28362

Available online at www.elixirpublishers.com (Elixir International Journal)

Marketing Management



Elixir Marketing Mgmt. 76 (2014) 28362-28366

Review of Hyderabad pharmaceutical industry: An emerging Global pharma hub

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ARTICLE INFO

Article history: Received: 20 September 2014; Received in revised form: 27 October 2014; Accepted: 6 November 2014;

Keywords

Hyderabad pharma industry, Global pharma hub, Generic drugs Bulk drugs.

ABSTRACT

India is one of the fastest growing pharmaceutical markets in the world and has established itself as a key global hub for research & development, manufacturing of raw materials, excipients, intermediates, finished dosage formulations, packaging materials, and clinical trials for both synthetic and biological drugs. This review paper discusses on how Hyderabad which was known as a bulk drug capital transformed in to an emerging pharma global pharma hub. Business friendly government policies, visionary entrepreneurs and a large pool of knowledge base specialized to support industry has transformed Hyderabad a place for many SME's, Indian & Foreign Multinational Pharma companies.

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Introduction

Global Pharmaceutical Industry

The Global pharma market is estimated to be around USD 1 Trillion in 2012 and to reach USD 1.2 Trillion by 2016. The generic pharma industry contributes around USD 250 Billion and expected to reach to USD 430 Billion by 2016. It is estimated that by 2016, emerging markets will collectively account of almost a third of the total global market. [1] The major share of around 40% business comes from North America. It is a fact that the success of Indian pharma industry is scripted by companies that are supplying to the North American market with generic products.

Indian Pharmaceutical Industry

As per the BMI, the combined sales of Indian Domestic pharmaceutical industry was estimated to be worth USD 20 billion in 2013 and is expected to touch USD 36 billion by 2025. It is expected to grow with a CAGR of 17.8% [2].



Note: F stands for Forecasts Figure 1. Revenue of Indian Pharma Industry

Globally, India ranks third in terms of volume of production and fourteenth largest by value and is also expected to move up to eleventh place by 2017. As per the Pharmexcil latest report Indian Pharma exports touched 90,000 crores (Around USD 15 Billion) and slated to cross 100,000 crores in 2014 with a double digit growth of 15% and the majority of the pharma exports revenues coming from formulations. Majority of the pharma companies are shifting towards to formulations and hence accounted for around 71% of total exports in 2013[3]. India is rated as 10th largest Pharma exporter in the world.

As per the datamonitor reports, in Asia pacific India pharma market occupies a 10% share and 2% in global market [4].



Figure 2. Market share by value in Asia-Pacific 2010 Evolution of Hyderabad Pharma Industry:

The evolution of pharma industry of Hyderabad in the last three decades is an inspirational one, from house of few bulk drug manufacturers the city has grown up in value chain of the industry to become pharma and biotech hub. The city is well known as bulk drug capital of India, the evolution of city into a pharma hub for bulk drugs started with Establishment of sector pharma company public Indian Drugs and pharmaceuticals Ltd (IDPL). The first and foremost reason for the growth of pharmaceutical industry in the state can be attributed to the presence of IDPL, set up in the year 1961 at the behest of India's first Prime Minister, Pandit Jawaharlal Nehru.[5] IDPL was India's largest public sector drug maker in the early days. The company was set up to enable the country attain self-sufficiency in life-saving drugs. Unfortunately IDPL is saddled with accumulated losses of more than Rs. 5000 crores and has a negative net worth of Rs. 4816 crores[6].While IDPL provided the environment for spawning drug firms in Hyderabad, the credit for turning the State into a breeding ground for entrepreneurs should go to Standard Organics Ltd. It was one of the first private sector companies to venture into making active pharmaceutical ingredients (APIs) for multinationals. From here emerged Dr. Anji Reddy, founder and builder of global brand Dr Reddy's Laboratories.

