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Structure of the Pharmaceutical Industries in India

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Abstract - The health status of every nation is directly related to its ability to prevent, treat, and promote disease. Nevertheless, the pharmaceutical industry's expansion is important to implementing these steps with available qualified people resources and infrastructure. Health professionals, health infrastructure, medical invention and innovation, and the form of government programmes and regulations all have a role in health status. Pharma Vision 2020, a plan to make India the world's leading producer of end-to-end pharmaceuticals, was unveiled by the Indian government. To encourage more investment, the approval process for new facilities has been sped up. To address this problem, the government has implemented measures such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority (www.idma.com). The manufacturing costs in India are much cheaper than those in the United States and Europe. It offers India an advantage in the competition. (Sectoral Report / September 2016)... The rivalry in these marketplaces is critical to the production of high-quality pharmaceuticals at reasonable rates for customers. Anti-competitive practises in the industry must be addressed, and the rule of law plays a critical role in ensuring that markets remain competitive. To this end, the researcher sought to assess the current state of the Indian pharmaceutical market's organisation and laws, as well as the prevalence of anti-competitive practises. The market becomes less competitive when there is too much regulation. Human society's out-of-pocket costs for pharmaceutical items may be reduced by an equal act of management and competition.

Keywords - Pharmaceutical industry, Structure, India

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1. INTRODUCTION

With annual sales of over USD 38 billion2 today, the sector may be credited to its world-class formulation development talents, the entrepreneurial ability of the enterprises and its vision to build India's presence in big international markets such as the US.

With its inexpensive and high-quality generic medications, the business has had a significant impact on global health outcomes. One of the most important factors in reducing the illness load in India has been the increased availability of inexpensive medications. From a 61 per cent illness burden in 1990 to 33 per cent in 2016, infectious and related diseases were the driving force behind the decreased disease burden in the United States. A 50% rise in drug use in India occurred throughout the same period of time. An unprecedented level of cooperation between the country's government, vaccine makers, healthcare professionals and development organisations has resulted in India's Polio-free status. Chronic Myeloid Leukemia (CML) and Hepatitis C (HCV) treatment expenses are now less than 5% of what they were before the business got involved.

2. INDIAN PHARMACEUTICAL INDUSTRY

It is possible to separate the Indian pharmaceutical sector into two distinct periods: pre-patent and post-patent. Unlike the pre-patent or process patent regime, the post-patent or product patent regime seeks to promote new drug discoveries over the long term. It is a world-class generics business. However, the introduction of trademarked goods has been gradual in India.

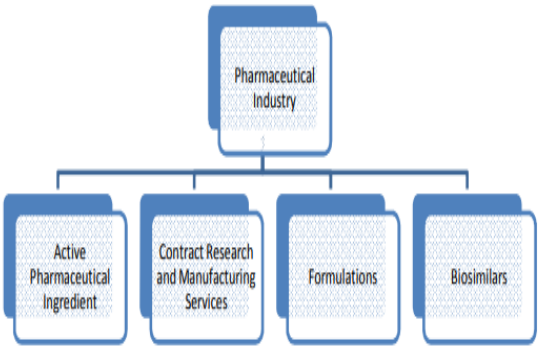
Generic pharmaceuticals and active pharmaceutical ingredients (APIs) from India have given them a footing in the global arena and now they want to become a key player in contract research and manufacturing services (CRAMS).

India has the most FDA-approved manufacturing facilities in the world (332). There are two areas where Indian pharmaceutical businesses may make a profit: formulations and bulk medications. About 60 per cent of the industry's revenues in 2013-14 were generated by exports (in both bulk pharmaceuticals and formulations). It is estimated that over 100,000 different types of pharmaceuticals are made in the country each year. Both in terms of the number of

producers and the range of goods available, the domestic formulations sector is extremely fragmented in this country. It's estimated that between 300 and 400 players are organised and roughly 15,000 players are unorganised. The formulations market, on the other hand, is dominated by organised companies.

