Chapter 13.

Findings And Recommendations.

<table>
<thead>
<tr>
<th></th>
<th>Findings.</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>13.1</td>
<td></td>
<td>283</td>
</tr>
<tr>
<td>13.2</td>
<td>Recommendations.</td>
<td>286</td>
</tr>
</tbody>
</table>
13.1

FINDINGS.

Findings and conclusions are made on the basis of various parameters discussed above.

Findings Vary Within Following Areas:

1. Prices of Formulations:
   Due to reduction in span of control under Drug Price Control Order (DPCO), profitability of manufacturer may go up. Patents may not have any significant effect on prices of essential drugs because less than 10% of these essential drugs come under patent regime.

2. Drug Price Control Order (DPCO) is unlikely to be completely scraped. Some changes in span of control are expected.

3. We expect modernization of Drug Controller’s Office machinery for approval of Investigational New Drugs (IND) and approval of phase I, II & III clinical trials of new drugs.

4. Market Characteristics:
   Can be summed up as prescription driven in generic market. By the year 2012, for some global companies, Indian pharmaceutical market will have major value in their core chain. By year 2013, leading Indian pharmaceutical companies will make a mark in international pharmaceutical market. India can be among the top three in generic drugs destination in world, both in manufacturing and exports. New areas such as Contract Research, Contract Manufacture, and Clinical Trials will contribute significantly to this segment.

5. Formation TRIPS compliant patent framework in India is implemented in year 2005. If these policies are applied in spirit and manner of WTO goals, it will prove beneficial to Indian pharmaceutical sector.
6. Research and Development:

We will see beginning of Research and Development era in the Indian pharmaceutical sector. But no dramatic changes are expected in coming ten years. As far as research is concerned, it is difficult to make any predictions, because drug research is 10-15 year process and time span of ten years for making any predictions is too short for this aspect. By the year 2015 we will see little more than 50 products in R and D pipeline.

7. It is expected that about 60% pharmaceutical production in private sector.

8. Medical advances and new technologies like biotechnology and genetics will get more dominance. India is expected to excel in this area also, because present results in this area are encouraging. Prices of drugs from this category will be a key factor. But only those products will succeed which have affordability in their appropriate segments. We expect monoclonal antibodies will occupy 40 share of new drugs business.

9. Herbal Industry requires more attention. International approach in standardization of systems is required in this area. This segment needs to explore tremendous market potential in this segment.

10. Change in value chain distribution of drugs is expected with the entry of multinational corporations in the distribution of drugs. Although in a span of ten years it cannot substitute present retail and wholesale drug distribution chain in India.

11. Globalization of economy will give more access to quality of healthcare services. Tertiary healthcare services in India will be at par with world standard. It is expected that India will emerge as leading player in specialty and super specialty healthcare services within next ten years.

12. By the year 2015, total pharmaceutical industry market segmentation will be:

- General, Exports and others.
- Domestic Market
- Generic Exports (both dosage forms & active pharmaceutical ingredients).
- Services and R & D products.
• New R & D products like structure based drug design, bioinformatics.
• Clinical developmental services.
• New chemical entities (NCEs).

13. In coming decade i.e. up to year 2015, 30-40% business will be from branded generics having some type of Intellectual Property Right Protection.

14. It is expected that leading Indian pharmaceutical firms like Ranbaxy and DRL will introduce 3-4 molecules for new drug applications (NDA) every year up to phase II clinical trials.

15. It is possible to shorten period for getting USFDA approvals for exports to developed markets by making collaborations with other countries like China, Brazil and Israel.

16. Exports of new innovated products from India to developed countries like Japan, Europe, and United States are minimal in coming ten years. This is because of developmental cost of product and time constrain in new drug development.

17. Indian pharmaceutical firms may adopt newer techniques like value addition and innovative products based on target based drug discovery tools. These techniques will shorten the span of drug discovery up to 7 years by carrying out routine developmental work in India and performing innovative or lead part in other countries. This will also solve problem of availability of high-end technical expertise in biological sciences in India.

18. Indian firms will excel in global generic market because they are good in reverse engineering and chemistry of molecules. But to enter in innovative product market, they have to upgrade themselves in the area of drug delivery tools and target based drug discovery methods.

19. Out of present around 20,000 production units, after year 2005 it is assumed that around 1200 will survive in three categories.

