Chapter 1.

Introduction.

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1.1
INTRODUCTION.

Globally, the healthcare delivery system is undergoing a revolution, triggered by social, economic and technological changes and the emerging epidemiological patterns in various countries. Healthcare industry backed by technology sees a future with far reaching social, commercial and economic impact.

With the rise in income of the traditional middle-income group, there is likely to be increasing pressure on healthcare facilities. The increase in disposable income and the propensity to spend on healthcare will serve as huge potential for healthcare industry in general and pharmaceutical industry in particular. The booming middle-income market will shift the fulcrum of activities from the developed economies to developing countries, including India. As financial markets become global and capital flows freely from one continent to another, we can expect some Rs 154000 crore worth of private capital in flows annually. Which may grow to a total of over Rs 44000 crore in a short span of time. This would account for almost a third of the total healthcare spending in the world. India’s share will be significant.

On a broader social scale, we will see more radical change. There will be village and town care units, regional centers and centralized hospitals forming an integrated network. Such a system would see integration not only of structures but also of systems involving private, governmental and no-profit healthcare organizations. At the macro level, these systems will ensure that medical expertise and service standardize globally.

The role of the tertiary care hospital in such a scenario would also undergo change in the society that it serves; and transcend national boundaries. There will be increased pressure on such institutes to extend their activities at subsidized rates or for free, as social causes increase. Their investment in technology will multiply, as they will have to network not only with governmental but also many non-profit organizations. The responsibility of such units will rapidly extend beyond the spheres of environmental protection to information exchange that will benefit the future generations. Indian hospitals and healthcare institutions are going to be pulled into the
global arena and we will have to match global healthcare players with our knowledge, service and skills.

Research and development will accelerate and the rate of obsolescence of drugs and medicines as well as medical protocols will keep up with new discoveries.

Another significant change factor is private capital, which will find enormous investment opportunities in the areas of healthcare technology as cost effective and highly skilled manpower become available in India. The private sector will consolidate itself in the capital-intensive tertiary care arena, and in some cases, the private sector and the government might partner in business.

As the insurance sector opens up, financing and delivery would become part of the same organization and managed care companies on the model of healthcare management organizations (HMOs) will take shape in the next few years. The focus will shift from curative to preventive medicine, as the cost of keeping a man healthy would be much less than that of treating one who is sick health and recreation. And healthcare and tourism will converge. Traditional methods of healthcare such as Yoga and Ayurveda will reemerge and play a significant role in promoting health and well being.

The growth of the private healthcare sector can best be predicted by the healthcare-spending pattern we see in the West today, which is almost 12 percent of the GDP of the richer countries. In India, the government is spending under 2 percent on healthcare and the private spending would add another 2 percent to that sum. The share of public spending in higher income countries is close to 70 percent of the total. This, then, is the potential for growth in India, with its population of almost 1.2 billion with the opening up of the health insurance market; larger segments will come under social safety nets. This would result in improved efficiency in service delivery, controlled costs and increased availability, accessibility and affordability of medicine.

Indian market is important field to absorb all these changes with its peculiar characteristics like demand for innovative drugs, increasing penetration of allopathic medicine in low-income group, generic drugs section developments. Increase in health insurance coverage and governments involvement in healthcare activities is also encouraging factor. All these
results in more penetration of essential medicine in middle and low income group section of society.

With all these considerations, we choose this topic to study developments in pharmaceutical sector. Health is not an isolated subject; it is directly linked with social economics. Market forces play important role in supply of medicines at differential prices. Innovative medicines having high cost comes in to fray and issues of patentability, ownership of knowledge and cost as well as affordability of medicines in developing and least developed economies are points which are correlated with our study.

Issues such as research and development cost and its relation with patentability of medicine thus become issues related with commercialization of patent (predictability) and relative importance of market affected by patent holder (importance or market significance).

Therefore in this study, along with pharmaceutical sector, healthcare cost, demand, pricing, economic indignity, Trade Related Intellectual Property Rights (TRIPS) and Trade Related Intellectual Marketing Rights (TRIMS), role of government, on governmental organizations, traditional medicine, role of biotechnology are referred for drawing conclusions of our work.

Impact of insurance sector developments on drug cost is not referred in depth in this study because many researchers already did lot of work and as far as governmental sector involvement is considered, it is negligible at this point of time and only 3.5% of population have health insurance coverage. Government initiatives in group health insurances are just entered in market and evaluated data is not available for drawing conclusions.
1.2
OBJECTIVES OF STUDY.
1 To study Indian healthcare environment and Indian pharmaceutical market characteristics.
2 To evaluate market changes that can produce impact on Indian pharmaceutical market.
3 To assess various socio economic parameters affecting growth of Indian pharmaceutical sector.
4 To predict future scenario for Indian pharmaceutical environment, an assessment of our position in year 2015.
5 To study policies of government towards healthcare system.

