



## Industry Forecast - Generics

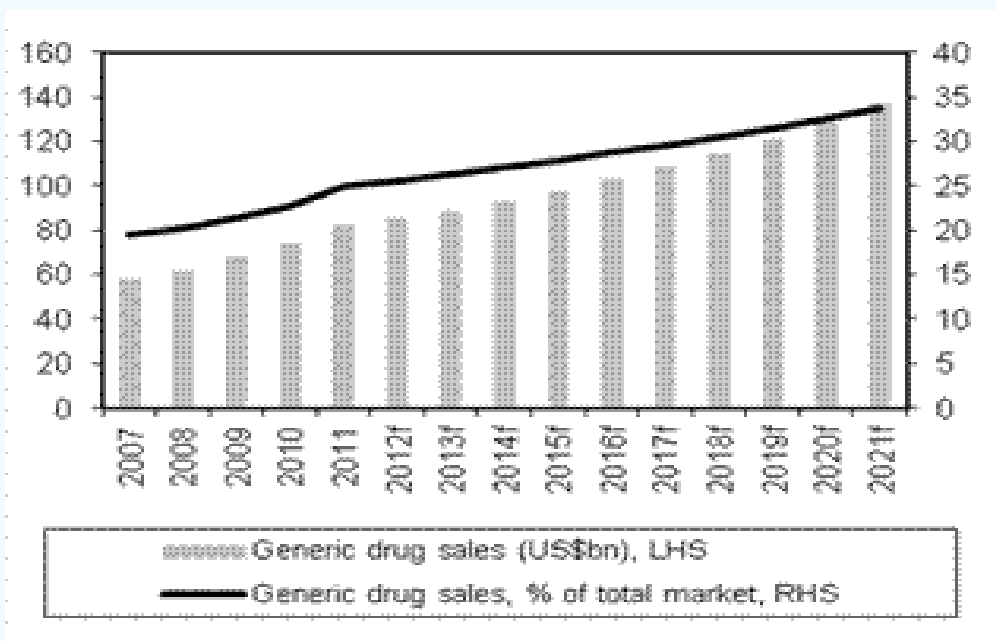
### GENERIC DRUG MARKET FORECAST

#### *United State Market*

Cost-saving efforts, patent expiries and improved perceptions with regard to the efficacy and safety of generic drugs have led to increasing penetration over the past five years. From 2006 to 2011, the market share for generic drugs by value grew from 18.7% to 24.9%, posting a CAGR of 8.90%. By volume, generic drugs account for around 70% of prescriptions, highlighting the strong pricing differential against patented products, driven by high levels of competition. According to a study commissioned by the GPhA, the use of generic drugs saved the US healthcare system more than US\$734bn from 1999 to 2008 and approximately US\$121bn in 2008 alone.

#### **Generic Drug Market Forecast**

2007-2021



On going price wars in the retail segment has helped boost the use of generic drugs although it has also placed downward pressure on headline market value. Supermarket **Publix** has made seven high-volume generic antibiotics available free of charge. The move follows the implementation of discounted drug programmes at a number of retailers, including **Wal-Mart** and **Kmart**. Companies such as **Express Scripts**, which manage drug benefit plans, are promoting the use of generic drugs by offering lower co-payments, reducing out-of-pocket expenditure for consumers.

From 2011 to 2016, **it is** anticipated generic drugs will continue to capture market share, with an acceleration of the upward trend towards the end of the forecast period, as patent expiries boost spending significantly. By 2016, the generic drugs market is forecast to reach a value of US\$102.5bn, up from US\$82.4bn in 2011, growing at a CAGR of 4.47%. Through to 2021, the market will likely see a slight uptick in growth, with a CAGR of 5.20% projected over the full 10-year period - more than double the rate of the overall pharmaceutical market.

Ongoing reforms to the US healthcare market, as a result of Obama taking office, mean there are significant risks to our forecasts. This is of particular relevance to the generic drug market, as much of the proposed legislation could have a considerable effect on market dynamics. Obama has outlined that purchasing cheap foreign made generic drugs - particularly within state-subsidised healthcare schemes - will become an essential tool in ensuring better access to healthcare.

Another major determinant of the growth of the generics segment will be the outcome of the introduction of legislation of biosimilars (biogenerics, follow-on biologics, bio-betters etc). Establishing a clearly defined approval pathway will considerably expand the potential generics market. Length of exclusivity for biologics is yet to be determined. The US Senate Health, Education, Labor and Pensions (HELP) Committee voted in favour of 12-year data exclusivity for originator biologics in July 2009, although alternative legislation supports a shorter seven-year period.

The number of deals struck between branded and generic drug makers to keep generic competition off the US market rose by 60% in 2010, says the Federal Trade Commission (FTC). There were 19 such deals in FY09 but 31 in FY10 (October 1 2009-September 30 2010), and the agreements reached in the latest fiscal year involved 22 different brand-name pharmaceutical products with combined annual US sales of around US\$9.3bn, according to a new report from the Commission.

**Table: Generic Drug Sales Indicators 2008-2016**

	2008	2009	2010	2011f	2012f	2013f	2014f	2015f	2016f
Generic drug sales (US\$bn)	61.71	68.14	73.88	82.39	85.61	88.84	92.86	97.43	102.52
Generic drug sales (US\$bn), % chg y-o-y	6.28	10.42	8.41	11.53	3.91	3.76	4.53	4.92	5.23
Generic drug sales, % of prescription sales	21.60	22.69	24.03	26.46	27.20	27.98	28.80	29.67	30.59
Generic drug sales, % of total sales	20.30	21.35	22.59	24.87	25.55	26.27	27.03	27.83	28.67

*Source: IMS Health, Pharmaceutical Research and Manufacturers of America (PhRMA), AC Nielsen, Food and Drug Administration (FDA), AESGP, BMI*