   Top = High value addition market and products.
   Medium = Moderate value addition market.
   Low cost, low value addition market.
20. There will be higher multinational corporations (MNC) activity in country. Two-four companies will work in innovative global market and specialty product marketing. Due to inherent advantage in chemistry, some Indian companies will work in the area of pure drug discovery.

21. In total hierarchical structure, basic commodity players will work primarily in low cost, low value addition market

22. Large pharmaceutical companies will spend nearly half of their research budget in licensing their products from small companies.

23. Herbal Drug Industry market has tremendous scope for development if properly nurtured.

13.2

RECOMMENDATIONS.

Following are recommendations made to achieve targeted results in all spheres of pharmaceutical industry.

1. Stronger Industry – Academic interaction is recommended for trained technical human resources.


3. Input in the other sectors like insurance, pollution control, environmental safety is essential for controlling adverse factors affecting healthcare.

4. To face legal challenges in various clauses of TRIPS, establishment of effective legal framework with proper number of legal expertise is very necessary.

5. Transparency in policies, rules and procedures is required. India must confirm with new regime of multilateral arrangements and outward orientation of economic policies.

6. Proper allocations of capital resources in development strategy on all aspects of household economy and towards pricing mechanism should be given due impetus.

7. Foreign Direct Investment (FDI) in pharmaceutical sector should be encouraged. This will help in better infrastructure in research and development and for more competitive nature of pharmaceutical industry.
8. To benefit from World Trade Organization (WTO) regime, there is need to have macro level economic discipline in the area of fiscal stability, price stability and exchange rate management.

9. Indian firms should work in the areas of patented database to track worldwide technology development. This will help in the areas of biotechnology and bioinformatics.

10. With India’s inherent advantage in the area of chemistry and process technology, there is scope for cost effective research and development infrastructure in India. For this we require to nurture our human capabilities in the areas of pure sciences.

11. On going disputes over various clauses of TRIPS on which decision is not yet taken will compel us to work more in the areas of research in public domain. We should not give away totally the concept of socialism for the cause of competition and private ownership.

12. Pricing of drugs will remain a decisive issue in coming decade. For this national health policy, national drug policy and other policies should be implemented with true spirit. It requires having consistency and pragmatic approach towards health.

13. Exports to Middle East, Central Asia and Africa require stable manufacturing capabilities. Indian pharmaceutical firms require paying more attention in this area for export of non-patented and generic bulk drugs and formulations.

14. Indian pharmaceutical companies require cumulative efforts at national and international levels to persuade policy matters related to pharmaceutical and health sector.

15. Many Indian pharmaceutical firms are devoid of pragmatic clear vision about their role in total future industrial set up and existing sluggish markets. This needs to be rectified by more comprehensive macro economic policies.
16. To achieve better outputs in the area of genomics, following measures may be more practicable.
   a) Establish balance between conventional methods of public health and clinical practice.
   b) Introduce new technologies in pilot plant studies before making it more general.
   c) Make maximum use of local expertise.
   d) Form partnerships with developing countries and international agencies in healthcare projects.

17. Venture capital is major source of raising finance for biotechnology firms in developed stock markets. For developing countries where stock markets are having limitations in raising finance, following parameters must be looked after for investments in this segment by investors.
   a) Look for the company that understands the role of information science in biology, commitments to information and companies build on solid hypothesis driven science.
   b) Invest in product, not in unproven technology platforms.
   c) Choose that company having good downstream technology and which are capable of delivering on the values of their upstream technologies.
   d) Look for the profitable companies that can sustain 20% earning per share (EPS) growth rate as well as non profitable companies with proprietary position that have 40% growth rate in revenue terms.

18. For more speedy results in the areas of biotechnology and research and development, there is need for dilution of impracticable restrictions on animal experimentations as per guidelines of Committee For The Purpose Of Control And Supervision Of Experiments On Animals (CPSCEA).

19. There is need for faster approvals for clinical trials of drugs from the office of Drugs Controller General of India (DCGI).
20. Government should consider granting of permission for clinical trials of new drugs not developed in India to boost contract drug research market.

21. Professional pharmaceutical associations should keep watch on possible competition from ASEAN countries like Singapore, Taiwan and Korea in genomic drug delivery.