1.3
HYPOTHESIS.

Major assumptions while drawing hypothesis of this subject were based on four parameters, which are discussed and interpreted as follows,

1. Signing WTO agreement will adversely affect Indian pharmaceutical industry.
2. There will be many legislative changes required to suit our legal system, compliant with that of international treaties.
3. Research and development activities in Indian pharmaceutical sector will be adversely affected due to impact of these policies.
4. All the above factors will lead to increase in prices of drugs and formulations to consumers.
This hypothesis way tested during course of study and tested results are,

1. There will be no major adverse effect on Indian pharmaceutical industry due to shifting of paradigm from process patent to product patent.

2. By making legislative changes, which are compliant with international practice will only strengthen Indian pharmaceutical sector in long run.

3. It will help in streamlining research and developmental activities in pharmaceutical field. This will make Indian pharmaceutical industry more research oriented and will benefit industry in monetary terms in long run.

4. Prices of medicines will increase marginally. But if primary and secondary healthcare delivery systems are strengthen, this price rise can be effectively digested.

1.4

SCOPE OF THE STUDY.

Indian pharmaceutical industry is one of the promising sectors of the Indian economy. It fulfills almost all requirements of bulk drugs and formulations of domestic market. Pharmaceutical industry is also showing encouraging results in exports and research and development in last decade (year 1990 – 2000). The Last decade was the decisive period for Indian economy. This was because of challenges lying ahead due to globalization and liberalization of Indian economy. Indian pharmaceutical Industry took it as an opportunity and acquitted to position itself as one of the most promising sector of Indian economy. Present study is performed to predict changes expected to happen in various sectors of pharmaceutical industry and its effect on final beneficiary i.e. customer. While making study, various macro economical factors are studied involving various parameters, which have capacity to affect various sections of pharmaceutical industry.

Results of study are predicted for coming ten years i.e. up to year 2015. Implementation of WTO compliant system and its results on pharmaceutical sector and allied fields were tested with reference to following parameters;

1. National and Trans-national pharmaceutical corporations.
2 Consumers.
3 Research and Development.
4 Government Policies.

Results –
1 Globalization and liberalization will only strengthen Indian pharmaceutical sector.
2 Consumers will have to pay slightly higher amount, but in and large excessive price hike in essential medicines is not expected due to only product patent system of patenting.
3 Since ten years span is too short to comment on research and development, but we expect more investment in research and development sector, which will benefit sector in long run.
4 Government is responding positively to the changes by adopting pragmatic health and drug policies. There is no need of bothering excessively about patents and WTO at this stage.

1.5 ORGANISATION OF THESIS

Chapter 1.
Introduction.

This topic gives introduction of our topic of study, objectives of study, hypothesis of study, scope of study and organization of thesis. Thus this topic represents entire of skeleton of our research work.

Chapter 2.
Indian Pharmaceutical Industry: Data Analysis.

This topic deals with present position of Indian pharmaceutical industry. It includes various sub-segments of industry like bulk drugs, formulations, research and development etc.
Chapter 3.

World Trade Organization and Indian Pharmaceutical Industry.

This topic provides the aspects of WTO and its implications on Indian pharmaceutical industry. Various clauses of TRIPs affecting growth of pharmaceutical industry and response by Indian pharmaceutical companies are discussed in this topic.

Chapter 4.

Regulatory changes in National Policies.

This topic throws the lights on various measures taken by Indian Government to cope effectively with policies and rules of World Trade Organization.

Chapter 5.

National Health Policy and National Drug Policy.

This topic discusses expectations and allocation off resources in new national health and drug policy towards Indian healthcare sector, especially pharmaceuticals.

Chapter 6.

Generics and Biogenerics.

This topic gives various aspects of growth of Indian generic drug business. It enumerates various factors responsible for generic drug business in India. This topic also includes export of generic bulk drugs and formulations. Emerging sector of biogenerics is also included in this topic.

Chapter 7.

Biotechnology and Pharmaceutical Industry.

This topic presents trends in development of biotechnology industry globally in general and specifically with Indian reference. It correlates increasing interaction of biotech and pharmaceautical sector. Topic gives predictions about growth of pharmaceutical biotechnology Industry in India in coming decade. Limitations of biotech products in Indian market are also enumerated in this topic.
Chapter 8.
Research and Developmental Activities in Indian Pharmaceutical Industry.

This topic predicts trends in research and development in Indian pharmaceutical sector. Results are drawn with reference to past trends and present inputs in research and development. Various factors leading to increase in research and development are also listed in this topic.

Chapter 9.
Hospitals.

This topic includes increasing role of hospitals in giving better cost effective treatment to patients.

Chapter 10.
Drug Pricing.

Various factors affecting prices of drugs in market are discussed in this Chapter. Special reference is given to government mechanism that controls prices of drugs in India i.e. National Drug Pricing Authority (NDPA). Private sector investment in hospitals and healthcare services and future trends in this area is also enumerated in this topic.

Chapter 11.
Herbals and Complementary Systems of Medicine.

This topic deals with growing importance of herbals and complimentary systems of medicine with reference to standardization of herbals and efforts to improve standardization of herbal formulations.

Chapter 12.
Research methodology.

This topic presents research methodology. The details regarding primary data and secondary data have been given. Thus, it presents details regarding the data collected, systemization of data, analysis and presentation of work.
Chapter 13.

Findings and Recommendations.

This topic highlights summary and findings of study as well as the recommendations made by the researcher.

Bibliography.