PHARMACEUTICAL MARKET FORECAST

S. THIRIPURASUNDARI, M. Com., (M. Phil.,)
sundarisridhar88@gmail.com
(Reg. No. 1803CM3001)
M. PHIL., RESEARCH SCHOLAR
PRIST UNIVERSITY

ABSTRACT

Indian per capita spending on medicine will remain relatively low: USD12 in 2013, USD20 in 2018 and USD31 in 2023). India represents one of the most attractive pharmaceutical markets and within a decade the value of the pharmaceutical market will exceed USD40bn. There are about 3,000 pharmaceutical manufacturers, the vast majority of which focus on generic drugs. Department of Pharmaceuticals has announced the Price Control Order 2013, which will reduce the prices of 384 essential drugs in the country.

It is forecasted that pharmaceutical sales in the country to grow from INR904.0bn (USD15.4bn) in 2013 to INR1, 563.4bn (USD26.3bn) by 2018 with a local currency CAGR of 11.6% and a USD CAGR of 11.25%. This is a rebound from the negative effects of the 2013 Drug Price Control Order. India's large, growing and ageing population is an obvious enticement for pharmaceutical firms. According to the UN Population Division, the number of people living in the country will increase from 1.05bn in 2000 to 1.39bn in 2020 - a rise of 32%. The percentage of the population aged 65 and over will increase from 4% to 6% over the same period. However, Indian per capita spending on medicine will remain relatively low: USD12 in 2013, USD20 in 2018 and USD31 in 2023). Nevertheless, India represents one of the most attractive pharmaceutical markets and within a decade the value of the pharmaceutical market will exceed USD40bn. The proposed plan by Prime Minister Modi to roll out universal healthcare in the country in phases starting from April 2015 will provide further upside for the industry should it be carriedout.

Market Overview

India is the third-largest pharmaceutical market in the Asia Pacific region, behind Japan and China. However, its per capita expenditure of USD12.32 in 2013 is one of the lowest in the world, similar to the level in Pakistan and Vietnam. Pharmaceutical expenditure in 2013 was approximately 0.9% of GDP, well below the global average of 1.4%. Generic drugs will continue to account for the vast majority of drug consumptionin India (over 75% of total spending), largely due to the low cost and limited purchasing power of most of the population. A substantial amount of the Indian generic drug market comprises illicit products due to the country's lax patent laws. However, conditions are changing for the better. In recent years, India has begun to export large amounts of generic drugs to the international market, which has proved highly lucrative.

The separation of the prescription and over-the-counter (OTC) medicines remains problematic given the large volume of prescription drugs available over the counter as well as the presence of counterfeit drugs. The development of the healthcare system over the longer term should improve the situation with the respective sectors gradually becoming more clearly defined.

While prescription drugs account for over 85% of sales, the share of drugs prescribed by a doctor is likely to be far lower. Traditional and Ayurvedic medicines are very popular; however, these types of interventions are not included in our pharmaceutical market calculation. Alimentary tract, antibiotics and respiratory drugs are some of the most prominent prescription segments as are cardiovascular and nervous system remedies, with vitamins leading the OTCsector.

India accounts for almost 10% of global drug production by volume and is increasingly focusing on indigenous research and development (R&D). There are about 3,000 pharmaceutical manufacturers, the vast majority of which focus on generic drugs. India is home to 250 large manufacturers, and the domestic drug industry employs a workforce of approximately 460,000.

According to HabilKhorakiwala, CEO of **Wockhardt**, India's pharmaceutical industry is highly fragmented, with the top ten domestic firms occupying 40% of the market. Meanwhile, multinational pharmaceutical firms occupy 27% of the total market share.

Competitive Landscape

India boasts a diverse pharmaceutical industry portfolio, directly employing nearly 5mn people. It consists of pharmaceutical manufacturers in India (primarily research-based companies with international links) organized under the Organization of Pharmaceutical Producers of India umbrella and foreign players operating from abroad. The Indian pharmaceutical sector has seen tremendous growth in the last decade and is showing few signs of abating. Indian drug companies are making their mark on the wider international market.

The domestic market ranks relatively high in quality, technology, organisation and range of products manufactured in comparison with other countries at a similar stage of economic development. However, it is fragmented with more than 20,000 sites registered for production. Around 250 firms hold more than 70% of the market. The concentration in the hands of the top 10 players is more than 5%. Local producers supply 70%+ of the market for bulk drugs, intermediates, formulations, capsules and injectables. High output is guaranteed by a large and cheap labour force, low production and research and development costs as well as a strong balance of trade. India is one of the regional leaders in biotech and similar advances, taking advantage of its internal resources and internationalconnections.

