market as well as the outlook of the sector. It also enlists a general SWOT analysis of the company.

**Report Methodology**

- The authoring methodology for this CBR report was multi-faceted and involved the analysis of a mixture of primary research, extensive secondary research and the interrogation of GBI Research’s robust proprietary database. GBI Research’s in-house analysts examined an array of technical and commercial sources relevant to the generics industry, which included academic journals, publications, review articles, government sources, internal research and industry resources.

- GBI Research also conducted a targeted industry survey of experts and key opinion leaders in the generics field to gather insight and opinions on the current trends and future commercial prospects of generics.

- The results from the secondary research efforts and proprietary industry survey have been integrated and triangulated with GBI Research’s analytical views to create a cohesive, insightful and objective assessment, examining both the current state and future commercial prospects of the generic drugs market.
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2 Introduction

2.1 What are Generic Drugs?

A generic drug is identical or bioequivalent to a branded drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. Generic drugs are usually intended to be interchangeable with an innovator product (branded drug), manufactured without a license from the innovator company (the company holding the patent for the branded drug), and marketed after the expiry date of the patent or other exclusive rights that the innovator product may possess (Thakkar and Billa, 2013).

Although the active ingredients in a generic drug are the same as in the innovator drug, the excipients (inactive ingredients) may differ. This is only important in rare cases when a patient has an allergy or sensitivity to one of the excipients. The product may also be slightly different in color, shape, or markings.

Branded drugs, also called innovator drugs, are initially marketed as new chemical entities and are the first version sold by the innovator manufacturer. The biggest difference between generic drugs and brand-name drugs is cost; generic drugs are generally XX–XX% less expensive than branded comparators. Moreover, the average difference in absorption into the body between a generic and a branded drug is XX% (Bera and Mukherjee, 2012).

The time it takes to develop a pharmaceutical drug generally varies from seven to XX years, with the average cost of bringing it to market generally reported as between $XXm and $XX billion (CSDD, 2014; Thakur and Ramacha, 2012). However, each of these new drugs runs the risk of not being able to match or exceed their R&D cost before losing patent protection and a very large proportion fail to enter the market. Generic companies, by developing copycat versions of branded drugs, are able to leverage the R&D data from the innovator company and sell these at a substantial discount from the branded price, as they are not required to repeat the costly clinical trials that the innovator company performed. This typically enables generic manufacturers to generate significant profits and quickly capture market share from the innovator company.

In general, generic manufacturers do not pay much for advertising, marketing and promotion, as the efficacy and quality of the drug in treatment has already been well-established. In addition, multiple generic companies are often approved to market the same product. This creates significant competition in the marketplace, often resulting in even lower prices. For this reason, generic drugs are important options that allow greater access to healthcare, and have become increasingly crucial in regions where significant economic and financial instability have created the need to reduce healthcare expenditure.

This CBR report provides an in-depth assessment of the various factors promoting and hindering generic drug usage at a global level, with a particular focus on the US and Europe. Additionally, this report analyzes recent and upcoming patent expiries of notable small molecules, their potential generic competition, and their revenue forecasts at a global level from 2011 to 2021. GBI Research also conducted a targeted industry survey of experts and key opinion leaders in the generic drugs industry to gather insight and opinions on the current trends and future commercial prospects of generic drugs. The results from the secondary research effort and responses from XX survey respondents have been integrated with our own analytical views to create a cohesive, insightful and objective assessment, examining both the current state and future commercial prospects of generic drugs.
Physicians in both developed and developing markets have shown mixed opinions in terms of their perception of generic drugs. Negative opinions regarding generic drugs have also derived from a number of generic manufacturers failing to meet manufacturing standards set by regulatory bodies, leading to high-profile bans and restrictions, particularly in India. In November 2012, Ranbaxy (acquired by Sun Pharma in 2014), stopped production of Lipitor at its Mohali plant in India, after reports of glass particles being found in the pills that were dispensed to the public. However, production at the plant was reported to have resumed in 2013. The company paid $XXm in fines to settle claims that it made false statements to the FDA about manufacturing practices at two plants in India. In 2015, the FDA issued a warning letter to Sun Pharma for its plant in Halol, India, a facility that accounts for nearly XX% of its US sales. The company stated the FDA letter cited violations of good manufacturing practices at its manufacturing plant in Halol, after issues were identified during a surprise FDA inspection of the facility in September 2014, a few months after the agency had banned the import (US) of all products made at another Sun Pharma plant, an antibiotics plant in Karkhadi. In Japan and some European countries (such as Italy and Spain), there is a strong perception of generic drugs being inferior to branded drugs and this has been a major hindrance to generic drug market expansion in these regions.