Transformation

In a way, Standard Organics in the early 1980s and Dr Reddy's in the early 1990s became the Spring boards for more than two dozen entrepreneurs, who built up companies of significant size. In three decades, with 2500 pharma companies Hyderabad has seen the rise of pharma majors such as Dr Reddy's Laboratories, Aurobindo Pharma, Hetero Drugs, Divi's Laboratories, Matrix Labs (sold to Mylan Inc), MSN Labs, Natco Pharma, Granules India Limited, Virchow Labs (the only manufacturer of sulfamethoxazole), Neuland Labs, SMS Pharma, Gland Pharma, Jupitor Biosciences, Lee Pharma, and Suven Lifesciences. Due to the success of these companies, many technocrats ventured in to their business which helped the industry to transform it as one of the highest contributor to economy, exports, intellectual property and created huge employment opportunities for all levels.

Growing up in the Value Chain – Branded generics formulations

Retaining its no 1 position in API production the city based pharma companies moved up in value chain to produce generic formulations .Dr Reddy's, Aurobindo, Hetero and Natco Pharma, along with companies from Mumbai, Ahmedabad and New Delhi, have post the 1970 Patent Amendment Act (that facilitated process patents), brought generic drugs to the market, forcing global giants to cut prices while bringing medicines within the reach of the public in India and developing world.

In anti-cancer segment, the efforts of companies such as Natco Pharma challenging patent rights of multinationals and offering cheaper alternatives are proving beneficial to both Indian pharma and poor patients. In at least two areas, Hyderabad has emerged a big supplier. First, in producing antiretrovirals. Hetero Drugs, Mylan and Aurobindo are key contributors of such drugs to the Clinton Foundation as well as international markets and have helped alleviate the suffering of AIDS patients. For bird flu remedies too, Hetero has been a major supplier, procured a licence from Roche. According to Government estimates, AP has registered pharma exports worth close to Rs 25,000 crore and the industry is growing at about 20 per cent [7].

Another unique position held by Hyderabad in the national healthcare and pharma sector is as a major vaccine developer and manufacturer. Companies like Shantha Biotech (now owned by Sanofi Pasteur), Bharat Biotech International, Biological E and Indian Immunologicals are the leading players. Starting from simple pencillins the city now manufactures formulations across various therapeutic segments like cephlosporins, CVS, CNS, Oncology, plasma products, bio similar, vaccines, Retrovirals, Nutraceuticals etc.

Vaccine hub

Biological E, the first vaccine producer in the private sector in the South, is a major supplier of vaccines to the national immunization program. BE has developed a vaccine for Japanese Encephalitis. It has cut the prices for the pentavalent vaccine it supplies to the GAVI Alliance, which provides the vaccine to poor and developing countries. Hetero drugs got the license to develop and manufacture generic version of Ostalmavir from Roche. It supported the world in combating epidemic of swine flu [8]. City based Bharath Biotech made first Indian version of Typhoid Vaccine [9].

The entire hepatitis B vaccine development was led by K.I. Varaprasad Reddy of Shantha and Krishna Ella of Bharat Biotech from Hyderabad in the mid-1990s. Then came the other over-half-a-dozen manufacturers, pushing down the price of this essential vaccine to around Rs 50 a shot in national program. **Exports**

Hyderabad pharma industry is a big foreign exchange earner for the country. It ranks first in manufacturing of bulk drugs and third in formulations in the country. 40 % of the country's bulk drugs gets manufactured in Hyderabad & 44% of country's bulk drugs exports are from the city based companies. The state pharma industry and exports are expected to grow at 20 per cent annually [10].

Pharma exports from State (values in USD million)			
Category	India	Andhra Pradesh	% contribution
Bulk drugs	4535.97	1996	44.0
Formulations	9749	2349	24.1
Herbals	232.14		0.0
Ayush	163.44		0.0
Total Exports	14680.55	4345	29.6

 Table 1. DGCIS report on Indian Pharma exports in 2013

 Pharma exports from State (values in LISD million)

In value terms, Hyderabad pharma industry is worth USD 5 Billion and the state will leverage its strong position to emerge as the next global hub of pharmaceuticals with a share of around US\$ 15-20 billion by 2020. Moving up in the value chain the city based companies are strengthening their position in generic formulations and stand as leading suppliers to international markets.

