The US Pharmaceutical Market Outlook to 2014

Market trends, leading players and forecasts

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Report Overview

The US pharmaceutical and biotech industry is currently facing a number of macroeconomic challenges and industry specific issues such as a slowed innovation process, a stringent FDA and significant patent losses in the near future. Large pharma companies are considering strategic acquisitions and re-evaluating their business models in a bid for survival. President Obama’s administration has also planned extensive healthcare reforms that will involve significant investments, in an attempt to revamp the healthcare landscape of the country.

‘The US Pharmaceutical Market Outlook to 2014’ is a new report published by Business Insights that provides comprehensive coverage of the US pharma market, incorporating the market structure, pricing and regulation, in addition to detailed analysis of leading companies and potential healthcare reforms. This report assesses the marketed product portfolios, R&D pipelines, market share data, sales forecasts and competitive landscape of the major players in the US market. It highlights the key market and R&D trends that may influence treatment sales with a thorough analysis of the competitive dynamics of leading brands within each indication. This report also identifies growth trends and developments for key drug classes and leading players through to 2014.

“Use this report to understand the imminent reforms to the US healthcare system, examine trends in major therapeutic areas and identify the future prospects of key companies and the challenges that face them...”

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The US pharmaceutical market recorded sales of $279bn in 2007, a 3.9% increase over 2006. The top 10 brands of the US market represented 14.4% of total market value in 2007.

CNS disorders constitute the leading therapeutic category of the US pharma market, with sales of $60.2bn and a market share of 21.6% in 2007. This is followed by CVD treatments, which amassed sales worth $38.2bn and a market share of 13.7% in 2007.

Pfizer was the leading player in the US pharma market in 2007, with sales of $22.5bn, a decline of 12.3% over 2006. This was largely due to a drop in sales posted by its leading brand Lipitor.

Pharma companies are focusing on acquisitions of smaller biotech firms to strengthen their drug pipelines. This tactic is also being pursued to diversify portfolios with an array of market offerings, in an effort to lessen the impact of poor performance within individual therapy areas or industry segments.

The US biotech industry saw high growth from key players such as Gilead Sciences, which posted a growth rate of 54.2% between 2006-07. This was primarily driven by sales from its HIV franchise, which includes Atripla, Truvada and its Hepatitis B drugs.

### Table 6.29: Amgen’s leading brands in the US pharmaceutical market, 2007

<table>
<thead>
<tr>
<th>Brand</th>
<th>Sales H106 (Bm)</th>
<th>Sales 2007 (Bm)</th>
<th>Sales growth 2006-07</th>
<th>Share 2007 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enbrel</td>
<td>1,609</td>
<td>3,300</td>
<td>11.1</td>
<td>23.9</td>
</tr>
<tr>
<td>Aranesp</td>
<td>1,117</td>
<td>3,076</td>
<td>-19</td>
<td>22.3</td>
</tr>
<tr>
<td>EpoGen</td>
<td>1,468</td>
<td>2,666</td>
<td>-5</td>
<td>21.5</td>
</tr>
<tr>
<td>Neulasta</td>
<td>1,546</td>
<td>2,846</td>
<td>48</td>
<td>21.4</td>
</tr>
<tr>
<td>Neupogen</td>
<td>487</td>
<td>956</td>
<td>1.8</td>
<td>6.9</td>
</tr>
<tr>
<td>Semax</td>
<td>192</td>
<td>333</td>
<td>58.5</td>
<td>2.4</td>
</tr>
<tr>
<td>Vectibix</td>
<td>83</td>
<td>175</td>
<td>439.1</td>
<td>1.3</td>
</tr>
<tr>
<td>Kineret</td>
<td>11</td>
<td>25</td>
<td>-18.5</td>
<td>0.2</td>
</tr>
<tr>
<td>Keplacine</td>
<td>5</td>
<td>9</td>
<td>13</td>
<td>0.1</td>
</tr>
<tr>
<td>ThioGel</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>6,568</strong></td>
<td><strong>13,789</strong></td>
<td><strong>-1.2</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

"Enbrel (etanercept) was the Amgen’s leading product in 2007, having recorded $3.3bn in sales, a y-o-y growth of 11.1%. Neulasta, a sustained-duration form of Neupogen (G-CSF), recorded sales of $2.9bn in 2007."

### Use this report to...

- Examine the forecast prevalence of major diseases in the US pharma market over 2008-14 with this report’s analysis of various cancer types and indications within cardiovascular, autoimmune, skin, CNS, and metabolic disorders.