Drug manufacturing is one of the relatively few industries in India open to 100% foreign ownership. The situation will continue to encourage international interest in the local market, which continues to increase because of the growing population and economic improvements. However, foreign interest will be a challenge to the local players as well as the general affordability of pharmaceutical in the country. The government is therefore increasingly scrutinizing foreign direct investments in the pharmaceutical sector.

Pricing Policy

India's pharmaceutical pricing policy is unusually transparent for an emerging market. It also attempts to balance the requirements of the key stakeholders: patients, manufacturers and regulators although in recent months, the government's focus on providing affordable healthcare has led to eroding profit margins for drug makers due to price-containment policies. Despite stringent medicine price controls in India, continue to view the emerging market as very attractive to drug makers, primarily due to the underlying fundamentals of high growth and the majority of spending being out-of- pocket.

As implemented by the Drug Prices (Control) Order of 1995, the Drug Policy of 1994 was a key change in oversight of the pharmaceutical market. It was introduced in conjunction with general liberalization of India's economy. These new rules meant medicines were brought under price control when the manufacturer's turnover and the market share of the leading products were above a certain level. Prices were set using a calculation based on production costs and ex-manufacturing expenses. In total, 74 active pharmaceutical ingredients (APIs) were covered by the Drug Policy of 1994. Further sector liberalization took place in 2000, when 100% foreign direct investment (FDI) in local drug makers through the automatic route was permitted. The legislation was amended in 2002 to raise the company turnover threshold from INR4 crore (USD800,000) to INR25 crore (USD5mn). The parameters of 'market share' were relaxed simultaneously. Medicines with a unit price not exceeding INR2 (USD0.04) were excluded from price control. However, due to a Supreme Court order, the 2002 Drug Policy was neverimplemented.

In May 2013, the country released a new Drug Price Control Order (2013) that aimed to reduce the prices of 348 essential medicines. The price of pharmaceuticals has been a contentious issue in the country, with the government issuing compulsory licenses and revoking patents as these items were deemed too expensive for the population. In addition to these actions, the government also suggested in September 2012 to reduce the prices of patented medicines using a reference pricing methodology.

Drug Price Control Order(2013)

The ceiling price will be fixed on the basis of weighted average price to the retailer (sum of the prices to the retailer of all brands and generic version of the medicines having more than or equal to 1% of the total market share) / (total of such brands and generic version of the medicines having more than or equal to 1% of the total marketshare).

The suggested formula for calculating the ceiling price of a new medicine's strength/dose is:
P(c) = P(s).[1 +M/100] Where:*

P(c) = ceiling price

P(s) = average price to retailer for the same strength and dosage of the medicine calculated under 'average price for retailer)

M = % margin to retailer and its value = 16.

Despite the legislation for drug price controls, a study by the Ministry of Corporate Affairs found drug price mark-ups of 200-500% in the country, highlighting the inability of the authorities to control drug prices. In light of the continued existence of highly-priced pharmaceuticals, in September 2012, India's Group of Ministers (GOM), headed by Minister of Agriculture SharadPawar, submitted a price policy proposal that will allow the government to control the prices of 348 essential drugs, instead of the current 74 drugs.

Minister of Fertilizers and Chemicals Srikant Jena said the GOM used weighted average prices for all drugs with more than 1% market share when developing the price policy. While the proposal was approved by the government in November 2012, the final approval of the policy lies with the Supreme Court which deferred the hearing till December 2012.

Subsequently in May 2013, the India's Department of Pharmaceuticals has announced the Price Control Order 2013, which will reduce the prices of 384 essential drugs in the country. While the legislation did not reveal the extent of the price reductions, news sources stated that price cuts could be between 30-60%. Subsequently in June 2013, major Indian pharmaceutical companies approached the department seeking to stop the introduction of the new drug price control formula. The move was driven by the Indian government's interpretation of brand to ascertain the price caps of essential medicines. While calculating the price caps of the first 150 essential medicines, the National Pharma Pricing Authority (NPPA) has brought together all brands of one medicine being sold by a single firm to ascertain whether it has more than 1% market share in a therapeutic segment. The NPPA has factored in the prices of all a firm's medicine brands to calculate the ceiling price, if its total accounts for more than 1% of the marketshare.