Benchmarking standards in International Business:

Hyderabad based pharma companies have made inroads in global markets especially regulated markets like North America, European Union, Japan etc. They could built an infrastructure to benchmark the global quality & regulatory standards. Over 60% revenues of these companies is generated from export markets and out of this the major revenues comes from regulated US & EU markets. Hyderabad based companies exploited generics business in North American & European markets and established them as some of the leading manufacturers in these markets.

Hyderabad headquartered Dr Reddy's is the first Indian Pharma company in Asia pacific (outside Japan) to be listed in NYSE in year 2001, thus setting standards in the industry for highest level of transparency in corporate governance. Dr Reddy's became the first Indian Pharma company to get 180 days exclusivity for its Antidepressant generic drug Fluoxetine in the US market in year 2001.

Apart from generics business, Dr Reddy's laboratories commands a leadership position in branded generics in Indian and emerging markets. In 2013, CIS countries alone contributed more than USD 400 Mn sales to Dr. Reddy's turnover [11].

Fig.3 indicates companies from Hyderabad namely Dr. Reddy's, Aurobindo Pharma are always in the top 5 positions in terms of ANDA approvals among Indian companies. The success of these companies as major exporters of finished formulations to regulated markets can be attributed to their state of the art manufacturing facilities approved by USFDA, UKMHRA, ANVISA, TGA etc.



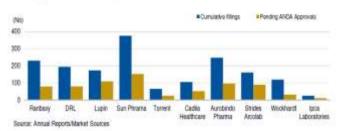


Figure 3. ANDA filings -Outlook report, Indian Pharmaceutical, India ratings & Research, 2013 outlook

Indian pharmaceutical industry has proved in the production of globally accepted quality pharmaceutical products and among the total drug master files at USFDA, India stands first with 2658 filings. The number of Indian companies registered as drug manufacturers with facilities that are approved at USFDA are 475 and 306 including sister concerns respectively (includes all the foreign company establishments in India). In addition to this, India stands first globally in export of drugs, pharmaceuticals and fine chemicals by volume in formulations [12]. The city based pharma companies particularly SME's effectively utilizing the services of PHARMEXIL for showcasing their capabilities across the world.

CRAMS (Contract research & manufacturing services):

It is expected that the Indian contract research is expected to touch USD 3.4 Billion with a CAGR of over 55% (2009-2012) [13]. Hyderabad-based is a house for many companies involved in CRAMS business model. Divi's Labs is one of the most promising companies in the CRAMS_segment. The company has built a strong customer base in its businesses of niche bulk drugs and custom synthesis while at the same time achieving cost leadership and higher market share. Suven Life sciences has grown from being a pure contract research player to become a collaborative research partner. Known for its capabilities in developing NCE (new chemical entities) the companies integrated business model encompasses all the processes from drug discovery and development services to clinical supplies, manufacturing and packaging. The company earns more than 65% of its revenues from the US and Europe. The company has three promising molecules under clinical trials, holding the potential for out licensing opportunities in future [14].

Testing & Analytical laboratories

Vimta laboratories is a leading provider of multidisciplinary contract research and testing services in India Vimta provides contract research and testing services in the areas of clinical research, pre-clinical (animal) studies, clinical reference lab services, environmental assessments and analytical testing of a wide variety of products. Established in 1984, Vimta labs serves to several prestigious clients across the world, including six "Fortune 500" companies, and three of world's "Top Ten" generic drug development companies [14] (http://www.vimta.com/html/drugs_pharma.html)

Clinical Trials

The clinical trial business in India is as big as USD 1.05 Billions. [13]. Hyderabad has few of India's top hospitals like NIMS, Apollo Hospitals, Care Hospital, Asian Institute of Gastro- Enterology, L V Prasad Eye Institute, Indo American Cancer Institute with tertiary care medical research facilities. The large pool of diversified medical professionals attracted many national & international clinical research firms to have their base here for phase 3 & 4 clinical trials. The city has already realized the potential business opportunity of clinical trials and houses some successful companies in this segment like GVK bio , $\ensuremath{\mathsf{PARAXEL}}$, Novartis, etc .

