Chapter 12.

Research Methodology.

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12.1

RESEARCH METHODOLOGY.

Exploratory research method was used to carry out research. Secondary data was collected by using originating sources. Use of syndicated services involving intermediate sources and ‘panel’ type syndicated services was done. Nature of questionnaire was non-distinguished (direct), non-structured, open-ended questions. Nonprobability sampling technique involving judgment sampling, convenience sampling was adopted. Purposive, nonprobability sample size of 120 was used for arriving of conclusions of testing of hypotheses. Multivariate analysis technique was adopted for testing hypotheses. Emphasis is given on structured and direct (depth interviews) techniques, since we are related with strategy implementation in macroeconomic environment. External or exogenous factors or ‘events’ are always difficult to anticipate. Therefore, forecast model is created which includes factors beyond supply, demand and historical trends. Key external drivers for pharmaceutical forecasting included in study are;

2. Regulatory intervention.
3. Pricing Controls.
4. Blockbuster sales expectations.

We adhere to structured scientific approach to predict the future over ten-year period i.e. from the year 2005 to 2015. Data collected by the above sources was analyzed while considering various dependable and undependable parameters affecting final conclusions.

At each stage, we consulted with the subject expertise that is responsible for strategic and technical policies. This helped us in determining and evaluating our topics of interest like percentage market share, future trends, etc.

Observations and results drawn in research work were indemnified by studying empirical work done in similar studies related to this topic. Observations drawn are based on demand, which is cross-price-sensitive, affected by persuasive advertising and pricing. Pharmaceutical market is imperfectly competitive and subject to regulations. Concept of reference pricing is important related with pricing of drugs, which is depend upon,
1. Availability of new drug.
2. Reimbursement levels.
3. Out of pocket surcharge to patient.

In India, when we consider pharmaceutical and healthcare sector, we observe that these factors, which are very crucial for statistical analysis, are almost negligible. Therefore we concluded that there would be minimal effect on the total price rise in all areas of pharmaceutical market. Other factors affecting empirical studies mentioned below were also insignificant in Indian context.

1. Approach towards subsidizing insurance coverage.
2. Pharmacy Benefit Managers (PBMs).
3. Therapeutic referencing.
4. Cross national referencing.
5. Standard daily dose.
6. Pharmacy reimbursement incentives.
7. Price spillover effect.

Demand forecasting approach adopted in empirical work by some researchers is discrete choice framework and multistage budgeting approach. It involves flexible functioning format Almost Ideal Demand System (AIDS). They calculated Global Welfare Loss and Forgone Profits of domestic firms in demand estimations, economic endogenisity, social welfare, elasticity of demand, cost and mark up estimates and counterfactual estimates of impact on price and welfare.

But it is very unlikely that such thing will actually happen in India. Because there is debate on cost of patenting. It is pointed that 50% of research and development cost is post patenting. Actual cost of drug in domestic market is depends on commercialization of patent (predictability) and relative importance of markets affected by licensee (importance) i.e. market significance. Habridge study and Eastman study supports this view. Recent approach of government of India towards decontrolling of drugs and formulations from Drug Price Control Order (DPCO) and legal litigations about new drug policy also support our conclusions. Increasing role of Planning Commission and approach of government towards agriculture and health also supports our views.
On global level, The Millennium Development Goals (MDGs) set by United Nations and debate on Global Public Goods and Global Private Goods also gives emphasis on strengthening voice and negotiating capacity of developing countries. Similar efforts at World Intellectual Property Organization (WIPO) on Traditional Knowledge, sui-generis, Folklore Medicine and International Treaty on Plants, Genetic Resources For Food And Agriculture (ITPGR), Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC), The Convention on Biological Diversity (CBD), Food and Agricultural Organization (FAO) supports social approach towards this issues of health and medicine.

12.2
DATA SOURCES.

A) Primary data Sources:

Primary data is collected by in-depth interviews with professionals in pharmaceutical field who are in the policy-making groups. Around 120 discussions were made to understand views and opinion of these people. To achieve this, we participated in the National level conferences and seminars on this topic. 14 National level conferences were attended like Indian Pharmaceutical Congress, National level Biotechnology workshop.

We made extensive use of information available on Internet to contact people and groups all the over world having similar interests. We became members of Internet discussion groups for participation in topics, such as pharmaceutical policy e-discussion group known as Ip-health. We received about 1000 communications through this channel. It helped us in updating our understanding of subject and apprises us with latest global trends.

B) Secondary data Sources

Total of about 150 references are listed in final text of this study. These references are collected from reputed organizations, which are involved in pharmaceutical policy making decisions at national and international level. Statistical data is also included for references, which is commonly use by Government organizations, in decision-making process.
Secondary data collected can be grouped together in six categories such as:

1) Data from International Associations.
2) Data collected from National Institutions and Ministries of Government.
3) Professional Pharmaceutical Associations at National level.
4) Market Research Agencies.
5) Internet.
6) Business journals and magazines of pharmaceutical Industry.

**Literature review includes following data sources:**

**International Associations**
World Bank, South Center, World Health Organization (WHO), United Nations Agencies involve in healthcare, world Intellectual Property Organization (WIPO).

**National Institutions / Ministries/ Policy Documents**

**Professional Pharmaceutical Associations at National level:**
Indian Pharmaceutical Association (IPA), Association Of Pharmaceutical Teachers Of India (APTI), Organization Of Pharmaceutical Producers of India (OPPI), Indian Drug Manufacturing Association (IDMA), Federation Of Indian Chambers Of Commerce And Industries (FICCI), Indian Pharmaceutical Alliance, Confederation Of Indian Industries (CII), Bombay Stock Exchange, Center For Study Of Global Trade System And Development, Associated Chambers Of Commerce And Industries (ASSOCHAM).

**Market Research Organizations**
Internet
Some sites regularly visited;
1) Pharmaceutical policy e-discussion group: http://lists.essential-org
2) Global pharmaceutical business policy site (www.IMShealth.com)
4) www.southcentre.org
6) National Pharmaceutical Pricing Authority (www.nppaindia.nic.in).
7) Indian Patent Office (www.patentoffice.nic.in).

12.3
SAMPLING METHOD USED.
Sampling method involved non-probability sampling, which is more qualitative in nature. Our study was at macroeconomic level. We selected some pioneering Institutions in pharmaceutical field, located at Bangalore, Ahmedabad, Delhi, Mumbai, and Pune. Mumbai is the place from where majority of the activities of pharmaceutical industry takes place. Most of national level professional bodies with whom we interact are located in Mumbai.

In this age of Information Technology we made exhaustive use of Internet to collect data so as to get the latest picture of global and national trends in the field of healthcare management systems.

All concern samples were selected on individual basis depending on their impact on research work. If needed questionnaire was designed to obtain and analyze specific data.
12.4
LIMITATIONS OF STUDY.

1) This is initial phase of implementation of all new policies affecting pharmaceutical industry. New National Health Policy, National pharmaceutical policy, EXIM Policy, 10th plane estimations are just introduced. As a result, predictions made in study are susceptible for change if these policies are implemented with different *spirit*.

2) Last few years the Indian economy experienced low inflation rate, high growth rate, stable and increasing forex reserves. These positive factors of economy are assumed will remain stable in the coming decade. Any negative changes in these factors may change results of this study.