COMPANYPROFILE

CIPLA PHARMACEUTICAL Strengths

i. One of the most prominent local pharmaceuticalcompanies.
ii. Capable of new manufacturinginvestments.
iii. Wide range ofproducts.
iv. Largest supplier of antiretroviral medications inIndia.

Weaknesses

i. Harsh government pricing policy, with the state keen to keep downward pressure onprices.
ii. The impact of new WTO-compliant domestic drug patent law on a product portfolio built on weak

patentlegislation.
iii. Vulnerability to foreign competition in the domesticmarket.
iv. Lack of strong internationalpresence.

Company Overview

Founded in 1935, Cipla is ranked among the leading 15 generic drug companies globally. The firm sells commodity generics, value-added generics, branded generics, intermediates and active pharmaceutical ingredients (APIs). Cipla is also involved in original research & development (R&D). As of mid-2010, the firm exported to 170 countries.

Strategy

Cipla is an archetypal generic drug manufacturer. Operating from a low-cost base, the company has expanded through pure organic growth. Exploitation of India's patent regime between 1972 and 2005 allowed Cipla to reverse engineer patented products. These medicines were then sold domestically and to other unregulated markets. The company is currently targeting the local hospital markets, the promising biosimilar sector, forging strategic partnerships and the stem cell sector. Risks to Cipla's strategy include non-availability of important raw materials, lower tender business in antiretrovirals, increased scrutiny from foreign regulators and unfavourable movements in foreign exchangerates.

DR. REDDY'S LABORATORIES Strengths

i. Leading Indian generic drugmanufacturer.
ii. Diverse and prominent global presence, including the developed Western markets.
iii. A significant number of recent productlaunches.

Weaknesses

i. Exposed to increasingly tough generic competition in the US in the key product lines.
ii. Undergoing costly restructuring in an attempt to boost R&D and increase generic filings with the USFDA.
iii. Authorized generic drugs will affect anticipated sales from first-to-file opportunities in theUS.

Company Overview

Founded in 1984, Dr Reddy's Laboratories are among the top 20 companies domestically and ranked in the leading 10 generic drug companies in the US. The company sells commodity generics, branded generics, authorized generics, APIs and is also involved in original R&D.

Strategy

The main focus for Dr. Reddy's Laboratories is the US, which has the world's largest generic drug market. Demand for the company's products is high due to their low cost. Dr Reddy's is also present in other developed states such as Germany and the UK. To maintain its impressive sales growth trajectory (20% compound annual growth between 2000 and 2010), Dr. Reddy's expanding into emerging markets including Brazil and Russia. To ensure long-term growth, the company has a pipeline of new molecular entities.

GLAXOSMITHKLINE Strengths

i. Diverse pharmaceutical portfolio includingOTCs.
ii. Strong political and historical ties between India and theUK.

Weaknesses

i. Opaque government drug-pricing policy continuing to favourlocal manufacturers.
ii. Counterfeit industry activity in thecountry.

Company Overview

GSK has been present in India since 1919 and is the leading foreign pharmaceutical company engaged in R&D, additionally employing more than 2,000 marketing representatives to deal with 4,000 businesses countrywide. GSK deals with a number of medicines and vaccines, and consumer health items. Consumer health medicines and nutritional goods are produced at three local sites, involving more than 2,700 staff. An additional 40 employees are engaged in clinical data management, supporting GSK's global biological R&D activities.

Until recently, GSK was the most prominent local manufacturer of animal health and fine chemical products. However, in April 2006, the company sold its veterinary
business, which accounts for more than 10% of the local market, to French firm Virbac. The move follows the company's wider intention to exit the animal health business and to focus on human pharmaceuticals.

Strategy

GSK aimed to outpace the market in 2011 after underperforming in 2010, according to MehernoshKapadia, senior executive director, in February 2011. To achieve this goal, GSK will launch new patented and branded generic drugs, and expand its sales and marketingnetwork.

On April 2011, GSK said it was planning to achieve growth by acquiring brands in India. However, the company remains cautious over acquisitions, owing to the high valuations sought by potential targets. The company is aiming to carry out acquisitions in its core area as well as other synergistic categories in order to enhance its product portfolio. The firm also has a listed subsidiary, GSK Consumer Healthcare in India where in February 2013, GSK increased its stakes in GSK Consumer Healthcare to 73%. Given the low per-capita healthcare and pharmaceutical spending, company expect this onsumer healthcare segment to fare well as the products are generally sold over the counter.