3. INDUSTRY STRUCTURE

As a percentage of total world production, the Indian pharmaceutical sector ranks as one of the top five biggest. Active Pharmaceutical Ingredients, Contract Research and Manufacturing Services, Formulations and Biosimilars are the four main categories of products.



3.1 Active Pharmaceutical Ingredient (API):

API is a pharmaceutical drug's raw ingredient, and the precise ratio depends on the drug's intended effect. There may be more than one API in a given medicine, and the percentage of each varies from one drug to another. In light of patent expirations in the United States and Europe, expansion in developing markets, and rising need for vital pharmaceuticals, the API industry is likely to continue to expand strongly.

3.2 Contract Research and Manufacturing Services (CRAMS):

Low-cost manufacturing and research services may be outsourced via CRAMS. With its low costs and high quality production, India is a major participant in contract research and manufacturing services.

3.3 Formulations:

Formulation is the process of combining API with other chemicals to create the final product (medicine). Each chemical involved in the creation of a medicine is tested for compatibility and the end product's effect/reaction is studied as well.

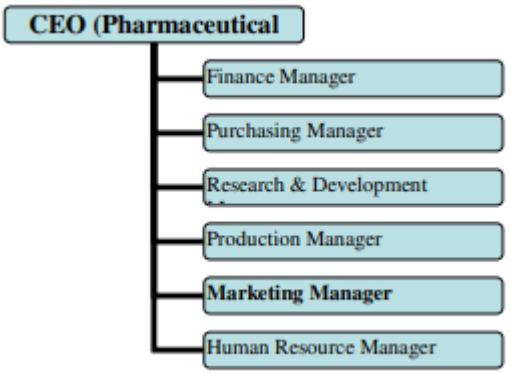
3.4 Biosimilars:

It is possible to develop a new biological treatment that is biosimilar to an existing biological medication. Bacteria, for example, are used as a source of these medications. They might be made up of simple molecules like human insulin or they can be made up of complicated molecules. Over the next five to seven years, a lot of firms producing biologic treatments will lose their patent protection, which would open up substantial potential for biosimilars players. Cancer, diabetes, and rheumatoid arthritis are expected to drive this segment's rise.

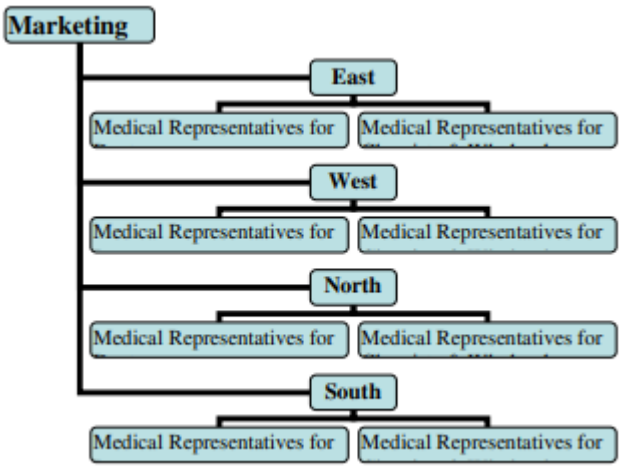
4. THE NEW STRUCTURE

More specialisation is possible with the new structure, which may be the answer to the problem. Specialization is required in every organisation. However, we are proposing a two-tiered approach to Medical Representatives. It's best if you break it up into two halves. Doctor Medical Representative and Chemist and Wholesalers Medical Representative are two of the new job titles we've given them, together with the abbreviations MRD and MRCW.