Pre formulation Intermediaries (PFI's)

A PFI is the intermediate product between an API and a Finished Dosage. Hyderabad based Granules pioneered the concept of commercializing PFIs, It enabled formulation makers to outsource PFI, which can be directly compressed to make formulation. The model transformed the conventional pharmaceutical manufacturing by offering customers significant savings, fewer handling hurdles and higher efficiency.

The Companies manufactures 'ready-to-compress' mix of APIs and excipients that can be fed directly into a compression machine to manufacture finished dosages which is a single step process. This greatly helps formulation companies to spend on granulation, process significant savings covering complex preformulation studies, process development and scale-up expenditure [15].

Compulsory Licensing (CL) development of Orphan drugs

Orphan drugs are given in a very rare diseases and they are considered as very expensive to treat the patients. Compulsory license is issued by the courts. Courts can force a drug company to grant a license to another company to make and sell their patented drug on the grounds that the drug is un-affordable, or not available widely enough. ing opportunities is the NATCO way of ensuring affordable medication. Natco Pharma a Hyderabad based specialty pharma major is showing the way for others in procuring compulsory license to produce affordable generic products to the nation by challenging patents of MNC's. For example the company successfully challenged and obtained CL to produce Sorafenin Tosylate, a generic version of Bayer's NEXAVAR at a cost of INR 9000, which oherwise cost 290,000 which is used as a first line treatment of Liver & Kidney cancer [16]. Earlier Natco successfully challenged and won compulsory license for Imatinib a generic version of Novartis's GLIVAC used in the treatment of Chronic Myeloid Leukemia which is a rare type of cancer [17]. NATCO is all set to launch Glatiramer acetate a generic version of COPAXONE of Teva used for multiple sclerosis [18].

Evolving Pharma R&D hub

The Indian Institute of Chemical Technology, a top research centre in chemistry and drugs, the Centre for Cellular and Molecular Biology (CCMB), the Centre for DNA Fingerprinting Technology (CDFT), Osmania University, University of Hyderabad and Indian Institute of Life Sciences have all provided solid support in putting Hyderabad on the global pharma map.

With The availability of talented professionals Hyderabad becoming a preferred destination for pharma research .The research spans from basic process development to pre-clinical & clinical trials, to basic drug development. Pharma key players like Dr. Reddy's, Suven Life sciences, GSK, Novartis, PAREXEL, United Health Group, Bayer, Thomson Reuters, Inventiva Health Clinical, Ocimum Bio Solutions, Covidien have their R&D Centers based in Hyderabad. Dr. Reddy's was one of the very few first Indian pharma companies to invest in basic drug discovery research and successfully developed new chemical entities in the area of cardio vascular, diabetes and cancer. Dr Reddy's has been a frontrunner in many aspects of the Indian Pharmaceutical Industry Growth Story that has been witnessed by the globe. Licensing is one of such aspect. In fact, even during the times when India had just opened its gate to a global economy, Dr Reddy's had inked its first Outlicensing deal.In 1997, an in-house developed anti-diabetic molecule, DRF 2593 (Balaglitazone), was licensed to Novo Nordisk. In

fact, with this deal Reddy's became the first Indian pharmaceutical company to out-license an original molecule [19]. There are couple of new chemical entities in different phases of clinical trials.

Bio pharmaceutical cluster- Genome valley

Genome Valley is a systematically developed bio medical cluster spread over 600 sq, km, located in Shameerpet. It is a perfect blend of knowledge parks, special economic zones (SEZs), multi-tenanted lab space buildings, incubation facilities, office spaces and outstanding support facilities. It has a healthy mix of companies in the realm of agri biotech, CROs, bio pharma, vaccine manufacturing, regulatory and testing which makes it one of the most vibrant clusters today in India. The cluster has over 100 life science companies, including some of the world's fastest growing MNCs. It hosts some of the prestigious MNC's like Novartis, AMRI, Dupont, Aizant, Daichi apart from Indian majors. The US pharmacopoeia has also set up a facility in Genome valley, which is the first of its kind of facility outside the US [20].