LUPIN

Strengths

i. Worldwide leader in Cephalosporin and Anti TBdrugs.
ii. Considerable presence in the market for drugs against Asthma, Pediatrics, Diabetes, and CNS boosts thesales.
iii. In the US and Japanese market it is the largest genericplayer.
iv. Acquisition of Lupin Pharmaceutical helped to increase its product list and in turn sales.
v. Wide global footprint as it is present in over 70countries.

Weaknesses

i. High dependence on global formulation business with 84% revenue coming from the USmarket.
ii. Forecasting done on technological level isless.
iii. It operates in low growth segments such CNS, respiratorydiseases.

Company Overview

Lupin Pharmaceuticals, Inc. is the U.S. wholly owned subsidiary of Lupin Limited, which is among the top five pharmaceutical companies in India. Through our sales and marketing headquarters in Baltimore, MD, Lupin Pharmaceuticals, Inc. is dedicated to delivering high-quality, branded and generic medications trusted by healthcare professionals and patients across geographies.

Lupin Limited, headquartered in Mumbai, India, is strongly research focused. It has a program for developing New Chemical Entities. The company has a state-of-the-art R&D center in Pune and is a leading global player in Anti-TB, Cephalosporins (anti- infectives) and Cardiovascular drugs (ACE-inhibitors and cholesterol reducing agents) and has a notable presence in the areas of diabetes, anti-inflammatory and respiratory therapy.

Lupin pharmaceutical is building on our parent company's strengths of vertical integration in discovery research, process chemistry, active pharmaceutical ingredient production, formulation development and regulatory filings. Lupin Pharmaceuticals, Inc.is committed to achieving its vision and mission of becoming an innovation led transnational pharmaceutical company.

Vinita Gupta, CEO of Lupin Pharmaceuticals, Inc. says "founded on the strengths of our parent company Lupin Limited, Lupin Pharmaceuticals, Inc. intends to bring a portfolio of generics as well as branded products to the US market." For the financial year ended March 2012, Lupin Limited's Revenues & Profit after Tax were Rs.69, 597 Mn (US $1,392 Mn) &Rs. 8,676 Mn (US $ 174 Mn)respectively.

Strategy

Lupin was founded to meet the very basic need for effective treatment of tuberculosis. Lupin pharmaceutical success is tied to continually meeting the need for basic products promote human health. The lupin pharmaceutical company strives to bring important new products to market each year. Lupin pharmaceutical expect our products to come from: (i) In-house product development; (ii) Licensing andacquisitions;
(iii) Marketing alliances.

SUN PHARMACEUTICALS Strengths

i. Strong growth in emerging marketbusiness
ii. Introduction of Pantoprazole &Eloxatin in US market has very limited competition
iii. They have strong marketing & a sales force of over 12,000employees
iv. They have successfully acquired Taro pharma which has further consolidated their position in Indian markets
v. Strong brand presence in India and USmarkets

Weakness

i. Stiff competition from many Indian and other global brands means limited market share growth
ii. Limited presence in emerging markets and Europeancountries

Company Overview

Sun Pharmais an international specialitypharma company. Sun pharma has a significant presence in the US through our subsidiary Caraco. In the rest of world markets, Sun pharma has a strong ground network of 600 committed field forces in 41 countries, with a pipeline of over 2600 products of which 1600 are registered and marketed. Sun pharma have 3300-person strong sales team in India distributes through 2400 stockists, Sun pharma are now at a stage of rapid growth acrossgeographies spanning Russia and CIS countries, China and South east Asia, Africa and Latin America, where Sun pharma is rapidly emerging as a branded generic company of choice.

In India, Sun pharma are among the largest pharmaceutical companies and command a 4% market share (ORG IMS Stockist Audit, April 2012). InIndia,Sun pharma market over 500 products through 18 speciality marketing divisions that are built around chronic therapy areas. Typically, every year the company introduces 25-30 new products. All of these are developed in-house supported by strong bulk synthesis, formulation development, bioequivalence and regulatory teams. CMARC (A prescription audit agency) has ranked us as No.1 in key chronic therapy areas of Neuropsychiatry, Cardiology, Gastroenterology, Orthopedics and Ophthalmology. Sun pharma rank among the top 5 companies for Diabetology, Respiratory, Pain, Cancer and Gynecology.

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