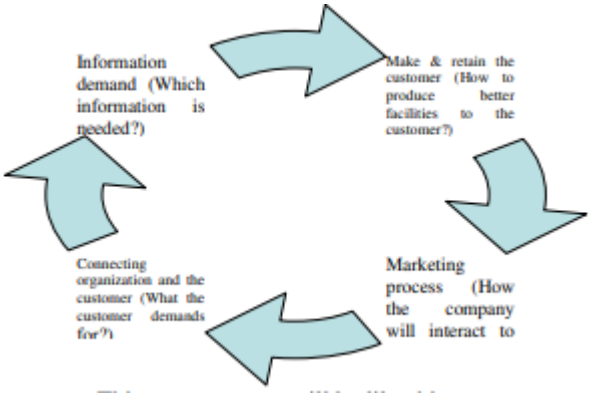
A pharmaceutical company's functional organisation is shown in the diagram below.



As a result, we've created a marketing division structure that can be seen in almost every major pharmaceutical business today.



However, as we've already seen, this design has several drawbacks. As a result, we are proposing a new framework for a pharmaceutical company's marketing department. Basically, it will look like this:



5. PHARMACEUTICAL MARKET STRUCTURE

For the development and manufacture of high-quality goods at competitive prices, Indian pharmaceutical markets are essential. Competition laws play a critical role in addressing anticompetitive practises in the pharmaceutical business and ensuring that markets remain competitive.

5.1 Pharmaceutical Market Structure Characteristics

Pharmaceutics market characteristics in India are similar to the worldwide market, except that there may be extra aspects that complicate things:

Information Asymmetry: Pharmaceutical items are difficult to comprehend because of their technical complexity. They may pose a danger to human life that is not readily apparent. In other words, there is a major knowledge imbalance across the whole pharmaceutical distribution and consumption supply chain, as this suggests. There may be a lack of communication between the manufacturer, distributor, physicians, chemists, and users of medication. Producers of pharmaceuticals may more often advocate for drugs with higher profit margins to the medical community. Another problem with information asymmetry is that consumers aren't aware of the availability of generic pharmaceuticals. As a consequence of this information inequity, generic manufacturers may be pushed out of business, producing an artificial demand for branded drugs.

Consumers are not Decision-Makers: The only exception to this is the prescription-free over-the-counter medications, which may be purchased without a doctor's prescription. Users of pharmaceutical items are unaware of the medications, and thus are unable to purchase them on their own. As a result, patients are at the mercy of the medical professionals who treat them. Physicians are often the ones who make the final decision on which drug to prescribe and which brand to use, rather than relying only on economic considerations. There is no legal authorization for pharmacies to substitute the prescription brand-name medication with a generic one.

Consumers are Price Takers: In contrast to other essential items, the demand for pharmaceutical products is not a direct one. Prescriptions for medications to treat an illness, whether acute or long-term, are written by the doctor on behalf of the patient. The doctor's advise compelled the patient to purchase pharmaceutical items at the stated price, without any negotiation. The provider sets the price in accordance with government requirements. There is no bargaining power for the patient who calls as a customer since the patient is a price taker. People don't know what a Rx sign means, and they can't examine all of these price discrepancies because they're ill at that time of the day. As a result, in a market like this, all customers are only price takers, not producers.

Relatively Inelastic Demand: There is a somewhat inflexible demand for medicinal items (low price elasticity).

Lack of Countervailing Power: Out-of-pocket payments are the most common method of paying for medications in India (OOP). Out-of-pocket healthcare spending in India was 85.9% of total private health expenditure in 2013, while public spending accounted for just 32.2% of overall health spending in same year1 (one of the highest in the world). In addition, health insurance coverage in India is quite poor. Due to the lack of institutions such as the government and hospitals, the Indian market's countervailing power is reduced.

5.2 Market Concentration

The three-tier structure of the Indian pharmaceutical sector is the norm. Indian generic organisations and multinational MNCs functioning as original drug organisations make up the first layer of the pharmaceutical industry's supply chains. It is the second layer of music businesses that produce marked generics and contract-related operations in the second tier. Many units in the third tier of small-scale manufacturing are interested in producing generic-generic drugs. In 2014, the top four companies in the category predicted a 20% revenue share. The top 10 companies, on the other hand, accounted for 39% of the market. The Indian pharmaceutical industry is dominated by small size enterprises, if we look at only a few companies. Maharashtra, Gujarat, West Bengal, Andhra Pradesh, and Tamil Nadu are the states with the greatest concentrations of pharmaceutical manufacturing in India.