However, recently, due to governments promoting generic drugs in developed markets by initiating various policies, initiatives and strategies, including GS, parallel trade, value-based pricing and RP, both healthcare personnel and consumers are beginning to perceive generics as being equally safe and effective as brand name drugs.

As shown in the following figure, in the GBI Research industry survey most of the respondents did not believe that physicians in developed markets perceive generic drugs to be as safe and effective as branded drugs.

**Figure 10: Industry Survey Results, Do Physicians in Developed Markets Regard Generic Drugs to be as Safe and Effective as Branded Drugs? (%)**

<table>
<thead>
<tr>
<th>Region</th>
<th>Proportion of respondents in agreement (%)</th>
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<tbody>
<tr>
<td>North America</td>
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<tr>
<td>Europe</td>
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Source: GBI Proprietary Industry Survey

As seen in the figure, the majority of respondents from the North American, European and Asian panel agreed that physicians in developed markets perceive generic drugs as safe and effective. However, a large proportion of the European respondents (XX%) held the opposite viewpoint, which is in line with our secondary research. A recent study suggested that physicians in southern Europe depended on information provided by the brand drug manufacturers to a greater degree than physicians in northern Europe (Toverud, et al, 2015). The vast majority of the North American respondents (XX%) believe physicians perceive generics as safe.
4.7.1 Key Patent Expiry Dates and Potential Generic Competition

The patent for the fixed-dose combination is expected to expire in 2020 in the US, 2017 in the EU and 2022 in Japan.

In 2011 and 2012, Teva filed an application to market a generic version of Truvada in Canada. Gilead filed lawsuits against Teva, and the court prohibited Teva from marketing the generic drug until 2017. Teva appealed this decision in the Canadian federal court, for which a trial is set in November 2016. Another company that attempted to launch a generic in Canada was Apotex, in 2014, and Gilead filed a lawsuit in the federal court against this as well.

In 2014, Mylan filed for an ANDA to market a generic version of Truvada in the US. Gilead filed lawsuits against Mylan, for which the latter submitted petitions. In October 2015, Gilead reached an agreement with Mylan to settle the proceedings – although terms of the settlement agreement are confidential. Mylan, Teva and Apotex claimed that the patents associated with Truvada are invalid and unenforceable, and that manufacture of the generic will not infringe the patents. Similar ANDAs were submitted by Watson and Sigman, for which lawsuits were filed against them in 2015 (Gilead, 2015).

4.7.2 Truvada Sales Forecast, 2011–2021

Gilead entered into a collaboration arrangement with Bristol-Myers Squibb to develop and commercialize a single-tablet regimen containing Truvada (emtricitabine plus tenofovir) and Bristol-Myers Squibb’s Sustiva (efavirenz) in the US. This combination was approved under the brand name Atripla in the US in 2006. The net selling price for Truvada may change over time relative to the net selling price of Sustiva, whose patent is set to expire in 2016 in the US, and expired in the EU in 2013. Hence, a dip in global revenue by XX% is expected after 2016, due to which the revenue in 2017 will fall to $XX billion, from $XX billion in 2016.

Generics are expected to enter the US market in 2017, due to which revenue is expected to decline by XX% in 2018 to $XX billion. In 2019, revenue is expected to decline by XXX% to $XX billion. The drug’s revenue in 2020 is expected to reach $XX billion due to a XX% drop from 2019. In 2021, revenue for the drug is expected to reach $XX billion, a XX% drop from the previous year. Its revenue between 2015 and 2021 is expected to register a negative CAGR of XX%.

Figure 17: Truvada, Global Revenue ($m), 2011–2021

![Global Revenue Chart]

Source: GBI Proprietary Database
The survey results subdivided between the North American, European and Asian respondents are displayed in the following figure.

**Figure 28: GBI Industry Survey Results, Market Dynamics Affected By Continued Consolidation in Generics Market, North American Panel vs European Panel vs Asian Panel**

The majority of respondents from the North American panel agreed that an increase in M&As and consolidation of generic companies will ultimately increase generic drug prices in the market (XX% agreed). If the market becomes more consolidated, the number of companies manufacturing specific drugs will decrease, and the remaining companies would have the opportunity to increase their drug prices according to the market demand. Only a very small proportion of respondents in the European and Asian panels agreed that it would increase generic prices. The stark difference between the panels regarding potential increases in pricing is due to the fact that manufacturers in the US are free to set prices for their products, whereas there are more restrictions to price manipulation in Europe and Asia.