22. For the development of bioinformatics sector, following drawbacks must be rectified before reaching on concrete outcome in this field,
   a) Bioinformatics is only one aspect of complete drug discovery process.
   b) There are limitations on out sourcing in this field to reduce cost.
   c) High-end expertise in biology is not available in India.
   d) Constrains on data mining are there, as there are shortage of data as compare to developed world.

23. Following policy issues must be addressed in bioinformatics sector.
   a) Drug research approach.
   b) Ownership of human genetics.
   c) Education.
   d) Developments on the area of Linux based cluster computing and Artificial Intelligence (AI).

24. Some trends of global pharmaceutical industry, which have special relevance for Indian pharmaceutical industry in coming decade are;
   a) Intense pressure on research and development cost, consequently increasing outsourcing such as for combinatorial libraries around specific structures, drug developmental studies, clinical trials and manufacturing.
   b) Increasing interest in herbal drugs and indigenous systems of medicine (ISMs).
   c) Moving away totally from new drug developmental research (NDDR) for diseases affecting only developing countries, such as parasitic infections or even fertility control and thus imperative need for Indian drug industry to pay special attention for NDDR in these areas.
25. Involvement of small and medium sector enterprises in drug research process will benefit in reducing cost and time constraints in drug research.

26. Hospitals are going to play crucial role in drug delivery structure in coming decade because near about 30% of total net profit in hospitals arises from drug store management in total hospital setup. We are experiencing boom in private investment in this sector since year 2000. In future we will witness more mergers and acquisitions in hospital management sector. For this following factors may prove important in success of these enterprises.

a) Relative size of hospitals.

b) Their geographic proximity.

c) Strength of ties between individual hospitals and physicians.

d) Degree of unity in leadership structure of various Institutes.

27. Any development in herbal medicine is correlated with working in following areas to achieve international recognition for indigenous systems of medicines (ISMs) from India like Ayurveda,

a) Botanical identification of herbs.

b) Processing of medicinal herbs.

c) Isolation and characterization of active principles from herbals.

d) Standardization of herbal formulations.

e) Documentation of herbal medicine practice.
MODEL

National Policies
* Implementation of National Drug Policy
* National Health Policy of India 2002
* Pharmaceutical Policy of India 2002
* EXIM Policy of India 2002-2007
* The Indian Patent Act 1940
* DPCO

Health Related Sectors

Health

Pharmaceuticals

Globalization
* WTO rules
* TRIPS
* Environment

National Economy
* Market Forces
* Macro Economy
* Insurance

Legal Challenges
* Selection Patent
* Prior Public Availability
* Polymorphism
* Analogy Processes
* Compositions
* Optical Isomer
* Active Metabolites
* Prodrug
* Disclosure

Affordability of Drugs
* Cycle of Health and Poverty
* Drug Financing / Pricing
* Supply System
* Rational Use
* Research
National Policies
* National Drug Policy
* Access to Essential Drugs
* Quality of Medicine
* Rational use of Drugs

National Health Policy of India 2002
* Financial Resources. (6% GDP)
* Equity
* Use of Generic Drugs and Vaccines.
(Revision of essential drug list, 50% requirement of vaccines for public sector institutions)
* Health Research
(By 2005-1% of total health spending, 2% by 2010)
* Roll of Private Sector
(Quality standards, Accreditation, Private Insurance Package, Social Health Insurance, Standard Protocols)
* Telemedicine.
* Providing Medical Facility From Abroad.
(Foreign Earnings, Health Services.)
* The impact of globalisation on health sector.
(Flexible TRIPS aspects, Patent laws.)
* Alternative System of Medicine.
(Evidence Based Research)

Pharmaceutical Policy of India 2002
* Industrial Licensing
* Foreign Investment
* Imports
* Pricing:
  - Span of price control
  - Maximum Allowable Post Mfg. Expenses (MAPE)
  - Margin for Imported formulation
  - Ceiling Prices
  - Pricing of schedule bulk drugs
  - Monitoring.
  - Drug Pricing Equalisation Account. (DPEA)
  - Quality Aspects.

Import-Export Policy (EXIM) of India 2002-2007
* General
* Duty Exemption Schemes
* Trading Status
  * Export Oriented Units

The Patent Act 1940
(Third Amendment by 31st Day of Dec. 2004)