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INDIAN PHARMA INDUSTRY IN GLOBAL CONTEXT : A STATISTICAL OVERVIEW

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“Indian pharmaceutical sector is gearing up for the next level of growth”- a CII (Confederation of Indian Industry) Report admires very concisely the performance of Indian pharmaceutical arena over last few years, says it all about the ever expanding industry.

With advances in research based therapeutics, increased investment in healthcare and consumer-driven private health coverage, increasing geriatric population and rising numbers of patients suffering from Cardiovascular disease, Cancer and Degenerative diseases; global market for pharmaceuticals is increasing arithmetically. In such international healthcare scenario, India seems to be a riding unicorn.

Previously known as supplier of generic drugs, India, by far now has undergone a pool of changes to mark its footprint in worldwide pharmaceutical domain, changing its identity from a supplier of generic drug to a global key competitor and performer in areas like pharmaceutical research and development (R&D), manufacturing of branded, generic and branded generic drugs, manufacturing APIs, laboratory testing and clinical research etc.

Access to strong pool of scientific and technical human resource, healthy competitiveness and Government’s Drug Patent Policy has brought down the pricing of formulation, making them really affordable, saving lives of not only country’s own population but also an enormous global population. Many of the global counterparts furnish their livestock of medicines from pharmaceuticals brought from India to treat TB, HIV, Cancer, Major institutions like United nations and UNDP’s Health program, PEPAFAR(US president’s Emergency Plan for AIDS Relief), Obama healthcare etc. use Indian generics to furnish life saving drugs to millions of patients.

Speaking in terms of numbers, the Indian domestic pharmaceutical market was expected to be US \$ 10.76 billion in 2008 and was expected to grow at Compound Annual Growth Rate (CAGR) of 9.9 % till 2010. However, **performing well than predicted, Indian pharmaceutical industry** has come out as world’s largest and most developed industry, **ranking 4th in volume terms and 13th in value terms** with **over 14.5 % Annual growth rate**. Reliable as manufacturer and supplier of affordable medicines.

Noticeable to mention is a fact that, it was post 1970 regulatory enactment which has made this all possible. In 1970, India passed **‘India Patents Acts 1970’** to allow only **‘Process patent’** for Pharmaceutical molecules and NCEs. This act was the main reason for the fast and continuous growth of Indian pharmaceutical industry in generics. Until 2005, Indian pharmaceutical industry was engaged in bulk drug manufacturing and hence, there was no significant activity in patenting in India.

However, **in 2005, the Indian patent act was modified** to include ‘**Product patent**’ to make Indian Patent Law affable with TRIPs, shifting the focus of Indian Pharmaceutical Industry from Generics to Research based NCEs and NDDS products. This is very well evident that, India, **in the post 2005 era** has witnessed a vigorous activity in patenting. Supporting this statement is the data which reports that, the **value of pharmaceutical production** was only **U.S. \$ 0.3 billion in 1980**, which **rose to U.S. \$ 20 billion by 2012** registering an average annual growth (CAGR) of **over 10 %**. This growth of the domestic market was also triggered by strong economic growth in the country resulting in an increase in the purchasing parity of citizens, higher penetration into semi-urban and rural markets, the emergence of health insurance programs, awareness of healthcare problems and needs among the population and national programs for control of many diseases through prophylaxis and therapeutics, development of infrastructure at all levels and most importantly availability of skilled human resources.

It is worth remarkable that, **over 45 per cent of the production** of pharmaceuticals in India, which includes active pharmaceutical ingredients (APIs) as well as formulations, is **being exported** to the most regulated markets **like US and Western Europe** which yields India, a significant amount of forex reserve. It will not be wrong to say that, **one out of every five dosage forms** consumed worldwide **is manufactured in India** or **formulated from bulk drugs imported from India**. Formulations manufactured in **India share around 20% of global generic market** by value. However, to continue such ride, the Indian bulk drug manufacturing sector needs to be more economical in terms of its cost of production, financing costs, better infrastructure and reduced power and other utility costs, lower taxes and tariffs.

According to 5th Annual report of **Generic Pharmaceutical Association**, Indian generic pharmaceutical sector continues to generate unprecedented financial savings to US healthcare system. None the less India has **around 300 registered pharmaceutical firms, more than 100 of which are US-FDA**. These are the key players which are adding to the Indian revenue from world over. **The National patenting policy** that involved (1) allowing **process patent** instead of a product patent and (2) **shortening the life of patent** in India facilitated these pharmaceutical firms to scale such great heights.

As per the industrial reports, around **US \$ 60-\$70 billion worth of drugs** are expected **to go off patent** in coming few years with **Indian pharmaceutical companies accounting** for almost **35% of Abbreviated New Drug Application (ANDA) approvals** granted by FDA. This will be a delight in time to come.