Respondents in North America also agreed that market consolidation will decrease the bargaining power of buyers (XX%). Again, a very low proportion of respondents from the European and Asian panels agreed it would decrease the bargaining power of buyers and this could be due to the fact that payer and provider consolidation has not been as prominent in these regions as in the US.

Half of the respondents (XX%) from the North American panel also agreed that increase in M&As would eventually establish a monopolistic market, with only a few companies dominating the generics sector, as seen in the case of Canada. Studies show that the American market is more competitive than the Canadian market, having a larger relative number of players and a more equal distribution of market share among producers – whereas only two major companies dominate the market for generic drugs in Canada. Furthermore, generic drug prices in Canada are usually higher than American prices (ISEDC, 2013). A very low proportion of respondents from the Asian panel agreed it would create a monopolistic market, and this is likely to be due to the fact that barriers to entry are significantly lower in Asian markets, which makes it unlikely that a small number of companies would be able to establish control over the vast majority of the market.

Most of the respondents from the Asian panels (XX%) agreed that M&As will increase competition in the market, which is in line with their response on the likelihood that M&A activities would create a monopolistic market. This would ultimately increase the R&D activity in the market, and therefore the majority of the respondents from the Asian panel agreed that an increase in M&As will increase R&D activities. This is in line with literary findings as mentioned previously.

A small proportion of respondents from the European and North American panel agreed that M&A activities would make the market more competitive. As previously mentioned, in countries like the US there is less oversight on pricing, which means market consolidation would allow top companies to make the market less competitive through higher pricing.
8.6.2  Hospira: Drugs SWOT analysis

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<th>Table 12: Hospira, SWOT Analysis</th>
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<td><strong>Strengths</strong></td>
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<td>Source: GBI Proprietary Database</td>
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8.7  Fresenius Kabi

Fresenius Kabi, a subsidiary of Fresenius SE & Co, develops, manufactures and markets pharmaceuticals and medical devices. It is one of the four Fresenius business segments which comprise Fresenius Medical Care, Fresenius Kabi, Fresenius Helios and Fresenius Vamed. The portfolio includes intravenously administered generic anesthetics, analgesics and anti-infectives, and drugs for the treatment of oncological and other critical diseases. Its products and services are used for the treatment of critically and chronically ill patients. The company reported sales of $XX billion in 2015, of which generic intravenous drugs contributed $XX billion (Fresenius Kabi, 2015).

It has manufacturing facilities and operations in Europe, North America, Latin America, Asia Pacific and Africa. Fresenius Kabi is headquartered in Germany.

8.7.1  Recent Activity in the Generic Drugs Market

In January 2016 Fresenius Kabi acquired the prescription business, a pharmaceutical manufacturing plant, and BD Simplist – a line of seven drugs in ready-to-administer prefilled glass syringes – from Becton, Dickinson and Company (BD), a medical technology company.

BD and Fresenius Kabi have signed a 10-year supply and distribution agreement under which Fresenius Kabi will supply a portfolio of intravenous solutions to BD. In addition, the companies plan to offer a range of intravenous solutions in the US, beginning in 2016. This deal enables Fresenius Kabi to expand its portfolio of injectable medicines in vials.

In March 2016, Fresenius Kabi launched amikacin sulfate injection in the US. Amikacin sulfate is an anti-infective, antibacterial drug, formulated as an injection solution for intramuscular and intravenous administration. It is indicated for the short-term treatment of severe infections caused by species of bacteria of the gram-negative type.
10 Appendix

10.1 Industry Survey Results, Therapy Areas with Highest Levels Of Genericization, 2016–2021

Figure 29: Industry Survey Results, Therapy Areas with Highest Levels of Genericization, 2016–2021

Source: GBI Research Proprietary Industry Survey

10.2 Industry Survey Results, Therapy Areas with Highest Levels of Genericization, R&D Expert Panel vs Commercial Expert Panel, 2016–2021

Figure 30: Industry Survey Results, Therapy Areas with Highest Levels of Genericization, R&D Expert Panel vs Commercial Expert Panel, 2016–2021

Source: GBI Research Proprietary Industry Survey

Note: Percentage refers to the number of respondents who chose the respective therapy areas
10.18 Bibliography


10.19 Disclaimer

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