Table 1: India's Pharmaceutical Product Development Trends

Value of Production (Including Exports) of Bulk Drugs and Formulations	Bulk Drugs Rs in crores	Growth (%)	Formulations Rs in crores	Growth (%)
2001-02	5439	19.7	21104	15
2002-03	6529	19.3	24185	14.8
2003-04	7779	19.14	27692	14.5
2004-05	9249	18.9	31685	14.4
2005-06	10635	15	38022	20
2006-07	12125	14	45626	20
2007-08	13822	14	54751	20
2008-09	15204	10	66796	22
2009-10	17487	15	83495	25
2010-11	17894	15.2	98691	18.1
2011-12	20936	17	112014	13.5

Using Table-1, states how pharmaceutical product manufacturing has grown over time. The value of output has been rising steadily throughout the years, according to the real facts. However, the zig-zag tendency in percentage increase throughout the years is the topic of interest. Meanwhile, there was an increase in the percentage of growth in value produced by formulations throughout the same period of time (2004 to 2010). In certain cases, product demand or sales may necessitate modifications in inventory. All other years except 2009-10 have seen the sum of total output value and growth at a given point in time remain consistent at 35 percent. Another way to see India's steady rise in pharmaceutical product output value is to add up both of its annual growth rates and add them up to 34-35 percent. As a result, the flow of pharmaceuticals remains steady throughout time.

Table 2: Status of International Trade in India

Year	Exports of Medicines & Pharmaceuticals Products	Import of Medicines & Pharmaceuticals Products
	(Rupees in Crore)	(Rupees in Crore)
2012-13	79840	32691.98
2013-14	90341	31077.95
2014-15	94275	32214.27
2015-16 (upto Dec)	---	24926.01

Source: Annual Report 2015-16, Department of Pharmaceutical, Import figures in USD converted to INR.

Table 2 illustrates the value of pharmaceutical exports and imports. India benefits from both absolute and relative disparity in the value of trade in the pharmaceutical industry, as can be shown by looking at the gap between export and import. More than 200 nations throughout the globe get Indian pharmaceuticals, with the United States being the most important. In terms of volume, generic medications make for 20 percent of worldwide exports, making the nation the world's largest supplier of generic medicines. A $25 billion pharmaceutical export market is expected in 2015, according to the Pharmaceutical Exports Promotion Council (Pharmexcil). By establishing a US$640 million venture fund, the Indian government intends to enhance drug research and improve the country's pharmaceutics infrastructure. Pharma Vision 2020 is an effort by the Indian government's Department of Pharmaceuticals to make India the world's leading centre for drug development from start to finish. It is estimated that India's pharmaceutical exports increased 11.44 percent year-on-year to $12.91 billion in FY 2015-16, cementing its lead over China. The value of pharmaceutical products imported into the country increased by just 0.80% on-year to US$ 1,641.15 million. Overall, the US Food and Drug Administration (USFDA) granted 201 drug permits to Indian firms in FY 2015-16, up from 109 in the previous year. Around 30 percent (volume) and 10 percent (value) of the US$ 70-80 billion generics market is held by the nation. Global pharmaceutical production is predicted to increase at a pace of 5% per year between 2015 and 2020, however the Indian pharmaceutical sector is expected to develop at a rate of 15% per year. The pharmaceuticals industry is dominated by branded generics, which account for over 80% of the market share (in terms of revenues).

6. CONCLUSION

Regulating the pharmaceutical industry is required because of its unique qualities (e.g., dealing with human lives, customers being price takers, knowledge asymmetry, poor price elasticity, etc.). But tighter controls on business may sometimes lead to less competition on the market.

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