We will take a short roundup of some recent **forecasts** for the Pharmaceutical Global Market share and of its contributors; which implies an extremely conducive environment for Indian Pharmaceutical Sector to flourish like anything. The **US pharmaceutical market** is projected to grow at 3-5%. While **European pharmaceutical markets** are expected to experience a CAGR of 0–1% which is currently less than 1%, and the **rest of Europe** is projected to have a CAGR of (-1%) to 2%. **Emerging markets, including India, however, are expected to see strong growth.** By 2017, **50% of drugs by volume** are projected to come from emerging markets. **The US and Europe** each respectively **will account for only 13% of this volume** whereas, **BRIC countries** (Brazil, Russia, **India**, and China) on the other part, will **account for about 70%** of all emerging market sales by 2017 **on a value basis** and strategically will continue to be the important engines of growth among emerging pharmaceutical industries worldwide.

With slow growth for pharmaceutical sales in developed markets, multinational companies (**MNCs**) have placed **substantial organic and inorganic investments** into emerging markets like India in recent years. The revenue driver at almost all MNCs remains the innovative medicines, despite some companies' diversification into generics, consumer medicines, diagnostics and other related healthcare markets. However, **generics account for half the sales and** more than half of the **growth in emerging markets.** India can take **advantage** of this fact.

If everything proceeds consistently well, **Indian pharmaceutical industry**, would become a US \$20 billion by the end 2015 and **by 2020**, it is expected to be a **US \$50 billion industry** which by then will enlist it into the **top 10 global markets in value terms**, according to a **PwC report** entitled 'Global Pharma Looks to India: Prospects for Growth.'

However, **looking beyond the fascinating prospects** for Indian Pharmaceutical world, the forecasted dominion of India on international platform is achievable, given that, the Indian pharmaceutical arena is cognizant to some of the crucial challenges it may face. Let's throw some light on these key aspects.

- First and foremost is the **Quality of production.** Lately, some of the domestic firms have failed to meet the FDA regulations. Known world over for Quality, Indian firms need to perform well to give reproducible and reliable production consistently from the manufacturing lines to meet the specifications of FDA, keeping economical the cost of production, financing costs, better infrastructure and reduced power and other utility costs, lower taxes and tariffs.

- Apart from **lax manufacturing practices**, what we need to focus the data integrity issues which recently have come with major domestic companies like Ranbaxy, Wockhardt, Cadila etc. facing a new checkpoint by US-FDA for unauthorized manipulation of raw data
- What comes next is an obligation to implement **the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)**. The patent law enables Product Patenting unbolting the way for legal recourse by major pharma players. Here, Government has to take care of the patent law not being diluted due to pressure from drawn in Pharmaceutical firms.
- While switching to Product patent regime to be in compliance with WTO, the issues like **compulsory licensing provision** for Indian Pharmaceutical majors after paying requisite Royalty to innovators, is anticipated.
- **China**, the largest emerging market among the BRIC countries and a global key competitor of India, is moving with a CAGR of 14–17% over last few years. However, despite the healthy projections, pharmaceutical industry growth in China is seen to be sliding due to a slowdown in GDP growth coming out of a loss in business confidence, along with lower investment in the market. We need to be cost effective in order to compete them.
- With some of the **legal discourses** seen recently, as with **Novartis, India's stand** both at Judicial and Government level is **constructive**; helping check the MNCs from their attempts to impede the bringing of Generic version of Life saving drugs out. This is worth welcoming for Indian pharma sector, indulged largely in Bulk drug manufacturing. This will not only empower the nation with **greater flexibility to produce generic versions of essential life saving drugs** but will also provide affordable healthcare for the poor and needy.
- As far as Generic market is concerned, currently, there is very little additional spending for medicines in developed markets due to **economic slowdown**, so innovation must have compelling evidence to shift budgets from other areas and it must center on developing drugs that address unattended needs and not merely making marginal improvements. Thus, **attaining a value based health outcome**.

- Another key trend observed, is the rising importance of **specialty products** in the overall pharmaceutical market. Specialty products are medicines that treat specific, complex and chronic diseases with four or more of the following attributes: initiated only by a specialist; require special handling and administration; unique distribution; high cost; warrants intensive patient care. More than half of the pharmaceutical industry pipeline is specialist driven and approximately one-third is biologics or **biopharmaceutical** driven, a study shows. Along with a lead in **Vaccine manufacturing**, Indian industries will have to look for some other better novel formulations as well.
- Expanding the wings, we should look at **Foreign Direct Investment (FDI) in pharmaceutical sector** more positively. The Biotechnological field is attracting huge investments in recent time. This can come out to be a boon for overall industrial growth.
- Market leaders such as Ranbaxy and Dr. Reddy's Laboratories spent only 5–10% of their revenues on R&D, lagging behind Western pharmaceuticals like Pfizer, whose research budget last year was greater than the combined revenues of the entire Indian pharmaceutical industry. This gap in **spending more money on Research and development** is a key concern. Thus, as mentioned previously, much more work is required in Innovative drugs area.

All these issues are within the scope of native pharmaceutical players of India. The individual companies and Indian Pharmaceutical industry collectively, have to walk coherently with necessary competence while combating legal battles. They should undoubtedly be consistent and in accordance with the specifications and standards set by the regulatory bodies keeping in mind the cGMP which directly relates India's Pharmaceutical upsurge globally. So that India can carve its name as a true Unicorn in global pharmaceutical run.

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