India's first Airport based pharma zone:

70% of the exports from GMR Hyderabad International airport are pharma products .To support the growing local industry which has now has strong global footprints, GHIAL and Menzies Aviation, launched India's first airport-based pharma zone, a dedicated pharmaceutical cargo storage and handling facility, at Hyderabad airport. Pharma Zone provide temperature controlled care while handling pharmaceutical products. The facility also has a dedicated area for products requiring temperature control between 02 to 08 degrees as well as sterile area for vital active ingredients and vaccines .It has a capacity of handling 50,000 tons per annum [21].

Government Initiatives & Policies

Both state and central governments are supporting the growth of SME's & large pharma companies in terms of setting up dedicated Special Economic Zones (SEZ) for 100% export oriented units (EOU), tax benefits for exports like Duty exemption pass book scheme (DEPB) for selected areas and products, Export credit guarantee corporation (ECGC) to safeguard the financial interest, Pharmaceutical promotions export promotion council of India (Pharmexcil) to support and promote brand India in global markets, National Institute of Pharmaceutical education & research (NIPER) to cater the need of highly skilful pharma professionals to Hyderabad Pharma Industry. These initiatives have helped pharma companies to compete in global markets and sustain for future challenges.

Pharmexcil (Pharmaceutical promotions export promotion council of India)

Hyderabad being a pharma hub, Pharmexcil is head quartered in Hyderabad. It is a brain child of Ministry of Commerce & Industry to promote exports of Pharmaceutical products from India. In order to live up to the challenges of increasing market share in existing and new markets and countering the negative publicity in some countries by vested interests, Ministry of Commerce & Industry, Government of India has advised Pharmexcil to launch a Brand India Pharma campaign globally.Brand India Pharma campaign is being led under the aegis of Department of Commerce, Government of India, by Pharmexcil in partnership with India Brand Equity Foundation [22]. Council assist the members in the following areas:

• Organizing Trade delegations/Buyer-Seller Meetings at abroad

• Organizing Reverse Buyer-Seller Meetings in India

• Assisting members to get their MDA/MAI claims refunded from Govt. of India

• Issue of Certificate of Origin

• Organizing periodical Seminars/Interactive meetings on exports related issues

• Disseminate trade enquiries received from abroad

• Make suggestions to Govt. of India on policy issues relating to Pharma exports

Apart from assisting all pharma companies at policy and trade level, Pharmexcil has been spending huge resources to position India as a global pharmacy of the world through participating in international conferences like CPhI, Arab health etc. Pharmexcil sends frequent delegations with diplomats to meet regulatory bodies, policy makers across the globe to create the awareness on strengths and capabilities of Indian pharma industry.

Intellectual capital & Net worth of Hyderabad Pharma companies

The city based Pharma companies built word class plants, research facilities, and intellectual property. City based companies have created huge intellectual properties in terms of some of the best scientists, process patents, product patents. Some companies are successful in developing new chemical entities (NCE), new biological entities (NBE). Industry is hopeful that these new products will commercialize soon.

Success of pharma companies in Hyderabad has also resulted in emergence of richest individuals in the country. In the recent 2012 Forbes 100 richest Indians 3 pharma giants of the city are placed .Satish Reddy & GV Prasad of Dr. Reddy's (64th rank), Murali Divi of Divis pharmaceuticals (59th rank) PV Ramaprasadreddy of Aurobindo Pharma (84thrank) [23]. As per the latest statistics, P.V. Ramaprasad Reddy, the co-founder of Indian drugmaker Aurobindo Pharma Ltd, is a billionaire as the stock more than tripled in the past year to a record [24].

Dr. Reddy's is the only Pharma Company in Asia pacific (Outside Japan) to be listed on NYSE (New York stock exchange). Dr. Reddy's was also selected as Asia's Fab 50 companies [25].