- Understand the latest developments within the US healthcare system, including pricing and reimbursement, health insurance and regulatory issues, and identify how the healthcare reforms of the new administration will affect the future of the pharma and biotech industries.

- Forecast sales for key therapy/sub therapy areas and leading brands in the US pharma market over 2009-2014, identify key industry trends and events and evaluate leading companies and products within the US biotech market and generics industry.

- Compare the franchises of major pharma companies across key indications, with this report’s analysis of sales by drug class/leading brands, pipeline focus and a strategic analysis for Amgen, Gilead, GSK, J&J, Pfizer, Roche-Genentech, Sandoz, Teva-Barr.

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**Key issues...**

**Healthcare reforms to halt rising costs.** The new administration is driving healthcare reforms with savings to be generated from measures including disease prevention and the implementation of electronic medical records. Other potential strategies being considered are Medicare pricing reform, universal healthcare, increased Medicaid rebates, a comparative effectiveness institute and a new pathway for biosimilar approval.

**Greater FDA stringency.** Growing political pressure and criticism over drug safety issues in the past have led to the FDA becoming increasingly vigilant, resulting in fewer drugs being approved. The agency is currently suffering from a lack of funds and expert staff.

**Significant patent losses ahead.** The US pharma industry is facing a wave of patent expirations over the forecast period. Key expirations through 2012 include the cholesterol-lowering drug Lipitor, platelet drug Plavix, antipsychotic Zyprexa, antidepressant Effexor, and asthma drug Singulair. Almost every major company will lose patent protection on their largest products over the forecast period.

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**Discover...**

- What will be the major growth drivers in the US pharma market over 2009-14?
- Which companies were the winners and losers in the US pharma market in 2007?
- What are the key strengths of the leading pharmaceutical, biotechnology and generic companies?
- Which products will be affected by generic competitors over the period 2009-14?
- Which pipeline products will be the growth drivers of the future?
- Which therapy areas and indications are forecast to have significant commercial prospects over the period 2009-14?
- How will the US pharma market's competitive landscape change by 2014?
- What are the key healthcare reforms being considered by the new administration?

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*Fig 5.7: Comparative performance of global pharma markets, 2007*

“The US remains the largest pharma market in the world recording sales of $279bn in 2007 and contributing 42% of global pharma market sales. Market growth has begun to slow down as the market matures...”

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Chapter 4: The pharmaceutical industry in the US

Therapy Area Analysis: Cardiovascular system
Cardiovascular disorders represent the second largest therapeutic class in the US market, posting $38.2bn in sales in 2007, equivalent to a market share of 13.7%. This therapeutic segment is driven by cholesterol and triglyceride regulating preparations which are indicated for dyslipidemia and registered cumulative sales of $15.8bn. The cholesterol and triglyceride regulating preparations are followed by the hypertension category, led by beta blocking agents with sales of $3.5bn in sales in 2007.

The dyslipidemia market is dominated by the statins drug class with only a nominal presence of the other drug classes. Market share of branded statins is however falling due to patent expirations of key products such as Zocor in the recent past (2006). The imminent patent expiration of Pfizer’s Lipitor (expected in 2011), the current market leading drug, is likely to further diminish the branded drugs’ market share. Among drugs in the statin class, individual statins reflect differences in various aspects such as their ability to lower blood cholesterol. Lipitor (atorvastatin) and Crestor (rosuvastatin), for instance, are the most potent statins, while Lescol (fluvastatin) is the least potent.

In light of the JUPITER trial data, released in late 2008, recommended cholesterol treatment goals are likely to be lowered further, which would help capture more patients and lead to market expansion. However, the market still faces several challenges. The multiplicity of statins in the market is making the launch of new products and their combinations difficult. Additionally, the wealth of data underscoring the favorable efficacy and safety profile of statins further hinders new product launches. Another factor plaguing the market is the dominance of cost-saving policies in the seven major markets, making generics the drugs of choice as and when possible. The cost-saving policies override even the low treatment goals and the large patient populations.

The hypertension market in the US is led by beta blocking agents, even though this drug class is dominated by generics such as metoprolol, atenolol, pindolol and nadolol. (Continued...)

Note: C10A – Cholesterol and triglyceride regulating preparations, C7A – Beta blocking agents (plain), C9C – Angiotensin II antagonists (plain), C8A – Calcium antagonists (plain), C1D – Angiotensin II antagonists (combination), C10C – Lipid regulators in combination with other lipid regulators, C9B – Ace inhibitors (combinations), C9A – Ace inhibitors (plain), C3A – Diuretics, C2A – Antihypertensives (of non herbal origin) plain
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