The net sales of some of the leading city based listed companies are depicted below:

Table 2. Hyderabad based companies 2013 net sales; source				
DSE & company wohgitag				

- BSE & company websites			
Company	Net Sales in INR Crores		
Dr Reddy's	9,728		
Aurobindo Pharma	7,111		
Divis laboratories	2,513		
Granules India	1,002		
Natco Pharma	552		
Suven Life Sciences	510		

Opportunities for Hyderabad Pharma Industry

Large pool of scientists roll out from premier institutes like IICT, CCMB, CDFT, NIPER, Osmania University, and Jawaharlal Nehru University. Genome valley is strategically located to provide a world class infrastructural cluster for life sciences Company in the science and biotechnology domain. There are more than 350 pharmaceutical colleges under various state and central universities offering professional education in the state. Apart from this, there are numerous hospitals, research and diagnostic laboratories which all are enabling the domestic pharma sector to grow. A successful story of the top pharma companies and leaders inspire the new entrepreneurs to venture in to new startups. Hyderabad is also credited for its infrastructure, diversity, and weather to attract investments and talent pool across the world. For a start-up pharma company, Hyderabad would be an ideal place due to the availability of the best talent pool, technology, international quality bulk drugs, intermediates, excipients and packaging materials.

Hyderabad is located in southern part of India and the current capital of Telangana, which is a newly born state carved out of Andhra Pradesh. Post bifurcation, new state of Telangana is focusing to make Hyderabad as a smart city and lot of initiatives are taken towards this by the new government to enhance the brand image of Hyderabad. New government is also in the process of releasing a blue print to support new startups & the existing pharma companies, and to attract global health care and pharma companies to setup their development and manufacturing base in and around Hyderabad. Also discussions in place for setting up new dedicated pharma & biotech zones.

In the global Pharma market Hyderabad is already known for its affordable quality medicines. Looking at strengths the city based companies have enormous opportunities to become world's preferred generic producers. In other areas the city based Pharma companies have a major role in R&D, process development, NCE development, CRAMS business

Challenges faced by Hyderabad Pharma Industry

The main challenge for the sector is to sustain its growth. The industry should sustain its base as a bulk drug maker and move up the value chain. Though the situation seems to be stable, more industry friendly environment is required .Otherwise the pharma sector may slowly drift its base to other states like Gujarat, Maharashtra, Himachal Pradesh and Jammu and Kashmir which are offering better incentives with less bureaucracy and sharp timelines for govt. processes. The acute power shortages in the state is hampering production activity, particularly the small and medium scale enterprises. In the last few years power shortage has forced many SME's to shut down their operations. Due to the shutdown of these companies, many skilled and unskilled people lost their jobs. To address this issue state should supply the uninterrupted power supply to the SME's.

The state should also reduce the time required for renewal of statutory documents like manufacturing license & GMP certificates. The delays eventually hit the companies engaged in exports.

Today the pharma industry is facing the Supreme Court ban in four districts of the state such as Mahaboobnagar, Medak, Ranga Reddy and Nalgonda because of pollution problems. The industry's indifferent attitude towards environmental safety and lack of social responsibility have forced the regulatory authorities like Pollution control board (PCB) and Drug control authority (DCA) in the state to clamp a ban on expansion and production of new products. To address this issue new state has to setup special zones in the new industrial areas so that the companies do not suffer.

A brief review on opportunities & challenges done keeping in mind that many Hyderabad based SME's are venturing in to exports to exploit the huge opportunities in global markets.

Conclusion

With world class manufacturing plants, infrastructure, highly talented and economical work force the brand Hyderabad

acquired a premium brand equity in world pharma industry. If the newly formed state addresses the issues and challenges faced by Hyderabad Pharma companies, the city will remain as a favorite destination for the global healthcare companies.

With a steady growth of 15-20 % it greatly contributes to states economy, around USD 5 billion export earnings & provides a direct & indirect employment to lakhs of people. The highest contribution of the industry is its affordable quality medication to millions of people across the world. The city and people always cherish this cause.

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